Exploring Preventive Interventions and Risk Factors of Hospital-Acquired Pressure Ulcers: A Retrospective Matched Case-Control Design

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Dedication

This thesis is dedicated to my father, who taught me that the best kind of knowledge to have is that which is learned for its own sake. It is also dedicated to my mother, who taught me that even the largest task can be accomplished if it is done one step at a time.

Acknowledgments

Though only my name appears on the cover of this thesis, a great many people have contributed to its production. I owe my gratitude to all those people who have made this work possible and because of whom my graduate experience has been one that I will cherish forever.

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Publications during the study period (2008-2011)

Journal paper:

Anthony, DM., Rafter, L., Reynolds, T. and Aljezawi, M. (2011). An evaluation of serum albumin and the sub-scores of the Waterlow score in pressure ulcer risk assessment. *Journal of Tissue Viability*, in press.

Conferences:

Aljezawi, M. and Anthony, D. (2010). A retrospective approach to explore effective nursing interventions that prevented hospital acquired pressure ulcers in a Waterlow sub-scores matched cohort. 29th Tissue Viability Society Annual Conference: *Looking at things differently: collaboration, evidence and innovation for practice. April 13-14*, Telford, UK. (Appendix M)

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Abstract

Previous literature showed weak and sometimes contradictory evidence regarding the best interventions to prevent pressure ulcers and the best factors that can serve as predictors for ulceration.

The aim of this study was to explore effective interventions and associated risk factors in the area of pressure ulcer. A retrospective approach was used to explore such interventions and risk factors in a more natural clinical environment than found in a prospective study. While retrospective studies have their limitations, one problem of prospective studies, the Hawthorn effect, is not present.

In order to meet the aims of the study, a matched case-controlled design was employed. A convenience sampling technique was used to select all patients who matched the study criteria. Two groups of patients were selected. The first group developed pressure ulcer during hospitalization, the other did not. In order to have a sound and robust comparison, each patient from the pressure ulcer groups was matched or at least nearly matched with another patient from the non-pressure ulcer group for a number Waterlow sub-scores. Further criteria for selection included a minimum of three days total length of stay in hospital and being initially free of any pressure ulcer on admission for both of the study groups. Electronic medical records for all patients were revised, and multidimensional data were extracted using a data extraction sheet.

Data analyses were carried out using univariate analysis (t-test, Mann-Whitney, Chi-square and Fisher's exact test) and multivariate analysis (binary logistic regression). In univariate analysis for preventive interventions, the following interventions were significantly associated with pressure ulcer prevention ($P \leq 0.05$): standard hospital bed, seating cushion, static pressure redistributing mattress, re-positioning every four hours and helping the patient to sit regularly in a chair. When the effect of all interventions was adjusted through the multivariate model, the following interventions were independently associated with prevention: draw sheet, re-positioning every four hours and helping patient to sit regularly in chair (odds ratio = 0.24, 0.06 and 0.13 respectively; $P \leq 0.05$). In univariate analysis for risk factors related to physical activity and mobility, the following factors were significantly associated with developing pressure ulcer ($P \leq 0.05$): moving in bed with help, the ability to take a bath only in bed, needing two helpers in performing activities of daily living and moving outside bed only by a hoist. When adjusting the effect of all variables related to physical activity and mobility through the multivariate model, only two factors were independently associated with developing pressure ulcer: moving in bed with help and the ability to take a bath only in bed (odds ratio = 7.69 and 3.67 respectively; $P \leq 0.05$). In univariate analysis for risk factors related to pressure ulcer intrinsic risk factors, the following factors were significantly associated with developing pressure ulcer ($P \leq 0.05$): presence of three underlying medical conditions, dehydration, depression, having a blood

transfusion, serum albumin <32mg/dl, haemoglobin <130 g/l in males or <115 for females and systolic blood pressure <113 mmHg. When adjusting the effect of all variables related to intrinsic risk factors through the multivariate model, the following risk factors were independently associated with pressure ulcer: presence of two underlying medical conditions, presence of three underlying medical conditions, cognitive impairment, serum albumin <32mg/dl and haemoglobin <130 g/l in males or <115 for females (odds ratio = 13.3, 143, 4.3, 0.10 and 0.14 respectively; $P \leq 0.05$).

Findings from this study suggest a number of interventions to be effective in PUs prevention, and a number of risk factors that can predict risk of PUs. Findings were based on statistical association between acquiring PUs and the independent variables (preventive interventions and risk factors). This cannot constitute a cause and effect relationship due to the retrospective nature of data analyzed; it only supports the association between a number of interventions and risk factors in preventing or predicting PUs. This can guide further research to investigate these interventions and risk factors by employing the same approach used, but in a prospective manner.

Abbreviations and Acronyms

ADLs	.....	Activities of Daily Living
AHCPR	.....	Agency for Health Care Policy
α	.....	Significance level
BNI	.....	British Nursing Index
B	.....	Coefficient estimations associated with independent variables in logistic regression
CCU	.....	Coronary Care Unit
CDSR	.....	Cochrane Database of Systematic Reviews
C.I.	.....	Confidence Interval
CINIHAL	.....	Cumulative Index to Nursing and Allied Health Literature
COPD	.....	Chronic Obstructive Pulmonary Disease
CRP	.....	C-reactive Protein
d.f.	.....	Degree of Freedom
DMU	.....	De Montfort University
DM	.....	Diabetes Mellitus
EPUAP	.....	European Pressure Ulcer Advisory Panel
GI	.....	Gastrointestinal
HISS	.....	Hospital Information Support System
HTN	.....	Hypertension
ITU	.....	Intensive Therapy Unit
LOS	.....	Length of Stay
NHS	.....	National Health Services
NICE	.....	National Institute for Health and Clinical Excellence
NOF	.....	Neck of Femur
NPUAP	.....	National Pressure Ulcer Advisory Panel

N	.....	Total number of cases in the sample
n	.....	Number of cases in a subgroup of the sample
Phi	.....	Effect size statistics for continuous variables associated with t-test
PUs	.....	Pressure Ulcers
PU	.....	Pressure Ulcer
P	.....	Probability value
RASs	.....	Risk Assessment Scales
RAS	.....	Risk Assessment Scale
RCTs	.....	Randomized Controlled Trials
RCT	.....	Randomized Controlled Trial
ROC	.....	Receiver Operating Characteristic
r	.....	Effect size statistics for continuous variables associated with Mann-Whitney U test
SD	.....	Standard Deviation of the mean
SPSS	.....	Statistical Package for Social Sciences
TVN	.....	Tissue Viability Nurse
UK	.....	United Kingdom
WCC	.....	White Cells Count
χ^2	.....	Chi-square

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Chapter One: Introduction

In this thesis the prevention and risk factors of pressure ulcers (PUs) were explored. One motive behind conducting this study arises from the researcher's own interest in this problem. During the researcher's work as a registered nurse, he noticed that PUs were a significant problem that caused patient and family suffering, in addition to increased workload and cost of caring. Pressure ulcer (PU) was an underestimated problem and there was no awareness of the importance of risk assessment and proper prevention.

This introductory chapter is intended to provide the reader with background information about PUs. It discusses the definition and aetiology of PUs and explores the historical perspective and impacts of PUs on both patients and the health care system. The aims and significance of the study are also addressed in this chapter.

1.1 Definition, pathogenesis and prevention of PUs

PUs are also known as decubitus ulcers (decubitus: from the Latin *decumbere*, to lie down) or bed sores (Bansal et al., 2005). According to the definition of the European Pressure Ulcers Advisory Panel (EPUAP), a PU is defined as "A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear" (EPUAP and NPUAP, 2009, p.5). Unrelieved interface pressure can lead to decrease in capillary blood flow or occlusion of blood vessels. This can decrease tissue oxygenation, thus leading to tissue ischemia and eventually tissue necrosis and breakdown (Benbow, 2008).

PUs can develop on any part of the body that is affected by the aforementioned forces. However, there are also other contributors to tissue vulnerability to breakdown, (e.g. malnutrition, dehydration, medications, fever and anaemia). These factors can decrease tissue tolerance to pressure. If combined with the presence of compressive forces, they can increase the risk of developing PUs (Bansal et al., 2005).

Prevention of PUs can be effectively attained through identifying different risk factors and preventing them (Lindgren et al., 2002). However, prevention requires the collaboration of different caring specialities, because the problem is multifactorial (Theaker, 2003). Nurses and other health care workers (e.g. dieticians, physiotherapists and physicians) need to work collaboratively to reduce the effect of different risk factors for an effective prevention process. For instance, nurses have to relive compressive forces using different techniques and equipment, while simultaneously working collaboratively with the dietician to enhance the nutritional status of their patients.

1.2 Brief historical perspective

PUs have a long history, and the earliest examples were described in a study concerning pathological changes in the remaining parts of Egyptian mummies. PUs were discovered on both the buttocks and shoulders of these corpses (Theaker, 2003). One of the first medical records of PUs date from the sixteenth century, describing a wounded French aristocrat who developed PU and was successfully cured (Levine, 1992b). Another French surgeon, De La Motte, noticed that mechanical pressure and incontinence were playing an important part in the initiation of PUs in 1722 (Defloor, 1999). In the nineteenth-century French physician Jean-Martin Charcot described PUs in terms of neurological theory. He claimed that the cause of PUs is damage to the

central nervous system; he did not consider pressure or local irritation to be among the causative factors of PUs (Levine, 1992a).

The importance of pressure forces was generally established through research in the twentieth century. In 1958 it was suggested that shear forces in addition to pressure forces contribute to PU development. Since then, PUs have been of interest to researchers, who have identified many causative factors and prevention modalities, in addition to inventing scales to assess the risk of PUs (Defloor, 1999).

1.3 Impact of PUs

Knowing the impact of PUs will help in highlighting their devastating effect on care outcomes, increasing the realization of the importance of the problem for both patients and the care system, both of whom are affected by PUs. Patients with PU usually suffer from many side effects that can decrease quality of life and delay healing (Baranoski, 2006). These effects include:

- Mortality: exploring factors affecting the survival of older adults, PUs were among other factors that predicted death in older adults (Dale et al., 2001, Bo et al., 2003). Moreover, PUs constitute seven to eight per cent of death causes in paraplegic patients (Bansal et al., 2005).

- Pain: the presence of pain in PUs is related to presence of open ulcers (Zeller et al., 2006). Pain can be experienced during rest, changing dressings or applying preventive measures (Szor and Bourguignon, 1999).

- Infection: infection in PUs can happen as a natural result of skin breaking. This infection may be superficial, or it can spread and cause osteomyelitis (Livesley and

Chow, 2002). Infection requires additional nursing interventions, which in turn increases the workload on nurses.

- Open ulcers may drain, causing protein loss, worsening patients' nutritional status.

- Length of stay: studies showed that PUs are one of the significant factors that extend the length of patient stay. The presence of PUs result in a median of 4.3 days extra hospital stay (Graves et al., 2005). Length of stay could be also considered to negatively impact the health care system, due to the increased cost of extra hospital days and occupying otherwise vacant beds and other resources (Graves et al., 2005).

- Quality of live: quality of life can be disturbed as a result of pain, life restrictions, increased length of hospital stay and treatment modalities (Hopkins et al., 2006).

- Self image: the appearance of wounds, smell and leakage can disturb body image. This disturbance may affect the social, emotional and mental status of patients (Spilsbury et al., 2007).

As mentioned above, PUs also affect the health care system and health care workers. This effect can take many forms, including:

- Quality of care: high incidence of PUs in certain clinical settings may indicate negligence and shortage in care. For this reason many clinical settings consider low PU incidence and prevalence as an indicator of good quality care (Scott and Newens, 1999).
- Cost of PUs: additional costs related to occurrence of PUs can result from treatment and management (e.g. wound dressings, management of infection, cost of health care workers, diagnostic procedures and use of medication) (Brem and

Lyder, 2004). The estimated cost of PUs varied between different studies. This may result from different estimates of cost, different years of studies which reflected on prices, different settings and patients conditions and use of different care standards. In one study, 80 per cent of the total cost of PU treatment resulted from four per cent of patients who needed hospitalization for their PUs (Xakellis et al., 1998). In this study, a condition suffered by only four per cent of patients increased costs dramatically, which may not give a clear picture about cost. Even so, PUs' treatment constitutes a considerable portion of expenditure in health care systems. In the UK, the total cost for PU care (based on 2000 prices) is £1.4-2.1 billion. This amount accounts for four per cent of the total National Health Service (NHS) expenditure. Treatment costs are expected to increase in the future as more people will age (Bennett et al., 2004).

- Litigation: health care systems can be sued as a result of a patient developing a PU. The basis of these lawsuits is the assertion that negligence and malpractice lead to PUs. The legal liability of health care systems can cost these systems money and reputation (Voss et al., 2005).

1.4 Significance of the study

PU is considered a major health problem in the caring system of many countries, including the UK (Bennett et al., 2004), where this study took place**.** Literature suggests that this problem is underreported, and that there is a lack of awareness concerning PUs prevention and management through the health care systems (Anthony et al., 2008). Numerous previous works have studied PU risk factors and prevention with different methodological approaches and in different clinical settings. These studies aimed at

informing clinical decision makers and health care workers of the best predictors and prevention modalities to prevent PUs. This should enhance prevention of PUs, thus decreasing its prevalence and incidence. Even so, reports from the literature show little evidence of improvement (Pancorbo-Hidalgo et al., 2006).

The present study used a new approach and methodology, differing from previous studies in this area of research. Exploring different prevention methods and risk factors using a new approach might add new scientific evidence to the body of knowledge in this area. Additionally, using the new approach in this study can open the door for further studies using it and addressing its shortcomings.

1.5 Aims of the study

This study aimed to:

1- Explore different nursing interventions and their effectiveness in reducing the occurrence of hospital-acquired PUs.
2- Explore the relationship between certain risk factors and their association with hospital-acquired PUs.
3- Contribute to the body of knowledge in this field of inquiry.

1.6 Structure of thesis

This thesis consists of six main chapters:

- Introduction: this chapter includes a brief background about the study problem and the significance of the study, in addition to the study aims.

- Literature review: this chapter reviews previous studies in the same field and related factors; also it critically appraises these studies' findings and methodologies.
- Methodology: this chapter explains the rationale behind using the study methodology and discusses its strength and weaknesses.
- Findings: this chapter presents different findings from the study in detail, including results from descriptive and inferential statistics.
- Discussion: this chapter interprets the main findings of the study in view of the previous literature.
- Limitations, recommendations and conclusion: this chapter presents limitations of the study that were evident during the course of the study. Also, it presents recommendations for both health care practitioners and researchers. Conclusion was given at the end of this chapter to provide a clearer picture regarding results interpretation.

1.7 Chapter summary

This chapter provided the essential background information that will help in understanding the problem under investigation. This information included definition of PUs and its pathogenesis. Main factors that include pressure, shear and friction, which contribute to PU development, in addition to other risk factors that increase the tissue susceptibility to breakdown were described. Consideration of the historical perspective of PUs indicates that it is not a concurrent problem; it has historical roots, although scientific research in this area only began in the second half of the twentieth century. The significance of the study was also presented in this chapter. The study's

significance rests on the poverty of evidence of improvement in incidence and prevalence of PUs, despite many studies in the area of prevention and risk factors.

Chapter Two: Literature Review

2.1 Introduction

A research literature review is “a written summary of the state of existing knowledge on a research problem” (Polit and Beck, 2004, p.111). It is designed to assimilate and compare relevant evidence on an intended area of inquiry. This chapter aimed at reviewing and critiquing previous literature relevant to PU risk factors and preventive interventions. The purpose of this was to ascertain the current state of knowledge in this area, and identify drawbacks in order to overcome some of them during the course of the study, as well as to identify a relevant theoretical or conceptual framework that relates different study variables and clarifies the relationship between them.

Although the main themes of the review were PU risk factors and preventive interventions, other areas of research related to these terms were also explored. These included: PU prevalence and incidence, risk assessment scales (RASs) for PU, grading systems for PUs and PUs prevention guidelines.

2.2 Search strategy

The search strategy was influenced by the nature of this inquiry, which was intended to identify evidence regarding PUs’ preventive interventions and risk factors. For this purpose, literature was searched using specialized nursing databases, which were: Cumulative Index to Nursing and Allied Health Literature (CINIHAL), Medline, British Nursing Index (BNI), and Cochrane Database of Systematic Reviews (CDSR). These

resources contained related subjects and journals collections that were relevant to the area of inquiry. Google scholar was searched for additional literature not included in the databases. Additionally, reference lists of the retrieved studies were also manually searched. This was to check for any relevant studies missed during the initial search. The email alert features of data bases were also utilized, which enabled the researcher to keep up to date with newly published studies after the initial search was conducted. The search for relevant studies comprised the key words ‘pressure ulcers’, ‘bed sores’ or ‘decubitus ’ combined with each of the following terms: prevention and risk. These words were used to search studies’ titles and abstracts in order to identify relevant works. Literature was initially searched using the aforementioned key words before conducting the research work. Databases alerts were utilized to keep up to date with recent publications. After the research work was concluded, a comprehensive literature search was conducted to fill any gaps which have had happened during the initial search.

Literature searching was confined to the English language and covered all articles that met the inclusion criteria. Articles included for relevancy were published and unpublished research articles, commentaries and systematic reviews. Access to studies was through the De Montfort University (DMU) electronic database, DMU library holdings and the web.

Papers on PU risk factors were included if they were epidemiological studies that explored risk factors of PUs and had PU as their main outcome measure. Papers on PU prevention were included if they were empirical studies that investigated the efficacy or effectiveness of different prevention devices or strategies in terms of PU prevention. Papers which did not follow a legitimate known scientific path to generate empirical evidence were excluded.

These included commercial studies that aimed at advertising certain product without giving any attention to the different details in proper research (e.g. no sampling method, results generated without analysis or based on a personal opinion). Papers without references were also excluded. Conducting research without a literature base could result in misinterpreting the finding which could end with wrong research output.

In order to further focus the literature search on empirical papers that had PUs as their main outcome, the following exclusion criteria were applied:

- Studies that had measures other than PU development as their main outcome (e.g. histological skin changes, measuring the amount of interface pressure)
- Commercial research to promote a specific brand
- Opinion based on personal judgement
- Letters
- Qualitative studies
- Lab-based studies
- PUs in non-human subjects
- Case studies
- Articles without references

2.2.1 Evaluating studies

After retrieving papers relevant to risk factors or preventive interventions according to the inclusion and exclusion criteria, relevant information was extracted from these papers. For studies investigating different interventions the following information was extracted: study,

setting, design, type of intervention investigated, main result, limitations and category of interventions investigated. For studies investigating risk factors the following information was extracted: study, setting, design, risk factors investigated, limitations and significant risk factors.

Retrieved studies addressing preventive interventions were grouped according to the type of intervention(s) or risk factor(s) reported within different studies. This was helpful in comparing different studies in order to reach a conclusion regarding their findings. Moreover, grouping studies was beneficial in generating titles and subtitles in the literature review chapter.

In this study, Hawker's tool was used to assess quality of research papers (Appendix A). In this tool a number of areas are evaluated, including: abstract and title, introduction and aims, method and data, sampling, data analysis, ethics and bias, findings, transferability, implications and usefulness (Hawker et al., 2002). Using this tool enabled the researcher to evaluate the quality of different studies and discover their shortcomings. Quality issues were considered for each single study and indicated within the text in form of collective discussion and in tables that summarized different studies (Appendices B, E &F).

2.2.2 Search results

Results for searching the literature from January 2000 until March 2011 using the aforementioned databases and reference lists are presented in Figure 2.1. Although searching the databases was limited to these years, additional searching was done using Google Scholar to catch older but relevant studies, especially in areas that had no or limited studies.

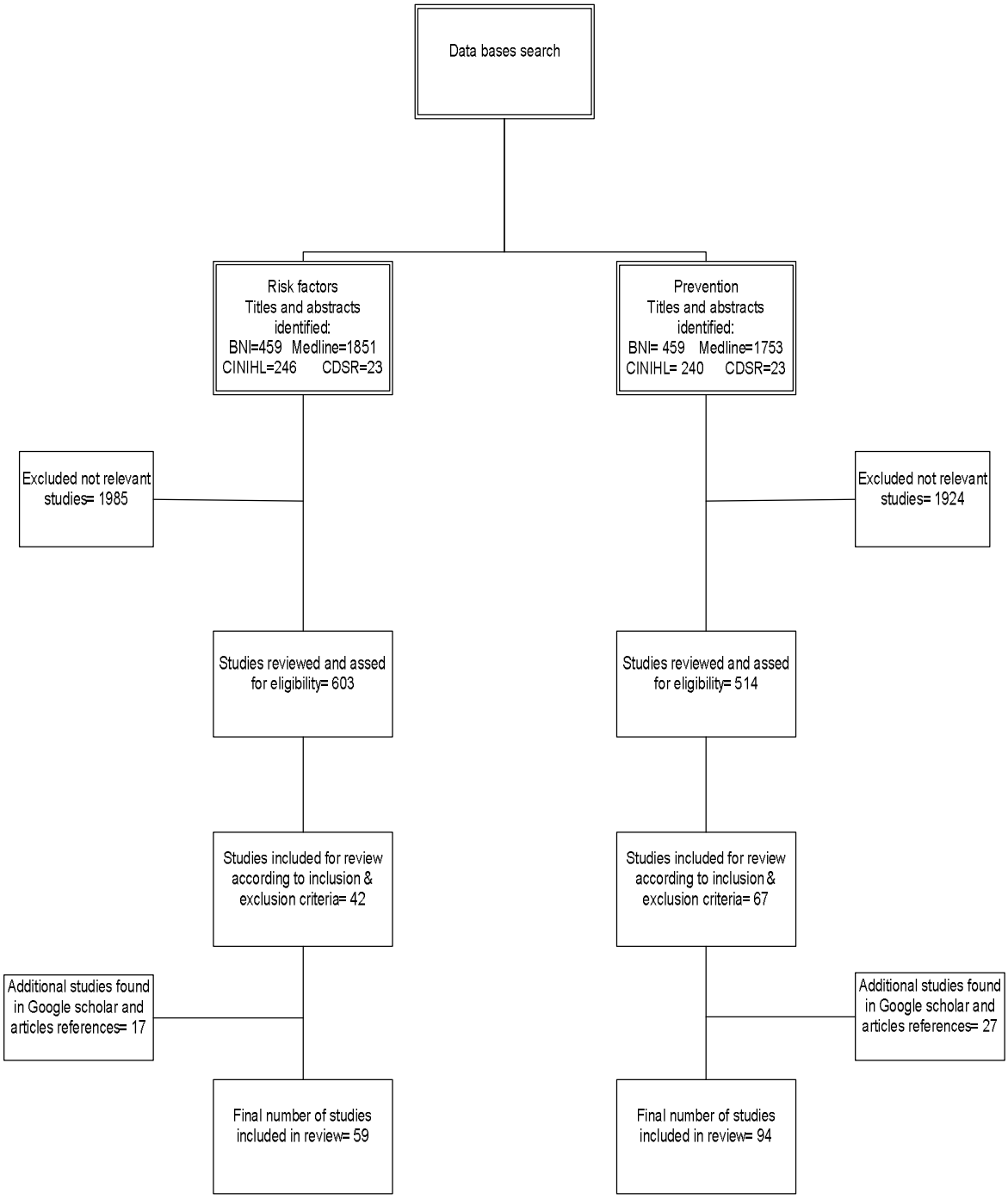


Figure 2.1: Literature review search results

2.3 Prevalence and incidence of PUs

Prevalence of PUs is the total number of PUs among the whole population at a specific point in time. In contrast, incidence measures the total number of persons developing new PUs during a whole period of time. The reason to focus on incidence and prevalence is that these measures provide in-depth insight into the quality of the caring process, as well as serving as comparison criteria for the effectiveness of different PU protective modalities and equipment (Friis and Sellers, 2009).

Exploring the clinical interpretation of these rates (incidence and prevalence) is important. High incidence of PUs can reflect either the ineffectiveness of preventive measures, or that care givers do not comply with these measures. Increased numbers of patients with PUs due to high incidence results in an increased hospital stay in order to manage these ulcers. In this situation, the chance for these patients to be counted in a prevalence survey will be increased, ending in a high prevalence rate (Shahin et al., 2008).

Numerous studies reported PU incidence and prevalence in different clinical settings. In a review study of prevalence and incidence in the UK, USA and Canada, acute care prevalence in the UK ranged from 5.1 to 32.1 per cent, while prevalence ranged from 4.4 to 6.8 per cent for community settings, and from 4.6 to 7.5 per cent in nursing homes. Incidence in UK acute care ranged from 2.2 to 29 per cent per annum for a maximum period of six weeks. In the USA and Canada, prevalence ranged from 4.7 to 29.7 per cent in acute care and from 19.2 to 29, and 15.3 to 20.7 per cent in community settings and nursing

homes respectively. Incidence ranged from 8.5 to 13.4 per cent over a one-to-four week period in acute care. Community settings had a range of 0 to 16.5 per cent (period not specified) (Kaltenthaler et al., 2001).

In different study that was conducted in five European countries, the prevalence of PUs was 21.1, 8.3, 12.5, 23, 21.9 per cent in Belgium, Italy, Portugal, Sweden, and the UK respectively (Vanderwee et al., 2007a).

Other studies of PU prevalence reported different prevalence figures in different European countries. In Ireland, prevalence of PU over a two days period was reported to be 18.5 per cent in three teaching hospitals (Gallagher et al., 2008). In Germany, Wilborn et al. (2006) showed that prevalence in hospitals was 16.6, 16.1, 10.3 per cent in hospitals with no PU prevention protocols, with prevention protocol, and in the process of developing a protocol correspondingly. Furthermore, a comparison study between the Netherlands and Germany showed a range in prevalence from 28.1 to 41.1 percent in Dutch hospitals, compared to a lower range in German hospitals from 18.1 to 28.8 per cent (Tannen et al., 2008). Further European studies reported lower prevalence than those previously mentioned. In Finland, the prevalence was 6.4 per cent (Lepisto et al., 2001), and in Sweden the prevalence over a two-week period in acute care was 4.1 per cent (Lindgren et al., 2000). These results apparently reflect a notable assortment of PU prevalence and incidence in different studies.

To sum up, different studies reported different figures for incidence and prevalence. Comparing different figures is difficult due to the different methodologies used in studies reporting these figures, including using different samples and sample sizes, mixing

different patient groups, different clinical settings with different aspects of prevention and specialization, different degrees of risk according to RASs, using different inclusion and exclusion criteria, and using different designs, which implies different data collection methods (Gould et al., 2000, Kaltenthaler et al., 2001, Shahin et al., 2008).

2.4 PU risk factors

Understanding risk factors contributing to the development of PUs is crucial. This understanding will help in gaining insight into the physiological process of PU formation, and eventually understanding how different prevention methods work to prevent these factors. Additionally, this will help in understanding the rationale behind constructing different RASs. Risk factors for PUs can be classified as extrinsic and intrinsic risk factors:

- **Extrinsic risk factors**

Extrinsic risk factors for PU include external interface pressure, in addition to other forces that accompany it, namely: shear and friction. PUs develop when the skin surface is exposed to a persisting external interface pressure that is higher than the pressure in blood capillaries in the skin, causing its closure. If this pressure persists it can cause tissue necrosis (Lyder, 2003).

Shear force is generated when the surface of the skin remains static while the patient is dragging a particular body part against the support surface (e.g. a bed or chair). In this case, the blood capillaries between the static skin and moving bones are broken. These broken capillaries cannot transport oxygen and nutrients to tissue, leading to tissue ischemia. It is

important to note here that distorting shear forces only exist when pressure forces exists too. Pressure in this case is caused by the patient's own weight (Waterlow, 2005b).

Friction force can happen as a result of rubbing the skin over the supporting surface while a body part is moving. Friction can cause intraepidermal blisters; these in turn can create erosions in the epidermal layer, causing the skin to breakdown (Waterlow, 2005b, Grey et al., 2006).

- **Intrinsic risk factors**

The ability of skin to tolerate compressive forces before developing tissue necrosis depends on a number of factors that are referred to as intrinsic risk factors (Ousey, 2009). Severity of illness and general medical conditions are intrinsic risk factors. These also include malnutrition, immobility, medications, dehydration, body weight, skin condition, incontinence and advanced age (Waterlow, 2005b).

Increased vulnerability to PUs results from a combination of increased interface pressure, shear and friction forces and intrinsic risk factors (Bansal et al., 2005).

- **Effect of different intrinsic risk factors on skin vulnerability to breakdown**

In general, intrinsic risk factors can play an important role in increasing vulnerability to PUs, either by increasing the intensity and duration of pressure, shear and friction forces, or by decreasing the tissue tolerance (immunity) to these forces (Defloor, 1999).

Pressure forces that can affect the skin are usually generated from the patient's own weight. Consequently, increased body weight will increase the intensity of pressure force

(Waterlow, 2005b). Other factors also play a role in increasing the intensity of pressure force, including hardness of the support surface, certain body positions (e.g. semi-Fowler position) and type of nursing interventions used to relieve pressure force (Defloor, 1999). Intensity of shear and friction forces can also be increased in the presence of moist skin. Incontinence in addition to wound drainage and excessive perspiration can increase skin moisture, leading to skin maceration. The presence of this condition can increase the intensity of shear and friction, thus making the skin more vulnerable to breaking down (Grey et al., 2006).

Duration of pressure, shear and friction forces depends to a large extent on the patient's mobility and activity level. Immobility was found to be one of the most important risk factors that can contribute directly to development of PUs, because it increases the duration of skin exposure to pressure force (Baumgarten et al., 2003, Papanikolaou et al., 2003, Wann-Hansson et al., 2008). Additionally, other factors can contribute to immobility and in turn increase the duration of exposure to the compressive forces, such as lengthy surgical procedures, hip fractures, intensive care stay, sedatives, old age and obesity (Andrychuk, 1998, Theaker et al., 2000, Mino et al., 2001, Markoff and Amsterdam, 2008). Also, patients with decreased levels of pain sensation are at a greater risk of developing PUs. These patients cannot feel the pain resultant from long immobility, and consequently do not change their positions frequently enough to prevent PUs (Berlowitz and Wilking, 1989). Decreased sensation of pain can result from medical conditions that can cause neuropathies (e.g. diabetes), or through administering analgesics (Keller et al., 2002, Walton-Geer, 2009).

As mentioned earlier, there are intrinsic risk factors that can decrease tissue tolerance for compressive forces. These factors can determine if the amount and duration of the compressive forces affecting the skin will cause PU or not (Defloor, 1999). A number of factors were mentioned in literature that can play a role in decreasing tissue tolerance of pressure. The main examples reported in the literature included: malnutrition, dehydration, age, stress, fever, medications, low blood pressure and comorbidities.

Malnutrition is an important risk factor that can contribute to developing PUs (Anthony et al., 2000b, Westergren et al., 2001, Akyol, 2006, Hommel et al., 2007, Dioguardi, 2008). Malnutrition can cause a number of problems like anaemia, low vitamin c, low serum albumin level, protein deficiency and poor skin condition (Nonnemacher et al., 2009). Deficiency in these factors can decrease lean body mass, which protects from compressive forces, making skin more vulnerable to breakdown in the presence of these forces (Harris and Fraser, 2004, Mathus-Vliegen, 2004). In addition, poor appetite can lead to malnutrition. Patients with poor appetite were found to be more likely to develop PUs (Papanikolaou et al., 2003). Dehydration, which can be considered a type of malnutrition, is another risk factor in the occurrence of PUs (Keller et al., 2002). In this situation, dehydration decreases blood volume; this compromises both circulation and skin turgor, and decreases tissue tolerance of pressure.

Old age (as mentioned above) can be considered a risk factor for PUs (Fogerty et al., 2008b). As a result of the aging process, collagen syntheses changes result in decreased mechanical potential of tissue, and muscles lose their tone (Dioguardi, 2008). Skin ability to regenerate is also decreased with advancement in age, eventually resulting in decreased

tissue tolerance for pressure. Moreover, the older age group has higher susceptibility for chronic conditions such as motor dysfunctions, diabetes mellitus (DM), hypotensive episodes and vascular diseases (Bansal et al., 2005). These conditions are accompanied by decreased sensation of pressure, as well as decreased ability for self re-positioning (Mino et al., 2001).

Emotional stress was also mentioned as a risk factor that can decrease tissue tolerance for compressive forces. During emotional stress periods, the production of systematic glucocorticoids increases, which can inhibit collagen synthesis in the skin, decreasing tolerance of pressure (Sanders, 1992). Administration of synthetic glucocorticoids (steroidal medications) can result in the same thing (Smith et al., 1999, Baranoski, 2006). Other medications can also decrease tissue tolerance to pressure, but in different mechanisms. Hypotensive agents may decrease oxygen and nutrient flow to skin through their effect in decreasing blood supply to the skin (Andrychuk, 1998). Low blood pressure can work in a similar way by decreasing the amount of blood that flows to the skin, thus decreasing its tolerance for pressure (Ayello and Braden, 2002).

A number of comorbidities can play an important role in decreasing the tissue tolerance for pressure, though through different mechanisms. Comorbidities like anaemia and respiratory diseases can decrease oxygen levels in the blood (Defloor, 1999). Other comorbidities like diabetes or low systolic blood pressure can delay reactive hyperaemia (the “reaction to restore blood flow after pressure is released”), or decrease the amount of pressure needed to close blood capillaries in the skin (Defloor, 1999, Lyder, 2003). Comorbidities like

infection associated with fever can increase tissue metabolic rate, thus increasing the demand for oxygen and nutrients (Bansal et al., 2005).

In summary, it can be noticed from this brief description of the main risk factors contributing to PU development that multiple risk factors exist, interacting in a complex way. The presence of one or more risk factors with the presence of pressure and shearing forces can create vulnerable individuals who are considered to be at risk of developing PUs.

2.4.1 Review of PUs risk factors studies

Numerous studies have mentioned PU risk factors; more than 200 different risk factors were reported in the literature (Anthony et al., 2008). Some of these risk factors were related to a certain patient group, such as older patients or spinal cord injury patients. In this case, generalizing group-related specific risk factors to other groups, especially younger patients, would be difficult. For this reason, the purpose of reviewing studies that addressed PU risk factors was to reach a conclusion on which of these risk factors can be generalized. If a conclusion cannot be reached, then causes for this will be discussed based on analysing the studies' methodologies and approaches.

For the purpose of this review, epidemiological studies that explored risk factors for PUs that had PUs as their main outcome were reviewed. Due to the large number of these studies, it was difficult to review them narratively; instead they were analyzed in a table (Appendix B), showing different epidemiological studies with different methodologies and approaches. All of these studies investigated the association between a number of risk

factors and PUs. Risk factors that were found were related in direct or indirect ways to either pressure or shear forces, or to factors that can affect tissue tolerance for pressure.

Drawing a conclusion to generalize results of these studies and accept their findings as valid is difficult due to the following reasons:

1. Different studies used varying methodological approaches, leading to both incommensurable and non-generalizable results (Ash, 2002, Capon et al., 2007, Fogerty et al., 2008a, Wann-Hansson et al., 2008).
2. Different follow-up periods for patients were used. A number of studies did not follow patients for PU development until discharge from the health care facility (Allman et al., 1986, Perneger et al., 2002, Lindholm et al., 2008, Kwong et al., 2009, Nijs et al., 2009).
3. In a number of studies the results were restricted to high risk populations or to certain age groups (e.g. older patients, hip fracture patients, spinal cord injury patients). This makes it difficult to generalize these results for other groups of patients (Kemp et al., 1990, Anthony et al., 2000a, Ash, 2002, Baumgarten et al., 2003, Hatanaka et al., 2008, Lindholm et al., 2008, Martz et al., 2010).
4. Some studies had a small sample size, which makes it difficult to draw a conclusion about the validity of results (Goode et al., 1992, Jones et al., 2005, Correa et al., 2006, Fernandes and Caliri, 2008).
5. In some studies, univariate analysis instead of multivariate analysis was used to analyze data. PU is a multifactorial problem; reaching a statistical conclusion through using univariate analysis does not grantee that all other extraneous variables

are controlled. The effect of other risk factors must be adjusted through multivariate analysis (Ash, 2002, Horn et al., 2002, Lindgren et al., 2004, Söderqvist et al., 2007, Lindholm et al., 2008, Haleem et al., 2008, Fernandes and Caliri, 2008).

6. Excluding PU grade one from analysis in a number of studies. In this case, patients who developed grade one are excluded from analysis. This could give biased results by excluding risk factors of those patients from analysis (Allman et al., 1995, Reed et al., 2003, Schoonhoven et al., 2005, Frankel et al., 2007, Nijs et al., 2009, Manzano et al., 2010).
7. Some studies included patients with PUs on admission. Patients with pre-existing PUs are at higher risk of developing PUs. This could give biased results (Boyle and Green, 2001, Horn et al., 2004, Fogerty et al., 2008a).
8. Some studies used retrospective data. Retrospective data is not guaranteed for its accuracy (Anthony et al., 2000a, Ash, 2002, Papanikolaou et al., 2003, Baumgarten et al., 2003, Horn et al., 2004, Fogerty et al., 2008a, Nonnemacher et al., 2009).
9. Some studies used cross-sectional designs. These studies depend on PU prevalence instead of incidence. In other words, patients are inspected for PU and risk factors at a single point of time, and not followed from admission until discharge (Allman et al., 1986, Capon et al., 2007, Wann-Hansson et al., 2008, Banks et al., 2009). Such studies ignore risk factors and patient condition on admission, which could give valuable information about risk factors.
10. Contradicting results concerning the role of some risk factors were found in some studies (e.g. concerning age and gender). For instance Perenger et al (2002) did not

find gender as a risk factor for PU while Jones et al (2005) did. This can create some doubts about the roles of those risk factors.

In a nutshell, contradictory evidence was found regarding the effect of some risk factors on PU development. For example: some studies found that age and gender were related to the development of PUs (Jones et al., 2005, Wann-Hansson et al., 2008), other studies that investigated these two factors did not (Schoonhoven et al., 2005, Capon et al., 2007). The same thing applies to a number of other risk factors such as race, mobility, low serum albumin, blood pressure, activity level, severity of illness and others. While some studies found the aforementioned factors to be associated with PUs, other studies did not. Different studies had different methodological or statistical approaches and investigated different sets of risk factors. Also, follow-up periods and patient medical conditions varied between studies. All of these factors, in addition to the methodological weaknesses found in some studies, make it difficult to draw conclusions concerning the best factors that can predict PUs.

2.5 Risk assessment scales for predicting the risk of PUs

A scale is simply defined as “ordered marks at fixed intervals used as a reference or standard in measurement” (Bisharat, 2004, p.32). Scales are widely used in our daily living to measure different items. The simplest scale known to us is the ruler, which measures length. This measurement can give us an idea about the relative length of different items (e.g. this item is longer than that). In other words, scales are tools for assessment.

In the clinical area, it is important to divide patients into risk groups in order to inform the clinical decision of where to focus care efforts (Ayello and Braden, 2002). RASs for PUs are clinical tools or risk calculators that were designed by experts in tissue viability to differentiate which patients are at risk of PUs (Defloor and Grypdonck, 2004). These scales were based on risk factors that were proven by research to cause PUs, and have been widely used over the last 50 years in different clinical settings (Anthony et al., 2008).

2.5.1 Rationale for using RASs

RASs, as mentioned above, help nurses to identify patients at risk. They also provide a communication assessment mechanism for health care professionals, which aids them in identifying which patients are at risk (Smith, 1995). This can act as a formal way to inform other health care professionals to mark these patients.

Moreover, RASs can help to focus nursing interventions on patients who are at risk for developing PUs. This includes standardized PU prevention protocols based on certain levels of risk, which are obtained from a risk assessment scale (RAS). These protocols were found to be cost-effective (Xakellis et al., 1998, Lyder et al., 2002). In addition, the use of RASs helps to increase the quantity and effectiveness of preventive measures (Pancorbo-Hidalgo et al., 2006).

RASs are also helpful tools for initiating the assessment process for patients, which can help in effective prevention (Waterlow, 2005a). In clinical settings where no formal programmes for PUs risk assessment are present, less frequent preventive interventions can be introduced to patients, whereas in clinical settings that have formal programmes for

assessing risk, preventive interventions can be introduced more frequently to patients in need. This results in a decrease in the prevalence and incidence of PUs (Braden and Maklebust, 2005). For instance, in a retrospective study of two nursing homes, Lyder et al. (2002) found a significant reduction in PU incidence from 13.2 to 1.7 per cent in the first nursing home and from 15 to 3.5 per cent in the second nursing home. This significant reduction in incidence was a result of the introduction of a prevention protocol. This study showed that it is possible to reduce the incidence of PUs in long-term care by introducing a prevention protocol with labour and support surfaces being the most expensive components of prevention. In addition to that, using RASs in the preventive programme for a certain health institution can help in building a robust defence should lawsuits arise involving malpractice or negligence (Voss et al., 2005).

Overall, many health care agencies are now adopting preventing programmes for PUs that constitutes an RAS in their structure. The role of these programmes is not only focused on patients' benefit; it can also benefit the health care workers, by decreasing vulnerability to litigation due to malpractice lawsuits (Goebel and Goebel, 1999).

In the field of research, RAS can act as a useful tool for classifying patients into different groups. This can help in testing new prevention modalities on patients at risk in order to evaluate their efficacy (Vanderwee et al., 2005).

2.5.2 Common RASs in clinical use

Several RASs are being used in clinical settings (e.g. Gosnell, Braden, Knoll, Norton and Waterlow). The three most commonly used scales in the UK are the Norton, Braden and

Waterlow scales, which are also the most well-known in the world (Gould et al., 2001). The Norton and Waterlow scales were developed in Europe, and the Braden was developed in the USA.

- Norton scale

Norton scale was the first scale designed to predict the risk of PUs (Pancorbo-Hidalgo et al., 2006) (Appendix C). It was developed from clinical experience, and initially consisted of five risk factors: general physical condition, mental status, activity, mobility and incontinence. These risk factors increase individual susceptibility to PUs with the presence of pressure and shear forces. Each category (risk factor) is given a score between one and four. The total maximum score is 20, with lower values indicating greater risk. A cut-off point of ≤ 14 or ≤ 16 has been used for prediction of patients at risk (Lindgren et al., 2002).

A modified version of the Norton scale was introduced in 1987. Modified Norton scale includes seven subscales: mental condition, physical activity, mobility, food intake, fluid intake, incontinence and general physical condition, with four items in each subscale (Baath et al., 2008). The maximum score in this version is 28, and patients with a score of ≤ 21 are considered to be at risk of developing PUs.

- Braden scale

Braden scale (Appendix C) was developed in the USA by Barbra Braden and Nancy Bergstorm. It was based on the conceptual model of pressure and tissue tolerance as causes for PUs developed by the authors (Bergstrom et al., 1987). This scale combines six sub-scales (which are considered the risk factors): sensory perception, exposure to moisture,

activity level, mobility, nutritional status and friction/shear forces. Scores from one to four (four is the highest) are given for sensory perception, mobility, activity, moisture and nutrition. Scores from one to three (three is the highest) are given for friction and shear forces. Score summation of these six sub-scales represents the total Braden score, which ranges from 6 to 23. As the total score decreases, the risk for PUs increases.

Different cut-off points for considering a patient to be at risk were reported in the literature for this RAS. A multisite study for the predictive validity of Braden scale established the critical cut-off point of ≤ 18 for a patient to be at risk of PUs (Bergstrom et al., 1998).

- **Waterlow scale**

Waterlow scale (Appendix C) was developed in 1985 by Judy Waterlow in the UK. The scale was designed to assist in the prevention of PUs, and as a determinant of patients at risk of PUs (Anthony et al., 2008). The scale, which appears to be the first choice for many hospitals in the UK (O'Dea, 1999), consists of 11 risk indicators/areas, including: build/weight for height, continence, skin type, mobility, gender, age, appetite and specific medication, in addition to areas that addresses special risks, including tissue malnutrition, neurological deficit and major surgery or trauma. In the Waterlow scale, the higher the score, the higher the degree of risk, (contrary to the Norton and Braden scales).

In Waterlow scale, risk degree was divided into three categories: 10 to 14 at risk (10 is the cut-off point), 15 to 19 at high risk and ≥ 20 at a very high risk of developing PUs. Waterlow scale was designed as a double-sided card, the first side of which assesses risk,

and the other contains guidelines for prevention measures (e.g. cushions and bedclothes, nursing care and wound care) (Waterlow, 2005a).

2.5.3 Criteria for an effective RAS

From an epidemiological point of view, it is obvious that the best scale to be used is the one with the best reliability (consistency) and validity (accuracy) (Pancorbo-Hidalgo et al., 2006). Validity is the ability of the tool to correctly predict who will get PUs and who will not. Predictive validity in the clinical setting is expressed in terms of sensitivity and specificity. Sensitivity is the percentage of patients who developed PU who were assessed by the RAS to be at risk (true positive). Specificity is another measure of predictive validity. Specificity is the percentage of patients who did not develop PU who were assessed to be not at risk for developing PUs (true negative). RAS has good sensitivity if it minimizes false negatives (β error), and good specificity if it minimizes false positives (α error) (Langemo et al., 1991, Seongsook et al., 2004).

Reliability in the area of evaluating clinical tools is best described by interrater reliability. Interrater reliability is the percentage of agreement instances for different people using the tool for the same subject. Usually, when this percentage of agreement is higher, the tool is considered more reliable (Bergstrom et al., 1998).

In addition for an RAS to be valid and reliable, it must also be easy to use and cost-effective (Keller et al., 2002, Defloor and Grypdonck, 2005). Cost effectiveness can be considered in two ways. Firstly, if the RAS was over-predicting risk, unneeded preventive interventions will be implemented. Secondly, if the RAS was not a good predictor, it will

not identify patients at risk, so nurses will not provide preventive measures. Such patients may end up developing PUs. In both ways, cost will increase either by providing costly and unnecessary preventions, or by treating the newly developed PUs.

2.5.4 Review of RASs' validity and reliability

There are more than 40 different RASs. Studies that aimed to review clinical effectiveness in terms of reliability and validity are limited to the most commonly used: the Waterlow, Norton and Braden scales (Schoonhoven et al., 2002, Pancorbo Hidalgo et al., 2006).

- **Validity of RASs**

In clinical settings, an effort is made to identify patients at risk of PUs. For this reason, nurses are using RAS as a tool for detecting patients at risk. However, there are numerous risk factors reported in literature that can contribute to developing PUs. Salzberg et al. (1999) reported more than 200 different risk factors that can contribute to developing PUs. The commonly used RASs (Norton, Braden and Waterlow) incorporate limited numbers of these factors in their structure, which in turn decrease their content validity. Halfens (2000) argued that it is not possible to create an RAS with perfect content validity. In this context, Anthony et al. (2008) mentioned that not all risk factors are relevant to all patient groups (e.g. smoking as a risk factor in the Waterlow scale does not apply to neonates). This in turn affects the content validity.

To further review validation of RASs; sensitivity and specificity as means of validation were also explored. Sensitivity and specificity are recommended and are the most used

epidemiological tools to evaluate the predictive validity of RASs (Defloor and Grypdonck, 2005).

Many studies have examined the predictive validity of RASs in terms of sensitivity and specificity. The Braden scale established a range of 70 to 100 per cent and 64 to 90 per cent for sensitivity and specificity respectively in different studies (Braden and Maklebust, 2005). Different studies also examined the validity of the Norton scale. In these studies, sensitivity ranged from 81 to 16 per cent; and specificity from 94 to 31 per cent. Waterlow scale also has a different range of sensitivity, from 100 to 75.8 per cent, and specificity ranging from 38 to 10.3 per cent (Pancorbo-Hidalgo et al., 2006). The Waterlow scale provides a high sensitivity score, but low specificity, which means that this scale over-predicts patients to be at risk of developing PUs (Pancorbo-Hidalgo et al., 2006).

We can notice from the above figures for sensitivity and specificity that there is a wide range in these figures for the individual scales. This is most probably due to methodological differences among these studies (e.g. using different data collection methods, different settings and different population characteristics) (Keller et al., 2002).

- **Factors that affect the predictive validity of RASs**

In a validation study for Braden scale, sensitivity for predicting non-blanchable erythema (stage one PU) was 79.8 per cent (using cut-off point <17), and specificity was 64.6 per cent. When cut-off was changed (<18), sensitivity became 83.1 per cent, and specificity 58.2 per cent. In the same study Norton scale was assessed for predictive validity (sensitivity and specificity). Using a cut-off point of <12, sensitivity and specificity were

62.3 and 71.8 per cent respectively. Changing the cut-off point to <14, sensitivity increased to 81.8 per cent and specificity decreased to 59.4 per cent (Defloor and Grypdonck, 2005).

Changing the cut-off point for the Waterlow scale, as has been done for the other two scales, the sensitivity and specificity were changed. This can be seen in a study that aimed at examining the predictive validity of Waterlow scale in intensive care unit. When increasing the cut-off point for Waterlow scale to 30, sensitivity and specificity increased to 64.6 and 48.8 per cent respectively (Compton et al., 2008).

These examples demonstrate clearly that changing the cut-off points for RASs will change their predictive validity figures.

One more factor that affects RASs' predictive validity is the different preventive measures applied in different studies (Shahin et al., 2007). This can decrease the predictive validity for RASs (Defloor and Grypdonck, 2005, Feuchtinger et al., 2007).This is because preventive measures can decrease the incidence of PUs in the group identified to be at risk according to the RAS. In this case, the only way that accurate sensitivity and specificity of RASs could be calculated would be to stop prevention measures and let patients develop PUs, which of course would be unethical (Anthony et al., 2008).

Time of assessing risk is another factor that can affect validity. RASs were highly predictive on admission, but not as predictive as doing the assessment 48 or 72 hours after admission (Bergstrom et al., 1987).

- **Reliability of RASs**

Waterlow scale is often referred to as having low reliability. In a systematic review, the interrater reliability in respect to agreement ranged from zero to 57 per cent (Kottner et al., 2008). The author of this study argues that empirical evidence for reliability for Waterlow sale is rare, making the ability to evaluate Waterlow reliability limited. Another opinion suggests that low reliability may result from large number of items in the scale, and lack of operational definitions for these items (Edwards, 1994).

Braden scale demonstrated higher interrater reliability, with 88 per cent for registered nurses, and a lower percentage of agreement between nursing assistants ranged from 11 to 19 per cent (Braden and Maklebust, 2005).

In a systematic review of RASs, it was found that Braden scale has the best reported interrater-reliability compared to the Waterlow and Braden scales (Pancorbo-Hidalgo et al., 2006). However, Norton and Waterlow scales were not reported in studies that investigated reliability, as Braden scale was. In this context, some factors such as lack of understanding and proper training on using scales, especially the Waterlow scale, may also affect reliability.

- **Should nurses use RASs?**

EPUAP considered the use of RASs as an essential part in the prevention process of PUs (EPUAP and NPUAP, 2009). At the same time, studies that examined their accuracy showed that there is no RAS that meets all criteria for the optimum prediction of PUs. The

reason for this is due to scales' accuracy (validity and reliability); no RASs achieved optimum accuracy (Papanikolaou et al., 2007a).

Comparing findings from different studies that addressed the accuracy of RASs cannot be meaningful. This can be linked to the lack of consistency between the studies that addressed RASs' accuracy. Based on the systematic review findings of Hidalgo et al. (2006), lack of consistency and potential inaccuracy of different studies could be argued based on the following reasons:

- Using different cut-off points for the same scale in different studies. In a number of studies it was found that changing cut-off points of an RAS changes its accuracy (predictive validity) of prediction (Defloor and Grypdonck, 2005, Compton et al., 2008)
- Different settings in which RASs were examined (e.g. hospitals ranging from chronic to acute wards, home care, community, geriatric centres, long-term care facilities, rehabilitation and skilled nursing facilities). Different clinical settings have different patients groups. Risk factors are not the same for all of these groups (Anthony et al., 2008). Using an RAS that incorporates only a limited number of risk factors that can cover only a small portion of the risk factors. This can decrease its accuracy in predicting risk of PUs (Halfens et al., 2000)
- Using different sampling methods: convenient, systematic and random. Some of these samplings methods i.e. convenient could be biased and do not represent the population drawn from. Testing an RAS using a convenient sample could have

different results when doing that with more representative sample i.e. random sample (Polit and Beck, 2004).

- Using different sample size, which sometimes could not be appropriate for the sampling method.
- Follow-up periods for patients varied from a few days to weeks, with some patients missing follow-up in some studies that had a small sample size and convenient sampling. In case patients are not followed for enough time some of them could develop a PU that is not included in the study. This could affect the accuracy of the results.
- Some studies excluded stage one PUs. In other words grade one was not considered a PU when in fact it is. This could give biased results when it comes to testing the accuracy of an RAS.
- A number of studies did not mention anything about using prevention measures, which may affect validity of RASs. Using preventive measures could interfere with the possibility of developing a PU, thus affecting the accuracy of RAS (Moore and Cowman, 2009).

Based on these factors, it is difficult to reach a verdict regarding the best RAS to use. In addition, it is also unclear whether it is useful to use RASs to predict risk.

In addition to doubts about RASs' accuracy, their effect on PU prevention is also unclear. In a Cochrane review it was found that few studies addressed the effect of RAS on PU prevention, with no conclusions drawn regarding their effect on PU prevention (Moore and Cowman, 2008).

Some studies tried to overcome the doubted accuracy and effectiveness of RAS in predicting and preventing PUs by offering a comprehensive care programme to prevent PU that included the use of an RAS. These comprehensive programmes included regimens for skin care, nutritional management and using RASs. As reported in one study, this comprehensive programme was effective in reducing PU incidence (Lyder et al., 2002). The aforementioned study found a significant reduction in PU incidence in two nursing homes. This significant reduction in incidence was attributed to the introduction of a prevention protocol based on an RAS (Braden scale). This study showed that it is possible to reduce the incidence of PUs in long-term care by introducing a prevention protocol. Similar findings were also reported concerning a dedicated pressure ulcer unit in a geriatric ward, in which worked a multidisciplinary team composed of nurses, doctors, dieticians, occupational therapists, auxiliary staff and social workers. Comprehensive assessment, treatment and preventive measures were carried out. The programme led to an improvement in patients' conditions, decreased numbers of ulcers and the prevention of new ones (Jaul, 2003).

While doubts exist regarding RASs usefulness in the clinical area, nurses must not ignore using one when offering care to their patients. A formal programme for prevention needs a formal risk assessment tool to create continuity of care (Waterlow, 2005a), and the initiation of preventive measures based on specific patient risk factors (Feuchtinger et al., 2007).

2.6 Grading systems for PUs

PU grading or classifying systems are subjective measures that rely on inspection rather that histopathology for assessing the extent of tissue damage that can result from different risk factors contributing to PUs occurrence. This damage can vary from simple redness (erythema) to severe muscle and bone damage, leading in some cases to systematic infections (Pedley, 2004). Using grading system aims at identifying the presence of PU, in addition to measuring its severity by giving grades to different levels of tissue damage.

Grading systems are beneficial in standardizing the assessment process, making the research process more visible and applicable because it provides a standardize method for assessing the presence and severity of PUs (Nixon et al., 2005). In the clinical area there is a need for a robust grading system of PUs in order to indicate PUs presence and degree of severity, and to enhance the quality of incidence and prevalence studies. In this regard, it is important to highlight the relationship between PU prevalence and incidence using accurate grading systems. Within the clinical setting, figures of PU prevalence and incidence can indicate the degree to which suitable preventive measures are provided. These figures, if taken as a robust measure to judge quality of care, must be supported by an accurate PU grading system.

Nevertheless, there are disadvantages to using such a grading system, which are related to different users' inaccuracy when grading a PU, and to some technical problems when assessing the ulcer. Examples of these problems include the presence of necrotic tissue covering the ulcer and difficulty in assessing the depth of skin damage (Russell, 2002).

2.6.1 Examples of grading systems

Grading systems try to follow the stages of tissue damage by assigning different numerical figures to each stage. These stages usually start by blanching erythema (redness). Blanching erythema means increased blood flow to the tissue as a reaction of the normal tissue to pressure. At this stage, damage to the tissue has not yet occurred, and the skin still blanches (whitens) if light finger pressure is applied. If pressure persists and nothing has been done to relive it, then this will develop into non-blanching erythema. Non-blanching erythema do not blanch when finger pressure is applied, signalling permanent damage to the skin microcirculation (Vanderwee et al., 2007b). After developing non-blanchable erythema, if pressure and other risk factors persist, ulceration will take place. In this case, ulceration will invade the first dermal layer. Again, if no prevention occurs, and the factors persist, deeper skin layers will be involved (Russell, 2002).

Different grading systems are available to classify the degree of PU damage. There are approximately 16 different tools. The most commonly used grading systems are: Torrance, Stirling, National Pressure Ulcer Advisory Panel (NPUAP) and EPUAP. In British hospitals, the most commonly used are Torrance 37 per cent and Stirling 25 per cent (Scott and Newens, 1999). However, in a recent publication the EPUAP grading system appeared to be the most commonly used grading system in the UK (Wilson, 2010).

- **Torrance system**

Torrance classification system (Appendix D) grades PUs through dividing the severity into five different stages. Blanching erythema is the first stage in this grading system, followed by non-blanching. In the first two stages the skin remains intact, unless blistering or

epidermal ulceration exposes the dermis. Pain can accompany the second stage if sensory nerves are intact.

Stage three ulceration progresses through the dermis until it reaches subcutaneous tissue. Until this stage the damage is reversible. In stage four and five the damage invades deeper layers until it reaches muscles and bones (Russell, 2002).

The main controversy that this system raises is considering blanchable erythema as a stage one PU. Many practitioners consider blanchable erythema a normal physiological activity of the body, which cannot be considered as skin damage. However, it can be regarded as an early sign of skin damage, and it should not be overlooked (Bethell, 2003).

- **Stirling system**

This system was developed in the UK, as a result of an amalgamation of elements from previously published scales (Appendix D). This scale has five different stages, from zero (no clinical evidence of PUs) to five (full thickness skin loss with extensive destruction). Each stage is further divided into sub-sets of codes that describe severity and nature of damage, nature of wound bed, and signs of infection that can accompany PUs. This scale can be used in its full version (four digits) or in shorter versions (three, two or one digits) (Pedley, 2004).

Stirling scale attempts to give further details regarding wound nature and accompanying characters, which results in a more complex scale.

- **The EPUAP system**

The EPUAP scale was established as part of their PU guidelines (Appendix D). It is a four digit system that starts from non-blanchable erythema as stage one PU, and then gradually describes damage until it reaches extensive tissue damage, which is stage four. This system gives special attention to people with darkly pigmented skin, to allow a chance to differentiate non-blanchable erythema (Russell, 2002).

- **NPUAP system**

This system (Appendix D) is similar to the EPUAP scale except for stage one, which was updated in 1997. The update addressed special attention to darkly pigmented skin and changes in the skin, like warmth or coolness, tissue consistency and sensation (Black et al., 2007).

2.6.2 Review of the grading systems

Although nurses accept grading systems without taking account of their accuracy, studies that investigated this were limited by many methodological weaknesses.

One study measured inter-observer agreement (reliability) of two- and one-digit Stirling grading system in addition to the EPUAP system. It found moderate agreement for two-digit Stirling scale, fair agreement for the one-digit system, and fair agreement for the EPUAP scale (Pedley, 2004). Despite this, the study used actual patients to assess patient ulcers; the number of observers was only two nurses, which may constitute limited evidence for the accuracy of these scales. I n this study the author notes that using only two nurses to assess patients and rate PU was for the sack of patients' convenience. If a larger

number of nurses was used to assess the patients this will disturb patients and interfere with their daily activities and treatment.

Another example of a flawed methodology can be found in a study that examined the reliability of the EPUAP system. This study revealed that PUs were classified erroneously. Nurses in this study disagreed largely about the difference between blanchable erythema and non-blanchable erythema (stage one), and there was disagreement about stages two and three. The study was introduced in the form of a survey, to include the largest number of nurses (n=1452) from different European countries (Beeckman et al., 2007). Due to that, a convenient sample was chosen which may not be representative of all nurses in these countries. In addition, photographs were assessed rather than patients, due to the large number of nurses recruited. Using ulcer photographs instead of ulcers *in vivo* is also considered another weakness. When photographs are used; the ratter can not distinguish between blanching and non-blanching erythema. Skin must be pressed with a finger to distinguish if the erythema blanches or not when pressure is applied.

The same scale was the target of another study, which study showed higher agreement between assessors expert in tissue viability (Defloor and Schoonhoven, 2004). One weakness of this study was that it recruited experts in tissue viability instead of nurses. This may hinder the generalizability of results.

In general, studies that addressed the reliability of grading systems are few, and lacking consistency, which makes it difficult to compare between them (Sharp, 2004). Methodological issues noticed in these studies prevented their generalizability, including:

- Using photographs to measure reliability (Defloor et al., 2006a, Stausberg et al., 2007). Although it is considered a weakness in the studies, researchers were not able to let large number of assessors examine the same patient in the same day. This could result in disturbing the patient, and could raise ethical issues.

- Using a convenient sample that is not representative of the nurses' population.

- Some studies recruited nurses as assessors without taking into consideration their experience and education (Hart et al., 2006).

2.7 Prevention of PUs

Prevention of PUs is a collaborative and interdisciplinary process that involves many activities. Moreover, prevention of PUs is a wide concept that incorporates many issues that need to be elucidated. In current nursing practice, the best strategy to deal with PUs is to prevent them. Since the majority of PUs are preventable, if prevention takes the right course and is practiced in the appropriate context (Waterlow, 2005a). This section emphasizes different issues that are related to the prevention process, including guidelines for prevention and preventive interventions for PUs.

2.7.1 Clinical guidelines for prevention

Clinical guidelines have been defined as "systematically developed statement(s) to assist practitioners and patients decision about health care for specific clinical circumstances" (van Zelm et al., 2006, p.169). This definition pictures guidelines as a set of instructions that aim to help care givers to deal efficiently and securely with a clinical situation. In

addition, it augments the clinical decision by giving it the chance to be more adaptive with different patients' conditions. This will create a more flexible environment for caregivers to manage a health problem.

Guidelines for preventing PUs were established to guide clinical decisions towards the most effective and recent techniques, in order to decrease the incidence and prevalence of PUs. They arise from the fact that PUs can be prevented, and prevention can optimize outcomes of the health care system. In addition to that, guidelines can be used for treatment and can be utilized in teaching standards of care in a formal manner (Lyder, 2003).

2.7.1.1 Developing PU guidelines

Developing PU guidelines is achieved by using formal and/or informal techniques. An informal technique implies using the sum of knowledge and experience of experts in the PU field rather than driving evidence from research. Formal technique implies using the formal empirical methods (research) to develop guidelines. In this regard, the formal process of developing guidelines follows a systematic method. Using this method implies using a systematic approach that starts from defining the scope of the problem (in this case the prevention of PUs), then developing a draft for guidelines, which is subjected to external review. After reviewing, guidelines are disseminated to be used in the clinical practice. Feedback is important to further evaluate and update these guidelines (van Zelm et al., 2006). In 2009 the NPUAP and the EPUAP developed their recent PU prevention and treatment guidelines following a formal process. These guidelines represent a collaborative effort between the two organizations in Europe and the USA. These guidelines were developed based on recent advances in tissue viability and research and a collaborative

effort that took four years (EPUAP and NPUAP, 2009). The goal of developing these guidelines was to provide evidence-based guidelines for both prevention and treatment of PUs.

There are some important components that PU guidelines must contain (Stechmiller et al., 2008):

1- Definition and aetiology of PUs

2- Effective methods for risk assessment

3- Diagnosis and staging

4- Effective prevention and treatment measures

2.7.1.2 Common PU prevention guidelines

The first guidelines for PU prevention were published in 1985 in the Netherlands. These guidelines were a collective effort of a multidisciplinary team of experts (an informal process of development). NPUAP in the USA initially developed its guidelines through an informal process. After establishing the Agency for Health Care Policy and Research (AHCPR), the approach was changed to adopt research-based guidelines. In 1990, EPUAP published prevention guidelines that were developed by a panel of experts using the informal approach. To overcome this weakness, EPUAP started to adopt an evidence-based approach in developing guidelines, in addition to the informal approach. This result was a draft containing the two approaches, which is open to review and updating (Clark, 1999).

EPUAP and NPUAP developed new prevention guidelines in 2009 through a collaborative process between the two organizations. These guidelines were developed using a unique methodology to evaluate research in this area. Each relevant research paper was examined and rated according to specified criteria to evaluate the strength of evidence reported within each study. In case of absence of a robust evidence to support regarding a certain prevention method, expert opinion was used (EPUAP and NPUAP, 2009).

In the UK, National Institute for Health and Clinical Excellence (NICE) published national PU guidelines for prevention and treatment. The approach used to develop these guidelines was similar to the evidence-based method, and followed a systematic approach. NICE guidelines are prepared by a group of health care professionals based on available evidence. It is not only forwarded to health care professionals, but also to carers and the public (Stephen-Haynes, 2006).

2.7.1.3 Barriers to implementing PU prevention guidelines

The literature revealed some barriers that face caregivers and organizations when implementing PU prevention guidelines (Haynes and Haines, 1998, Saliba et al., 2003, Tan, 2006), including:

- Lack of caregivers' awareness and acceptance of guidelines

- Failure to monitor outcomes

- Poor access to guidelines

- Organizational barriers; lack of essential resources for implementation, and ineffective continuous education programmes.

Nevertheless, adherence to prevention guidelines (which is also considered a barrier) was found to be low for both nurses and clients; in addition, there was high variation in degrees of adherence in different clinical settings. This may suggest that studies assessment of the effectiveness of different guidelines may be inaccurate. To discuss this further, a study was found that support this point. Haynes and Haines (1998) indicated in their paper that evaluating evidence based policy may be inaccurate. This is because the new strategies recommended in these policies are slowly disseminated to the clinical areas. This means that those strategies (or interventions) recommended within the new policy may not be available in the clinical areas. In other words these polices are not implemented as they should be. As a result studies that evaluated these results may not be accurate. Mentioned barriers may slow the dissemination of guidelines to health care professionals, and disturb their desirable effects.

2.7.1.4 Clinical effectiveness of PU guidelines

In the clinical setting, the desirable attribute of PU guidelines is to effectively prevent the development of new PUs. In order for this to be accomplished, these guidelines must be flexible to adapt with different circumstances; they should be valid, reliable and cost effective, as well as easy and clear for different users (Tan, 2006).

Studies that examined the clinical effectiveness of these guidelines for PUs showed that guidelines improved the outcome in preventing PUs. In addition, they enhanced formal

assessment and interdisciplinary work (Clark, 1999, Whittington et al., 1999, Clarke et al., 2005). In this context Xakellis et al (1998) conducted a study in a long-term care facility to evaluate the cost effectiveness of a new PU prevention guidelines. Incidence and cost of PU treatment were measured before and after implementing these guidelines. In this study it was found that the incidence and cost of PU treatment decreased significantly after the new protocol was introduced. In this area other study was found that had similar results. In this study PU prevention guidelines were implemented in intensive care units for critically ill patients. Again implementing these guidelines significantly decreased the incidence of grade 2 to 4 PUs (De Laat et al., 2007). From these two studies it can be noticed that implementing guidelines in a specific clinical area can decrease the incidence of PUs. However, the reported effectiveness of these guidelines is contradicted by the high incidence and prevalence figures reported in literature. One explanation for this could be due to a number of reasons that can decrease the dissemination and adoption of guidelines in different clinical settings. These include: Lack of caregivers' awareness and acceptance of guidelines, unavailability of required preventive equipments and poor dissemination of the guidelines (Tan, 2006, Saliba et al., 2003, Haynes and Haines, 1998). Also in this domain it was found that Studies that addressed the effectiveness of guidelines did not establish their effectiveness against robust criteria (Stephens and Bick, 2002, Stephen-Haynes, 2006). Some of these studies only addressed effectiveness in certain types of clinical setting, like intensive care (De Laat et al., 2007), not in a variety of settings. Furthermore, it is not known for sure which component of these prevention guidelines contributed the most to prevention. Studies of effectiveness gave only a general judgement

about effectiveness, not taking into account the role of particular interventions (Whitfield et al., 2000).

2.7.2 Review of PU preventive interventions

This section aims to review evidence from previous literature regarding different interventions that aimed at preventing the development of PUs.

As discussed earlier, PU risk factors can be classified as extrinsic and intrinsic. Extrinsic risk factors include pressure, shearing and friction forces. Intrinsic risk factors include general medical condition malnutrition, immobility, medications, dehydration, body weight, skin condition, incontinence and advanced age. To some extent, all extrinsic risk factors can be relieved or prevented. On the other hand, not all intrinsic risk factors can be prevented (e.g. advanced age).

Based on the nature of risk factors behind PU development, preventive interventions could be classified into two major categories. The first one is interventions aiming at relieving pressure, shearing and friction forces (preventing extrinsic risk factors). The second one is interventions aiming at maintaining a healthy skin and increasing tissue tolerance for pressure forces (preventing intrinsic risk factors).

2.7.2.1 Prevention methods to relieve pressure, shearing and friction forces

This sub-section reviews preventive interventions reported in the literature as working to decrease the intensity or duration of pressure shear and friction forces (PU extrinsic risk factors) on skin surface. These included re-positioning regimens and techniques, different support surfaces, heel protecting devices and referral to physiotherapist.

1- Re-positioning regimens and techniques:

Changing position (or turning) of patients at risk of PUs has been adopted for many years by nurses in different clinical settings. It aims at decreasing the pressure duration on specific areas of the body by regularly changing the patient position from side to side. This rotation enables microcirculation to deliver blood to body parts that were under pressure (Reddy et al., 2006).

Most protocols recommend a two hourly turning regimen. The base of this trend is not clear, and there is insufficient evidence to support it (Reddy et al., 2006, Vanderwee et al., 2007c). Some sources in the literature reveal that this number was determined by historical nursing shortages: the time for a nurse to complete the rotation of all patients on a ward was two hours; alternatively, nurses may have adopted the two-hour system based on their clinical experience (Bansal et al., 2005). However, one study reported that the two hours regimen came from studies on animals (Hagisawa and Ferguson-Pell, 2008).

In this area, a paucity of research was found considering re-positioning as a PU preventive technique. Defloor et al. (2005) investigated four turning regimens with the use of supporting surface versus standard care. They found that re-positioning every four hours on a pressure redistributing mattress was better than re-positioning every two hours on a standard mattress in terms of lowering PU incidence. However, the four-hour turning regimens efficacy cannot be adopted based on this study, due to a number of limitations. Firstly, the turning regimen was accompanied by the use of a special type of mattress that may have a role in decreasing PU incidence, which may have affected the results of the

study. Secondly, the study methodology was problematic, as there was no mention of patient characteristics assigned to each of the turning regimens, which cannot guarantee the effect of other risk factors on PU development.

Another study examined the effect of turning with unequal time intervals on PU incidence. Alternating at two- to four-hour intervals did not significantly differ from uniformly four-hour intervals in terms of PUs' incidence, location, and time of development (Vanderwee et al., 2007c). Subjects in this study were not initially free of PUs. Patients with non-blanchable erythema (grade one PU) were included in the study. Such inclusion criteria may have affected the results of the study, because patients with grade one PU may be at a greater risk of developing PUs. Another retrospective study that investigated the effect of different turning frequencies on PU incidence had similar results. In this study, incidence of PUs did not significantly differ between patients with more frequent re-positioning (at least every two hours), and patients with less frequent re-positioning (more than two hours) (Rich et al., 2010). No significant conclusion could be drawn from this study because it only included older patients with hip fractures. Such patients have additional risk for PU as a result of their lower level of mobility resulted from the fractured hip. This additional risk may interfere with the results of mentioned study.

In this context, studies that were found concerning re-positioning did solely address frequency of re-positioning; other techniques were also investigated (e.g. small shifts in body position, tilting and sitting in chairs). Two Randomized Controlled Trials (RCTs) were found that investigated the effect of unscheduled small shifts in body position on the incidence of PU. In both of these studies, all patients had standard nursing care for

prevention of PUs, including two-hourly turns. Patients in the study group had additional small unscheduled shifts in body position compared to patients in the control group. No significant difference was found between the two study groups in both of these studies in terms of PU incidence. In both of these studies the sample size was small. In addition, the incidence of PUs was very low. This makes it difficult to draw a conclusion regarding the efficacy of unscheduled shifts in body position (Brown et al., 1985, Smith and Malone, 1990).

Another Randomized Controlled Trial (RCT) evaluated a different re-positioning technique to prevent PUs. In this study, 30^{o} tilt position (placing pillows under patients' buttocks and legs to prevent compressive forces) was compared with 90^{o} supine and lateral positions. No significant difference in terms of PU incidence was found. Again, in this study it is difficult to draw robust scientific evidence because only 39 patients were included (Young, 2004).

Moreover, assisting or encouraging patients lying in bed to change position and sit regularly in a chair was found to be one of the re-positioning techniques that helped in preventing PUs. One study revealed that prolonged immobility on a certain body area can increase the interface pressure causing blood capillaries to collapse and eventually causing ulceration. Changing position between bed and chair can decrease interface pressure duration on certain body areas (Thomas, 2006). However, recommendations of the EPUAP and NPUAP contradicted with this and recommended that patients must not be allowed to set out of bed for long periods of time (EPUAP and NPUAP, 2009). In this area, only one study was found; a prospective descriptive study that investigated different factors that contributed to developing stage 2 to 4 PU in intensive care unit at least 48 hours after

admission. Using multivariate analysis this study found that changing position from lying in bed to sitting in a chair for one hour or less daily was associated with decreasing the incidence of PUs grades 2 to 4 (Nijs et al., 2009). This finding does not contradict with EPUAP guidelines regarding prolonged sitting because sitting in this study was only for short periods (less than one hour). One limitation of this study was that it did not follow patients until discharge; they were only followed during their intensive care stay.

In brief, a number of studies investigated re-positioning as a technique to prevent PUs; however, no clear evidence about the best technique could be found. The paucity of studies on a particular technique, in addition to the presence of limitations of these studies, prevented reaching a conclusion about which of these techniques or regimens is most effective. Even so, the literature revealed that the most effective re-positioning technique should be accompanied with other pressure relieving devices. An example of that is using pressure-relieving mattresses or cushions, in addition to re-positioning. Re-positioning only decreases the duration of pressure, but there is also a need to decrease the intensity of pressure. This can be accomplished by mixing re-positioning with other relieving techniques (Defloor et al., 2006b).

2- Support surfaces

According to the Support Surface Standards Initiative published by the NPUAP support surfaces are classified into the following categories (NPUAP, 2007):.

- Reactive support surface: powered or non-powered surfaces that can change its weight distribution properties according to applied weight.

- Active support surface: this is a powered surface and can change weight distribution with or without a load.

- Integrated bed system: bed and mattress are integrated into one unit and can not function separately.

- Non-powered surface: any support surface that needs no external power to be moved.

- Powered surface: any support surface that uses external power to be moved.

- Overlay: any support surface that is designed to be put above other support surfaces.

- Mattress: a support surface that can be directly put on the top of bed.

The principle behind using support surfaces is to reduce or relieve pressure that is exerted on the skin surface as a result of body weight. This could be achieved by redistributing or relieving interface pressure over bony prominences and pressure points on the skin surface (Reddy et al., 2006). In clinical practice there are many types of protective support surfaces, such as special mattresses and overlays, profiling beds and seating cushions.

- **Mattresses, overlays and seating cushions**

According to the consistency of the pressure gradient under the skin of patient, mattresses can be classified as static or dynamic (Bansal et al., 2005, Gray-Siracusa and Schrier, 2011). The pressure gradient in static surfaces is constant; there is no alteration in the pressure under the patient. These surfaces are made of special materials that have the ability to decrease the intensity of interface pressure on the skin surface. Examples of this type are mattresses filed with air, water, fibre, gel and foam, or any combination of these. In

dynamic mattresses, the pressure gradient varies under the skin of patient due to the work of mechanical parts or compressors. Changing the pressure gradient under the patient can reduce the duration of high pressure force. Dynamic mattresses include alternating pressure mattresses (that change pressure intermittently by inflating or deflating cells in the mattress), low air loss beds (that maintain low pressure within the mattress) and air fluidized mattresses (with silicon-coated beads that liquefy when air is pumped into the mattress).

Another development in support surfaces is overlays. Overlays are special support surfaces (that could be dynamic or static), which can reduce the extent or duration of pressure, preventing PUs. They were developed as a cheap substitute for specialized mattresses (Cullum et al., 2004).

Seating cushions are another type of support surface that are filled with water, air, foam and gel, or any combination of these. They can help in reducing the pressure intensity while the patient is seated (Maklebust, 1997). Their use is particularly important in patients who sit for long periods of time (e.g. wheelchair users) (Stockton and Rithalia, 2009).

In order to compare the superiority of certain types of special support surfaces over each other or over standard support surfaces, studies that addressed these support surfaces were tabulated (see Appendix E). Appendix E tabulates summaries of empirical studies that compared different types of support surfaces (whether special or standard) in terms of PU prevention. The main limitations and weaknesses noticed when revising these study reports were also addressed.

The summary table showed a large number of comparisons between different types of support surfaces. For instance, special mattresses and overlays were compared with each other and with standard support surfaces. Making a sound comparison to reach a conclusion about the best support surface is difficult due to the following reasons:

1- Contradictory evidence supporting the use of different types of support surfaces.

2- The presence of limitations and methodological weaknesses in the studies that prevent their generalizability (e.g. some studies were restricted to a specific group of patients; some had small sample numbers; some included patients with different degrees of risk; some excluded PU grade one; some used descriptive statistics; some used prevalence of PUs instead of incidence as an outcome; and there was a low incidence of PUs in some studies).

3- Most of the studies found were RCTs. This could give a chance for the Hawthorn effect to take place, thus giving biased results. Nurses may give extra preventive care for patients lying on the surface as they think that it is better in prevention. On the other hand, comparative studies that evaluated effectiveness did not control for other prevention methods. Uncontrolled prevention could mask the ineffectiveness of some supporting surfaces.

4- Different support surfaces were made from different materials even in the same category of comparison. For instance, the static mattresses reported in the table were made of different types of materials; some were filled with air, some with gel.

Different materials may have different physical and chemical properties that vary in their ability to relieve interface pressure.

5- It was found that the risk of developing PUs increased with increasing length of stay on the supporting surface (Theaker et al., 2005). In this domain, different studies investigated the efficacy of mattresses and overlays with varied periods for length of stay on these surfaces. This does not control for the increased risk of some patients on certain surfaces, thus giving inaccurate results.

6- Most of the studies that compared standard hospital mattresses to other specialized static or pressure-alternating mattresses do not give a clear definition of the standard hospital mattress.

Literature review studies in this area also concluded that there is a lack of robust and sound evidence that can support the use of one special support surface over another, or over standard support surfaces in terms of preventing PUs (Cullum et al., 2004, Bell, 2005, Jones, 2005, Reddy et al., 2006, McInnes, 2010).

In this concern, selecting the type of mattress or overlay and incorporating it into a prevention programme is not always governed by evidence-based practice alone; other factors play a role. These factors may include ease of use, impact on patient lifestyle, comfort, speed of obtaining equipment and affordability (Papanikolaou et al., 2007b, Stechmiller et al., 2008).

- **Profiling beds**

In profiling beds, sections of the bed can be moved using electrical power for the benefit and comfort of patient. This can enable patients to more frequently reposition, thus decreasing the duration of interface pressure on a certain body part. Additionally, they can help prevent patients from sliding down in bed, sparing them friction forces that result from sliding down, thus preventing PUs (Maklebust, 1997, Keogh and Dealey, 2001, Benbow, 2008). Manually operated beds with no mechanical power are considered as standard hospital beds.

During the literature search, only two studies were found that investigated the efficacy of profiling beds on preventing PUs. The first one compared electrical profiling beds with standard hospital beds. This study involved only 70 patients, who were equally randomized to either an electric profiling bed or standard hospital bed. No significant difference in terms of PU incidence was found between the two beds (Keogh and Dealey, 2001). The study followed patients for ten days, not until discharge. This could compromise the results, because some patients could develop PUs after the tenth day.

The second study involved a large number of patients with similar ages and medical conditions. It found a significantly lower incidence of PUs in patients who were on a profiling bed compared to patients on standard bed (Hampton, 1998). Mattresses used in this study were not controlled between profiling and standard beds. Selection of mattress type depended on the Waterlow score. This could stand as a confounding factor for the study results.

It can be noticed that the two studies revealed contradicting results in regard to using profiling beds, and both of them had limitations. In view of this scant evidence, no conclusion could be drawn regarding the use of profiling beds. A recent literature review also found that there was not enough evidence to support using profiling beds as an effective intervention to prevent PUs (Cullum and Petherick, 2008).

- **Draw sheets**

A draw sheet or slide sheet is a wide sheet placed transversely on the bed (under the patient) for easy lifting and handling. Using draw sheet is considered a safe handling technique that protects both the nurse and patient. For nurses, it minimizes the risk of back injuries while moving and handling patients across and out of bed (Marras et al., 1999). For patients, draw sheets act by completely lifting the patient up when moved, without sliding them along the bed surface (Frantz et al., 2004). Lifting patients without rubbing their body parts on the bed surface will protect their skin from shearing and friction forces. These forces are considered as extrinsic risk factors for PUs (Waterlow, 2005b).

The literature search for preventive interventions revealed that there was no clear empirical evidence to support the use of draw sheets in preventing PUs. All of the evidence found in this area was in the form of recommendations reported within RASs or guidelines. No prospective or retrospective studies were found that had been conducted specifically to test the effect of using draw sheets for the prevention of PUs.

Guidelines presented with Braden RAS recommended using draw sheets as a preventive measure, using them to lift patients up or to turn them in bed if the patient activity level was

limited (Fowler et al., 2008). In the same context, Judith Waterlow recommended safe patient handling in her manual for PU prevention. She argued that the most important feature when moving the patient is not to slide them directly on the bed surface, but to use transfer devices (Waterlow, 2005b). Braden and Waterlow recommendations were based on the evidence that friction and shear forces can cause skin breakdown. Moreover, a number PU prevention guidelines and standardized criteria for care recommended the use of draw sheet as a safe handling technique (Glavis and Barbour, 1990, Gordon et al., 2004, Frantz et al., 2004, Ryan, 2006, Werkman et al., 2008). These guidelines were based on the same evidence; that using draw sheets will protect patients from shearing and friction forces that can cause skin breakdown.

It is important to notice here that the use of draw sheets while simultaneously using alternating pressure redistributing devices (e.g. alternating air mattresses) could be harmful (South-Australian-Department-of-Health, 2004). The presence of these sheets on the surface of these devices can hinder their pressure-redistributing properties, therefore increasing the chance of acquiring PUs.

3- Heel protecting devices

Heels, like any other body part, are prone to ulceration, and can benefit from the pressure-relieving surfaces mentioned earlier. However, heels need further attention to protect from pressure, shear and friction forces (Donnelly, 2001). This is due the thin layer of skin and adipose tissue covering this sharp bony prominence which makes it more vulnerable to shear and friction forces. Heels as any other part of the body can benefit from PU protective

measures such as re-positioning and support surfaces. Guidelines for PU prevention suggest that pressure relief (pressure offloading) is the most important aspect in PU heel prevention (Fowler et al., 2008). Nurses and other health care professional e.g. physiotherapist can have an active role in the preventing of heels ulcers by implementing the right moving and handling techniques and using heel protecting devices or just elevate the heels above the support surface to prevent pressure and shear forces from damaging the skin over the heels. A small number of clinical studies have discussed implementing different prevention modalities specially developed to protect heels.

In a randomized study, four types of heel protecting devices were compared: foam splints, eggshell foam, duoderm and heel protector boots. Foam splints and eggshell foam were the most effective in prevention (Zernikern, 1994). Results in the latter study must be adopted with caution, due to the relatively small sample (41 patients), and patients not being followed until discharge. Further studies on high risk groups revealed the efficacy of anatomical foam body support devices and hydropolymer foam in decreasing the incidence of PUs (Bots and Apotheker, 2004, Cadue et al., 2008). Again, these two studies were limited to high risk groups, which create some obstacles to generalizing the results.

Another quasi-prospective study evaluated three heel protector devices, namely high-cushion heel protector (bunny boot), heel Lift positioner (egg crate), or foot waffle air cushion (foot waffle). Results from this study indicated that there was no significant difference between the three devices in terms of PU incidence. There was a caring bias, as the author noted. Nurses were supporting patients' heels in the bunny foot group with extra pillows (Gilcreast et al., 2005).

Hospital pillows as a standard heel elevating device were also considered in a different study, in which patients were randomized either to receive a standard hospital pillow or a commercial elevating device (foot waffle) for heel protection. No significant difference was found between the two in preventing heel PUs (Tymec et al., 1997). Result from this study cannot be accepted as valid, because different risk factors and other prevention techniques were not controlled in the study population.

Evidence in this area of research is scant. No clear evidence was found to support the adoption of a certain heel protector device. Studies that investigated the efficacy of heel protector devices faced a number of limitations that hinder their generalizability. These limitations include: small number of participants which could decrease the power of the study, not all patients were followed until discharge from hospital, including only high risk patients, presence of caring bias e.g. providing extra care for patients in the study and using univariate analysis to analyse data.

4- Referral to a physiotherapist

Interventions that can increase level of mobility (e.g. bed exercise) play a major role in PU prevention by decreasing the duration of interface pressure, besides transferring and re-positioning patients in the right way, sparing them friction and shear forces, which can also help in prevention. Physiotherapists can assist in implementing these interventions, thus playing a role in PU prevention (Stirling, 2009).

In literature there was no empirical study that specifically investigated the sole role of the physiotherapist in preventing PUs. However, a number of previous studies that reported the

effect of implementing a new PU prevention programme implicitly addressed the role of physiotherapists in PU prevention. These programmes were based on delivering PU prevention through a multidisciplinary team (including physiotherapists). Implementing these programmes significantly decreased the incidence of PUs (Baker, 1998, Harrison et al., 2008, Stirling, 2009). In these studies, attributing the decrease in PUs incidence to a certain member(s) in a multidisciplinary team is difficult. Moreover, other factors not mentioned in these studies may affect the outcome (e.g. different patients' characteristics and types of preventive interventions).

Evidence in this area is unclear, especially in the absence of direct empirical evidence, and drawing a conclusion regarding the role of physiotherapists is difficult.

2.7.2.2 Maintaining a healthy skin and increasing tissue tolerance for pressure forces

This sub-section reviews preventive interventions reported in the literature that aimed to increase tissue tolerance of pressure by preventing some intrinsic risk factors. These interventions included: nutritional interventions, referral to a dietician and topical skin care interventions.

1- Nutritional interventions

Poor nutritional status has been reported in research to decrease tissue tolerance for pressure, thus making tissue more vulnerable to breakdown (Arnold, 2003, Banks et al., 2009). Correcting poor nutritional status through nutritional interventions is assumed to increase tissue tolerance for compressive forces and protect from PUs (Horn et al., 2004).

A literature search for studies addressing nutritional interventions as a PU preventive measure found a number of studies. Howing et al. (2003) conducted a double-blinded RCT, in which a nutritional supplement composed of protein, zinc and antioxidants was administered to an experimental group. The control group received the placebo supplement. No significant difference was found between the two groups regarding PU incidence. This study was underpowered due to its small sample size. A different RCT tried to enhance nutritional status through delivering nutritional supplements using a feeding tube. In this trial, no significant difference was found in the incidence of PUs between patients who received tube feeding and those who did not. Tube feeding in this study was not continued for all of the study period, because some patients were unable to tolerate the tube (Hartgrink et al., 1998). The presence of this problem means that the intervention (tube feeding) was not implemented as it should have been which has an effect on the results.

In this context, two RCTs were also found that compared adding a daily oral nutritional supplement to the standard diet to standard diet alone. In both of these RCTs, adding a nutritional supplement did not decrease the incidence of PUs (Delmi et al., 1990, Ek et al., 1991). In both of these studies other risk factors for PUs were controlled, but not other preventive interventions. Different preventive interventions between patients could affect PU incidence.

Previously discussed studies found no relationship between providing extra nutritional supplements and the prevention of PUs. Conversely, other studies found that implementing nutritional interventions can decrease the incidence of PUs.

One clinical trial found that it was possible to decrease the incidence of hospital-acquired PUs through implementing a new clinical pathway. This pathway consisted of providing preventive measures that included giving a nutritional drink twice a day for post-operative patients. Patients in this study were old, and basically had poor nutritional status before surgery (Hommel et al., 2007). It was difficult to randomize patients to control and study groups due to the nature of the study.

In a different multi-centre trial, a nutritional intervention was introduced to critically ill patients. It consisted of giving two oral nutritional supplements for a period of 15 days. Patients in the experimental group were having initially lower serum albumin than the control group. In this study, dietary intake for the experimental group was enhanced. PU incidence was also decreased in the experimental group compared to the control group (Bourdel-Marchasson et al., 2000). A methodological weakness was the randomization process, because patient wards were randomized to either experimental or control group (not the patients themselves).

In previous studies, contradictory evidence was found regarding nutritional supplementation's effect on PU prevention. Different studies used different approaches, using different types of supplements, with different follow-up periods and different patients' medical conditions. All of these factors, in addition to the methodological weaknesses, make it difficult to draw conclusions about the efficacy of these supplements in preventing PUs.

In this regard, a number of systematic reviews were found in the literature that discussed the relationship between nutritional supplementation and prevention of PUs. Reviews addressed different nutritional support regimens that included different combinations of nutritional supplements. Unclear evidence was found in all reviews to support the role of a particular nutritional supplement on PUs prevention. This unclear evidence is due to the low methodological quality of studies reviewed. Authors of these reviews suggest further research to ascertain the most effective method for nutritional supplementation (Langer et al., 2003, Stratton et al., 2005, Stratton and Elia, 2007, Stechmiller et al., 2008).

PU prevention guidelines also recognized this limited evidence. For this reason, guidelines focused on patients' nutritional screening instead of recommending a particular supplement (Meijers et al., 2008). If nurses find a particular patient to be at risk of developing PUs and simultaneously malnourished or at risk of malnourishment, more comprehensive screening should be done through referring to a dietician or a multidisciplinary nutritional team (Posthauer, 2006). This can promote nutritional interventions that are able to fulfil patients' needs while preventing the risk factors for PUs (Schols and de Jager-vd Ende, 2004).

2- Referral to a dietician

Deteriorated nutritional status is considered a risk factor for developing PUs (Arnold, 2003). The role of a dietician is to assess alterations in nutritional status and intervene to improve them. These interventions include adjusting dietary intake by giving different types of supplement or increasing calorie or fluid intake. Such interventions can increase

tissue tolerance for compressive forces and eventually assist in preventing PUs (Stirling, 2009).

The literature search did not reveal any empirical evidence to support the role of dieticians in preventing PUs. Nevertheless, some previous studies that reported the effect of implementing a new PU prevention programme implicitly addressed the role of dietician in PUs prevention. These programmes were based on delivering PU prevention through a multidisciplinary team (including dieticians). Implementing these programmes significantly decreased the incidence of PUs (Baker, 1998, Harrison et al., 2008, Stirling, 2009). The drop of PU incidence in these studies is difficult to attribute to a certain member of the multidisciplinary team. Moreover, other factors not mentioned in these studies may affect the outcome (e.g. different patients' characteristics and other types of preventive interventions).

The absence of empirical evidence regarding the individual role of dieticians in preventing PUs makes drawing conclusions about this issue extremely difficult.

3- Topical skin care interventions

This section aims at reviewing studies that investigated different topical skin interventions and their role in PUs prevention. In this review, only empirical studies that addressed PU as an outcome were included. For this purpose, all studies found in this area were analysed in a table (Appendix F).

After analysing different studies found in this area, three categories of topical skin care preventive interventions were found: topical skin care for incontinence, barrier creams and moisturizing creams.

- **Topical skin care for incontinence**

Increased skin moisture resulting from urinary or faecal incontinence can cause skin irritation and maceration. Consequently, incontinence can decrease tissue tolerance to pressure, and shearing forces making it more vulnerable to breakdown. Combining the two types of incontinence (urinary and faecal) can cause higher degrees of irritation than each type alone, thus further increasing the risk of PUs (Ersser et al., 2005). This means that nurses must focus on evidence-based topical skin care intervention in order to prevent this consequence.

Studies found that addressed the prevention of PUs in incontinent patients compared cleansing the skin with special washing liquids and foams against ordinary cleansing with soap and water (see Appendix F). Cleansing the skin after incontinence episodes can remove chemical irritants and organic debris that have a role in skin breakdown (Ersser et al., 2005). Results from these studies reflect contradictory evidence regarding the superiority of special cleansing liquids over soap and water. In addition, the small number of these studies and their limitations and methodological weaknesses inhibit the drawing of conclusions regarding the superiority of a particular intervention.

Systematic reviews argue that non-rinse cleansers may be superior to soap and water, because the former can cause skin dryness. However, authors of these reviews note that the evidence to support this is weak and unclear (Ersser et al., 2005, Hodgkinson et al., 2006).

Absorbent pads and disposable bodyworns were also discussed in the literature as a caring modality for patients with incontinence, because they can decrease excess moisture resulting from incontinence. However, studies that addressed these interventions were excluded because they did not have PU as an outcome, or were laboratory based (Brazzelli et al., 2002, Fader et al., 2003, Fader et al., 2004).

- **Barrier and moisturizing creams**

Barrier creams are composed of lipid and water emulsion base with anti-oxidants. Some of them may contain silicon or antiseptic agents to enhance their effect. Their job is to form a thin layer over the skin surface to prevent skin breakdown by keeping skin moist. They can also act as a barrier to protect the skin from the adverse effects of external factors such as incontinence and friction (Ersser et al., 2005, Nakagami et al., 2007). Some barrier products may also have some hydration effect on the skin (Voegeli, 2008b).

A literature search concerning the effect of barrier creams on PU prevention found a small number of empirical studies that addressed this intervention (see Appendix F). Studies that evaluated the efficacy of barrier creams alone against placebo or no barrier with all other interventions controlled found a significant decrease in PU incidence when a barrier cream or film was used (Bou et al., 2005, Meaume et al., 2005, Nakagami et al., 2007). Studies that compared barrier creams with other interventions, like moisturizing creams or

cleansing regimens, found contradictory evidence regarding the efficacy of barrier creams (Dealey, 1995, Lewis-Byers et al., 2002, Hunter et al., 2003, Bale et al., 2004). Nevertheless, drawing a conclusion about the merits of using barrier creams in preventing PUs is difficult due to the small number of studies addressing this intervention, and the limitations and weaknesses in these studies.

On the other hand, moisturizing creams or emollients are basically composed of water and emulsifying agent (usually a type of lipid). Some of them may contain some surfactant materials to enhance their stability (Voege, 2010). Through their moisturizing effect they can improve skin barrier, thus increasing tissue tolerance for external compressive forces. The best time for applying them is after cleaning with soap and water; because soap and water can cause skin dryness and consequent breakdown (Lawton, 2007).

The literature search for empirical evidence to support the use of moisturizing creams to prevent PUs did not find any study that investigated the efficacy of moisturizing cream separately. However, two studies that evaluated barrier creams with moisturizing properties were found (Lewis-Byers et al., 2002, Bou et al., 2005). These studies showed contradictory evidence about the efficacy of this type of moisturizing barrier cream. In view of this, no conclusion could be drawn about the efficacy of moisturizing creams in preventing PUs. Paucity and unclear evidence in this area are the main reasons.

In this context, literature review papers concerning the effect of barrier creams and emollients also showed that a conclusion about their efficacy cannot be made because of the weak and unclear evidence in this area. Besides that, it was found that much of the

nursing practice in this area is based on experience and tradition (Benbow, 2008, Voege, 2010, Voegeli, 2008a).

2.8 Summary of the main research weaknesses found in studies concerning intervention to prevent PUs

This section illustrates in general a number of weaknesses that were noticed in different studies that addressed PU preventive interventions, which were:

1- Not all patients in the different studies run at the same degree or have equal risk. An example of this is a study conducted by Vyhlidal et al (1997) that aimed at evaluating a special type of mattresses. This study included only patients at risk according to Braden scale. On the contrast, other study was found that evaluated the same type of mattress but did not have a criterion for selecting at risk patient (van Leen et al., 2010). Unequal risk between studies can make some interventions look more effective in patients who are at a leaser degree of risk.

2- Not all types of management for patients in clinical trials were recorded and evaluated. An example of this limitation can be found in a study that evaluated three heel protector devices. As the author of this study notes that nurses used extra pillows to support patient heels which were not recorded (Gilcreast et al., 2005). This can create a degree of uncertainty about the effect of tested intervention on the outcome.

3- Methodological weaknesses were found in some studies, including lack of randomization, small sample size, previous knowledge about the intervention implemented or mixing between staff in experimental group and control group. Lack of randomization

was present in a number of studies; an example of this limitation was a study evaluated special type of mattresses on preventing PUs (Theaker et al., 2005). In this study there was no randomization of the tested mattress. Lack of randomization can affect the internal validity of the study because non-randomly selecting patients who have certain characteristics can have a profound effect on the outcome. Small sample size was also found in a number of studies that tested the efficacy of special types of mattresses (Economides et al., 1995, Vyhlidal et al., 1997, Cavicchioli and Carella, 2007). Small sample size makes it difficult to draw an inference from the sample to the population thus decreasing the power of the study (Polit and Beck, 2004). Hawthorn effect or previous knowledge about the intervention implemented was found in a number of studies that investigated the efficacy of certain preventive interventions. For instance, in a study that investigated the effect of incontinence and exercise intervention against standard care, nurses in the standard care group knew about the implementation of study (Bates-Jensen et al., 2003). In this case nurses may have improved their caring activity. Presence of Hawthorn effect in certain studies may limit their results usability.

4- Some studies excluded stage-one PUs. This limitation was found in a number of studies that investigated the effectiveness topical skin care (Thompson et al., 2005, Bou et al., 2005). Also in studies that investigated the efficacy of certain protective mattresses (Nixon et al., 2006a). Excluding PU grade one from analysis means that it is not considered an ulcer when in fact it is. This may give a false impression about the effectiveness of some preventive interventions.

5- Follow-up periods in some studies were relatively short. An example of this limitation is a study conducted by Chalian and Kagan (2001). In this study the researcher tested the efficacy of a fluid mattress versus a standard mattress in terms of preventing PU. Patients were only followed for three days. In this case some PUs may develop after three days thus giving wrong results (PU can develop at any time during hospitalization (Waterlow, 2005b).

6- The evaluation of some products was funded by the manufacturers; this may result in biased results. In a study that tested a special type of multi-cell dynamic mattress versus a standard hospital mattress the manufacture of the special mattress funded the study (Russell and Lichtenstein, 2000). This may create a caring bias for patients in the special mattress group thus giving biased results.

In a line, research weaknesses can create unclear evidence when it comes to adopting a certain prevention modality. This can keep the door open for further studies to explore effective intervention in more controlled conditions.

2.9 Key points that must be considered in the prevention process

In the prevention process it is not only important to recommend evidenced-based intervention; other factors must also be considered, namely: nurses' education, timely interventions, nursing documentation and adopting comprehensive programmes for prevention and management.

Timely interventions for patients vulnerable to PUs can decrease the incidence of PUs, thus preventing further complications and patient suffering (De Laat et al., 2006a). A key point to timely interventions is to correctly predict which patients are at risk. This necessitates a good knowledge about PU risk factors, and using valid RASs (Ayello and Cwocn, 2007).

Documentation helps nurses to organize the care process more formally. In addition it can help in maintaining continuity of care and preventing negligence (Whittington et al., 1999). Lack of documenting PU prevention indicates that nurses are not aware of the importance of the problem (Gunningberg et al., 2000a). Additionally, other nurses cannot continue the same pathway of care if it was not documented.

Nurses' education is an important factor that can enhance the prevention process and result in decreased PU rates. Although new interventions and guidelines are being introduced, PU prevalence is still high in Europe. One of the reasons for that may be nurses' lack of knowledge regarding these interventions (Anthony et al., 2008). Knowledge concerning different prevention guidelines is still not distributed in an appropriate manner. Consequently, there is a need to focus educational efforts in this area (Duimel-Peeters et al., 2006).

Comprehensive programmes that adopt evidence-based policy are crucial for the prevention of PUs (Lyder et al., 2002). They can help in creating a more suitable environment for prevention. This ensures that prevention modalities are carried out in an appropriate manner. Also, when prevention comes in the form of a specialized programme, it covers all aspects of care through using a multi-disciplinary team (Theaker, 2003, Jaul,

2003). Another advantage is that successful programmes can attract financial backing, which can help in improving the prevention process (Eyers, 2001).

2.10 Theoretical background of the study

The prevention of PUs aims at reducing the morbidity that can happen to skin as a result of pressure, shear and friction forces. As shown in earlier sections, the prevention process highlights two key points that are considered important in the prevention process: using evidence-based preventive interventions and identifying risk factors that are associated with developing PUs.

Using evidence-based interventions ensures that caregivers are using the appropriate interventions. Moreover, knowing which factors are associated with ulceration is also an important aspect of prevention. This will aid nurses in identifying such factors, and hence in intervening to prevent them.

Revising the literature revealed a conceptual model that can enhance the understanding of the two key points of PU prevention. This conceptual model was the web of causation.

Web of causation model: This model is concerned with multi-causal relationships between a medical condition (or a state) and the number of factors that can contribute to its occurrence or development. In this model the cause of a disease is conceptualized as a web or matrix made up of a number of causal factors or determinants (Charlton, 1996). According to this model, the disease pattern in a population is a result of a complex web of risks and protective interventions. Population health can be improved if the risk factors in

the web can be identified and prevented. This model facilitates understanding complex relationships between a disease and risk factors, rather than understanding disease origin alone. Multivariate analysis is the statistical technique embedded in this model (Krieger, 1994), which assumes that the effect is caused by a combination of factors (variables).

In the current study, the web of causation model is the sum of interventions and risk factors that can contribute to development of PUs or their prevention. The direct cause of PUs, as mentioned earlier, is exposing a body area to pressure, shear and friction. In fact, literature has identified many other interrelated risk factors that can contribute to PUs and increase the risk of them. Interrelations between preventive interventions and risk factors in the presence of pressure formulate the web of causation that contributes to PU development or prevention.

Web of causation model was found to explain the relation between different variables. However other two models were also found that could also explain this relation. These were: Brunswik lens model and Levine's conservation model.

Brunswik lens model: This model was originally initiated to explain the process of creating human perception (perceived image) about the actual environmental stimuli (real object). Brunswik during his work simulated the process of judgement (perception) similar to a light passing through a convex lens (this is the reason it was called lens model). In this model, light is reflected from the actual object through a convex lens to be reflected on retina. Characters of the image (e.g. size, shape) can vary according to the lens curvature. In addition other factors can disturb our perception, in this case dim light, reflections or any

other factors that can prevent us from getting a clear image. In order to apply this model to real life events, real object is on one side of the lens. Cues (factors that can disturb perception) are on the middle of the lens. Perceived image is on the other side of the lens (judgment or conclusion). Cues in this model are used to draw conclusion about real life object.

Nonetheless, the perception in this model is probabilistic because the relation between the perception and object in the environment is correlational, not deterministic. In view of that, the perception is governed by the degree of correlation between the cues and real object (Wigton, 2008). The application of this model on identifying PU risk factors and preventive interventions can highlight the correlational relation between the out come (PUs) and risk factors and preventive interventions. This means that the relation between risk factors and preventive interventions, and PUs is associative (correlational) not causative. This applies to the nature of the data in current study i.e. retrospective. Retrospective data can not prove a cause and effect relation; it only can highlight association between variables.

According to this model one part of the lens represents the judgement made (whether patient will acquire PUs or not). Cues (risk factors and preventive interventions) are the opposite parte of the lens. Based on the quality of the cues (risk factors and interventions); the judgement will be right or wrong. In other words the more valid the cues (risk factors and interventions) are; the more the nursing judgment is correlated with the actual fact (acquiring PUs or not).

Levine's conservation model: conservation principle is used to maintain integrity and prevent harm. Furthermore, conservation can constitute an important part of the nursing care. This is because one of the nursing goals is to prevent harm and promote health. In order to apply this model to health care; the author defined four conservation principles that underline this model. These four principles are: conservation of energy, conservation of structural integrity, conservation of personal integrity and conservation of social integrity.

When a patient is at risk of developing PU; there is a threat to his/ her integrity. In this case nurses must implement preventive interventions to preserve this integrity.

According to this four principles model; implementing appropriate and effective preventive measures could result in preserving patients' integrity; which mean no development of PUs. At the contrary implementing inappropriate and ineffective interventions will result in developing PUs.

Conserving energy is the first principle in this model. Conserving energy implies providing interventions that maintain energy balance; which is important to maintain a healthy skin function. In respect to this, providing balanced diet will preserve energy. This will help the skin to maintain its barrier function, thus preventing it from breaking down.

Conservation of structural integrity is the second principle of conservation. According to this principle, maintaining structure will maintain function. In the case of preventing PUs, preventing skin break down (ulceration) will conserve function.

The third principle is conservation of personal integrity. This principle argues that hospitalization compromise personal integrity by making the patient more dependent. In

respect to this decreasing the hospital stay period will result in improving personal integrity. PUs can increase the hospital stay period, so preventing them will decrease the hospital stay, thus improving personal integrity.

In addition, preventive interventions that are aimed at preserving energy and restore structural integrity may also establish patient independence, thus personal integrity.

Conservation of social integrity is the fourth principle in Levine's model. Social integrity may be impaired due to hospitalization and consequence of disease. PUs is one of the consequences that can cause prolonged hospitalization. As a result, preventive measures can contribute by an indirect way to preserve patient social integrity (Levine, 1996, Leach, 2006, Mock et al., 2007). The use of conservation model in this study stresses the importance of selecting preventing interventions and indentifying risk factors based of scientific method. Moreover using preventive measures does not only preserve physical integrity. It acts also on other perspectives of the patient, demonstrating the holistic approach in nursing care.

2.11 Conceptual framework of the study

"A conceptual model is a set of highly abstract, related constructs that broadly explains phenomena of interest, express assumptions, and reflects a philosophical stance" (Burns and Grove, 2001, p.458). The term "conceptual framework" is used in this study because a model instead of theory was used to understand the relationships between different variables.

In this study, a conceptual framework was developed to explore the association between a number of interventions and PU prevention. It is also intended to explore the association between a number of assumed risk factors and acquiring PUs. The current conceptual framework was based on the literature review findings. Evidence to support effective interventions that prevented PUs in the literature reviewed was unclear. Also, the evidence to support the relationship between certain risk factors and PU was vague, and sometimes contradictory. The lack of a robust methodological design was common in some of the studies reviewed. Likewise, the literature revealed the doubtful effectiveness of RAS. In order to overcome this doubt, the current enquiry employed Waterlow scale in a different manner. Waterlow scale was used here not as a tool for predicting PUs, but primarily to control some of the risk factors that can make a difference in patients' susceptibility to PUs. Matching two sets of patients who shared a number of Waterlow sub-scores can control a number of these risk factors. Doing this will create a more suitable environment for comparing different interventions, as well as risk factors, between patients who developed PU and those who didn't.

Different concepts in this study were linked together using the web of causation model. As stated earlier, the web of causation model can reveal which risk and preventive factors were related to the phenomenon of interest (PUs). As a result, using the web of causation model sets the conceptual basis for a sound comparison that can reveal which intervention were associated with prevention and which risk factors were associated with PUs. Moreover, using this model as a theoretical basis for the study may provide clear evidence for both risk factors and interventions, as well as resolving the interaction between different

variables through using multivariate analysis. The schematic presentation (Figure 2.2) shows the general conceptual approach of this study. In order to explore which interventions were effective and which risk factors were associated with ulceration, two groups of patients were retrospectively chosen. These two groups overlap in the area of Waterlow sub-scores and differ in PU status. Applying this framework facilitates isolating effective intervention and risk factors as they occur in an actual clinical setting. This could give empirical evidence to suggest which interventions were effective. In addition, this framework controls only a number of risk factors (matched Waterlow sub-scores). This means that other factors (in addition to interventions) could vary, and possibly be linked to PUs.

In area of health care, wound care and PUs, matching patients on specific characteristics was also implemented in order to control the effect of certain variable (confounders) on the outcome, consequently having more accurate results. Girou et al (2000) conducted a matched design study to explore the relation between non-invasive ventilation and lowering the risk of hospital acquired pneumonia. This study matched patient on a number of risk factors that are related to pneumonia. In the area of wound care this matched design was also used. Lerman et al (2010) matched two groups of patients on pre-established characterstics that are known to effect wound healing to investigate the efficacy of two wound treatment approaches.

The matched design was also used in the area of PUs. In a retrospective study conducted to identify risk factors of severe PUs, cases and controls were matched on age, gender,

immobility and cachexia to indentify other risk factors of PUs more accurately (Von Renteln-Kruse et al., 2005).

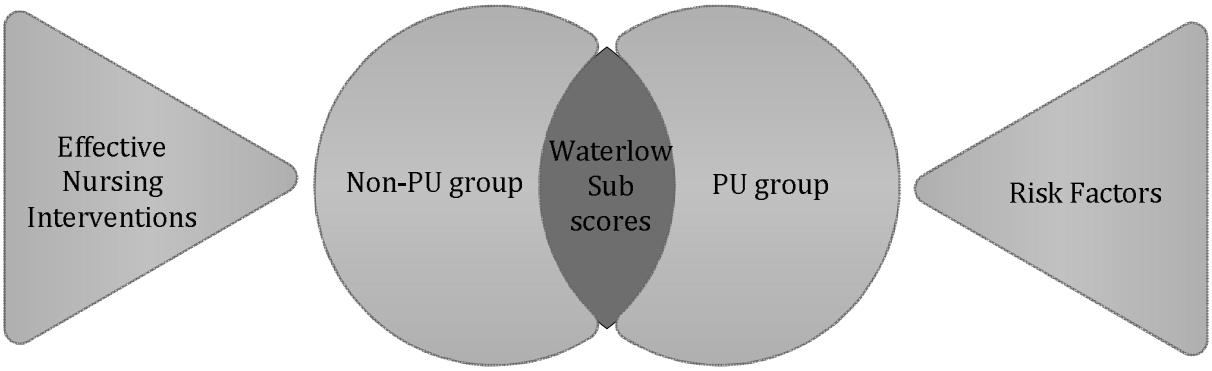


Figure 2.2: General conceptual approach of this study

2.12 Chapter summary

This chapter reviewed and critiqued previous literature related to PU risk factors and preventive interventions. The purpose of this was to identify any consensus in previous studies regarding the role of a certain risk factor(s) in the development of PUs, or the role of any interventions that can prevent PUs, and to critically analyze and identify shortcomings in the previous literature in order to overcome some of them during the study course, as well as to build on their contributions.

Literature was searched with relevant key words according to a predetermined search strategy. Retrieved studies were evaluated for their relatedness and quality. The main

themes in the literature review were PU risk factors and preventive interventions. Focusing on these themes was to explore available evidence in the area of the current study.

Reviewing the studies that investigated PU risk factors revealed contradictory and sometimes weak evidence regarding the effect of some risk factors on PUs development. Different studies had different methodological or statistical approaches and investigated different sets of risk factors. Also, different follow-up periods were used, and patients' medical conditions varied between studies. All of these factors, in addition to the methodological weaknesses found in some studies, make it difficult to draw a conclusion concerning the best factors that can predict PUs.

In the area of preventive interventions, numerous studies were found that investigated different modalities and strategies for prevention, including re-positioning regimens and techniques, support surfaces, heel-protecting devices, referral to physiotherapist, nutritional interventions, referral to a dietician, interventions to prevent incontinence adverse effects, barrier creams and emollients. Making a sound comparison between different studies to reach a conclusion about the best preventive intervention is difficult due to contradicting and weak evidence reported in the literature.

Although the main themes of literature review were PU risk factors and preventive interventions, other areas of research related to these terms were also explored. These included PU prevalence and incidence, RASs for PU, grading systems for PUs and PUs prevention guidelines. Prevalence and incidence studies reported varied figures of these

rates. Comparisons between these different figures were difficult due to different methodologies and settings of studies reporting these figures.

RASs were also important in this area because they can divide patients into risk groups in order to direct nursing preventive interventions. The most commonly used RASs were Waterlow, Braden and Norton. In order for an RAS to be effective in predicting patients at risk of PUs, it must be valid and reliable. A wide range of these measures were reported in different studies for different scales. This is most probably due to methodological differences among these studies (e.g. using different data collection methods, different settings and different population characteristics). This created some doubt regarding their effectiveness. However, nurses must not ignore using one when offering care for their patients. Formal programmes for prevention needs a formal risk assessment tool to create continuity of care and initiate preventive measures based on specific patient risk factors.

Different grading systems were also explored. In the clinical area there is a need for a robust grading system of PUs in order to indicate PUs presence and degree of severity. This is also reflected in the current study, because through using a grading system patients can be divided as having PUs or not. In general, studies that addressed the reliability of grading systems are few, and they lack consistency, which makes it difficult to compare them. Methodological issues noticed in these studies prevented their generalizability.

In the clinical setting, the desirable attribute of PU guidelines is to effectively prevent the development of new PUs. Studies that examined the clinical effectiveness of these guidelines showed that they improved the outcome in preventing pressure ulcers. However,

this conflicted with the high incidence and prevalence rates reported in literature. Studies that addressed effectiveness of guidelines did not establish their effectiveness against robust criteria. Also, some of these studies only addressed effectiveness in a certain type of clinical setting.

A general conceptual framework was developed to explore the association between a number of interventions and PU prevention, while exploring the association between a number of risk factors and acquiring PUs. The conceptual model of the study was based on a web of causation epidemiological model, which is concerned with multi-causal relationships between a medical condition and the number of factors that can contribute to its occurrence or prevention.

Chapter Three: Methodology

3.1 Introduction

This chapter is intended to guide the study's plan of action. It involves explanation of the methodology used to answer research questions and test study hypotheses. Polit and Hungler (1999, P.707) defined research methods as "the steps, procedures and strategies for gathering and analyzing the data in a research investigation". These steps used to collect and analyse data represent a scientific method of inquiry. This scientific method is denoted as research. In this concern, research is used to create evidence-based answers to the research questions.

However, for these questions to be answered in a logical and robust manner, an appropriate approach must be followed. This approach must be consistent with the nature of inquiry and data collected. In addition, other aspects of the study are affected due to this approach. These include the data collection method, data analysis and later results interpretation.

3.2 Research problem, purpose, question and hypothesis

- **Research problem**

Defining the research problem is the starting point of any research. Without a defined problem the research is worthless. Stating the research problem facilitates a clear understanding of the area under investigation.

Despite the large amount of research and guidelines for PU prevention, the scope of the problem is still large (Bennett et al., 2004). This is obvious from the considerably high

rates of incidence and prevalence that were discussed in the literature review. Such high rates indicate some deficits in the prevention process. One reason for this deficit could have happened due to limitations in research methods that aimed at identifying effective PU preventive interventions or associated risk factors (Pancorbo-Hidalgo et al., 2006).

Based on the findings from the literature chapter, the evidence concerning the effectiveness of preventive interventions is still unclear and contradicted. Similarly, the evidence to support the association of many risk factors with PUs remains unclear and contradicting. Studies that reported preventive interventions and associated risk factors had a number of limitations that made usability of their findings limited.

This inquiry identifies some of these problems and tries to establish a new, useful approach that aims at identifying effective interventions and associated risk factors. The new approach implies identifying effective interventions through comparing patients who share some degree of risk, but who differ in PU status (some with PU the others with none). Adjusting the degree of risk is done through pairing patients who shared a number of Waterlow sub-scores. Another important feature of this comparison is that it can identify other covert risk factors that are not predicted and contributed to PU incidence. In addition, risk factors that were debatable in previous literature in regard to their link to PU development can be studied further using the new approach.

- **Research purpose**

This study aims at identifying specific interventions that were associated with the prevention of PUs. It also aims at discovering new, covert risk factors that might contribute to the outcome (PUs). Debatable risk factors in PU development discussed in previous literature can also be analysed using the new study approach. Moreover,

results would be used to inform policy and clinical decision makers in order to enhance the prevention process.

- **Research questions**

1- What are the interventions associated with PU prevention in Waterlow sub-score matched patients?

2-What are the risk factors associated with the occurrence of PUs in Waterlow sub-score matched patients?

- **Research hypotheses**

The research hypothesis is “a formal statement of the expected relationships(s) between two or more variables in a specific population”(Burns and Grove, 1999, p.84).

In order translate research questions into a more testable form, the following hypotheses were formulated:

- There is no association between different types of interventions in the study population and PU prevention.
- There are no existent risk factors that might contribute to the occurrence of PUs in the study population.

These two hypotheses were formulated in simple, associative and null formats for the following reasons:

1- Formulating the hypotheses in an associative format indicates that there is a relation between different study variables. Thus, they do not indicate the direction of this relation.

2- These two hypotheses are formulated in a simple format in order to state that there might be a relation between variables. In the same time not predicting it.

3- Hypotheses were formulated in the null format for practical reasons. The null format helps to statistically interpret the outcome of the study.

4- Different study variables (PU, nursing interventions and risk factors) are clearly stated in the hypotheses, making them easy to measure.

3.3 Study approach

In order to logically build and plan the study, an approach that specifies key concepts and terms of the research must be adopted. Nurses tend to use quantitative or qualitative approaches, or sometimes a mixture of the two. Deciding which approach to be used is governed by the nature of the study, and in what terms the researcher wants to answer the research question. Quantitative researchers are interested in deductive reasoning, and use numbers to express results in an objective manner. Contrarily, the qualitative approach tends to be inductive in reasoning (generating theory), and also tends to express results in a narrative form. For this reason, research that uses the quantitative approach tends to be more generalizable than research that uses qualitative approach (Burns and Grove, 1999).

In this study the nature of the problem under investigation implies using quantitative approach due to the following reasons:

1- The nature of the study, which considers a direction of influence between different study variables. In this study it is proposed that preventive intervention and a number of factors influence the occurrence of PUs. In order to describe

this influence, a formal objective process must be followed. Objectivity needed here is as a feature of the quantitative approach.

2- Quantitative approach uses pieces of information that can easily be represented numerically. In this study, variables are best represented through numbers in order to examine the relation between them.

3- This study aims to describe the direction of relations between variables. This resembles a deductive way of reasoning, which is a characteristic of quantitative approach.

4- Using quantitative approach in research can produce results that can be generalized. Without being able to generalize results, no clinical benefit can result from this study.

5- Quantitative design is more efficient in testing study hypotheses and in providing numerical evidence.

3.4 Study variables

As this inquiry adopts a quantitative approach, the study concepts are referred to as variables, which are "concepts at various level of abstraction that are measured, manipulated, or controlled in a study"(Burns and Grove, 1999, p.34). According to this simple definition, a concept that can take more than one value is considered variable. In the current context, there is more than one concept that can take more than one value. The study hypotheses state three variables: PU status, preventive interventions and risk factors. For instance, PU status can take two values: affected with PU or free of PU.

Preventive measure and risk factors can vary between patients and take more than one value.

Based on the literature, both interventions and risk factors can play an important role in PU incidence and prevalence rates. Effective interventions are supposed to be associated with decreasing these rates. Likewise, some risk factors were associated with higher incidence and prevalence rates of PUs.

Variables under investigation in this study have been classified into dependent and independent variables.

- PU status is the dependent or outcome variable. This is because it is the main focus of the study and the outcome variable. In addition, the study aims to understand what interventions are associated with PU prevention and which are not. This also applies to risk factors.

- Independent variables are nursing interventions and risk factors. These can contribute to changes in the dependent variable under investigation.

Although it is mainly the experimental studies that refer to variables as dependent and independent in order to indicate a direct causal relationship. These terms are used in this descriptive study for a practical reason; in order to indicate direction of influence rather a causal relation.

Details of different variables and their categories will be discussed in further detail in the results chapter.

3.4.1 Setting criteria for variables selection

This section was used to guide the selection of different study variables. The aim of setting criteria for variables selection will assure that all variables were selected under the same conditions. This can facilitate statistical analysis and ensure that the research questions are answered more accurately.

The most important use of these criteria was to set operational definitions for the study variables. Operational definitions and exact details for categories and grouping of different study variables will be discussed thoroughly in results chapter (section 4.3).

In this section, criteria for selecting independent variables (preventive interventions and risk factors) will be discussed. The dependant or outcome variable (PU) will be discussed with the subjects' inclusion criteria (section 3.10.1), because this variable is the base variable upon which subjects were selected.

- **Preventive intervention selection criteria**

Different nursing interventions that have a theoretical relation with PUs prevention will be included. Other activities of the nursing care process will be also included, because some aspects of the nursing care process may affect susceptibility to PUs.

Apart from dedicated PU preventive interventions, other activities of care or therapy from other healthcare providers (e.g. dieticians) will also be included and analysed. These activities may have an effect on the general condition of the patient, and in turn on susceptibility to PUs. Including other aspects of patients' care processes aimed to discover any covert interventions that could prevent PUs.

For any nursing intervention or aspect of care or therapy to be recorded included in this study, two conditions must be fulfilled:

- All nursing interventions or other aspects of care must be recorded for a particular patient, and must be continuously implemented (or implemented at regular intervals). Occasionally implemented interventions or interventions recorded at irregular intervals are not included in the analysis for a particular patient. Occasionally applied preventions may be effective, but due to their short duration there is no way to judge their effectiveness.

- Any interventions or aspect of the caring process to be included in this study comprise those implemented before PU developed in PU group. There is no utility in including newly implemented interventions, because the PU is already developed. For the free of PU group, all interventions implemented are included.

- **Risk factors selection criteria**

- Risk factors: related factors that were reported in literature to be associated with the development of PUs were recorded. Risk factors that represent Waterlow sub-scores that were matched between the two study groups were not recorded.

- The findings of patient assessment are also recorded as potential risk factors, to help in discovering new factors that might be related to developing PUs.

- Risk factors included are those on admission to hospital for both of the study groups. Baseline assessment is the key factor that can lead nurses to adopt preventive interventions against PUs. Discovering which factors on admission that are related to developing PUs is of great clinical importance because this

can help nurses at aiming preventive intervention as early as possible and prevent PU more effectively. Furthermore, early screening for the risk of PUs is important due to the high incidence of PUs immediately after admission (Perneger et al., 2002).

To sum up, the criteria for selecting variables in this study were expanded to cover all aspects of the care process and assessment data. Including all possible information about the care and assessment process aids in increasing the chance to find covert interventions, which might prevent PUs and/or new risk factors that might increase susceptibility to ulceration.

3.5 Developing a data extraction sheet

In order to collect data effectively, a data extraction sheet (Appendix G) was developed. This sheet was intended to act as standardized method for data abstraction from all medical records included in the study. It was also meant to guide data collection process and organize files abstraction. Using this sheet to abstract information from the medical record resembled doing a systematic investigation to reach certain pieces of information.

In order to collect relevant data and answer research questions more effectively, special considerations were taken into account when the data extraction sheet was developed, including:

1- The sheet was designed in order to collect quantitative data that can be numerically tested. For this purpose, data that represented quantified amounts (e.g. laboratory results) were recorded as their actual numbers, so these data

could be accounted as continuous variables later in the analysis phase. Data representing non-quantified amounts (e.g. types of preventive intervention) were sorted according to non-overlapping categories then recorded; such data represented categorical variables in subsequent data analysis.

2- The data sheet was designed with enough fields and a blank page to accommodate all relevant details from admission until discharge for a particular admission.

3- Generic products and drugs names will only be recorded. This will help in categorizing them later according to their effect or action. Also, this will facilitate communicating results with other settings that do not use the same commercial names.

4- Data extraction sheet was designed based on findings from literature. Depending on known literature concerning the investigated issue will ensure the content validity of the data extraction sheet and its ability to answer the research questions.

5- In order to capture are relevant information about the caring process; data extraction was extended to include all aspects of care, whether they were nursing or non-nursing. Also, clinical risk factors were extended to include patients' assessment data whether written by nurses or other healthcare professionals. This may reveal further interventions or risk factors that were not pointed out in literature.

6- Specifications about frequency, duration, amount and timing are incorporated in the data extraction sheet for different variables. This can provide needed details to decide if the variables are consistent with variables selection criteria or not.

3.5.1 Components of the data extraction sheet

Based on the literature, the following components that were related to skin health and PUs formation also to the caring process in general were included in detail:

- Patient biographical data
- Patient assessment data
- Stay in hospital details
- Severity of illness and chronic diseases
- Cognitive and psychological status
- Pharmacological treatment and laboratory results
- Activity and activities of daily living
- Physical measures
- Assessment of skin, including PUs
- Nutritional assessment
- Surgical procedures
- Details of different protective interventions for PUs
- Referrals to other healthcare professionals

3.6 Study design

A research design is “the overall plan for addressing a research question, including specifications for enhancing the integrity of the study” (Polit and Hungler, 1999, P.713). According to this definition; research design involves all the steps that lead to answering research questions and testing the proposed hypotheses. Adopting a research design directs a study’s methodological approach, including strategies for data collection, selecting target population and techniques for measuring variables. In addition, the study design affects how the data will be analysed and to what extent the results can be generalized (Burns and Grove, 2001).

The study design chosen must effectively be able to measure the association between the outcome variable (PU) and other variables that may prevent them (interventions) or variables that might contribute to their occurrence (risk factors).

Additionally, choosing a particular study design must be consistent with the study purpose, aims and hypotheses. Therefore the following designs were employed: quantitative, retrospective matched case-control and comparative descriptive.

These designs were used to answer the research questions and test the study hypotheses.

3.6.1 Quantitative design

Since this study is all about determining association between PU status and other study variables (interventions and risk factors), a robust and objective way to determine the associations between variables is by quantifying these associations, which implies using a quantitative design.

In the current study, choosing a quantitative design is most suitable to objectively examining the association between different study variables as they happen in a real life situation. This can provide an evidence-based practice, which in turn can help in improving prevention guidelines. Adopting this design permits comparison between the two study groups. This can be helpful in identifying effective interventions and associated risk factors. Moreover, quantitative design involves using statistics in order to clearly and accurately measure the association between the outcome variable (PUs) and different variables representing preventive interventions and risk factors. This feature of quantitative design makes it more suitable to deal with the numerical data collected, where interventions and risk factors were best represented by numbers.

3.6.2 Retrospective matched case-control design

Retrospective design "are investigations in which some phenomena existing in the present is linked to other phenomena that occurred in the past, before the study was initiated" (Polit and Hungler, 1999, P.164). In a retrospective study, the dependent variable previously happened at a certain point in the past before conducting the study. Effect and consequence of the independent variables are followed retrospectively over time through using records, since the investigator is collecting data after the dependant variable developed. Conversely, in a prospective study the study subjects are defined in terms of the independent variable(s) then followed through time to observe the occurrence of the dependant variable (Brink and Wood, 1998, Doll, 2001). Brink and Wood (1998) argued that being prospective and retrospective are just stipulations for the investigator place of time.

A matched case-control design uses a study and a control group through selecting cases with and without the outcome variable (case-control). Groups are matched in regard to certain characteristics. In this design, selection of groups can also be done retrospectively after the outcome variable has happened. Both of the study groups (cases and control) must be initially free of the outcome variable, whether prospectively or retrospectively (Hess, 2004).

In current inquiry, patients with PUs (cases) were retrospectively selected from electronic medical records and matched to patients free of PUs (control). Study (case) group was matched in pairs to control group based on a number of Waterlow sub-scores. Both groups were initially free of PUs when they were admitted to hospital. With time progression, the study group developed PUs, while the control group did not.

Matching cases (patients with PUs) to controls (patients free of PUs) facilitated a robust base for comparison between patients, since patients were matched on pre-established risk factors of PUs (Waterlow sub-scores). Revising the medical files of both groups was undertaken to spot points of difference between the two groups that were associated with developing or preventing PUs. In other words, this design looks for the difference in preventive intervention and risk factors as causes of difference in the outcome variable in the two groups.

In this context, previous literature reviews gave preference to studies that had a control group (especially RCTs) (Reddy et al., 2006), which is the group that was initially free of the dependant variable and did not develop it later in time. This study provides such a control group, albeit retrospectively. Where one group developed an ulcer (study group), the other did not (control group). Although the dependant had already occurred

in the past (before the study was conducted), the time sequence for events preceding ulcer development can be followed through medical records. Initiating a control and a study group retrospectively can resolve some inherent problems faced with RCTs (considered as golden standard), namely the ethical dilemmas of offering different treatments, the blindness of the investigator giving interventions and the randomization problem.

- **Characteristics of retrospective matched case-control design that helped in answering research questions more effectively**

A number of characteristics of retrospective matched case-control design highlight its appropriateness for this study and its ability to answer the research questions effectively:

1- This design provides a method to examine all individuals under the study criteria, saving considerable time.

2- It reflects the real world experience in prevention.

3- Expertise in implementing interventions, managerial skills and excusive planning are not required of the researcher.

4- There is no need for complicated procedures of randomization or training staff for implementing a new intervention. This is cost-effective compared to other types of design.

5- There is no Hawthorn effect, which reduces biased results to some extent. Implementing interventions was through daily routine care, nobody of the research team was monitoring nurses during their work.

6- It provides a robust method to identify effective interventions. This is done through matching patients, which unifies some previously established risk factors between each pair of patients through matching in some of the pre-established risk factors (Waterlow sub-scales). This provides a practical way to eliminate the hazard of confounders (factors that can affect the outcome) interfering with the study results.

7- The risk of subject drop-out from the study is not present.

8- It is suitable to study outcomes that need a considerable amount of time to develop. A patient may develop PU at any time during hospitalization. Retrospective approach provides a convenient method to follow patients for a longer time (till death or discharge).

9- Using this design facilitates having a retrospective control group (the group that did not develop PUs).

To sum up, retrospective matched case-control design was adopted in this study to support the evidence that some nursing interventions are effective more than others, and to find out further risk factors associated with PUs. Paired patients who were matched in some Waterlow sub-scores were compared for the independent variables (preventive interventions and risk factors). The aim was to identify these independent variables that contributed to the patient state of PUs (with PU or free of PU). Patients selected for the matched pairs had to initially be free of the dependent variable (PU), but with time some developed it and others did not. This is assumed to be as a result of their exposure to different independent variables.

3.6.3 Descriptive comparative designs

The sole purpose of employing a descriptive design is to describe the association between variables of a study without any manipulation or interferences from the research team. Descriptive study design is deliberately intended to describe phenomena and related variables as they exist in the real world. Optimal conditions are not applied to the environment; this can identify associations between variables as they happen naturally. One disadvantage of this design is that it cannot identify a cause and effect relationship between variables; only associations between variables can be described (Polit and Beck, 2004).

In the current study the purpose of using a descriptive design was to identify effective nursing interventions that can prevent PUs as implemented in the natural clinical setting. Using this design can help in identifying these interventions without any risk of manipulation. Manipulation can either increase or decrease the effect of these interventions in preventing PUs. Also, using this design can identify risk factors that can contribute to occurrence of PUs. Identifying these risk factors in a natural clinical environment can provide a description for the natural flow of influence for these factors in terms of developing PUs.

Descriptive design examines the real world phenomena in only one group. In order to make comparison between the two groups of this study, comparative design was added. Descriptive comparative design is used to describe the differences between two groups in terms of the dependant variable (Polit and Beck, 2004). In this study, comparison was made between two groups (one with PUs, the other without). The group of patients with PUs was paired with another group with none, who shared some of the Waterlow sub-scores. In other words, each individual patient in the PU group was compared with a

patient in the non-PU group who shared some Waterlow sub-scores. Paired comparisons were anticipated to identify effective preventive interventions that prevented PUs in the non-PU group, and risk factors that contributed to the occurrence of PUs in the PU group.

Comparison between the two paired groups resembles the same comparison pathway of a prospective experimental design. One difference is that the two comparison groups already existed in the past and occurred naturally without any manipulation. Interpretation of the comparison results served to answer the research questions and accept or reject the study hypotheses.

- **Reasons for choosing comparative descriptive non-experimental design:**

1- It is impractical and time consuming to identify preventive intervention based on the comparison criteria (shared Waterlow sub-scores) through an experimental design. Finding subjects who are willing to participate and sharing a number of Waterlow sub-scores then randomizing them to different intervention groups would be expensive and difficult to conduct in a short period of time.

2- Non-experimental design is needed prior to experimental design. This non-experimental study identifies the scope of the problem (interventions and risk factors). Description of the relations between variables can form the base for future experimental designs to investigate these variables.

3- Descriptive design offers the chance to measure the effectiveness of an intervention. Effectiveness reports the performance of intervention in the natural environment, while experimental design offers the chance to measure efficacy (the performance of intervention under controlled conditions; see (Clark et al.,

2002). The distinctive difference between efficacy and effectiveness denotes the need for both experimental and non-experimental designs to thoroughly explore certain phenomena of interest.

3.7 Setting of the study

Data collection took place at Queen's Hospital, a National Health Services (NHS) Trust hospital located in Burton-upon-Trent in Staffordshire (UK). It was established in 1993 as an NHS trust, and then became a foundation trust in 2008. Queen's Hospital is considered a medium-sized acute care setting, providing most treatment and diagnostic services. It is the primary provider of acute healthcare for the population in Burton and neighbouring areas, covering a population of 360,000 people. Queen's Hospital contains 420 beds in total, in addition to 13 beds for intermediate care (NHS, 2007).

Queen's Hospital provides hospital-based tertiary care with different specialities and services that cover the main aspects of healthcare needs. In addition, the hospital provides community consultant services in order to reach the local community.

Queen's Hospital adopts the use of electronic medical records in managing patients' data. For this it uses "Meditech Hospital Support System" (Version 5.4), a type of Hospital Information Support System (HISS), which was launched by the NHS for acute care settings in early 1989. HISS aims at providing necessary information to support clinical aspects of patient care (e.g. nursing notes, physician notes, and physiotherapist and dietician notes). It also includes other features related to the care process (e.g. pharmacy ordering, radiology and laboratory data).

HISS is designated to facilitate the caring process through unifying the information transfer environment. Moreover it is intended to record all activities of patients' daily caring activities in a comprehensive manner. This gives it the ability to be an electronic medical record that is able to cover all aspects of patient care, in addition to operating as a reliable reference for healthcare providers and researchers.

To put it briefly, HISS has certain features that enable it to serve as a reliable medical record for healthcare providers and researchers (Maguire, 2007), including that it:

1- Records all daily clinical activities that concern patient care.

2- Calculates accumulative costs that result from the care process. This could help in cost effectiveness research.

3- Is equipped with the ability to record various patient details, such as patients' personal data in addition to clinical data.

4- Can be easily revised or amended by authorized users, which can facilitate data retrieval for research purposes.

3.8 Usefulness of using electronic medical records for the study design

A computer-based patient record is "repository of electronically maintained information about individuals' lifetime health status and healthcare" (Tang and McDonald, 2001, p.336). Medical records commonly contain routinely collected data that contains different aspects and interventions implemented as a part of the care process. In addition, routine assessment and diagnostic procedures are documented in medical

records. Assessment results can reveal different risk factors that can affect patient health and lead to certain complications and illnesses (Cullum and Clark, 1992).

As shown in the study design section, data will be retrospectively collected from electronic medical records. Electronic medical records can be useful in this context and provide needed data that can serve the aim of the study and answer research questions. However, containing needed information is not the only reason for extracting data from electronic medical records. Other features of these records which are related to the accuracy, completeness and accessibility of these records are also important, including:

- Electronic medical records provide a research tool that helps the researcher to extract, interpret and organize data (Tang and McDonald, 2001).

- Computers can check the validity and completeness of data entered into the system, thus giving feedback for missing or incomplete data (Tang and McDonald, 2001). Owing to this reason, computer-based can give more accurate data than paper-based records (Mahler et al., 2007, Gunningberg et al., 2008, Gunningberg et al., 2009). Accordingly, it is preferable for research.

- This study includes a large number of subjects (all subjects who matched the inclusion criteria). For this reason it is more useful to use electronic records because they provide quick and easy access to all patients' data (Suleman et al., 2006).

3.9 Population of the study

A population is "the entire aggregation of cases that meet a designated set of criteria" (Polit and Hungler, 1999, P.278). Defining the study population implies defining all

subjects included in the study. This constitutes an important step in research because the nature of the subjects will have a profound impact on interpretation of the results and generalizability of the findings (Punch, 2005).

As mentioned earlier in study design section, the type of study design will define study population because this will enable more accurate answers for the research questions. For this reason, the population of this study was defined as: all patients admitted to the hospital and discharged with their information, including Waterlow sub-scores and caring aspects, being recorded on HISS. This definition was guided by the study design. The retrospective nature of the study had a noticeable effect on the population, which was translated as selecting patients' records instead of the actual patients. Moreover, it was stressed that these patients must have recorded Waterlow sub-scores in order to facilitate matching patients according to these sub-scores.

3.10 Sampling method

A sample is a "sub-set of the population that is selected for a particular study" (Burns and Grove, 1999, p.478). According to Field (2009), a sample must be selected under certain conditions to be able to answer study question. Sampling is "the process of selecting a group of people, events, behaviours or other elements that are representative of the population being studied" (Burns and Grove, 1999, p.479).

In the field of scientific research there are two broad categories for sampling, namely: probability sampling and non-probability sampling. Probability sampling implies that every member in the population has a probability greater than zero for being selected in the study sample using random methods for subjects' selection. In contrast, non-probability sampling implies that not every member in the population has the chance to

be selected in the study sample; this type of sampling uses non-random methods for subject selection (Burns and Grove, 2001). Consequently, probability sampling is preferred over non-probability sampling due to reducing selection bias that can affect the results of a study. However, different research needs and aims apply different methods of sampling (Burns and Grove, 1999). In this study, the aim was to investigate the most preventive nursing intervention and associated risk factors from matched patients within one hospital. Choosing all available matched patients within the population of the study is the ideal way to create large confidence in study results and increase precision in estimated population parameters. Demonstrating this and choosing all readily available subjects for the study entails the use of a non-probability convenient sample.

Convenient sample is "the use of the most conveniently available people or objects as subjects of the study" (Polit and Hungler, 1999, P.281). In the case of this research it was more appropriate to choose convenient sample over other types of probability sampling due the retrospective nature of the study. It was more logical and robust to select all subjects available within the sampling frame rather than selecting a random sample, which would give a smaller number of subjects.

3.10.1 Inclusion and exclusion criteria for recruiting subjects in the study

Another important aspect of the sampling process is deciding inclusion and exclusion criteria for subjects under investigation. Inclusion and exclusion criteria were developed based on the study design, aims, and research questions.

Such criteria can help in meeting the aim of the study and answering the study questions more accurately by focusing more on the effect of independent variables and

minimizing the variations between subjects (minimizing the effect of confounders). Accordingly, this will minimize bias in results and focus more on identifying effective preventive interventions and risk factors.

Moreover, this work was based on retrospective data collected from medical records. Retrospective data used in this study were collected by nurses and other healthcare providers who may not necessarily have proper research training; this may reflect some inaccuracies in data recorded. Hence, strict criteria for inclusion and exclusion were devised in order to reduce the hazard of inaccurate data as much as possible.

- **Inclusion criteria**

1- All patients included in the study were initially free of PUs on admission. This was to differentiate between hospital-acquired PUs and those acquired in the community. The medical records of these patients were followed from admission until discharge. Following patient progress to acquire PUs or to remain free of PUs can uncover what interventions or risk factors contributed to the outcome.

2- All patients included were over 14 years of age (less than 14 years is zero for the sub-score of age in Waterlow RAS). Risk factors that can contribute to PUs are not completely the same for adult and paediatric subjects. Anatomical sites for skin breakdown and concentration of collagen and elastin are different in the paediatric population. This can make a difference in pressure absorption ability, which in turn can reflect on susceptibility to PUs (Butler, 2006). Another point to be mentioned is that researchers are developing special RASs for paediatric populations different to those for adult ones. For instance, one of the sources for

developing RASs (including Waterlow) is patient data (Willock et al., 2008). The Waterlow scale, which is used in this study, was developed based on data from adult patients. This makes it more suitable for using in adult studies (over 14 years) rather than paediatric studies.

3- Each pair of patients used for comparison had a match or a near match in a number of Waterlow sub-scores, enabling the comparison of patients while excluding the effect of items in the sub-scores that can affect the outcome.

- **Exclusion criteria**

1- Patients with insufficient information in their medical file for different aspects of care, especially those related to prevention measures and risk factors, were excluded. Waterlow sub-scores are also of great importance; files that did not contain Waterlow sub-scores on admission were excluded.

2- Patients in the psychiatric, maternity or paediatric wards are also excluded. Patients in these wards may not have the same degree of risk or severity of illness compared to other wards or units (e.g. intensive care units, stroke ward).

3- Admissions with less than three days of hospital stay were excluded from both of the study groups. This was for three reasons: firstly, less than three days of hospitalization would not be enough in hospital to be at risk of PUs (Still et al., 2003); secondly, evaluating pressure prevention methods needs time, and consequently, enough time must be allowed for these interventions to work (Cavicchioli and Carella, 2007), which enables a sound comparison between different interventions against PUs; thirdly, three days would be reasonable to

give the nursing staff enough to notice of the PU to subsequently record it (Vanderwee et al., 2005).

4- If ulcers documented were related to peripheral vascular disease or neuropathy.

3.10.2 Sample size

Conducting a study with adequate sample size is a very important aspect in any study. This is more important as sample size is one of the most essential factors that can determine the capacity (power) of a study to detect difference or relations in a population or reject the null hypothesis (Burns and Grove, 2001). Besides sample size, the power of a study is also determined by the chosen significance α-level and effect size.

In order to calculate the sample size needed to detect differences in a population, three values are needed, namely: significance level (α level), degree of power needed and effect size.

Significance level (α level) is the probability of type one error, which is standardized in most social studies to 0.05. Power is (1-β), where β is type two error. The minimum power recommended to detect difference in a population is 0.8 (Field, 2009). Effect size (Phi co-efficient) is the magnitude of the measured event in the population (Field, 2009). It is best established through previous literature from meta-analysis studies (Burns and Grove, 2001, Field, 2009). Searching the literature for meta-analysis studies in the area of PU prevention showed RCTs with mostly small sample sizes (Reddy et al., 2006), and effect sizes ranging from small to large (Spencer, 2000). In view of this, a conventional medium effect size (Phi co-efficient = 0.3) was chosen to calculate sample size (Cohen, 1988).

Typically, sample size is calculated through a statistical procedure called power analysis, using different available software (e.g. G-Power). Alternatively, Cohen (1988) provided tables for calculating sample number using the three previously mentioned values. Matching the three values to Cohen's tables give a sample size of 85 subjects. Accordingly, 85 subjects are at least needed to achieve a detection power of 0.8 when magnitude (effect size) of PUs in the population is medium (Phi co-efficient = 0.3), given a probability (α-level) of 0.05 of having a genuine effect when in fact there is none.

This study used a convenience sampling method, which means that all available subjects' records present in HISS (matching the study criteria) were selected. Calculating sample size was not for arbitrary reasons but to set limits for the minimum number of subjects required to get consequential and significant results. In case a low number of subjects was obtained, the sampling plan was to be changed in order to get more subjects.

3.11 Preliminarily sampling plan

This section describes the preliminarily plan used to create the main list of paired patients from electronic medical records. The researcher used this list to identify possible subjects to collect information from their electronic medical records.

According to the study design, each patient with a hospital-acquired pressure ulcer must be matched with another patient who had the same (or nearly the same) Waterlow sub-scores, but free of PU on admission. In line with this, a list of all patients matching the study criteria must be obtained from the hospital database. In order to pair patients, this list must contain individual Waterlow sub-scores for each patient and their PU status.

As patients' data in the data collection site were recorded using electronic means, creating required patients list must be done using computer, due to the huge number of patients in the hospital data base. The aim of this was to identify the maximum number of sub-scores that pairs of patients could be matched on, and to find the largest possible number of matched pairs.

For the purpose of past studies, the research team had previously liaised with the information technology department at Queen's Hospital. The information department had helped in creating a list of all admissions to hospital with their PU status and Waterlow sub-scores. Only admissions from 2006 onwards were supposed to be included in the list (the year in which Waterlow sub-scores began to be recorded on the system). Patients with community-acquired PUs or who were less than fourteen years of age were excluded from this list.

The main list created by the information department was transferred to a Statistical Package for Social Sciences (SPSS) data file. Irrelevant data were deleted, keeping the important bits that enabled the researcher to create matched pairs. Eventually, the resultant data file contained patients' record numbers, Waterlow sub-scores and PU statuses. Waterlow sub-scores were used to create a numerical matching code containing the actual sub-scores values. Using SPSS, each patient with PU was matched with another patient free of PU. This resulted in creating 96 pairs (in each of which one patient had PU, the other did not). These patients were matched in 13 sub-scores; other subs were rarely recorded. Matching sub-scores were: continence, mobility, paraplegia/motor deficit, steroids/cytotoxics, age, skin, diabetes/CVA/MS, anaemia, smoking, orthopaedic, peripheral vascular disease, sex, single organ failure.

In addition to these exact matches, 45 nearly matched pairs were also found. Those shared the most important sub-scores, namely age, sex, mobility and continence, and differed in some of the remaining sub-scores. At this stage the intended plan was to collect data from the exact matches only, given the considerable number of them.

After preparing the exact matches list, medical record numbers were used to identify patients in an electronic records system. Relevant information was collected through reading each and every medical record within this list.

3.12 Pilot study

A pilot study is defined as "a smaller version of the proposed study, conducted to refine the methodology" (Burns and Grove, 1999, p.40). This means that the pilot study is done prior to the original study to discover any problems that might arise during conducting the original study. Piloting procedure consists of all steps that are proposed to be taken in the actual study.

In this study, the main aim of conducting a pilot study before going on with data collection was to check the accuracy of the computer-generated list of paired matches. This was to check if the actual documented status of PU in patients records matched what was in the computer-generated list. In addition, piloting aimed at counting the final number of eligible records to see if they were enough to run the statistical analysis and achieve the targeted effect size.

In addition, piloting was also intended to accomplish the following benefits before conducting the actual phase of data collection:

- To check the relevancy of data present in HISS to the study aim, and the ability of data to answer the research questions.

- To familiarize the researcher with HISS use.

- To help the researcher to identify any technical problems that might be encountered during data collection (e.g. logging on to and using HISS).

- To estimate the total time needed to complete the whole data collection, to help in planning the time frame of the study.

In order to start the piloting procedure, the information technology department of Queen's Hospital was approached. A username and password were provided in order to log into HISS. The research team also liaised with the Tissue Viability Nurse (TVN) at Queen's Hospital (Dr. Linda Rafter) in order to train the primary investigator to use HISS and use her office to go through medical records and document findings.

In the context of piloting, it has been reported in the literature that subjects included in the pilot study must not be reused again in the actual study. The pilot study may have an effect on the subjects during the actual study (Brink and Wood, 1998). This could be true in studies involving actual subjects (patients). In this study, subjects involved in piloting could be used again in the actual study. No influence on the study subjects was exerted, due to the retrospective nature of the study. Moreover, excluding the number of the piloted subjects would have decreased the number of eligible subjects in the actual study.

3.12.1 Piloting procedure findings

Piloting was conducted through using a paired matches list, which was created based on the preliminarily list obtained from the information technology department. Procedure for building the list was explained previously in preliminarily sampling plan section.

The primary investigator logged into HISS using the username and password provided. Using medical record numbers in the preliminarily list, electronic records of 96 pairs of patients were revised. This revision revealed that the preliminarily paired list was inappropriate for conducting this study. The problem lay in patients who were marked in the list as having PU. The majority of these patients did not match the study's criteria for two reasons. Firstly, a number of documented PUs were community-acquired, not hospital-acquired. Secondly, some of the patients that the list referred to as having PUs were not actually documented to have any ulcers at all.

A possible cause for this inaccuracy was that the computer depended on Waterlow skin score to specify PU status, and could not differentiate between community-acquired and hospital-acquired PUs. Furthermore, the computer considered all patients who had a skin sub-score value other than 0 or 1 to have PU. This is not always true, as skin scores in the Waterlow scale can be added. So, if free of PUs patients had a clammy and oedematous skin, they will be coded as 2, and the computer will identify them as having PU, while in fact they do not.

Excluding inaccurately listed patients left the sample with very few patients (below 85; see sample size). Carrying on with such a low number of patients would not achieve the targeted effect size, and would negatively affect the external validity of the study. Depending on the computer-generated list turned to be inaccurate and insufficient to

pick patients according to the study criteria. An alternative accurate sampling strategy had to be found in order to get enough subjects who matched the study criteria.

- **Waterlow RAS used at data collection site**

When the pilot study was conducted, a copy of Waterlow scale used at Queen's Hospital to assess risk of PUs was also revised. The Waterlow card used at Queen's (Appendix H) is different from the 2005 revised Waterlow risk assessment card (Appendix C). Instead of replacing the sub-score of appetite with Malnutrition Screening Tool, appetite score was kept. Other sub-scores of Burton nutritional score were added to the card in order to assess nutrition. Moreover, the Waterlow card was redesigned into three columns to distinguish Waterlow-specific information, general information and nutrition score specific information. Waterlow total score was the result of adding sub-scores of the first two columns (specific information and general information). Burton nutritional score was the result of adding the second and third column (general information and nutrition specific information). Added scores of Burton-specific nutritional information were in similar proportion to those used Waterlow sub-scores; this was to balance the contribution of each sub-score in the total score (Russell et al., 1998).

3.13 Alternative sampling plan

In order to reach the targeted number of subjects needed for the study, a reliable source for listing patients with hospital-acquired PUs was needed. The only reliable source found to locate patients with hospital-acquired PUs was the TVN list of wound patients. In April 2007, the TVN specialist at Queen's Hospital started to list patients suffering from chronic wounds who were referred to her. This list was intended to serve as a

source of information for both quality assurance and research purposes. Tissue viability list consisted of identifiable patient information and details about wound progress stored on a Microsoft Excel file.

Medical record numbers for patients suffering from PUs were cropped from the TVN list. The newly formed list of patients with PUs were then refined according to sampling criteria. Patients with community-acquired PUs and children under fourteen years of age were removed from the list. Refining the list was done manually through reading each individual patient medical record. This produced a cleaner and a more reliable list of patients with hospital-acquired PUs.

Almost all of the PUs that the list contained were grades three and four (grading was according to EPUAP system). According to the hospital policy, only grade three and four PUs are referred to the TVN. Overall, the refinement process picked up 76 patients with hospital-acquired PU, who matched the sampling criteria. The next step was to find other 76 patients free of PUs to match them in Waterlow sub-scores with the PUs group.

Since inaccuracy in the previously mentioned computer-generated list was only for patients having PUs (see piloting procedure findings, section: 3.12.1), it was possible to use patients free of PUs from this list to include in the sample. Free of PU patients from the computer-generated list were combined together in the same SPSS data file with manually generated PU patients. The data file contained medical record numbers for each patient in addition to Waterlow sub-scores. Combining the two lists will result in a 76 pairs of patients (one with PUs the other with none).

According to the recorded Waterlow sub-scores in the medical files, it was possible to match on 13 Waterlow sub-scores, namely:

1- Age

2- Sex

3- Mobility

4- Continence

5- Single Organ Failure

6- Peripheral Vascular Disease

7- Anaemia

8- Smoking

9- Orthopaedic

10- Diabetes/stroke/multiple sclerosis

11- Paraplegia/motor deficit

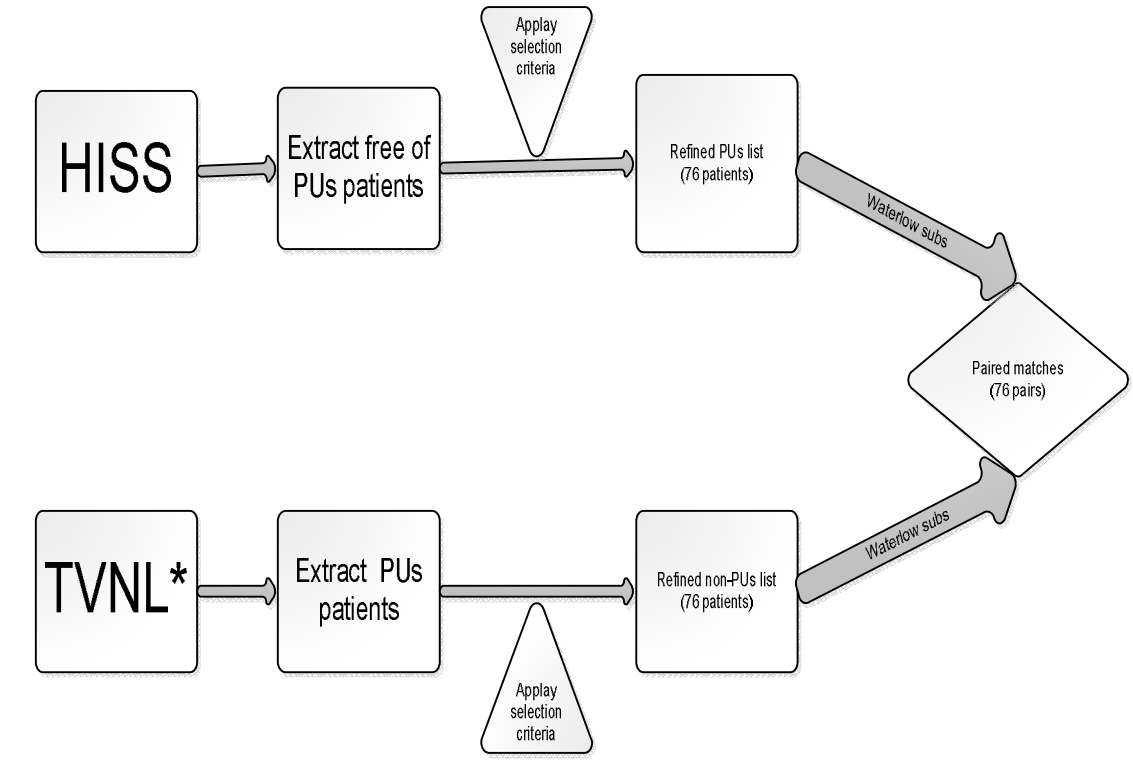
12- Steroids/Cytotoxics

13- Appetite

The remaining sub-scores were excluded for different reasons. Only one patient was recorded with on table >2 hours and multiple organ failure. No patients were recorded with on table > 6 hours and terminal cachexia. Moreover, body mass index sub-score was excluded due to many missing values (that may reflect inaccuracy either in patient assessment or recording). No patients were recorded to have sensory problems or below waist spinal surgery or trauma. The same thing was found for anti-inflammatory drugs; no patient was recorded to be taking such drugs.

A numerical matching code based on the above order of sub-scores was created (i.e. age first, then sex etc.) for all patients in the new combined list. Age and sex were ordered first; it makes more sense to match on demographical data initially. In order to match patients in pairs (with PUs and free of PUs) depending on their Waterlow sub-scores, the data file was sorted first by matching code and then by PU status.

Bearing in mind that number of patients free of PUs was higher than the number of patients with PUs (see preliminary sampling plan section, section: 3.11), more than one match for each of PU patients could be found. In case an exact match was not found, a near match could suffice. The presence of more than one match for each PU patient gave the chance to choose medical records with the most complete and accurate documentation. Figure 3.1 presents a schematic presentation that summarizes the alternative sampling strategy.



*TVNL: Tissue Viability Nurse List

Figure 3.1: Alternative sampling strategy

Details for the number of sub-scores different matches shared (out of 13 subs) are shown in table 3.1. As shown in table 3.1, 11 matched pairs shared all of the 13 sub-scores. The rest were near matches, the majority of which shared 10 sub-scores or more.

Table 3.2 shows the number of times each sub scores was identically matched. For instance, age was matched in 74 matches out of 76 matches (97.4%).

Table 3.1: Frequency for shared Waterlow sub-scores between different matches

Number of subs shared	Number of matches	% of total matches
7	2	2.6
8	3	3.9
9	7	9.2
10	11	14.5
11	23	30.3
12	19	25
13	11	17.5

Table 3.2: Frequency for matched Waterlow sub-scores

Waterlow sub-score	Number of times exactly matched out of 76	% out of 76
Age	74	97.4
Sex	76	100
Mobility	73	96.1
Continence	62	81.6
Single organ failure	68	89.5
Peripheral vascular disease	72	94.7
Anaemia	70	92.1
Smoking	70	92.1
Orthopaedic	68	89.5
DM/CVA/MS	40	52.6
Paraplegia/motor deficit	60	78.9
Steroids/cytotoxics	62	81.6
Appetite	40	52.6

3.14 Creating and coding study variables

This section explains how different study variables were created, and how different categories for categorical variables were assigned.

Study variables were created to summarize different pieces of information the data extraction sheet contained. Variables were created based on components of the data extraction sheet mentioned earlier. Choosing categories that were assigned to each variable was based on information recorded on the data extraction sheet. If the variable had the possibility of having more than two categories, data extraction sheets were scanned to identify common possibilities. Groups of similar possibilities were combined together, unless one of the possibilities was so unique that it could not be combined. The rationale for combining similar possibilities was the large number of possibilities that can be found in some variables that are difficult to be statistically analyzed. For example, the variable underlying medical disease can take many possibilities. These possibilities are extremely numerous, and difficult to analyse. Eventually, different possibilities (categories) were then numerically coded and entered to SPSS. On the other hand, continuous variables were recorded using the same actual numbers and decimal points as in the data extraction sheet.

Some variables represented situations wherein they could be recorded more than once. For instance, some patients had more than one mattress (as recorded in their file). In this case, the first mattress type used was referred to as “first mattress used”. Other mattresses used were recorded in other different variables (e.g. second mattress used). In the same context, some patients had more than one PU recorded. In this case, more than one variable was created for the ulcer grade; the first one recorded was the most severe.

3.15 Data collection procedure

Data collection is " the precise, systematic gathering of information relevant to the research process or the specific objectives, questions, or hypotheses of a study" (Burns and Grove, 1999, p.43). Data collection procedure can have an influence on the quality of data collected, and hence on the results. For this reason, certain considerations must be taken into account while collecting data from medical records to ensure data completeness and accuracy. These considerations included:

- Incomplete documentation, indicating missing data.
- Inaccurate documentation, reflecting unreasonable findings.
- Waterlow sub-scores not recorded.
- Ignorance of whether the PU recorded was hospital-acquired.
- Different findings, indicating contradictory information.

If any of the previous shortcomings were present in any of the medical records, those records were excluded from the study.

Data concerning PUs for both preventive interventions and risk factors were collected using a data extraction sheet. Variables recorded in the data extraction sheet were those consistent with the variables selection criteria.

All parts of the medical record were revised, including nurses' and physicians' notes. Other healthcare professionals notes (e.g. dieticians), diagnostic tests reports (e.g. laboratory results), medication logs, order sheets (that include different medical and nursing intervention) were also revised. Revising all parts of the medical records was

not undertaken arbitrarily. It was to decrease the chance of missing any relevant piece of data that might be relevant to any of the prevention interventions or risk factors, and to find any pieces of contradictory information that might be considered as inaccurate.

Data were collected by the primary investigator. During the comprehensive revision for each individual record, relevant data were directly recorded in the data extraction sheet. Using the data extraction sheet ordered pertinent categories of data together in the same section. Furthermore, it facilitated data coding and entry to SPSS.

After the data collection phase was completed, data were coded and then transferred into an SPSS data file. Data coding included assigning numerical values to different categories for variables measured on nominal or ordinal level. This was essential in order to be able to transfer categorical data into SPSS and run the analysis. Continuous variables were transferred into SPSS without any change because SPSS can deal directly with continuous data.

All activities of data collection took place at Queens's Hospital, Burton-upon-Trent, from the 1st of August 2009 until the 11th of November 2009 (the time needed for the primary investigator to finish revising all records for selected subjects). Admissions covered by the study were those admitted from January 2006 to November 2009. A back-up copy of the data file was stored on an optical disc and kept in a safe place. Paper forms used to document extracted data were stored in a locked metal cupboard.

3.16 Data analysis plan

The aim of the study design was to effectively answer the research questions and test hypotheses. As a consequence, research questions and hypotheses must be taken into

consideration when setting up the data analysis plan. For instance, data analysis procedure must be able to infer which nursing interventions were the most effective in PU prevention, in addition to discover which risk factors were most related to developing PUs. SPSS version 16 was used as the software for statistical analysis.

Data analysis procedure included three main steps: 1) preparing data for analysis; 2) conducting descriptive data analysis; and 3) conducting inferential data analysis.

Initially SPSS file was prepared by labelling different variables with codes from a pre-prepared code book. Labelling variables aids in designating variables when producing print-outs for the results, or when creating different graphical presentations for data. The complete processes for data preparation for analysis are further discussed in the results chapter.

Descriptive statistics were carried out in the beginning to describe the different characteristics of the subjects included in the study. Furthermore, variables representing both risk factors and nursing interventions were described for their measures of frequency, central tendency and dispersion using both numbers and graphs. Descriptive statistics are not intended to answer research questions or to test hypotheses, but to clear the picture, making the researcher and reader more familiar with the study variables. Likewise, graphical presentations and tables were used to serve the same purpose.

The second step in data analysis is inferential statistics, by which results are inferred from samples to populations (Field, 2009). Inferential statistics were used both on the univariate level and on the multivariate level. Univariate analysis is generally used to study the relationship between the dependant variable and one independent variable at a time. In contrast, multivariate analysis is generally used to examine the relation between

dependant variable(s) and a number of independent variables (Tabachnick and Fidell, 2007).

Univariate analysis in this study included the use of two types of tests, parametric and non-parametric. This was due to different assumptions of each type that applied to different variables in the study. One of the parametric tests' assumptions is that they assume that the population where the sample was drawn from is normally distributed. Conversely, non-parametric tests do not have such assumptions. Non-parametric tests are also used when the independent variable is measured on the nominal level (categorical) or ordinal (ranked) levels (Pallant, 2007).

Independent sample t-test was used as the parametric test in this study, while the non-parametric alternative Mann-Whitney U test was used when the assumption of parametric tests were violated. Non-parametric Chi-square test was used when the independent variable was measured on the nominal (categorical) level. In the current study the parametric tests were preferred over non-parametric if the assumption was met (data were normally distributed). This was because parametric test are more powerful in detecting differences between groups

Binary logistic regression was the multivariate statistical modelling technique used in this study. This is because it enables examining the relationship between a dichotomous dependant variable (with PUs or free of PUs) and a number of independent variables (interventions and risk factors). Logistic regression was used in this study to build statistical models that are able to predict which nursing interventions were independently associated with preventative, and to predict which risk factors were independently associated with PUs development.

A special algorithm namely purposeful selection macro was used to fit the logistic models in this study. This model has some advantages over the stepwise regression procedures available. This algorithm depends on human selection of variables that are removed from the model not merely depending on the significant level as in other stepwise procedures. This algorithm was first introduced by Hosmer and Lemeshow but not computationally tested (Tabachnick and Fidell, 2007). In 2007 this algorithm was tested using computer simulations and used in the area of research to produce more accurate model fitting (Bursac et al., 2007).

In the current study, univariate analysis was used as a preliminary step before conducting multivariate analysis. Multivariate analysis was used to examine the association between dependant variable (PU status) and different independent variables (interventions and risk factors). Using multivariate technique enables reaching independent results while other variables' effects on the dependant variable are controlled (Tabachnick and Fidell, 2007). Moreover, multivariate analysis was chosen according to the conceptual model of the study (web of causation). One premise of this model is to use multivariate analysis to understand the complex relationship between variables. Based on this, interpretations of the multivariate analysis results were used to answer the research questions and test hypotheses.

Receiver Operating Characteristic (ROC) curve is a graphical presentation of the relation between sensitivity (true positive) and 1-specificity (false positive) for a certain continuous variable in terms of another dichotomous variable (Marston, 2010). This relationship is presented by a curve which is compared to a reference line. The area under this curve represents the predictive performance of continuous variable in predicting the occurrence of a dichotomous variable. Therefore, the larger the area

under the curve, the better the variable is predicting the occurrence of the binary variable. ROC curve was used in this study to compare the predictive ability of PU for significant risk factors resulting from the regression model.

3.17 Ethical considerations

Conducting any research involving human subjects or any attributes of human subjects must be controlled by consideration and protection of human rights. Human rights are "claims and demands that have been justified in the eyes of an individual or by the consensus of a group of individuals" (Burns and Grove, 1999, p.157). Human rights are connected to five main rights in research, namely the rights to: self-determination; privacy; anonymity and confidentiality; fair treatment; and protection from discomfort and harm. Due to the retrospective nature of the study the only attribute of human subjects the study dealt with was medical records. Accessing patients' records means accessing information concerning patients' identities and private information. This implies assuring the rights of privacy and confidentiality. Other rights are not applicable to be assured in this study because no any intervention was applied, nor any direct contact with the human subjects.

In order to safeguard confidentiality and privacy of patients' identities included in the study, patients' names were unused in identifying patients and in recording data. To identify patients, medical record numbers were used. Numbers for cases substituted medical record numbers when data were recorded and transferred to the data file. This ensured further safeguarding of confidentiality and patients' identities. The data collection procedure also ensured confidentiality. Electronic medical files were not transferred out of the hospital (data collection site). All activities of data collection and

recording were held inside the hospital premises. Only needed information was recorded on a pre-developed data extraction sheet, with nothing documented that can reveal patient identity.

The data file containing extracted data was stored on De Montfort University (DMU) safe network with a user name and password-protected login. This enabled only the researcher to login. After the data was analyzed and final results obtained, it was completely destroyed, including hard and soft copies. Nothing was mentioned in this thesis that can reveal patients' identities implicitly or explicitly.

3.17.1 Ethical approval

Ethical approval includes the revision of the study plan by an external body (i.e. not the research team). The revising process includes reading the study plan and asking questions to guarantee that no human rights are violated, and that the study is safe to conduct.

In accordance with DMU research ethics regulation, ethical approval to carry out this study was granted from the Ethics Committee of the Faculty of Health and Life Sciences at DMU (Appendix I).

Given that the research team had previously gained ethical approval to access the same data at Queens' Hospital, no need was seen to have a new ethical approval from the intended NHS Trust. Instead, a Research Passport to access the same data set was obtained from the Staffordshire Trust (NHS) (Appendix J), since the primary investigator of this study had joined the research team to work on the same data set.

Research Passport is a part of a scheme presented to streamline procedures associated with issuing honorary contracts or access letters to researchers. It involves issuing a letter of access for the researchers who have no contractual agreements with NHS. Research Passport provides evidence that checks undertaken to grant the researcher access to NHS facilities are in accordance with NHS employment checks.

3.18 Controlling different sources of bias in the study

In any study it is important to control bias. Bias is "any influence or action in a study that distorts the findings or slants them away from the true or expected" (Burns and Grove, 1999, p.455). Controlling bias will increase study robustness and increase both the external and internal validity of the study. Bias was controlled in this study through different considerations that were a part of the study methodology. These considerations were:

1- The study sample included all possible subjects under the study criteria. This will eliminate any chance of sampling bias that can distort results. In addition, it can increase the extent to which study results can be generalized (increase external validity).

2- All parts of the medical file were revised by the primary investigator to make sure that every piece of information relevant to the study was recorded.

3- Randomization was replaced with matching. In experimental studies, randomization is applied to ensure that all study subjects are equalized to characteristics that can affect the outcome (Polit and Hungler, 1999). Due to the retrospective nature of the study, randomization of risk characteristics is

inapplicable. This was substituted with matching patients in pairs using a number of Waterlow sub-scores. To some extent, matching technique can be helpful in decreasing bias that can result from unequalized patients' characteristics between the study groups. This will increase trust in the results for both interventions and risk factors.

3.19 Chapter summary

This chapter represented the study methodology, which guided the study plan of action. A quantitative retrospective descriptive comparative matched case-control design was employed. This design is about matching patients with a condition (case) to patients with none (control), but who share a number of characteristics, then comparing the case and control groups for a number of independent variables in terms of the dependant variable. The current study employed this design to retrospectively match patients in pairs. Patients who had PUs were paired with patients free of PUs, but shared a number of Waterlow sub-scores. Upon this matching, different PUs' preventive interventions and risk factors were described in each group (case and control), then compared. The aim of this comparison was to differentiate between which interventions were associated with preventing PUs, and to explore which risk factors were associated with PUs. Using this design provides a robust method to answer research questions. Matching patients according to some Waterlow sub-scores adjusts some previously established risk factors between each pair of patients. This provides a practical way to eliminate the hazard of some confounders from interfering with the study results, and can increase the precision of the comparisons.

The electronic medical record system (HISS) at Queens's Hospital (UK) was used in this study to collect data retrospectively. A data extraction sheet was devised in order to extract data from electronic medical records. This sheet was built based on literature, so that it can extract necessary information to answer research questions.

In order to collect data from electronic medical records, a preliminarily sampling plan was set. This plan used automated method to extract a patient list that contained PU status and Waterlow sub-scores. Using SPSS, patients with hospital-acquired PUs were matched with other patients with none in terms of a number of available Waterlow sub-scores. Before going on with data collection, the automated generated list of paired patients was piloted to check its accuracy. Piloting revealed that preliminarily paired list was inappropriate for conducting this study due to many inaccuracies. Therefore, alternative sampling strategy combining TVN list and computer-generated list were used to get a more accurate list of paired patients. Data were only collected from patients if they matched the study inclusion criteria. This included selection of patients being initially free of PUs on admission and over 14 years of age. Preventive interventions included in the study were only those implemented before ulceration. Risk factors included were those recorded on admission to hospital. Convenience sampling method was used to select all eligible patients present on HISS and TVN list. This resulted in including 76 pairs (152 patients; 76 with PUs and 76 patients free of PUs). A data analysis plan using descriptive, univariate and multivariate statistics was considered.

Ethical approval to conduct this study was gained from the Ethics Committee in the Faculty of Health and Life Sciences at DMU. A Research Passport was obtained from Staffordshire Trust (NHS).

Chapter Four: Findings

4.1 Introduction

This chapter reports findings from this study according to the previously described methodology. Findings were the results of quantitatively analysing different study variables that represented both preventive interventions and risk factors in addition to other variables that were used to describe the sample and give a broader picture about the situation. Results from analysing variables representing interventions and risk factors were used to answer the research questions and test the study hypotheses in terms of available data. Moreover, this chapter describes the process of preparing data for analysis, which was done before data were analysed.

Details of the operational definition of different variables were also discussed. This was to explain the meaning of different variables and how they were recorded and categorized.

In this study, patients were divided into two groups in terms of dependant or outcome variable (hospital acquired PUs). Therefore, there was PU group and non-PU group. On the other hand, independent variables were grouped into four groups according to their relatedness (see operational definition, section: 4.3). Independent variables were compared between the two study groups.

4.2 Preparing data for analysis

After data were coded and different variables created (see creating and coding study variables, section: 4.14), different variables were entered into an SPSS data file in order to be statistically analyzed. Prior to conducting the statistical analysis using descriptive and inferential statistics, data were prepared for analysis. Preparation for analysis included a number of steps:

- Screening and cleaning the data from errors
- Indentifying missing data
- Recoding variables
- Calculating variables
- Making data backup

Screening and cleaning data from errors was an important step before getting it analysed. Cross-checks between the paper forms and the data file on the computer were performed to check for errors that might happen during data entry. Additionally, frequency analysis using computer was performed to check for any value out of the expected range for a particular variable or if it was missing. In case a missing value or an out of expected range value was not a result of an error in data entry, medical records for that particular variable were re-checked to make sure that the right value was obtained.

Recoding variables was necessary before initiating data analysis for some variables. Recoding variables was done either by collapsing categories within a variable, or categorizing some of the continuous variables to categorical variables. Collapsing variables

was done for variables collected in more categories than it is practical to use for analysis, or when some categories had a very small frequency. Categories with small frequency can reduce the power of inferential statistics, hence making it difficult to make an inference about these categories. Moreover, it is not possible for some inferential statistical tests used in the study to be completed with variables with a large number of categories. Collapsing categories was based on a theoretical basis; only categories that were similar were combined together. For instance, type of mattress used was initially categorized according to its brand name recorded by nurses, which created too many categories. Knowing that all mattresses used were pressure redistributing, categories for mattresses were collapsed to either static or alternating

Some variables with a large number of categories could not be collapsed because categories were distinct and unique; they therefore could not be combined together (e.g. underlying medical disorder).

Categorizing continuous variables (numerical) was done for the biological risk factors (i.e. laboratory tests and blood pressure (B.P.)). Categorizing was done depending on standard cut-off points. Categorized continuous variables were used in univariate and multivariate analysis. Original continuous variables were kept in the data set and analysed using descriptive statistics and univariate analysis.

Calculating variables was done to create a new variable from a group of variables that were recorded in the data set (i.e. number of underlying medical conditions). Number of underlying medical disorders was calculated from counting values of medical disorders

within different cases in the data set. Counting process was done through using SPSS to insure accuracy.

Finally, a copy of the prepared data was saved on an optical disc and kept in a safe place.

4.3 Variables groups and operational definitions

This section aims to elaborate upon variables' operational definitions. Individual variables and their categories are operationally defined based on the general variables' selection criteria that were presented in methodology chapter. Operational definitions are presented in this chapter to explain and present different categories of each variables and how they were measured. This will help in the interpretation of study results.

The only dependant variable (outcome variable) was PU status. This variable had two categories (dichotomous): having a PU and free of PU. PUs in this study were those only acquired at hospital. Free of PU means that the patient is free of hospital-acquired or community-acquired PUs. This variable divided the study subjects into two numerically equal groups: PU group and non-PU group.

Independent variables in this study were divided into four groups:

- **Group One**: Variables of descriptive nature
- **Group Two**: Variables representing preventive interventions
- **Group Three**: Variables related to physical activity and mobility
- **Group Four**: Variables related to PUs' intrinsic risk factors

Variables that were of a descriptive nature were so named because they were not included in inferential statistics. Including these variables would be pointless, as they cannot answer any of the research questions or test the hypotheses. Reasons for excluding these variables from inferential statistics are given, with each of these variables' operational definition.

For the purpose of univariate and multivariate analysis, variables that represented preventive interventions, variables related to physical activity and mobility and variables related to PUs intrinsic risk factors were included (groups 2, 3 and 4).

A number of variables had more than 20% of the cells with frequency of less than five, or cells with frequency of less than one (violated goodness-of-fit assumption in logistic regression); these were excluded from logistic regression analysis. These variables are referred to in the following sections.

- **Group One: Variables of descriptive nature**

This section represents the operational definition for group one variables that were only included in the descriptive analysis. Excluding these variables from inferential analysis was for different reasons specific to each variable. Reasons are given with the operational definition of each variable.

- **Gender**

- Variable categories: male/female

This variable was excluded from inferential analysis because it was matched within chosen Waterlow sub-scores.

- **Age** (continuous variable)

- Operational definition: age of patients in years (continuous variable)

This variable was excluded from inferential analysis because it was matched within chosen Waterlow sub-scores.

- **Ethnic group**:

- Variable categories: name of the ethnic group that patient belong to as recorded in medical file.

This variable was constant: all patients in the sample were white British, so it was excluded from inferential analysis.

- **Marital status**

- Variable categories: married/single/divorced/widow

This variable was excluded from inferential analysis. No clear theoretical link could be established between this variable and developing PUs. Moreover, all categories (except for two divorced patient) had approximately the same proportion of acquiring PUs.

- **Living arrangements before admission to hospital**

- Variable categories: Home with spouse or family/Home alone/living in caring facility e.g. nursing home/Home with caring service

- Operational definition: This variable identifies where the patient was living before admission to hospital

This variable was excluded from inferential analysis. Not enough information for the level of care and nutrition patients had in the place where they resided before admission. In view of that, a clear theoretical link could not be established between this variable and developing PUs.

- **Medical speciality on admission to hospital**

- Variable categories: acute medicine/medical care/male surgery or urology/acute elderly/surgical ward/orthopaedic/trauma/step down/care of elderly/stroke ward/ Coronary Care Unit (CCU)/ Intensive Therapy Unit (ITU).

- Operational definition: first ward the patient was admitted to when hospitalized.

This variable was excluded from inferential analysis. Details about staff numbers and level of care could not be obtained. As a result, no theoretical link could be established between the level of care in these wards and PUs. Moreover, some patients were transferred to a different ward after a period of hospitalization. Different transfers and the period spent in each ward were unclear in medical records.

- **Length of stay (LOS) at hospital** (continuous variable)

- Operational definition**:** actual number of hospitalization days

This variable was excluded from inferential analysis. Patients with PUs needs longer time to be managed, though increasing LOS. For this reason it was difficult to differentiate if the long LOS caused PUs or PUs caused long LOS.

- **Number of PUs developed** (continuous variable)

- Operational definition: quantifying the number of PUs each patient developed.

This variable was excluded from inferential analysis because PUs is what this study measuring, so it cannot be used as a predictor or risk factor.

- **PU grades** (continuous variable)

- Operational definition: quantifying PUs developed according to their grades for each patient. Grades were according to the EPUAP grading system.

This variable was excluded from inferential analysis because PUs is what this study measuring, so it cannot be used as a predictor or risk factor.

- **Sites of developed PUs** (continuous variable)

- Operational definition: quantifying different anatomical sites where PUs developed in.

This variable was excluded from inferential analysis because this study measures PUs, so it cannot be used as a predictor or risk factor.

- **Group Two: Variables representing preventive interventions**

Preventive interventions include all implemented activities of care that can be theoretically linked to the prevention of PUs. Whether these were previously reported in literature to protect from PUs, or are related to the prevention of any of any the PUs' risk factors. These interventions must be implemented before PUs develop. Also, these interventions must be implemented regularly and considered a part of the patient's plan of care.

- **Using barrier creams**

- Variable categories**:** barrier cream used (yes)/barrier cream not used (no).

- Operational definition: This variable was recorded "yes" if barrier creams were documented to be used. Barrier cream must be documented to be used regularly during hospitalization period.

- **Using moisturizing creams:**

- Variable categories**:** moisturizing creams used (yes)/moisturizing creams not used (no)

- Operational definition: This variable was recorded "yes" (moisturizing cream used) if moisturizing creams were documented to be used. Moisturizing creams must be documented to be used regularly during hospitalization period.

- **Type of hospital bed**

- Variable categories: profiling bed /standard hospital bed

- Operational definition: profiling beds: beds that moves electrically.

  Standard beds: beds that moves manually.

- **Using seating cushion**

- Variable categories: seating cushions used (yes)/seating cushion not used (no)

- Operational definition: This variable was recorded “yes” (seated on a cushion) if it was especially made for interface pressure relieving and used regularly during the admission period when the patient sat out of bed.

- **First mattress used**

- Variable categories: static /alternating

- Operational definition: this variable was recorded as “static” if patient was laid on a static pressure redistributing mattress when admitted to hospital. Variable was recorded as “alternating” if the patient was laid on alternating pressure redistributing mattress when admitted to hospital. In case first mattress was changed it must be used at least for a full day before changing it to a second one.

- **Second mattress used**

- Variable categories: static/alternating

- Operational definition: This variable was recorded as “static” if the first mattress was changed to static. Variable was recorded as “alternating” if the first mattress was changed to alternating. Second mattress was used from the time it replaced the

first one till discharge in the non-PU group. In the PU group second mattress must be used before first sign of PU appears (i.e. blanching erythema).

This variable could not be included in the logistic model due to the large number of missing values. This violated goodness-of-fit assumption in logistic regression.

- **Re-positioning patient in bed**

- Variable categories: no re-positioning/re-positioning 2-hourly/re-positioning 4-hourly

- Operational definition: This variable was recorded as “no re-positioning” if the patient was not documented to be re-positioned or was irregularly re-positioned during hospitalization period. Variable was recorded as “re-positioning 2-hourly” if the patient was documented to be re-positioned regularly every 2 hours during the hospitalization period. Variable was recorded “re-positioning 4-hourly” if the patient was documented to be positioned regularly every 4 hours during hospitalization period.

- **Sitting in chair**

- Variable categories: sat in a chair for regular intervals (yes)/did not sit in a chair, or occasionally sat (no).

- Operational definition: This variable means that nurses encouraged or assisted patients to sit in a chair for regular intervals during hospitalization. Patients were recorded as “yes” if they got out of bed and sat in a chair on a daily basis during

hospitalization for more than one hour. If patients did not sit regularly on a chair, they were recorded as “no”.

- **Using draw sheet**

- Variable categories: draw sheet used (yes)/draw sheet not used (no)

- Operational definition: This variable specifies if a draw sheet (sliding sheet) was used to turn patients in bed in order to change their position. Variable was recorded as “yes” if nurses used a draw sheet regularly to position patient. If draw sheets were not used to position patients, the variable was recorded as “no”.

- **Dietician referral**

- Variable categories: referred to a dietician (yes)/not referred to a dietician (no)

- Operational definition: variable was recorded as “yes” if the patient was referred and seen by a dietician, then instruction of the dietician were implemented. Variable was recorded as “no” if patient was not referred to a dietician, or the instructions of the dietician were not implemented. Referral should be before ulceration for patient in PU group.

- **Physiotherapy referral**

- Variable categories**:** refereed to a physiotherapist (yes)/not referred to a physiotherapist (no)

- Operational definition: variable was recorded as “yes” if the patient was referred and seen by a physiotherapist, then instructions of the physiotherapist were implemented. Variable was recorded as “no” if patient was not referred physiotherapist or when referred not seen or the instructions of the physiotherapist were not implemented. Referral should be before ulceration for patients in PU group.

➢ **Group Three: Variables representing factors related to physical activity and mobility**

These groups of variables are included to measure level of activity and mobility of the study sample in different ways. These ways are part of nursing routine and daily assessment and was based on nursing documentation on admission to hospital

- **Activity in bed**

- Variable categories: moves with help/moves independently

- Operational definition: Variable was recorded as “moves with help” if the patient needed assistance in order to turn off or move self up or down in bed. If the patient could do that independently without help then the variable was recorded as “moves independently. Recording this variable was based on nursing assessment of patients on admission to hospital.

This variable measures patient need for assistance in order to turn or d move while lying on bed. This can reflect patients' level of activity in bed. Patients who can move independently in bed are considered to have a higher level of activity.

- **Activity outside bed**

- Variable categories: moved by hoist only /moves with help or independently

- Operational definition: Variable was recorded as "moved by hoist only" if the patient was bedridden and the only way to transfer him/her out of bed was by using hoist. Variable was recorded as moved with help or independently if the patient can move out of bed with some assistance or independently. Recording this variable was based on nursing assessment of patients on admission to hospital.

This variable was designed to measure if the patient was able to walk outside bed independently or with some assistance, or if he/she was bed ridden and could only be moved by hoist. This can reflect the activity level of patients outside bed. Patients who can move independently or with some help outside bed are considered to have a higher level of activity than patients who cannot, and can only be moved by hoist.

- **Long surgical procedures**

- Variable categories: patient underwent long surgery two hours or more (yes)/patient had no surgery at all (no)

- Operational definition: Variable was recorded as “yes” if patient underwent a surgery that lasted two hours or more before PU developed. Variable was recorded as “no” if the patient had no surgery.

This variable was designed to catch patients who underwent major surgeries lasting two hours or more. There was no category in this variable for minor surgeries or surgeries that lasted less than two hours, because no patient in the study sample was found to match this category. Staying immobile for more than two hours represents a decrease in patient activity level. Recording this variable depended on the surgical report found in patients’ medical records.

- **Ability to do hygiene practices**

- Variable categories: shower or assisted bathing/bed bath/hoist bath

Operational definition: Variable was recorded as “Shower or assisted bathing” if patient could go to bathroom independently or with assistance. Variable was recorded as “bed bath” if the patient was bounded to bed (e.g. with traction) and only could be bathed in bed. Variable was recorded as “hoist bath” if the patient was bedridden but his/her situation allowed moving out of bed by hoist to be bathed.

This variable was to measure the level of dependency each patient had in maintaining skin hygiene through bathing. Increased dependency level represents a decrease in the level of mobility.

- **Ability to do Activities of Daily Living (ADLs)**

- Variable categories: needs one help/needs two help/independent or needs help in bathing only

- Operational definition: Variable was recorded as “one help” if patient needed one nurse’s help in all ADLs. Variable was recorded as “two help” if patient needed two nurses’ help in all ADLs. Variable was recorded as “independent or needs help in bathing only” if the patient was able to do ADLs without help, or only needed help in bathing. Recording this variable was based on nursing assessment for patients on admission to hospital.

This variable was to measure amount of assistance needed in doing ADLs. These include eating, grooming and personal hygiene: The more dependent the patient was in doing these activities the more he/she had a lower activity level.

- **Group Four: Variables related to PUs intrinsic risk factors**

This group represents variables that were related to PU intrinsic risk factors reported in the literature.

- **Reason for hospitalization**

- Categories of this variable: neck of femur (NOF) fracture/renal failure/chronic obstructive pulmonary disease (COPD)/arthritis/peripheral vascular disease/hypertension (HTN)/cancer/neurological disorders/musculoskeletal

injury/gastrointestinal (GI) problem/chest infection/wound infection/heart problem/dehydration/diabetes mellitus (DM)/brain attack

- Operational definition: Reason for hospitalization represents the main problem that needed management and was behind admission to hospital. Problems were categorized together according to their relatedness. If one reason for admission was with considerable frequency it was recorded alone.

- NOF fracture: patient was admitted for managing NOF fracture. Patients who were - surgically and non-surgically managed were included.

- Renal failure: patient had renal failure acute or chronic as the main reason for admission.

- COPD: patient was admitted for managing COPD, this included chronic bronchitis or emphysema.

- Arthritis: patient admitted for managing complications of arthritis.

- Peripheral vascular disease: patient was admitted for managing obstruction in peripheral circulation.

- HTN: patient was admitted for managing elevated B.P. as a primary cause for admission.

- Cancer: patient was mainly admitted for management of a malignancy whether this was for treatment or palliative care.

- Neurological disorders: includes disorders that affect the neurological system and cause mobility problems (e.g. Parkinson's, neuropathies, and multiple scleroses).

- Musculoskeletal injury: includes injuries and fractures to this system (e.g. femur shaft fracture, vertebral fracture and muscle injuries). NOF fracture was recorded alone in a category due the considerable number of patients with NOF fracture.

- GI problems: indicates that the patient had a problem affecting the GI system (e.g. diarrhoea, peritonitis).

- Chest infection: patient was admitted mainly for managing an infection in the respiratory system (e.g. pneumonia).

- Wound infection: patient was admitted for managing an infected wound that happened prior to admission.

- Heart problems: this category included patients having ischemic heart diseases (angina, infarctions), cardiac arrhythmias (e.g. atrial fibrillation, tachycardia) and heart failure.

- Dehydration: patient admitted for managing dehydration.

- DM: patient admitted for controlling blood glucose.

- Brain attack: patient was admitted post brain attack for management. Brain attack was recorded alone in a category because it had enough frequency to be recorded separately.

This variable could not be included in the logistic regression due to the large number of categories it contained which could not be collapsed. Large number of categories with low frequencies violates goodness-of-fit assumption in logistic regression.

- **First underlying medical condition**:

- Categories of this variable: renal failure/COPD/arthritis/peripheral vascular disease/HTN/cancer/neurological disorder/musculoskeletal injury/GI problem/chest infection/heart problem/dehydration/DM/brain attack

- Operational definition of categories: This variable represented medical conditions that were old and chronic or were developed during hospitalization before PU developed. Underlying medical conditions were a side problem that needed special consideration in the care process but were not the main reason for hospitalization.

This variable could not be included in the logistic regression due to the large number of categories it contained which could not be collapsed. A large number of categories with low frequencies violates goodness-of-fit assumption in logistic regression. Also it was not included in univariate analysis, because it was used to calculate other variable (i.e. number of underlying medical conditions).

First was added to the variable name to indicate quantity (not order), because some patients had more than one underlying condition.

- **Second underlying medical condition**:

- Categories of this variable: renal failure/COPD/arthritis/peripheral vascular disease/HTN/cancer/neurological disorder/musculoskeletal injury/chest infection/heart problem/dehydration/brain attack

- Operational definition: this variable represented medical conditions that were old and chronic or were developed during hospitalization before PU developed. Underlying medical conditions were a side problem that needed special consideration in the care process but were not the main reason for hospitalization.

This variable could not be included in the logistic regression due to the large number of categories it contained which could not be collapsed. A large number of categories with low frequencies violates goodness-of-fit assumption in logistic regression. Also it was not included in univariate analysis because it was used to calculate other variable (i.e. number of underlying medical conditions).

Second was added to the variable name to indicate quantity (not order) because some patients had more than one underlying condition.

- **Third underlying medical condition**:

- Categories of this variable: Heart problem/renal failure/COPD/arthritis/peripheral vascular disease/HTN/cancer/neurological disorder/musculoskeletal injury/GI problems/chest infection/wound infection/DM/Brain attack

- Operational definition: This variable represented medical conditions that were old and chronic or were developed during hospitalization before PU developed. Underlying medical conditions were a side problem that needed special consideration in the care process but were not the main reason for hospitalization.

This variable could not be included in logistic regression due to the large number of categories it contained, which could not be collapsed. Large number of categories with low frequencies violates goodness-of-fit assumption in logistic regression. Also it was not included in univariate analysis because it was used to calculate another variable (i.e. number of underlying medical conditions).

Third was added to the variable name to indicate quantity (not order) because some patients had more than one underlying condition.

- **Number of underlying medical conditions**

- Categories of this variable: not present/one disorder/two disorders/three disorders

- Operational definition: depending on tables of frequency for the first, second and third medical disorders; a new categorical variable was calculated. This variable represents number of underlying medical conditions represented by four categories. The first category represents patients who did not have any underlying medical condition at all; the second, patients who had one condition; the third, patients who had two conditions; And the fourth, patients who had three medical conditions. Three was the maximum number of underlying conditions patients in the data set had.

This variable summarized all three variables that were used to calculate it. In view of that, only descriptive statistics were performed on these three variables.

- **Level of consciousness**

- Categories of this variable: conscious/confused/unconscious

- Operational definition: patients were divided into three categories according to their level of consciousness. Only one patient in the sample was unconscious. As a result, this patient was removed when inferential statistics were performed because categories with one subject can decrease the power of analysis.

- **Presence of cognitive impairment**

- Variable categories**:** with cognitive impairment (yes)/without cognitive impairment (no).

- Operational definition: Patient was recorded as having a cognitive impairment if he/she had a condition that is known to affect cognitive abilities (e.g. Alzheimer's disease, dementia).

- **Depression**

- Variable categories: suffering from depression (yes)/not depressed (no)

- Operational definition: This variable shows if the patient was documented to be depressed or not.

- **Dehydration**

- Variable categories: not present/present

- Operational definition: This variable shows if the patient was dehydrated or not when admitted to hospital.

- **Presence of Dysphagia**

- Variable categories: dysphagia present (yes)/dysphagia not present (no)

- Operational definition: This variable shows if the patient had a problem with swallowing food (dysphagia) or not.

- **Blood transfusion**

- Variable categories: blood transfused (yes)/blood not transfused (no)

- Operational definition: this variable specifies if patient had any units of blood transfused.

- **Denture or chewing problems**

- Variable categories: problem with dentures or chewing present (yes)/problem with chewing or dentures not present (no)

- Operational definition: This variable represents patients that were assessed to have problems related to difficulty in chewing food or patients that had unfitted dentures.

- **Presence of pain**

- Variable categories: pain not present /mild pain/severe pain

- Operational definition: pain was rated using the same expressions used in medical records. Pain recorded here was the level of pain on admission to hospital.

This variable was not included in logistic regression, and only used as a descriptive variable because level of pain is constantly changing, assessed and managed during hospitalization.

- **Biological measures:** serum albumin/serum sodium/serum potassium/serum urea/serum creatinine/haemoglobin/white cells count (WCC)/C-reactive protein (CRP)/systolic B.P./diastolic B.P.

Biological measures were the routine laboratory tests most commonly done to patients, in addition to B.P.. Biological risk factors were used in the study in two forms: continuous variables, and as categorical variables with two categories (binary).

- Operational definition:

Continuous variables: values of these factors were recorded as their actual numerical values recorded in the medical files. Values that were included in the study were those measured on admission to hospital. Biological risk factors as continuous variables were only included in univariate analysis, not in multivariate analysis (reasons are discussed in discussion chapter, section: 5.3.2.3).

Binary variables: numerical biological factors were categorized to represent two categories according to standardized cut-off points reported in literature. Variables of serum albumin, serum sodium, serum potassium, haemoglobin, systolic B.P. and diastolic B.P. were categorized into two categories: normal value or below-normal value. Variables of serum

creatinine, serum urea, CRP and WCC were categorized into two categories: normal or above-normal values. Cut-off points used are reported with descriptive statistics for binary biological risk factors.

CRP could not be included in the logistic regression analysis due to many missing values that it contained. Only 111 patients out of 152 had their CRP tested.

4.4 Statistical analysis

Statistical analysis included the use of both descriptive and inferential statistics. Descriptive statistics were used for both categorical and continuous data. All categorical variables were described in terms of percentages and frequencies. Bar charts and tables were used to summarize some of the categorical variables. Continuous variables were summarized using mean as a measure of central tendency and standard deviation (S.D.) as a measure of dispersion.

Inferential statistics in this study included the use of univariate analysis and multivariate analysis. Univariate analysis for categorical variables included the use of contingency tables (crosstabulation) and chi-square ($\chi 2$). Contingency tables were used to compare different study independent categorical variables (one at a time) with the dependant variable (PU status). They showed the frequency and percentage of subjects of each of the study groups (with PU and free of PU) falling into each category of the independent variables categories. Chi-square was used to show if the difference in the proportion found between the two study groups in the contingency tables is statistically significant or not. If

the assumptions of chi-square test were violated, Fishers exact test was used instead of chi-square to compare categorical variables.

Univariate analysis for continuous variables included the use of parametric independent sample t-test for normally distributed variables. If the assumption of normality was violated, the non-parametric alternative Mann-Whitney U test was used. Continuous variables were not used to answer any of the research questions, but were analysed to discover if the results of analysing these variables as continuous variables differed from analysing them as categorical variables. As mentioned earlier, this applied only to biological risk factors that were collected originally as continuous variables.

To put it briefly, univariate analysis was used to show if there was a statistically significant difference between the two study groups in terms of the independent variables. Comparisons for independent variables were one at a time due to the statistical nature of the univariate analysis.

Multivariate analysis (i.e. binary logistic regression) was used to compare between the two groups of the study in terms of independent variables. Comparison here was for a group of independent variables as a set; not one at a time as in univariate analysis. Choosing logistic regression was to create a statistical model able to investigate the relation between the dichotomous (two categories) dependant variable and other sets of independent variables.

Significant level (α-level) used was $\alpha=0.05$ for all tests in the study. Where multiple pair-wise testing excited; Bonferonni correction was used to create a more conservative level of significance. As the number of multiple pair-wise comparisons increase; the chances of the

groups being different in a least one attribute increase (increase type one error). Using Bonferonni correction will decrease the chance of type one error. The revised *P* value would be α/n, where α=0.05, n= number of multiple pair-wise testing.

ROC curves were used to distinguish which variable was more associated with the occurrence of PUs. The comparison was held between biological risk factors that turned out to be significant in logistic regression. Biological risk factors were only included in this type of analysis because they were continuous variables before being categorized. ROC curve only works with continuous variables.

All statistical results in this study were rounded to the nearest two decimal points.

4.5 Statistical results

This section presents the results of different statistical procedures performed on the data set. As mentioned earlier, descriptive statistics were performed on all four groups of variables; inferential statistics were performed on second, third and fourth group. Multivariate analysis was used to answer research questions through creating three statistical models for the variables in groups two, three and four.

In view of the study's design (matched-case control), the total Waterlow score was not shown with the results because it was equal between each two paired patients. Conducting statistical analysis on the total Waterlow scale would be pointless because it has a constant value.

4.5.1 Descriptive statistics

Descriptive statistics reports mean and S.D. for numerical study variables (continuous variables). Also, it reports frequency and percentage for categorical variables. Tables and bar charts were used to summarize the results of some variables.

Variables in this section were grouped according to the previously mentioned grouping in operational definition section.

- **Group One: Variables of descriptive nature**

Group one variables were further categorized to represent sub-groups. These included:

- subjects' demographics and admission information

- pressure ulcers number and characteristics

- **Subjects' demographics and admission information**

The total number of patients' medical records was 152 records. This was the final number of medical records selected after patients who did not match the study selection criteria were excluded. Each of the study two groups (PU group and non-PU group) had 76 patients. This mean that this study had 76 paired Waterlow sub-scores matches. Details for the number of scores different matches shared were showed previously in the methodology chapter.

Out of the 152 patients, 92 (60.5%) were females and 60 (39.5%) were males. All of the study subjects were white British (100%). As a result, ethnicity was considered a constant variable and was not inferentially analysed. Table 4.1 shows frequency and percentage for

different demographical characteristics for the total sample as a whole and for the two study groups separately.

Table 4.1: Study subjects' demographical characteristics

Characteristic	Total sample	PU group	Non-PU group
Number of subjects	152	76	76
Age (mean ± S.D.*)	81.0± 9.	80.7± 8.6	81.4± 9.5
Age (Min-Max)	55-99	55-99	56-97
Gender (male)	60 (39.5%)	30 (39.5%)	30 (39.5%)
Gender(female)	92 (60.5%)	46 (60.5%)	46 (60.5%)
Ethnic group	100% white British	100% white British	100% white British
Marital status: Married Widow Single Divorced Missing data	 67 (44.1%) 58 (38.2%) 23 (15.1) 2 (1.3%) 2 (1.3%)	 34 (44.7%) 29 (38.2%) 11 (14.5%) 2 (2.6%) 0(0.0%)	 33 (43.4%) 29 (38.2%) 12 (15.8) 0 (0.0%) 2 (2.6%)

- Living arrangements before admission to hospital

Living arrangement variable describes the places wherein patients resided before admission to hospital. Table 4.2 shows the frequency and percentage of living arrangements for the total sample as a whole, and for the two study groups. Two patients in the non-PU group did not have this variable recorded in their files.

Table 4.2: Living arrangement

Type of arrangement	Total sample frequency (%)	PU group frequency (%)	Non- PU group frequency (%)
Home with spouse/family	57 (37.5%)	24 (31.6%)	33 (43.4%)
Home alone	48 (31.6%)	24 (31.6%)	24 (31.6%)
caring facility	31 (20.4%)	20 (26.3%)	11 (14.5%)
Home with caring service	14 (9.2%)	8 (10.5%)	6 (8.1%)
Total subjects	150 (98.7%)	76 (100%)	74 (2%)
Missing data	2 (1.3%)	0 (0.0%)	2 (2.6%)

- Medical speciality on admission to hospital

This sub-section specifies the first medical speciality on admission to hospital among study groups. Ward and units in this table were those the same recorded in medical files without any grouping. Table 4.3 specifies frequency and percentage for medical speciality for the total sample and the two study groups. Very small numbers were admitted to ITU and CCU. Only one patient was admitted to CCU in PU group, and only one patient was admitted to ITU in non-PU group.

Table 4.3: Medical specialties on admission to hospital

Medical specialty	Total sample frequency	PU group frequency	Non-PU group frequency
Acute medicine	39 (25.7%)	15 (19.7%)	24 (31.6%)
Medical care	4 (2.6%)	0 (0.0%)	4 (5.3%)
Male surgery/urology	6 (3.9%)	2 (2.6%)	4 (5.3%)
Acute elderly	22 (14.5)	5 (6.6%)	17 (22.4%)
Surgical	7 (4.6%)	4 (5.3%)	3 (3.9%)
Orthopaedic	11 (7.2%)	6 (7.9%)	5 (6.6%)
Trauma	11 (7.2%)	4 (5.3%)	7 (9.2%)
Step down	20 (13.2%)	17 (22.4%)	3 (3.9%)
Care of elderly	26 (17.1%)	19 (25%)	7 (9.2%)
Stroke ward	4 (2.6%)	3 (3.9%)	1 (1.3%)
CCU*	1 (0.7%)	1 (1.3%)	0 (0.0%)
ITU**	1 (0.7%)	0 (0.0%)	1 (1.3%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total subjects	152 (100%)	76 (100%)	76 (100%)

*Coronary Care Unit, **Intensive Therapy Unit

- LOS at hospital

Table 4.4 represents mean and S.D. for the variable LOS. It is noticed the mean LOS for the PU group is higher than for the non-PU group.

Table 4.4: LOS for both of the study groups

Descriptive statistics	Total sample	PU group	Non-PU group
Mean	44.32	72.3	16.38
S.D.	48.15	53.8	13.83
Maximum	222	222	65
Minimum	3	5	3
Total number	152	76	76
Missing cases	0	0	0

- **Pressure ulcers number and characteristics**

This section specifies the number of hospital-acquired PUs different patients developed and their grades, in addition to the sites where these ulcers developed.

- Number of PUs developed

This sub-section shows how many patients developed different numbers of PUs. Table 4.5 shows these numbers.

Table 4.5: Number of PU developed and number of patients developed them

Number of hospital acquired PU	Number of patients	percentage
1	40	52.6%
2	25	32.9%
3	8	10.5%
4	3	3.9%

- PU grades

This sub-section presents frequency and percentage for different grades of PUs. Figure 4.1 (bar chart) represents these grades. The total number of PUs developed was 126 ulcers. The majority were grade four (47 ulcers). Numbers of grade three, two and one were 32, 29, and 18 respectively.

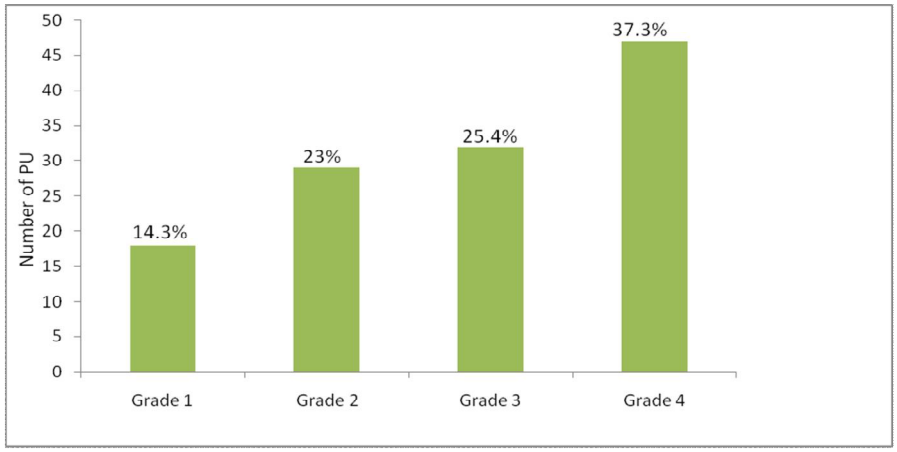


Figure 4.1: Frequencies of PUs according to grade

- Anatomical sites of developed PUs

This sub-section represents the frequency and percentage of PUs sites in the data set (figure 4.2, bar chart). More than half the number of PUs developed was on heels, with 67 PUs out of 126 PUs (53.2%). The lowest number was at leg, thigh, scapula and toes with 2, 1, 1 and 1 ulcer respectively.

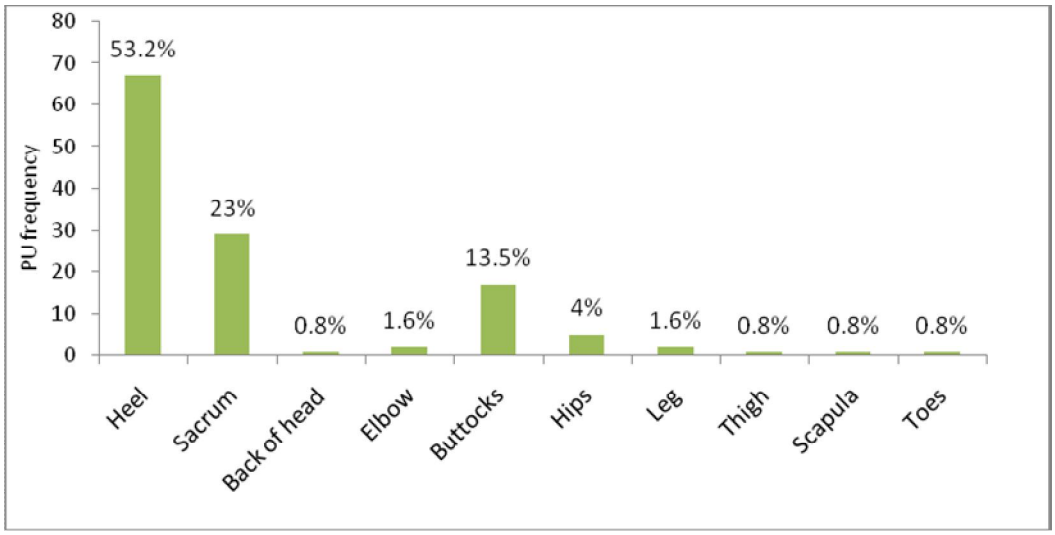


Figure 4.2: Frequency of the total number of PU in different body site

- **Group Two: Interventions and different aspects of care**

This section reports descriptive statistics for different intervention (nursing and non-nursing) and aspects of the care process. Variables representing preventive interventions and aspects of the care process were categorical. Therefore, they will be mainly reported as frequency and percentage.

- Using barrier creams

Very few patients had barrier creams used before PU developed. In the total sample, only 10 patients had barrier cream used before ulceration. Both of the study groups were equal in this variable with 5 patients (5.6%) in each group (table 4.6).

Table 4.6: Frequency for using barrier creams

Barrier cream used	Total sample	PU group	Non-PU group
Yes	10 (6.6%)	5 (6.6%)	5 (6.6%)
No	142 (93.4%)	71 (93.4%)	71 (93.4%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Using moisturizing creams

Few patients had been rubbed with a moisturizing cream before ulceration. In the PU group only 7 patients (9.2%) had a moisturizing cream applied before ulceration. Non-PU group had also the same frequency (table 4.7).

Table 4.7: Frequency for using moisturizing creams

Moisturizing cream used	Total sample	PU group	Non-PU group
Yes	14 (9.2%)	7 (9.2%)	7 (9.2%)
No	138 (90.8%)	69 (90.8%)	69 (90.8%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Type of hospital bed

Table 4.8 shows frequency and percentage for patients who were laid on profiling beds or standard bed in the two study groups. More patients in the PU group had profiling beds compared to patients in non-PU group. Two patients (2.6%) in the non-PU group had profiling beds, compared to 12 patients (15%) in the PU group.

Table 4.8: Frequency for type of hospital bed

Type of hospital bed	Total sample	PU group	Non-PU group
Standard	136 (89.5%)	64 (84.2%)	72 (94.7%)
Profiling	14 (9.2%)	12 (15.8%)	2 (2.6%)
Total number	150 (98.7%)	76 (100%)	74 (97.4%)
Missing data	2 (1.3%)	0 (0.0%)	2 (2.6%)

- Using seating cushion

Table 4.9 shows frequency and percentage of patients who had a seating cushion in the two study groups. More patients in the non-PU group had seating cushions compared to patients in PU group. Two patients (2.6%) in the PU group had seating cushions, compared to 13 patients (17.1%) in the non-PU group.

Table 4.9: Frequency for using seating cushion

Seating cushion used	Total sample	PU group	Non-PU group
No	137 (90.1%)	74 (97.4%)	63 (82.9%)
Yes	15 (9.9%)	2 (2.6%)	13 (17.1%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- First mattress used

Table 4.10 shows the first type of mattress a patient was laid on immediately after admission. Table 4.10 shows that patients in the PU group had more pressure alternating

mattresses used than patients in the non-PU group. 15 patients (19.7%) had a pressure alternating mattress in non-PU group compared to 27 patients (35.5%) in the PU group.

Table 4.10: Frequency for using first mattress

Mattress 1	Total sample	PU group	Non-PU group
Static	110 (72.4%)	49 (64.5%)	61 (80.3%)
Alternating	42 (27.6%)	27 (35.5%)	15 (19.7%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Second mattress used

Only a small proportion of patients (25%) had their mattresses changed after admission to a second one. Table 4.11 shows the second type of mattress a patient was laid on after admission. It shows that patients in the PU group had more alternating mattresses than patients in the non-PU group. 6 patients (7.9%) had a pressure alternating mattress in non-PU group compared to 26 patients (34.2%) in the PU group.

Table 4.11: Frequency for using second mattress

Mattress 2	Total sample	PU group	Non-PU group
Static	6 (3.9%)	3 (3.9%)	3 (3.9%)
Alternating	32 (21.1%)	26 (34.2%)	6 (7.9%)
Total number	38 (25%)	29 (38.2%)	9 (11.8%)
Missing data	114 (75%)	47 (61.8%)	67 (88.2%)

- Re-positioning patient in bed

Table 4.12 shows frequency for the two regimens of re-positioning also for patients not re-positioned. More patients in the PU group were re-positioned every 2 hours compared to non-PU group. Conversely, more patients in non-PU group were re-positioned every 4 hours compared to PU group.

Table 4.12: Re-positioning in bed

Re-positioning in bed	Total sample	PU group	Non-PU group
No re-positioning	22 (14.5%)	12 (15.8%)	10 (13.2%)
Re-positioning 2-hourly	115 (75.2%)	63 (82.9%)	52 (68.4%)
Re-positioning 4-hourly	15 (9.9%)	1 (1.3%)	14 (18.4%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Sitting in chair

Table 4.13 shows that more patients in non-PU sat on chair compared to patients in PU group.

Table 4.13: Frequency for sitting in chair

Sitting on chair	Total sample	PU group	Non-PU group
No	59 (38.8%)	44 (57.9%)	15 (19.7%)
Yes	93 (61.2%)	32 (42.1%)	61 (80.3%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Using draw sheets

More patients in non-PU were moved using a draw sheet compared to PU group. Table 4.14 shows frequency for using draw sheet in the two study groups.

Table 4.14: Frequency of using draw sheet

Draw sheet used	Total sample	PU group	Non-PU group
No	43 (28.3)	27 (35.5%)	16 (21.1%)
Yes	108 (71.1%)	49 (64.5%)	59 (77.6%)
Total number	151(99.3%)	76 (100%)	75 (98.7%)
Missing data	1 (0.7%)	0 (0.0%)	1(1.3%)

- Dietician referral

Table 4.15 specifies how many patients were referred to a dietician in the two study groups. Approximately the same number of patients was referred to a dietician in the two study groups.

Table 4.15: Frequency of dietician referral

Dietician referral	Total sample	PU group	Non-PU group
No	117 (77%)	58 (76.3%)	59 (77.6%)
Yes	35 (23%)	18 (23.7%)	17 (22.4%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Physiotherapy referral

This variable specifies if patients were referred to a physiotherapist or not. Table 4.16 specifies how many patients were referred to a physiotherapist in the two study groups. As can be noticed from the table, the number of patients refereed to a physiotherapist in the two groups was similar.

Table 4.16: Frequency for physiotherapy referral

Physiotherapy referral	Total sample	PU group	Non-PU group
No	106 (69.7%)	52 (68.4%)	54 (71.1%)
Yes	46 (30.3%)	24 (31.6%)	22 (28.9)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- **Group Three: Factors related to physical activities and mobility**

This section statistically describes factors related to physical activity and mobility. These factors included variables that are related to mobility or activity level.

- Activity in bed

This variable was examined to see if level of activity is associated with PUs. Table 4.17 shows different levels of activity in bed that were extracted from medical records. Three patients (3.3%) in the PU group were able to move independently inside bed compared to 24 patients (31.6%) in the non-PU group. Table 4.17 shows different categories of this variable and their frequency in the two study groups.

Table 4.17: Level of activity in bed

Activity in bed	Total sample	PU group	Non-PU group
Moves with help	125 (82.2%)	73 (96.1%)	52 (68.4%)
Moves independently	27 (17.8%)	3 (3.9%)	24 (31.6%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Activity outside bed

Table 4.18 shows that more patients in non-PU group were able to move alone or with help compared to PU group.

Table 4.18: Activity outside bed

Activity outside bed	Total sample	PU group	Non-PU group
Moved by hoist only	61 (40.1%)	44 (57.9%)	17 (22.4%)
Moved with help or independently	91 (59.9%)	32 (42.1%)	59 (77.6%0
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Long surgical procedures

Table 4.19 shows frequency and percentage of patients who underwent surgeries lasting two hours or more in each of the study groups. As shown in table 4.19, more patients in the PU group had undergone long surgeries compared to non-PU group.

Table 4.19: Long surgical procedure (≥ 2 hours)

Long surgery	Total sample	PU group	Non-PU group
No	114 (75%)	55 (72.4%)	59 (77.6%)
Yes	38 (25%)	21 (27.6%)	17 (22.4%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Ability to do hygiene practices

Skin hygiene practices were categorized into three categories, namely: shower or assisted bathing, bed bathing and hoist bathing. The frequency for these categories in the two study samples is shown in table 4.20. More than half of patients (65.8%) in the non-PU group

were able to bathe alone or with minimal help, while more than half of the patients (57.9%) in PU group were bathed in bed.

Table 4.20: Frequency of skin hygiene practices

Skin hygiene	Total sample	PU group	Non-PU group
Shower bathing/assisted	68 (44.7%)	18 (23.7%)	50 (65.8%)
Bed bath	33 (41.4%)	44(57.9%)	19 (25%)
Hoist bath	21 (13.8%)	14 (18.4%)	7 (9.2%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Ability to do ADLs

Activities of daily living were categorized into three categories according to the degree of assistance needed (Table 4.21). Patients in PU group needed two nurses' help in ADLs, more than patients in non-PU group. 39 patients (51.3%) in the PU group needed two nurses' help, while only 9 patients (11.8%) needed two nurses' help in non-PU group.

Table 4.21: Frequency of ADLs

Assistance needed in ADLs	Total sample	PU group	Non-PU group
One help	85 (55.9%)	34 (44.7%)	51 (67.1%)
Two help	48 (31.6%)	39 (51.3%)	9 (11.8%)
Independent or needs help in bathing only	19 (12.5%)	3 (3.9%)	16 (21.1%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- **Group Four: Variables related to intrinsic risk factors**

This section highlights variables in the data set that were related to intrinsic risk factors. The effect of these variables on ulceration can be theoretically related to one of the intrinsic risk factors.

- Reason for hospitalization

This sub-section describes frequency and percentage for the medical condition that was the main reason for admission to hospital. Table 4.22 shows that some variables had very low frequency e.g. DM. The most frequent reason for admission was NOF fracture in the PU group.

Table 4.22: Reasons for hospitalization

Reason for hospitalization	Total number	PU group	Non-PU group
NOF fracture	24 (15.8%)	17 (22.4%)	7 (9.2%)
Renal failure	4 (2.6%)	3 (3.9%)	1 (1.3%)
COPD	9 (5.9%)	5 (6.6%)	4 (5.3%)
Arthritis	2 (1.3%)	0 (0.0%)	2 (2.6%)
Peripheral vascular disease	4 (2.6%)	4 (5.3%)	0 (0.0%)
HTN	2 (1.3%)	1 (1.3%)	1 (1.3%)
Cancer	16 (10.5%)	10 (13.2)	6 (7.9%)
Neurological disorder	10 (6.6%)	2 (2.6%)	8 (10.5%)
Musculoskeletal injury	21 (13.8%)	9 (11.3%)	12 (15.8%)
GI problem	14 (9.2%)	3 (3.9%)	11 (14.5%)
Chest infection	11 (7.2%)	4 (5.3%)	7 (9.2%)
Wound infection	7 (4.6%)	4 (5.3%)	3 (3.9%)
Heart problem	10 (6.6%)	5 (6.6%)	5 (6.6%)
Dehydration	6 (3.9%)	2 (2.6%)	4 (5.3%)
DM	2 (1.3%)	2 (2.6%)	0 (0.0%)
Brain attack	10 (6.6%)	5 (6.6%)	5 (6.6%)
Total subjects	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- First underlying medical condition

This sub-section specifies the frequency of the first medical condition the patients had. Table 4.23 shows frequency and percentage for the first underlying medical condition (apart from the reason for admission). The most frequent medical condition recorded in both of the study groups was HTN. 38 patients in the total sample did not have any underlying medical condition, 7 in the PU group and 31 in the non-PU group.

Table 4.23: First underlying medical condition

Medical condition 1	Total sample	PU group	Non-PU group
Renal failure	6 (3.9%)	2 (2.6%)	4 (5.3%)
COPD	7 (4.6%)	4 (3.5%)	3 (3.9%)
Arthritis	6 (3.9%)	3 (3.9%)	3 (3.9%)
Peripheral vascular disease	1 (0.7%)	1 (1.3%)	0 (0.0%)
HTN	27 (17.8%)	12 (15.8%)	15 (19.7%)
Cancer	6 (3.9%)	4 (5.3%)	2 (2.6%)
Neurological disorder	2 (1.3%)	0 (0.0%)	2 (2.6%)
Musculoskeletal injury	2 (1.3%)	2 (2.6%)	0 (0.0%)
GI problem	3 (2.0%)	1 (1.3%)	2 (2.6%)
Chest infection	9 (5.9%)	4 (5.3%)	5 (6.6%)
Heart problem	14 (9.2%)	12 (15.8%)	2 (2.6%)
Dehydration	1 (0.7%)	1 (1.3%)	0 (0.0%)
DM	25 (16.4%)	20 (26.6)	5 (6.6%)
Brain attack	3 (2.0%)	2 (2.6%)	1 (1.3%)
Total subjects	114 (75%)	69 (90.8%)	45 (59.2%)
Disorder not present	38 (25%)	7 (9.2%)	31 (40.8%)

- Second underlying medical condition

This sub-section shows the frequency and percentage of the second underlying medical condition (table 4.24). 69 patients in the total sample had a second underlying medical condition, with 53 of them in the PU group and 16 in the non-PU group.

Table 4.24: Frequency of developing second underlying medical condition

Medical condition 2	Total sample	PU group	Non-PU group
Renal failure	4 (2.5%)	3 (3.9%)	1(1.3%)
COPD	3 (2%)	2 (2.6%)	1(1.3%)
Arthritis	8 (5.3%)	5 (5.6%)	3 (3.9%)
Peripheral vascular disease	3 (2%)	3 (3.9%)	0 (0.0%)
HTN	16 (10.5%)	12 (15.8%)	4 (5.3%)
Cancer	2 (1.3%)	2 (2.6%)	0 (0.0%)
Neurological disorder	3 (2%)	2 (2.6%)	1(1.3%)
Musculoskeletal injury	2 (1.3%)	2 (2.6%)	0 (0.0%)
Chest infection	4 (2.6%)	2 (2.6%)	2 (2.6%)
Heart problem	8 (5.3%)	6 (6.9%)	2 (2.6%)
Dehydration	1 (0.7%)	1 (1.3%)	0 (0.0%)
Brain attack	3 (3.9%)	3 (3.9%)	0 (0.0%)
Total subjects	69 (45.4%)	53 (69.7%)	16 (21.1%)
Disorder not present	83 (54.6%)	23 (30.3%)	60 (78.9%)

- Third underlying medical disorder

This sub-section shows the frequency and percentage of the third underlying medical condition (table 4.25). 35 patients in the total sample had a third underlying medical condition, with 31 of them in the PU group and 4 in the non-PU group.

Table 4.25: Frequency of developing third underlying medical condition

Medical condition 3	Total sample	PU group	Non-PU group
Heart problems	7 (5.2%)	7 (9.2%)	0 (0.0%)
Renal failure	1 (0.7%)	1 (1.3%)	0 (0.0%)
COPD	2 (1.3%)	2 (2.6%)	0 (0.0%)
Arthritis	3 (2%)	3 (3.9%)	0 (0.0%)
Peripheral vascular disease	1 (0.7%)	1 (1.3%)	0 (0.0%)
HTN	2 (1.3%)	2 (2.6%)	0 (0.0%)
Cancer	2 (1.3%)	2 (2.6%)	0 (0.0%)
Neurological disorder	2 (1.3%)	2 (2.6%)	0 (0.0%)
Musculoskeletal injury	1 (0.7%)	1 (1.3%)	0 (0.0%)
GI problems	2 (1.3%)	2 (2.6%)	0 (0.0%)
Chest infection	4 (2.6%)	3 (3.9%)	1 (1.3%)
Wound infection	3 (2%)	3 (3.9%)	0 (0.0%)
DM	3 (2%)	1 (1.3%)	2 (2.6%)
Brain attack	2 (1.3%)	1 (1.3%)	1 (1.3%)
Total subjects	35 (23%)	31 (40.8%)	4 (5.3%)
Disorder not present	117 (77%)	45 (59.2%)	72 (94.7%)

- Number of underlying medical conditions

Table 4.26 represents number of patients in each category that represented the number of underlying medical condition. The category representing the presence of three underlying medical conditions was higher for patients in the PU group.

Table 4.26: Number of patients in each category of the categories representing number of underlying medical condition

Category	Frequency (%) total sample	Frequency (%) PU group	Frequency (%) non-PU group
Not present	38 (25.0%)	7 (9.2%)	31 (40.8)
One disorder	45 (29.6%)	16 (21.1%)	29 (38.2%)
Two disorders	34 (22.4%)	22 (28.9%)	12 (15.8%)
Three disorders	35 (23.0%)	31 (40.8%)	4 (5.3%)
Total number	152 (100%)	76 (100%)	76 (100%)

- Level of consciousness

Table 4.27 represents the frequency of different categories in this variable. Frequency of confused patients was higher for patients in PU group compared to patients in non-PU group.

Table 4.27: Frequency for level of consciousness

Level of consciousness	Total sample	PU group	Non-PU group
Conscious	104 (68.4%)	47 (61.8%)	57 (75%)
Confused	47 (30.9%)	28 (36.8%)	19 (25%)
Unconscious	1 (0.7%)	1 (1.3%)	0 (0.0%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Presence of cognitive impairment

More patients in PU group had cognitive impairment than non-PU group. In PU group 18 (23.7%) patients had a cognitive problem, while only 10 patients (13.2%) had a cognitive problem in the non-PU group (table 4.28)

Table 4.28: Frequency for presence of cognitive impairment

Presence of cognitive impairment	Total sample	PU group	Non-PU group
Yes	28 (18.4%)	18 (23.7%)	10 (13.2%)
No	124 (81.6%)	58 (76.3%)	66 (86.8%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Depression

More patients in PU group had depression than non-PU group. In PU group 13 (17.1%) patients had depression while only 4 (5.3%) had a depression in the non-PU group (table 4.29).

Table 4.29: Frequency for the presence of depression

Depression	Total sample	PU group	Non-PU group
Yes	17 (11.2%)	13 (17.1%)	4 (5.3%)
No	135 (88.8%)	63 (82.9%)	72 (94.7%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Presence of dehydration

Table 4.30 describes presence of dehydration in terms of frequency and percentage in the two study groups. It is noted that more patients in the PU group were dehydrated compared to non-PU group.

Table 4.30: Presence of dehydration

Dehydration	Total sample	PU group	Non-PU group
Not present	24 (15.8%)	7 (9.2%)	17 (22.4%)
Present	128 (84.2%)	69 (90.8%)	59 (77.6%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Presence of dysphagia

Table 4.31 represents frequency of dysphagia in the two study groups. Small numbers of patients had dysphagia in the two study group with PU group having more patients with dysphagia.

Table 4.31: Frequency for dysphagia

Dysphagia	Total sample	PU group	Non-PU group
No	132 (86.8%)	62 (81.6%)	70 (92.1%)
Yes	20 (13.2%)	14 (18.4%)	6 (7.9%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Presence of pain

Table 4.32 shows different categories of pain in the two study groups. It can be noticed that more patients in PU group were in severe pain when admitted to hospital compared to patients in the non-PU group.

Table 4.32: Frequency for presence of pain

Presence of pain	Total sample	PU group	Non-PU group
Not present	39 (25.7%)	17 (22.4%)	22 (28.9%)
Mild pain	75 (49.3%)	33 (43.4%)	42 (55.3%)
Severe pain	38 (25%)	26 (34.2%)	12 (15.8%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Blood transfusion

Table 4.33 represents how many patients in the two study groups had blood transfusion. As noted, more patients in the PU group had blood transfusion compared to patients in non-PU group.

Table 4.33: Frequency for blood transfusion

Blood transfusion	Total sample	PU group	Non-PU group
No	112 (73.7%)	50 (65.8%)	62 (81.6%)
yes	40 (26.3%)	26 (34.2%)	14 (18.4%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Denture or chewing problem

Table 4.34 specifies frequency of having a chewing problem or unfitted dentures. More patients in PU group were having problems with chewing or dentures compared to patients in non-PU group.

Table 4.34: Frequency for using dentures

Dentures or chewing problem	Total sample	PU group	Non-PU group
No	95 (62.5%)	42 (55.3%)	53 (69.7%)
Yes	57 (37.5%)	34 (44.7%)	23 (30.3%)
Total number	152 (100%)	76 (100%)	76 (100%)
Missing data	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Biological risk factors

This sub-section reports descriptive statistics for biological risk factors (i.e. laboratory results and B.P.). Biological risk factors were analyzed as numerical (continuous) variables, then were categorized and analyzed as categorical variables. Table 4.35 represents a comparison between the two study groups in biological factors as continuous variables. Table 4.36 shows descriptive statistics for biological factors as categorical variables. Biological factors were categorized to represent normal or not normal values (binary variable) according to standardized cut-off points reported in literature.

Table 4.35: Numerical (continuous) biological risk factors

Biological risk factor	PU group		Non-PU group	
	n	Mean ±S.D.	n	Mean ± S.D.
Serum albumin	75	28.89 ±6.59	76	36.05 ±6.21
Serum sodium	76	137.72 ±6.76	76	135.36 ±8.47
Serum potassium	76	4.24 ±0.71	76	4.18 ±0.60
Serum urea	76	10.93 ±10.21	76	10.12 ±7.20
Serum Creatinine	76	111.09 ±77.25	76	120.05 ±76.91
CRP	64	116.72 ±105.23	47	97.81 ±107.54
Haemoglobin	76	107.59 ±19.70	76	122.38 ±21.75
WCC	75	11.94 ±6.23	76	15.34 ±25.10
Systolic BP	76	12.62 ±20.22	69	143.9 ±24.80
Diastolic BP	76	69.86 ±13.66	69	77.91 ±13.80

Table 4.36: Descriptive for biological risk factors as binary variables

Binary risk factor	Total sample			PU group			Non-PU group		
	Frequency (%)	n	missing	Frequency (%)	n	missing	Frequency (%)	n	missing
Albumin<32 mg/dl	63 (41.4%)	151	1	50(65.8%)	75	1	13(17.1%)	76	0
Albumin≥32 mg/dl	88 (57.9%)			25(32.9%)			63(82.9%)		
Sodium<135 mmol/L	45 (29.6%)	152	0	19(25%)	76	0	26(34.2%)	76	0
Sodium≥135 mmol/L	107(70.4%)			57(75%)			50(65.8%)		
Potassium<3.5 mmol/L	14 (9.2%)	152	0	7(9.2%)	76	0	7(9.2%)	76	0
Potasium≥3.5 mmol/L	138(90.8%)			69(90.8%)			69(90.8%)		
Urea≤21 mg/dl	141(92.8%)	151	1	71(93.4%)	76	1	70(92.1%)	75	1
Urea>21 mg/dl	10(6.6%)			5(6.6%)			5(6.6%)		
CRP<10 mg/L	12(7.9%)	111	41	4(5.3%)	64	12	8(10.5%)	47	29
CRP≥10 mg/L	99(65.1%)			60(78.9%)			39(51.3%)		
Creatinine≤120 µmol/L for M[1] or ≤110 µmol/L for F[2]	108(71.1%)	152	0	52(68.4%)	76	0	56(73.7%)	76	0
Creatinine>120 µmol/L for M[1] or >110 µmol/L for F[2]	44(28.9%)			24(31.6%)			20(26.3%)		
WCC[4]<10 ×10[9] cells/L	68(44.7%)	151	1	32(42.1%)	75	1	36(47.4%)	76	0
WCC≥10 ×10[9] cells/L	83(54.6%)			43(56.6%)			40(52.6%)		
HB[3]<130 g/L for M[1] or <115 g/L for F[2]	88(57.9%)	152	0	57(75%)	76	0	31(40.8%)	76	0
HB≥130 g/L for M[1] or ≥115g/L for F[2]	64(42.1%)			19(25%)			45(59.2%)		
Systolic BP[5]<113 mmHg	36 (23.7%)	145	7	27(35.5%)	76	0	9(11.8%)	69	7
Systolic BP≥113 mmHg	109(71.7%)			49(64.5%)			60(78.9%)		
Diastolic BP<60 mmHg	20(13.2%)	145	7	14(18.4%)	76	0	6(7.9%)	69	7
Diastolic BP≥60 mmHg	125(82.2%)			62(81.6%)			63(82.9%)		

1: Male, 2: Female, 3: Haemoglobin, 4: White Cells Count, 5: Blood Pressure

4.5.2 Inferential statistics

This section is about presenting the results of univariate analysis for categorical variables using chi-square and Fisher's exact test, and continuous variables using t-test and Mann-Whitney U test. A summary of the results of the contingency tables is also presented. Moreover, results of multivariate analysis (binary logistic regression) through using a special algorithm (purposeful selection macro) are presented.

As mentioned earlier in the operational definition section, only variable groups two, three and four will be analysed using inferential statistics. Group one, representing variables of descriptive nature, are not analysed using these techniques.

4.5.2.1 Univariate analysis and contingency tables

Univariate analysis was performed as a preliminary step towards answering research questions (see section 5.2 for detailed discussion of this). Results of univariate analysis will affect the order of testing these variables in the logistic model (see purposeful selection macro algorithm in section 4.5.2.3).

Group one was not included in univariate analysis (reasons are shown with variables operational definitions, section: 4.3). Likewise, some variables from group three were also not included for specific reasons (see operational definitions).

This section include summary of different univariate tests performed on the data set, in addition to summarizing the results from contingency tables. Chi-square test is used with the summarizing of contingency tables to show if the difference between the two study group in terms of a certain category in the independent variables is significant or not. Chi-

square assumes that no more than 20% of the cells have a frequency less than five or a certain case has a frequency less than one. When this assumption was violated, Fisher's exact test was used as an alternative.

Effect size values were reported with different univariate statistical tests. Univariate statistics provide a measure to indicate that the difference between groups has happened by chance or not. Effect size statistics represents the strength of this difference in terms of a certain values. These values are: Phi (for 2 by 2 contingency tables associated with chi-square), Cramer's V (for more than 2 by 2 tables associated with chi-square), Eta squared (for t-test), r (for Mann-Whitney U test).

Effect size values for 2 by 2 contingency tables associated with chi-square test (Phi), and for continuous variables using Mann-Whitney U test (r),were interpreted according to Cohen criteria, where: 0.10= small effect size, 0.30= medium effect size and 0.50 = large effect size. For contingency tables larger than 2 by 2, Cramer's V value was used. Interpretations of Cramer V values are different than Phi and depend on the degree of freedom. For independent variable with three categories: small=0.07, medium=0.21 and large effect size=0.35. For independent variable with four categories or more: small=0.06, medium=0.17 and large effect size=0.29. Effect size for continues variables using t-test (Eta squared) were interpreted according to guidelines proposed by Cohen, where 0.1= small effect, 0.06= moderate effect, 0.14= large effect (Pallant, 2007).

Variables are ordered according to their order as in the groups mentioned earlier (see operational definition section). Detailed output of all contingency tables for the analyzed variables is shown in (Appendix K).

- **Group Two: Variables representing preventive interventions**

- Contingency table and testing for significance for the variable using barrier cream

Contingency tables showed equal proportion for patients using barrier creams in both groups (PU and non-PU groups). Therefore, no conclusion could be inferred from these proportions. The difference between PU group and non-PU group in regards to using barrier creams was insignificant according to Chi-square test, χ^2 (1, n=152) = 0.00, p= 1.00.

- Contingency table and testing for significance for the variable using moisturizing cream

Contingency tables showed equal proportion for patients using moisturizing creams in both groups (PU and non-PU groups). Therefore, no conclusion could be inferred from these proportions. The difference between PU group and non-PU group in regards to using moisturizing creams was insignificant according to Chi-square test, χ^2 (1, n=152) = 0.00, p= 1.00.

- Contingency table and testing for significance for the variable type of hospital bed

Contingency tables showed that 12 out of 14 patients (85.7%) who were using profiling bed developed PUs, compared to 64 out of 136 patients (47.1%) using standard bed and developed PUs. These proportions show that patients using profiling beds were more

vulnerable for developing PUs compared to patients using standard bed. The difference between the two study groups in respect to this variable was significant according to Chi-square test, $\chi 2$ (1, n=150) = 6.12, p= 0.01, phi= 0.26, indicating a small effect size.

- Contingency table and testing for significance for the variable using seating cushion

According to contingency tables, patients using seating cushions were less likely to acquire PUs. Two out of 15 patients (13.3%) using seating cushions developed PUs, while 74 out of 137 (54%) patients not using seating cushions developed PUs. The difference between the two study groups in respect to using seating cushion was significant according to Chi-square test, $\chi 2$ (1, n=152) = 7.4, p= 0.007, phi= 0.24, indicating a small effect size.

- Contingency table and testing for significance for the variable using first mattress

According to data from this study, patients laid first on alternating mattresses were more likely to acquire PUs. In this respect, contingency tables showed that 27 out of 42 patients (64.3%) developed PUs while laid on alternating mattress. In contrast to this, 49 out of 110 (44.5%) patients who were laid on a static mattress got PUs. The difference between the two study groups in respect to first mattress used was marginally significant according to chi-square test, $\chi 2$ (1, n=152) = 3.98, p= 0.045, phi= 0.18, indicating a small effect size.

- Contingency table and testing for significance for the variable using second mattress

Only small proportion of patient (25%) had their mattress changed after admission to a second one. Comparing groups based on this may be unreliable. Moreover, most of the second mattresses used were alternating (32 out 38). Anyhow, proportions from

contingency tables showed that 26 out of 32 patients (81.2%) laid on an alternating mattress as their second mattress acquired PUs. In contrast, 3 out of 6 (50%) patients developed PUs when a second static mattress was used. These proportions suggest that patients laid on an alternating mattress are more likely to acquire PUs than those laid on a static mattress. The difference between the two study groups in respect to second mattress used was not significant according to Fisher's exact test, p= 0.13.

- Contingency table and testing for significance for the variable re-positioning patient in bed

According to contingency tables, patients re-positioned less frequently (every 4 hours) were less likely to develop PUs compared to patients more frequently re-positioned (every 2 hours) or patients not re-positioned at all. Contingency tables showed that 1 out of 15 (6.7%) patients developed a PU in the group re-positioned 4-hourly. 63 out of 115 patients (54.8%) in the group re-positioned every 2 hours developed a PU. Patients not re-positioned at all had similar proportion, whereas 12 out of 22 (54.5%) who were not turned developed PU. The difference between the two study groups was significant with regard to turning regimens according to chi-square test, $\chi 2$ (2, n=152) = 12.5 p= 0.002, Cramer's V= 0.29, indicating a small effect size.

- Contingency table and testing for significance for the variable sitting in chair

Patients who sat on chair during their hospitalization period were less likely to acquire PU when compared to patients who did not use to sit in a chair during hospitalization. Contingency tables showed that 44 out of 59 patients (74.6%) of those who did not use to

sit on a chair developed PUs. On the other hand, 32 out of 93 (34.4%) patients who used to sit in a chair developed PUs. The difference between the two study groups with regard to sitting in chair or not was highly significant according to chi-square test, $\chi 2$ (1, n=152) = 21.71, p<0.001, phi= 0.39, indicating a medium effect size.

- Contingency table and testing for significance for the variable using draw sheet

Using draw sheets to move patient in bed was less likely associated with developing PUs compared to moving patient without using a draw sheet. Contingency tables showed that 49 out of 108 patients (45.4%) developed a PU while using draw sheets to move them in bed. In the other group were draw sheet were not used, 27 out of 43 patients (62.8%) developed PUs. Differences between the two study groups were not significant according to the Chi-square test, $\chi 2$ (1, n=151) =3.07, p=0.07.

- Contingency table and testing for significance for the variable dietician referral

Frequency table showed that 18 out of 76 patients (23.7%) in PU group were referred to a dietician. Nearly similar proportion was found in the non-PU group (17 out of 76 patients (22.4%)). This nearly similar proportion makes it difficult to draw any inference to which the occurrence of PUs could be attributed. Contingency tables showed the same thing. 18 out of 35 (51.4%) patients of those referred to a dietician got PUs, nearly similar proportion could be found in the group not referred to a dietician (58 out of 117 (49.6%)). The small difference between the two study groups in respect to dietician referral was not significant according to Chi-square test, $\chi 2$ (1, n=152) =0.00, p=1.00.

- Contingency table and testing for significance for the variable physiotherapy referral

Frequency table showed that 24 out of 76 patients (31.6%) in PU group were referred to physiotherapy, nearly similar proportion was found in the non-PU group (22 out of 76 (28.9%)). This nearly similar proportion makes it difficult to draw any inference to which the occurrence of PUs could be attributed to. Contingency tables showed the same thing. 24out of 46 patients (52.2%) of those referred to physiotherapy got PUs, nearly similar proportion could be found in the group not referred to physiotherapy (52 out of 106 patients (49.1%)). The small difference between the two study groups in respect to physiotherapy referral is not significant according to Chi-square test, $\chi 2$ (1, n=152) =0.031, p=0.86.

- **Group Three: Variables representing factors related to physical activity and mobility**

- Contingency table and testing for significance for the variable activity in bed

According to the contingency table patients who moved independently were less likely to acquire PUs, compared to patients moved in bed with help. 73 out of 125 patients (58.4%) who were moved with help got PUs. In contrast, only 3 out of 27 patients (11.1%) who moved independently got PUs. The difference between the two study groups in respect to ability of movement inside bed was highly significant according to Chi-square test, χ^2 (1, n=152) = 18.015, p<0.001, phi= 0.36, indicating a medium effect size.

- Contingency table and testing for significance for the variable activity outside bed

According to the contingency table patients who walked alone or with help when moved out of bed were less likely to acquire PUs than those patients who were not able to move outside bed or moved with a hoist. Contingency tables showed that 44 out of 61 patients (72.1%) developed PUs of those who could not move outside bed. Patients who could move outside bed were less likely to get PUs, 32 out of 91 (35.2%) patients who could move outside bed developed PUs. Difference between the two study groups was highly significant according to Chi-square test, $\chi 2$ (1, n=152) = 18.51, p<0.001, phi= 0.36, indicating a medium effect size.

- Contingency table and testing for significance for the variable long surgical procedure

According to the contingency table patients who underwent long surgeries (≥ 2 hours) were slightly more likely to acquire PUs. Contingency tables showed that 21 out of 38 patients (55.3%) undergoing long surgeries developed PUs. In the group who did not have any surgery, 55 out of 114 (48.2%) patient developed PUs. the difference between the two study groups in respect to having surgery or not was not significant according to Chi-square test, (1, n=152) = 0.31, p= 0.57.

- Contingency table and testing for significance for the variable ability to do hygiene practices

According to the contingency table patients who were doing bathing independently or with assistance in the bathroom were the least group acquired PUs compared to patients having a

bed or a hoist bath. Contingency tables showed that 18 out of 68 patients (26.5%) developed PUs among those in the shower bathing group. The proportions were higher for patients having a bed or a hoist bath. 44 out of 63 (69.8%) of patients having a bed bath developed PU. In the hoist bath group, 14 out of 21 patients (66.7%) developed PU. The difference in the two study groups in respect to skin hygiene method was significant according to Chi-square test, $\chi 2$ (2, n=152) = 27.31, p< 0.001, Cramer's V= 0.42, indicating a large effect size.

- Contingency table and testing for significance for the variable ability to do ADLs

According to proportions in the contingency table, patients who were independent in doing ADLs or just needed help only in bathing were less likely to acquire PUs than those who needed one or two helpers in their ADLs. 34 out of 85 patients (40%) developed PU from those who needed one helper in ADLs. 39 out 48 (81.2%) patients of those who needed two helpers in ADLs acquired PU, which was the highest proportion among the three categories. For patients who were independent in doing their ADLs, or required help only in bathing, 3 out of 19 patients developed PUs. The difference between the two study groups in terms of their ability to do ADLs was significant according to Chi-square test, $\chi 2$ (2, n=152) = 31.04, p< 0.001, Cramer's V= 0.45 indicating a large effect size.

- **Group Four: Variables related to PUs intrinsic risk factors**

- Contingency table and testing for significance for the variable reason of hospitalization

All the patients had their reason for hospitalization recorded. Two underlying diseases had a percentage of 100% for acquiring PU after admission. These were peripheral vascular disease and DM, with 4 and 2 patients respectively, in each category. These results are not reliable due to small number of patients in each category. The next highest diagnosis with considerably larger number of patients was NOF fracture. 24 patients were admitted with a NOF fracture, 17 of whom developed PU during admission (70.8%). These results were marginally significant according to Fisher's exact test (p= 0.046), but with a large effect size (Cramer's V= 0.40). These results may be not reliable due to the considerably small number of patients in each category.

- Contingency table and testing for significance for the variable number of underlying medical conditions

Contingency tables showed that patient with three underlying medical conditions had the highest proportion of acquiring PUs. 31 out of 35 patients with three underlying medical conditions developed ulcers (88.6%). The proportion for acquiring PUs was decreasing with the number underlying conditions decreased. 22 out of 34 patient (64.7%) of patients with two underlying disorders developed PUs, while 16 out of 45 (35.6%) patients with one underlying disorder developed PUs. Patient with no underlying disorders had the lowest proportion of acquiring PUs. Only 7 out of 38 patients (18.4%) with no underlying disorders developed PUs. These differences were highly significant according to chi-square test, $\chi 2$ (3, n=152) = 42.68, p<0.001, Cramer's V= 0.53, indicating a large effect size.

- Contingency table and testing for significance for the variable level of consciousness

In order to compare categories without the low frequency category; unconscious patients were removed from analysis (only one unconscious patient found). Contingency tables showed that confused patients had higher proportions of acquiring PUs than conscious patients. 28 out of 47 patients (59.6%) who were confused had a PU, while 47 out of 104 patients (45.2%) who were conscious developed a PU. Difference between the two study groups was insignificant in regards to level of consciousness according to chi-square test, χ^2 (1, n=151) = 2.13, p= 0.14.

- Contingency table and testing for significance for presence for the variable cognitive impairment

According to proportions in contingency table, patients with cognitive impairment were more likely to develop PU compared to patients without cognitive impairment. 18 patients out of 28 (64.3%) with cognitive impairment developed PU's, while 85 out of 124 patients (46.8%) developed PU for patients free of cognitive impairment. This difference was not significant according to chi-square test, χ^2 (1, n=152) = 2.14, p= 0.14.

- Contingency table and significance for the variable presence of depression

According to proportions in contingency table, patients suffered from depression were more likely to acquire PU compared to those without depression. Proportions in contingency tables showed that 13 out of 17 (76.5%) with a depression developed PU, while 63 out of 135 patients (46.7%) without depression developed a PU. The difference between the PU

group and the non-PU group in regards to the presence of depression was marginally significant according to chi-square test, χ^2 (1, *n*=152) = 4.24, *p*= 0.04, phi= 0 .19, indicating a small effect size.

- Contingency table and testing for significance for the variable presence of dehydration

According to proportions in contingency table, dehydrated patients were more likely to develop PU compared to patients with no dehydration. Contingency tables showed that 69 out of 128 patients (53.9%) who were dehydrated developed PU. This proportion was lower in patients with no dehydration, only 7 out of 24 patients (29.2%) without dehydration developed a PU. The difference between the two study groups was marginally significant when compared for the presence of dehydration according to chi-square test, χ^2 (1, *n*=152) = 4.00, *p*= 0.045, phi= 0 .18, indicating a small effect size.

- Contingency table and testing for significance for the variable dysphagia

Proportions from contingency table showed that patients with dysphagia were more likely to acquire PUs. 62 out of 132 patients (47%) developed PUs among those without dysphagia, while 14 out of 20 (70%) patients of those with dysphagia developed PUs. Difference between the two study groups was not significant in respect to presence of dysphagia according to chi-square test, $\chi 2$ (1, *n*=152) = 3.68, *p*= 0.09.

- Contingency table and testing for significance for the variable blood transfusion

Contingency table showed that patients who had blood transfused to them were more likely to acquire PUs. Contingency tables showed that 26 out of 40 patients (65%) who had a blood transfusion developed a PU, while 50 out of 112 patients (44.6%) developed PUs of those who did not receive a blood transfusion. Difference between the two study groups was marginally significant in respect to having a blood transfusion or not according to chi-square test, $\chi 2$ (1, n=152) = 4.10 p= 0.043, phi= 0.18, indicating a small effect size.

- Contingency table and testing for significance for the variable presence of denture or chewing problems

Patients who had problems with chewing or dentures had higher proportion of acquiring PUs, 34 out of 57 patients (59.6%) with denture or chewing problems developed PUs. Patients who did not have denture or chewing problems had a lower proportion of acquiring PUs, 42 out of 95 patients (44.2%) with denture or chewing problems acquired PUs. difference between the two study groups was not significant according to chi-square test, $\chi 2$ (1, n=152) = 2.80, p= 0.09.

- Contingency table and testing for significance for binary biological risk factors

- Binary serum albumin

According to contingency table, patients with normal albumin (≥ 32 mg/dl) were less likely to develop PUs compared to patients with sub-normal level of albumin (< 32 mg/dl). 50 out of 63 patients (79.4%) with serum albumin less sub-normal albumin developed PUs. Patients with normal serum albumin had a lower proportion; 25 out of 88 patients (28.4%)

with normal serum albumin developed PUs. This difference was highly significant according to chi-square test, $\chi 2$ (1, n=151) = 36.12 p<0.001, phi= 0.50, indicating a large effect size.

- Binary serum sodium

19 out of 45 patients (42.2%) with serum sodium less than normal (< 135 mmol/L) developed PUs. Patients with normal serum sodium (≥ 135 mmol/L) had a higher proportion. 57 out of 107 patients (53.3%) with normal serum sodium developed PUs. These differences were not significant according to chi-square test, $\chi 2$ (1, n=152) = 1.14 p=0.29.

- Binary serum potassium

Similar proportions of acquiring PUs for patients with normal potassium level (≥ 3.5 mmol/L) and with low potassium level (< 3.5 mmol/L) were shown in contingency tables. 7 out of 14 patients (50%) with low potassium level developed PUs. Similarly, 69 out of 138 (50%) of patients with normal potassium level developed PUs. These differences were not significant according to chi-square test, $\chi 2$ (1, n=152) = 0.00 p=1.00.

- Binary serum urea

A small difference in the proportion of acquiring PUs was shown in contingency tables between patients with normal urea (≤ 21mg/dl) and elevated urea levels (> 21 mg/dl). 71 out of 141 patients (50.4%) with normal urea level developed PUs. Patients with elevated urea had slightly lower proportion, where 5 out of 11 patients (45.5%) with elevated urea

developed PUs. This small difference was not significant according to chi-square test, $\chi 2$ (1, n=152) = 0.00, p=1.00.

- Binary serum creatinine

A small difference in the proportion of acquiring PUs was shown in contingency tables between patients with normal creatinine (≤ 120 µmol/L for males or ≤ 110 µmol/L for females) and elevated creatinine levels (> 120 µmol/L for males or > 110 µmol/L for females). 52out of 108 patients (48.1%) with normal creatinine level developed PUs. Patients with elevated creatinine had slightly higher proportion, where 24 out of 44 patients (54.5%) with elevated creatinine developed PUs. This small difference was not significant according to chi-square test, $\chi 2$ (1, n=152) = 0.29, p=0.59.

- Binary CRP

Contingency tables showed that patients with elevated CRP (≥ 10 mg/L) had higher proportion of acquiring PUs compared to patients with normal CRP level (< 10 mg/L). 60 out of 99 patients (60.6%) with elevated CRP developed PUs, while 4 out of 12 patients (33.3%) with normal CRP level developed PUs. This difference was not significant according to chi-square test, $\chi 2$ (1, n=111) = 2.24, p=0.14.

- Binary haemoglobin

Contingency tables showed that patients with low haemoglobin level (<130 g/L for males or <115 g/L for females) have higher proportion of acquiring PUs compared to patients with normal haemoglobin level (≥130 g/L for males or ≥115 g/L for females). 57 out of 88

patients (64.8%) with low haemoglobin had PUs, while only 19 out of 67 patients (29.7%) with normal haemoglobin had PUs. This difference was highly significant using chi-square test, $\chi 2$ (1, n=152) = 16.87 p<0.001, phi= 0.35, indicating a medium effect size.

- Binary WCC

Contingency tables showed that patients with elevated WCC ($\geq 10\times10^9$ cells/L) had slightly higher proportion of acquiring PUs compared to patients with normal WCC ($< 10\times10^9$ cells/L). 43 out of 83 patients (51.8%) with elevated WCC had PUs. 32 out of 68 patients (47.1%) who had normal WCC count had PUs. This differences was not significant according to chi-square test, $\chi 2$ (1, n=151) = 0.17, p=0.68.

- Binary systolic B.P.

Contingency tables showed that patients with normal systolic B.P. ($\geq$ 113 mmHg) had lower proportion of acquiring PUs compared to patients with low systolic B.P.(< 113 mmHg). 27 out of 36 patients (75%) with low systolic B.P. developed PUs, while 49 out of 109 patients (45%) with normal systolic B.P. developed PUs. This difference was significant according to chi-square test, $\chi 2$ (1, n=145) = 8.63 p=0.003, phi= 0.26, indicating a small effect size.

- Binary diastolic B.P.

Contingency tables showed that patients with normal diastolic B.P. ($\geq$ 60 mmHg) had lower proportion of developing PUs compared to patients with low diastolic B.P.(< 60 mmHg). 14 out of 20 patients (70%) with low diastolic B.P. developed PUs, while 62 out of 125

patients (49.6%) with normal diastolic B.P. developed PUs. This difference was not significant according to chi-square test, $\chi 2$ (1, n=145) = 2.12 p=0.15.

4.5.2.2 Summary of results of univariate analysis

This sub-section presents the results of univariate analysis for categorical study variables. Results of univariate analysis for continuous variables that were later categorized are also presented. These were mainly the biological risk factors. Effect size interpretations were discussed earlier in the inferential statistics section.

- **Group Two: Variables representing preventive interventions**

Table (4.37) summarize results for this group. Chi-square test was used. In case chi-square assumptions were violated Fisher's exact test was used.

Table 4.37: Univariate analysis results for preventive interventions

Variable	N	d.f.	$\chi 2$	*P* value	Phi/Cramer's V	Effect size	Test used
Barrier cream	152	1	0.00	1,00	-	-	Chi-square
Moisturizing cream	152	1	0.00	1,00	-	-	Chi-square
Type of hospital bed*	150	1	6.12	0.01	0.26	small	Chi-square
Seating cushion *	152	1	7.39	0.007	0.24	Small	Chi-square
First mattress*	152	1	3.98	0.045	0.18	Small	Chi-square
Second mattress	38	1	-	0.13	-	-	Fisher's
Re-positioning*	152	2	12.5	0.002	0.29	Medium	Chi-square
Sitting in chair **	152	1	21.71	p<0.001	0.39	Medium	Chi-square
Draw sheet	151	1	3.07	0.08	-	-	Chi-square
Dietician referral	152	1	0.00	1,00	-	-	Chi-square
Physiotherapy referral	152	1	0.03	0.86	-	-	Chi-square

* Significant at α=0.05, ** Significant using Bonferonni correction

- **Group Three: Variables representing factors related to physical activity and mobility**

Table 4.38 presents a summary for the results of univariate analysis for group three of variables that represents factors related to physical activity and mobility. Chi-square test was used with all variables (none of them violated chi-square assumption).

Table 4.38: Summary of univariate analysis for group three

Variable	N	d.f.	$\chi 2$	*P* value	phi	Effect size	Test used
Activity in bed**	152	1	18.02	P<0.001	0.36	Medium	Chi-square
Activity outside bed**	152	1	18.51	P<0.001	0.36	Medium	Chi-square
Long surgical procedure	152	1	0.32	0.57	-	-	Chi-square
Ability to do hygiene practices**	152	2	27.31	P<0.001	0.42	Large	Chi-square
Ability to do ADLs**	152	2	31.04	P<0.001	0.45	Large	Chi-square

* Significant at α=0.05, ** Significant using Bonferonni correction

- **Group Four: Variables related to PUs intrinsic risk factors**

Table 4.39 presents the results of univariate analysis for the fourth group of variables related to intrinsic risk factors. Chi-square test was used. In case chi-square assumptions were violated Fisher's exact test was used. In this table biological risk factors were categorized into binary variables.

Table 4.39: Univariate analysis results for variables related to intrinsic risk factors

Variable	N	d.f.	$\chi 2$/Fisher's	*P* value	Phi/Cramer's V	Effect size	Test used
Reason for hospitalization*	152	15	23.61	0.046	0.40	Large	Fisher's
Number of underlying conditions**	152	3	42.68	P < 0.001	0.53	Large	Chi-square
Level of consciousness	151	1	2.13	0.14	-	-	Chi-square
Cognitive impairment	152	1	2.14	0.14	-	-	Chi-square
Depression*	152	1	4.24	0.04	0.19	Small	Chi-square
Presence of dehydration*	152	1	4.00	0.045	0.18	Small	Chi-square
Dysphagia	152	1	3.68	0.09	-	-	Chi-square
Blood transfusion*	152	1	4.10	0.043	0.18	Small	Chi-square
denture or chewing problems	152	1	2.80	0.90	-	-	Chi-square
Binary serum albumin**	151	1	36.12	P < 0.001	0 .503	Large	Chi-square
Binary serum sodium	152	1	1.13	0.286	0.101	Small	Chi-square
Binary serum potassium	152	1	0.000	1.000	0.000	Small	Chi-square
Binary haemoglobin**	152	1	16.86	P < 0.001	0.346	Medium	Chi-square
Binary serum urea	151	1	0.000	1.000	0.002	Small	Chi-square
Binary serum Creatinine	152	1	0.288	0.59	0.058	Small	Chi-square
Binary CRP	111	1	2.23	0 .14	0.171	Small	Chi-square
Binary WCC	151	1	0.174	0.68	0.047	Small	Chi-square
Binary systolic B.P.*	145	1	8.627	0.003	0.260	Small	Chi-square
Binary diastolic B.P.	145	1	2.117	0.146	0.141	Small	Chi-square

* Significant at α=0.05, ** Significant using Bonferonni correction

- **Univariate analysis for biological risk factors as continuous variables**

Table 4.40 presents the results of normally distributed biological risk factors using t-test. Eta squared value was used for effect size. Interpretations of Eta squared value are according to Cohen criteria mentioned earlier.

Table 4.40: Independent sample t-test for normally distributed biological risk factors (continuous variables)

Variable	t	d.f.	*P* value	95% confidence interval		Eta squared	Effect size
				Lower	Upper		
Serum albumin*	6.87	149	P < 0.001	5.1	9.21	0.24	Large
Serum sodium	-1.90	150	0.059	-4.82	0.09	0.02	Small
Serum potassium	-.62	150	0.54	-0.28	0.14	0.003	Small
Haemoglobin*	4.39	150	P < 0.001	8.14	21.44	0.11	Medium
Systolic BP*	5.95	143	P < 0.001	14.88	29.81	0.96	large
Diastolic BP*	3.53	143	0.001	3.55	12.57	0.08	Medium

* Significant using Bonferonni correction

Table 4.41 presents univariate results for non-normally distributed risk factors using Mann-Whitney U test. The (r) value was calculated as a value for effect size. Interpretations of r value were according to Cohen criteria mentioned earlier.

Table 4.41: Mann-Whitney U test for non-normally distributed biological risk factors (continuous variables)

Variable	N	Mann-Whitney U	Z	*P* value	r	Effect size
Serum urea	152	2731.0	-0.58	0.56	0.046	Small
Serum Creatinine*	152	2273.5	-2.27	0.02	0.18	Small
CRP	111	1231.5	-1.63	0.10	0.13	Small
WCC	151	2697.5	-0.57	0.57	0.046	Small

* Significant at α=0.05

4.5.2.3 Results of multivariate analysis

Binary logistic regression was used to assess the ability of a group of variables (interventions and risk factors) to predict the occurrence of PUs. Creating a mathematical model that assesses how well a group of predictor variables predicts the outcome variable independently. This means that the effect of other variables in the model is controlled for (Bursac et al., 2008). In current study, logistic regression is used to explore which group of interventions best predicts the prevention of PUs independently, and which group of risk factors best predicts the occurrence of PUs independently.

Binary logistic regression (a sub type of logistic regression) was used because it suited the level of measurement of the study variables. Binary logistic regression allows the use of one dichotomous variable (two categories) as the outcome variable. Predictor variables can be either categorical with two categories or more, or continuous. Also it can be a mix of both categorical and contiguous variables.

Outcome variable in this study which is PU status consisted of two categories, either patient have PU or free of PU. This is called a binary or dichotomous variable. Predictor variables

(independent variables) were all categorical variables with two categories or more. Continuous variables included in multivariate analysis after they were categorized (see operational definition section).

- **Assumptions of logistic regression**

Logistic regression can be conducted subject to some provisos (Field, 2009, Tabachnick and Fidell, 2007):

1- Linearity: logistic regression assumes a linear relationship between the logit of the outcome variable and continuous predictors. Since there are no continuous predictor variables in this study, this assumption was not violated.

2- Independence of errors: this assumption means that cases (patients) must be independent. For instance the same patient cannot be measured twice in two different points of time. This assumption was not violated in this study. Each patient in the study was only measured at a single point of time.

3- Multicollinearity: this assumption means that predictor variables must not be strongly correlated with each other. To test for multicollinearity; tolerance and VIF statistics were calculated within the three logistic models for all variables included in the multivariate analysis. For tolerance statistics there were no variables that had a tolerance value less than 0.1 in any of the three logistic models. A tolerance value less than 0.1 indicate a collinearity problem. For VIF statistics there was no variables that had a VIF value more than 10 in any of the three logistic models. A VIF value more than 10 indicates a collinearity problem. Results of these

collinearity diagnostic tests indicate that the problem of multicollinearity is not present within variables in each of the three logistic models used to answer the research questions.

4- Low frequency variables: this assumption is made by the goodness of fit test in logistic regression. It is concerned with the frequency and number of missing values each variable had. According to this assumption the lowest frequency for each case for all variables must be greater than one and no more than 20% of the cases in each variable have a frequency less than 5 (Field, 2009). This assumption is the same for chi-square, so it was tested during univariate analysis. Variables that violated this assumption were excluded from the logistic models.

- **Fitting logistic models**

Variable grouping presented earlier in the operational definition section will be used to fit logistic regression models. Groups two, three and four will be used to build three logistic models. These groups were especially designed in this way to include related variables in one set. This can easily relate different groups of variables to the study hypotheses.

The first statistical model used variables of the second group because all of them represented preventive interventions.

The second statistical model used variables of the third group because all of them were related to physical activity and mobility.

The third statistical model used variables of the fourth group because all of them were related to PUs intrinsic risk factors.

The second group of variables was used to test the first study hypothesis. All variables in this group represented preventive interventions.

- There is no association between different types of interventions in the study population and PU prevention.

The third and fourth groups of variables were used to test the second study hypothesis. All variables in these two groups represent risk factors.

- There are no existent risk factors that might contribute to the occurrence of PUs in the study population.

Building three logistic models incorporated a large amount of variables in each group. For this reason a robust and reliable algorithm for selecting variables in each model was used.

Purposeful selection macro algorithm was used to select variables that were entered into each logistic model. This algorithm depends on the significant level (*P* value) from chi-square. More details about the advantages of this algorithm are presented in discussion chapter.

- **Steps of building the logistic model according to purposeful selection macro algorithm** (Bursac et al., 2008)

1- Variables with a less conservative significant level in univariate analysis ($P \leq 0.25$) will be included in the preliminary model. These variables will be called covariates. The default "enter" method is used with these variables in SPSS.

2- After the preliminary model is fitted; non-significant variable with the highest *P* value is removed from the model and model refitted again.

3- Reduced model is evaluated for a change in parameter estimates (B value). If this parameter was changed by more than 20%; variable removed is retained back into the model as a confounder.

4- If the variable with the highest *P* value was retained (as in step 3), the next variable with the highest *P* value is removed and model refitted again and evaluated for any change in parameter estimates by more than 20%.

5- Steps 2 and 3 are repeated until all variables remain in the reduced model turn to be significant at $\alpha \leq 0.05$.

6- Variables with a significance level more than 0.25 ($P > 0.25$) are tested with the significant reduced model one at a time as confounders. If any of them turned to be significant or changed parameter estimates by more than 20% it will be retained back in the final model.

➢ **First logistic model: preventive interventions**

- Variables fitted in the preliminary model ($p \leq 0.25$ in univariate analysis) and did not violate goodness of fit assumption in logistic regression.

1- Sitting in chair

2- Draw sheets

3- Type of hospital bed

4- Seating cushion

5- First mattress type

6- Re-positioning frequency

- Variables tested as confounders (p> 0.25 in univariate analysis) and did not violate goodness of fit assumption in logistic regression.

1- Barrier creams

2- Moisturizing cream

3- Dietician referral

4- Physiotherapy referral

The final fitted model using purposeful selection macro algorithm is presented in table 4.42. All steps for fitting the model in details are shown in Appendix L.

Table 4.42: Final logistic model for the preventive interventions

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting in chair*	-2.07	0.431	23.05	1	P < 0.001	0.13	0.05	0.29
Draw sheet*	-1.42	0.478	8.78	1	0.00	0.24	0.1	0.62
Re-positioning frequency			7.29	2	0.03			
Re-positioning 2 hourly	.12	0.55	0.05	1	0.825	1.13	0.37	3.30
Re-positioning 4 hourly*	-2.8	1.168	5.75	1	0.02	0.06	0.01	0.60
Physiotherapy referral**	.561	0.43	1.68	1	0.2	1.75	0.75	4.09
Dietician referral**	.146	0.47	0.1	1	0.756	1.16	0.46	2.9
Constant	2.22	0.65	11.77	1	0.001	9.17		

*Significant at α= 0.05, ** Retained as confounders

- **Findings from the logistic model for preventive interventions**

Binary logistic regression was performed to evaluate the effectiveness of a number of PUs preventive interventions. Using purposeful selection macro algorithm; eligible variables were tested in two steps. The first step incorporated fitting the model with the six variables that had a *P* value equal to or less than 0.25 (previously listed). The second step incorporated the remaining five variables with *P* value more than 0.25 (previously listed). These were tested one at a time with the model containing only significant variables resulted from the first step.

The full model containing all risk factors regardless of their *P* value was statistically significant, χ^2 (12, N= 149) = 55.99, $p<0.001$. This reported significant chi-square result is a part from the out-put of SPSS that indicates that the model was able to differentiate between patients with PUs and patients free of PUs. The Full model explained between 31.3% (Cox and Snell R square) and 41.8% of the variance in PU status, and correctly classified 81.9% of cases.

After fitting the logistic model using purposeful selection macro algorithm; three variables made a significant contribution ($P \leq 0.05$) to the model. These were: sitting in chair, draw sheet and re-positioning frequency (table 4.42).

Draw sheets had two categories: draw sheets used or draw sheets not used. Using draw sheets was the significant category associated with prevention of PU, with an odds ratio of 0.24. Sitting in chair had two categories: sitting in chair or not sitting in chair. Sitting in chair was the significant category associated with prevention of PU, with an odds ratio of 0.13. Re-positioning frequency contained three categories, two are shown in table 4.42 and

the third is the reference category representing patients who were not re-positioned. Re-positioning every four hours was the significant category associated with PU prevention, with an odds ratio of 0.06.

Referral to physiotherapist and dietician were not significant when tested with the final model but were retained as confounders because they did not change B estimates of other covariates by more than 20% (table 4.42).

Note: in order to compare the results from purposeful selection macro algorithm with standard logistic regression, the model was refitted again using step wise regression. The results were the same for significant variables, however the step wise model did not control for confounders (see Appendix O).

- **Second logistic model: risk factors related to physical activity and mobility**

- Variables fitted into the preliminary model ($p \leq 0.25$ in univariate analysis) and did not violate goodness of fit assumption in logistic regression.

1- Activity in bed
2- Activity outside bed
3- Ability to do skin hygiene practices
4- Ability to do ADLs

- Variable tested with as a confounder ($p > 0.25$) and did not violate goodness of fit assumption in logistic regression.

1- Long surgical procedure (≥ 2 hours)

The final fitted model using purposeful selection macro algorithm is presented in table 4.43. All steps for fitting the model in details are shown in Appendix L.

Table 4.43: Final logistic model for factors related to mobility and physical activity

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Activity in bed*	2.04	0.78	6.84	1	0.009	7.69	1.67	35.46
Ability to do skin hygiene			7.86	2	0.020			
Bed bath*	1.30	0.47	7.82	1	0.00	3.67	1.48	9.15
Hoist bath	0.88	0.62	2.04	1	0.15	2.42	0.72	8.12
ADLs			8.66	2	0.01			
Need one help	-0.45	0.83	0.29	1	0.59	0.62	0.16	3.25
Need two help	0.94	0.94	0.99	1	0.32	2.55	0.4	16.13
Long Surgical procedure**	0.9	0.48	3.5	1	0.06	2.47	0.96	6.36
Constant	-2.66	0.8	11.11	1	0.00	0.07		

*Significant at α=0.05, **Retained as a confounder

- **Findings from the logistic model for variables related to physical activity and mobility**

Binary logistic regression was performed to evaluate the effect of factors related to mobility and physical activity on the likelihood of acquiring PUs. Using purposeful selection macro algorithm, eligible variables were tested in two steps. The first step incorporated fitting the model with the four variables that had a *P* value equal to or less than 0.25 (previously

listed). Second step incorporated testing the remaining variable that had a *P* value more than 0.25 (previously listed). This variable was tested with the model containing only significant variables resulted from the first step.

The full model containing all risk factors regardless of their *P* value was statistically significant, χ^2 (7, N= 152) = 51.52, $p<0.001$. This reported significant chi-square result is a part from the out-put of SPSS that indicates that the model was able to differentiate between patients with PUs and patients free of PUs. The Full model explained between 28.7% (Cox and Snell R square) and 38.3% of the variance in PU status, and correctly classified 71.7% of cases.

After the model was fitted using purposeful selection macro algorithm two variables made a significant contribution ($P\leq 0.05$) to the model. These were: activity in bed and ability to do skin hygiene (table 4.43). Activity in bed had two categories: moving in bed with help, or moving in bed independently. Moving with help was the significant category associated with developing PU, with an odds ratio of 7.69. Ability to do skin hygiene contained three categories; two are shown in table 4.43, and the third is the reference category, which represents patients who had shower or assisted bath. Bed bath was the significant category associated with developing PU, with an odds ratio of 3.67.

ADLs reached significant level, however none of its categories contributed significantly to the model. Surgical procedure turned to be insignificant when tested with the full model in the second step, but was retained as a confounder because it changed B estimates of other covariates by more than 20% (table 4.43).

Note: in order to compare the results from purposeful selection macro algorithm with standard logistic regression, the model was refitted again using step wise regression. The results were the same for significant variables, however the step wise model did not control for confounders (see Appendix O).

- **Third statistical model: variables related to intrinsic risk factors**

- Variables fitted into the preliminary model ($p \leq 0.25$ in univariate analysis) and did not violate goodness of fit assumption in logistic regression.

1- Presence of dehydration
2- Binary systolic BP
3- Binary diastolic BP
4- Binary serum albumin
5- Binary Haemoglobin
6- Blood transfusion
7- Cognitive impairment
8- Depression
9- Number of underlying medical condition
10- Denture or chewing problem
11- Presence of dysphagia
12- Level of consciousness

- Variables tested as confounders ($p>0.25$) and did not violate goodness of fit assumption in logistic regression.

1- Binary serum sodium

2- Binary serum creatinine

3- Binary WCC

4- Binary serum potassium

5- Binary serum urea

The final fitted model using purposeful selection macro algorithm is presented in table 4.44. All steps for fitting the model in details are shown in Appendix L.

Table 4.44: Final logistic model for variables related to intrinsic risk factors

Variable	B	S.E.	Wald	d.f	*P value*	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary serum Albumin*	-2.27	0.54	17.4	1	0.000	0.10	0.04	0.3
Binary Haemoglobin*	-1.98	0.59	11.37	1	0.001	0.14	0.04	0.44
Cognitive impairment*	1.47	0.69	4.51	1	0.03	4.30	1.12	16.84
Underlying medical conditions			30.27	3	0.000			
One condition	0.78	0.7	1.22	1	0.27	2.17	0.55	8.62
Two conditions*	2.59	0.77	11.35	1	0.001	13.3	2.95	60.0
Three conditions*	4.96	0.97	26.42	1	0.000	143	21.556	948.77
Binary serum urea**	-1.32	0.94	1.97	1	0.16	0.27	.043	1.69
Binary sodium**	1.03	0.6	2.94	1	0.07	2.79	.864	9.0
Constant	-0.64	0.71	0.8	1	0.37	0.53		

*Significant at α= 0.05, ** Retained as confounders

- **Findings from the logistic model for variables related to intrinsic risk factors**

Binary logistic regression was carried out to evaluate the effect of a set of PU intrinsic risk factors on acquiring PUs. Using purposeful selection macro algorithm; eligible variables were tested in two steps. The first step incorporated fitting the model with the twelve variables that had a *P* value equal or less than 0.25 (previously listed). Second step incorporated the remaining five variables with *P* value more than 0.25 (previously listed). These were tested one at a time with the model containing only significant variables resulted from the first step.

The full model containing all risk factors regardless of their *P* value was statistically significant, χ^2 (19, N= 141) = 101.05, $p<0.001$. This reported significant chi-square result is a part from the out-put of SPSS that indicates that the model was able to differentiate between patients with PUs and patients free of PUs. Full model explained between 51.2% (Cox and Snell R square) and 68.2% of the variance in PU status, and correctly classified 85.8% of cases. After fitting the logistic model using purposeful selection macro algorithm, four variables made a significant contribution ($P\leq 0.05$) to the model: binary serum albumin, binary haemoglobin, presence of cognitive impairment and number of underlying medical disorders (Table 4.44).

Number of underlying medical conditions contained four categories, three are shown in table 4.44 and the fourth is the reference category representing patients with no underlying medical conditions. Two categories in this variable were significantly associated with developing PU, namely: presence of two underlying medical conditions and presence of three underlying medical conditions with odds ratio of 13.3 and 143 respectively. Cognitive impairment had two categories: with cognitive impairment or without cognitive

impairment. Presence of cognitive impairment was the significant category associated with developing PU, with an odds ratio of 4.3. Binary albumin had two categories: albumin< 32 mg/dl or albumin ≥ 32 mg/dl. Albumin level < 32 mg/dl (hypoalbuminemia) was the significant category associated with developing PU, with an odds ratio of 0.10. The variable of binary haemoglobin had also two categories: haemoglobin <130 g/L for males or <115 g/L for females, or haemoglobin ≥130 g/L for males or ≥115 g/L for females. Haemoglobin < 130 g/L for males or <115 g/L for females was the significant category associated with developing PU, with an odds ratio of 0.14.

Binary serum sodium and binary serum urea were insignificant but retained in the final model as confounders because they changed B estimates of other covariates by more than 20% (table 4.44).

Note: in order to compare the results from purposeful selection macro algorithm with standard logistic regression, the model was refitted again using step wise regression. The results were the same for significant variables, however the step wise model did not control for confounders (see Appendix O).

4.5.3 Additional results

This section represents additional statistical results that will further help in exploring some of the study results. These included:

- Number of all documented preventive interventions in the two study groups.

- Difference in the number of significant interventions between the two study groups

- Additional logistic model contained only significant variables from the three models presented earlier.

- ROC curves for significant variables in logistic models (those that were continuous before categorized).

- **Number of documented interventions in medical files for both of the study groups**

Number of all preventive interventions for both study groups was counted regardless of their significant level in multivariate model. Table 4.45 presents the number of intervention in the in each of the study groups. In order to see if the difference between the numbers of preventive interventions was significant between the two study groups an independent sample t-test was conducted. Independent sample t-test showed that there is no significant difference in the number of interventions between PU group and non-PU group, $p = 0.10$.

Table 4.45: Number of documented interventions in medical files for both of the study groups

Preventive intervention	Number in PU group	Number in non-PU group
Barrier cream	5	5
Moisturizing cream	7	7
Sitting in chair	32	61
Draw sheets	49	59
Dietician referral	18	17
Physiotherapy referral	24	22
Profiling bed	12	2
Seating cushion	2	13
Alternating mattress	27	15
Re-positioning 2 hourly	63	52
Re-positioning 4hourly	1	14
Total number	240	267

- **Difference in the number of significant interventions between the two study groups**

Depending on the previous table (table 4.45), the number of all significant preventive interventions in logistic model (sitting on chair, using draw sheet and positioning every 4 hours) was higher in non-PU group compared to PU group. According to Mann-Whitney U test this difference was statistically significant, p <0.001.

- **Additional logistic model**

This additional model was fitted in order to statistically control for the effect of significant risk factors associated with the significant preventive interventions. In other words, will the significant preventive interventions stay significant after adding significant risk factors as

confounders. After fitting this model, all significant preventive interventions stayed significant after adding significant risk factors as confounders. Further argument about this extra model was presented in the discussion chapter. Table 4.46 shows the additional logistics model that was used for controlling significant risk factors.

Table 4.46: Additional logistic model

Variable	B	S.E.	Wald	d.f.	*P* value	Odds ratio	95.0% C.I. for odds ratio	
							Lower	Upper
Sitting in chair	-1.87	0.74	6.4	1	0.01	0.15	0.04	0.66
Draw sheet	-1.94	0.84	5.33	1	0.02	0.14	0.03	0.75
Re-positioning frequency			5.96	2	0.05			
Re-positioning 2 hourly	-0.46	1.01	0.17	1	0.68	0.66	0.09	4.74
Re-positioning 4 hourly	-4.10	1.73	5.61	1	0.02	0.02	0.00	0.49
Cognitive impairment	1.66	0.96	2.96	1	0.09	5.24	0.79	34.64
Binary serum Albumin	-2.65	0.74	12.96	1	0.00	0.07	0.02	0.3
Binary Haemoglobin	-1.47	0.71	4.32	1	0.03	0.23	0.06	0.92
Underlying medical conditions			15.64	3	0.00			
One condition	0.86	0.85	1.02	1	0.31	2.36	0.45	12.52
Two conditions	1.88	0.91	4.32	1	0.04	6.56	1.11	38.68
Three conditions	4.66	1.24	14.21	1	0.00	105.57	9.36	1190.3
Activity in bed	3.77	1.47	6.57	1	0.01	43.4	2.43	776.21
Ability to do skin hygiene			0.31	2	0.86			
Bed bath	-0.3	0.81	0.14	1	0.71	0.74	0.15	3.59
Hoist bath	0.19	1.08	0.03	1	0.86	1.21	0.14	10.06
Constant	0.1	1.68	0.00	1	0.96	1.1		

- **ROC curves**

Serum albumin and haemoglobin were significant in the final logistic model representing intrinsic risk factors that were originally continuous. Area under the ROC curve for albumin was 0.79 and for haemoglobin was 0.72. Figure 4.3 shows the ROC curve for the two variables.

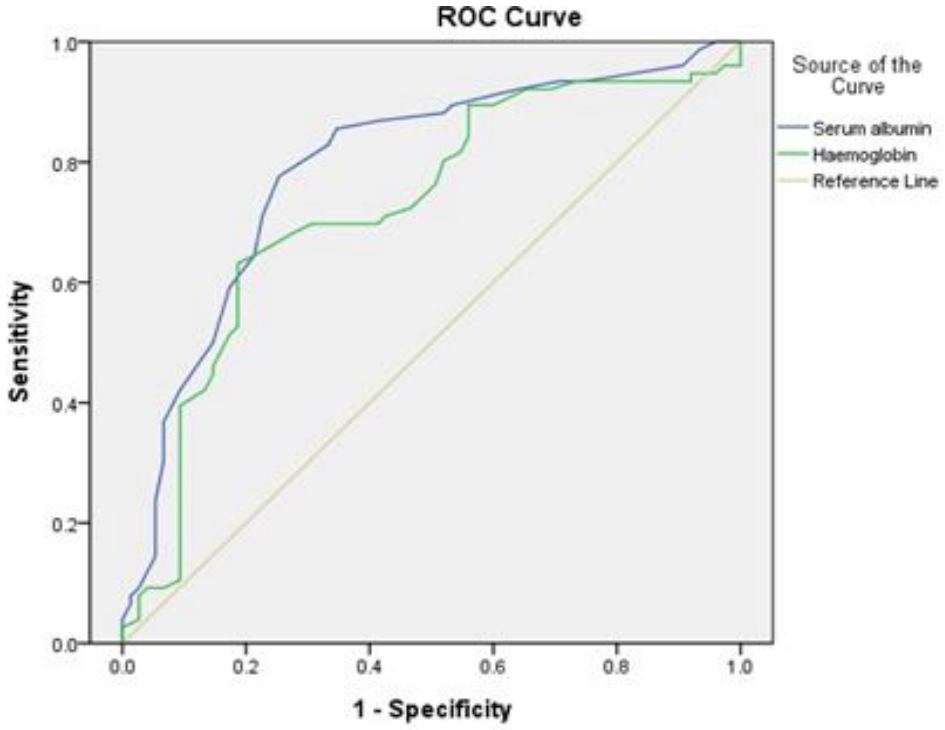


Figure 4.3: ROC curves for Albumin and Haemoglobin

4.6 Chapter summary

This chapter presented the results of statistical analysis of different study variables. The goal of this analysis was to identify PU preventive interventions and risk factors. Data

from 152 patients were analysed. Prior to conducting statistical analysis, data were prepared. This took an effect by screening data and cleaning it from errors.

The study had only one dependant variable, namely: PU status. According to this variable, sample of the study was divided into PU group and non-PU group. Independent variables of the study were PUs' preventive interventions and risk factors.

Statistical analysis was carried out using both descriptive and inferential statistics. Inferential statistics in this study included the use of univariate analysis and multivariate analysis. Univariate analysis included the use of contingency tables, chi-square test, Fisher's exact test, t-test and Mann-Whitney U test. Binary logistic regression with special purposeful selection algorithm was used as a multivariate statistical test. Multivariate analysis was used to answer research questions. Continuous variables were used in regression after being categorized. This was for clinical reasons in order to use them as an indicator for PU risk.

Univariate analyses for preventive interventions showed that using standard hospital bed, using seating cushion, using pressure redistributing static mattresses, re-positioning every 4 hours and helping the patient to sit regularly on chair were significantly associated ($P \leq 0.05$) with PU prevention.

Univariate analysis for factors related to physical activity and mobility showed that PUs were significantly ($P \leq 0.05$) associated with: moving in bed with help, the ability to take a bath only in bed, needing two helpers in performing activities of daily living and moving outside bed only by a hoist.

Univariate analysis for categorical variables related to intrinsic risk factors showed that PUs were significantly associated ($P \leq 0.05$) with: presence of three underlying medical conditions, dehydration, depression, having a blood transfusion, serum albumin <32mg/dl, haemoglobin <130 g/l in males or <115 for females and systolic B.P. <113 mmHg. Univariate analysis for continuous variables showed a significant difference between PU and non-PU patient in the following variables: serum albumin, haemoglobin, systolic and diastolic B.P. and serum Creatinine.

Multivariate analysis for preventive interventions revealed that using draw sheets, sitting patient in chair and re-positioning patient in bed every four hours were significantly associated with preventing PUs. Multivariate analysis for variables related to physical activity and mobility showed a significant association between PU and moving in bed with help and ability to take a bath only in bed. Multivariate analysis for variables related to intrinsic risk factors showed a significant association between PU and serum albumin <32mg/dl, haemoglobin <130 g/l in males or <115 for females, cognitive impairment and having two or three underlying medical conditions.

Additional statistical tests were also performed to further explore results from the study. These additional tests showed that there was no significant difference between the two study groups in regards to the total number of preventive interventions. However, the significant interventions from the multivariate model differed significantly between the two study groups, with the non-PU group having more significant interventions implemented. Moreover, an additional logistic model was fitted to control the effect of risk factors on the

significant level of preventive interventions. All the significant interventions remained significant after adjusting the effect of risk factors.

ROC curve for albumin and haemoglobin showed a larger area under the curve for albumin.

Chapter Five: Discussion

5.1 Introduction

The aim of this study was to explore preventive interventions and associated risk factors of hospital-acquired PUs. For this to be achieved, the present study employed a special matched approach that controls extraneous factors that can affect the study results. It also used special multivariate statistical algorithm modelling that can predict which preventive interventions or risk factors were independently associated with the prevention or acquisition of PUs.

This chapter discusses the strengths and weaknesses of using the methodological approach of this study. Interpretations of the study's main findings concerning PU preventive interventions and risk factors are also discussed in view of previous literature. Additionally, the impact of using the conceptual framework on interpretations of the study findings was also discussed.

5.2 Methodological considerations in the study

This section aims to clarify the usefulness and novelty of the study's methodological approach used to explore PU preventive interventions and risk factors. Furthermore, it discusses strengths and weaknesses of using this approach.

One of the novel contributions to the body of knowledge in this study is attributed to the methodological approach used to answer research questions regarding both preventive interventions and risk factors. The present study was based on a retrospective matched

case-control design that retrospectively described and compared two groups of patients through using data extracted from medical records.

Matched case control design is not new in the area of health research. For instance, Girou et al. (2000) conducted a pair-wise retrospective matched case-control design to explore the relation between non-invasive ventilation and lower risk of hospital-acquired pneumonia. The risk adjusted approach used in current study to explore preventive interventions and risk factors is the first to be used in this area of inquiry through matching on Waterlow sub-scores. Mentioning that, it is fair to say that this approach was used before to indentify risk factors of PUs but in a different way. This was through a study that aimed at identifying risk factors of PUs through matching patients on age, gender, immobility and cachexia (Von Renteln-Kruse et al., 2005). In this study only risk factors were investigated (not risk factors and interventions), also matching was on a different criterion (not Waterlow sub-scores). The novelty in using this approach is demonstrated through identifying risk factors and intervention in the same study, also in controlling a large number of risk factors (13 Waterlow sub-scores).

The new approach was based on matching a number of pre-established risk factors between two groups. One affected with PUs, the other was free. Matching was in respect to specific risk factors that were mentioned in literature that have a role in the development of PUs (a number of Waterlow sub-scores). Patients with PUs were matched in pairs to other patients with none. This resembles establishing two groups; one is the study group (with PUs), the other is control group (free of PUs). Matching patients for a number of Waterlow sub-scores adjusts to some extent the degree of PU risk between the two study groups.

Using risk adjusted approach will increase the efficiency and accuracy for detecting interventions that were related to PUs prevention or detecting risk factors that were linked to PUs development (Allman, 2001, Levine et al., 2009). The aim of adjusting risk factors (confounders) is to control for these confounders, thus eliminating their risk in interfering with the result of comparison. This approach is considered superior to other retrospective approaches due to presence of a matched case-control groups (Hess, 2004).

Another contribution of this study was that it tried to overcome some of the shortcomings present in previous studies in the same area of research. Some shortcomings in previous studies were overcome by using a robust methodological approach. One of the noticeable shortcomings in some of the previous studies was excluding PU stage one (Allman et al., 1995). Excluding this stage means that it was not considered as a PU, when in fact it is. This could negatively affect the results of the study, thus giving inaccurate results. In the current study this was overcome through including all stages of PUs.

Another shortcoming of previous studies was focusing only on a specific group of patients (e.g. patients with restricted mobility or those with spinal cord injuries) (Allman et al., 1995, Garber and Rintala, 2003). Such groups may have different risk factors. As a consequence, results cannot be generalized for other groups. The present study did not focus on any specific group of patients that have specific risk factors for PUs. In order to make results more generalizable, this study contained patients with different types of illnesses and comorbidities.

Some retrospective studies that used electronic medical records depended on an administrator to electronically extract specific information (Cho and Noh, 2010). In this case, computers will only extract coded data (data represented by numbers), which means that only specific information types will be extracted (e.g. laboratory results). Other valuable information that documented in narrative form is difficult to extract electronically (e.g. health care professionals' notes). Consequently, the scope of results will be narrowed to coded data only. The present study overcame this limitation. Medical records were revised manually by the principle investigator. All parts of the electronic medical record were revised, whether data were coded or not. This gave the ability to track the whole care process along the admission period. Tracking the whole care process will widen the scope of results and reflect more accurate and holistic results. Also in this context, other details that were incorporated in the methodological approach also contributed to the accuracy and completeness of retrospectively collected data. These were: operational definition of variables, data extraction sheet and subjects inclusion criteria. Incorporating these guiding criteria initiated homogenous conditions under which different variables were collected. This helped in more accurately meeting the aims of the study and answering research questions.

Including only patients at risk of PUs is another shortcoming for studies investigating preventive interventions (Pieper et al., 1997, Horn et al., 2002, Levine et al., 2009). This was through considering patients at risk of PUs according to a RAS (e.g. Braden scale). Including patients in the study according to this criterion can end in biased results. One can have a risk of developing a PU without actually developing it. Additionally, it is invalid to consider patients to be at risk by using an RAS. No scale has been proven to be perfectly valid because PUs are a multi-factorial problem (Halfens, 2000). Moreover,

RASs depend on adding sub-scores of the scale to produce a number that can predict risk of PUs. Research in this area proved that the actual importance of the sub-scores is not accurately reflected by their rang of values (Anthony et al., 2010). As a consequence it is imprecise to use the total score of a risk assessment scale to include patients in a study. Including only patients at risk was not a criterion for selecting patients in present study. Waterlow RAS was not used to measure the degree of risk. Its sub-scores were only used to control a number of PU risk factors between paired patients. The goal here is only to compare pairs of patients according to similarity in some characteristics that are linked to PU development. In this context, RAS (including Waterlow) are considered useful tools for research. In fact the first RAS i.e. Norton was originally designed for research purposes, but when the nurses found it to be a useful tool in clinical practice it became a PU RAS (Anthony et al., 2010). In this study, Waterlow scale was not used to assess risk but as a tool for research. According to this it could be argued that current study used the RAS as originally envisaged.

Some of the shortcomings of previous studies were not only limited to methodological aspects, but also involved methods of analyzing data. Some studies that involved investigating PU preventive interventions or risk factors used univariate analysis, not multivariate analysis, to answer research questions (Bours et al., 2001, Wipke Tevis et al., 2004). Using univariate analysis can only examine the relationship between PUs and one preventive intervention or risk factor at a time. In this case, using univariate analysis alone obscures the cofounding effect of other variables within the data set that may affect the results. Using multivariate analysis addresses this problem by looking at the whole picture. It examines the relation between related variables that can affect the outcome all together in one statistical model. Existing study used binary logistic

regression as a multivariate analysis technique in order to overcome such shortcoming. Using binary logistic regression can predict if one variable predicted the outcome (PUs) when the effect of other related variables is controlled (Tabachnick and Fidell, 2007). For instance, logistic regression can predict if a specific preventive intervention is significantly associated with preventing PUs when other interventions are equal (controlled) for a particular patient.

Another advantage of using multivariate analysis over univariate is controlling for type one error. In univariate analysis, type one error can result from multiple comparisons. This can refer to some variables as significant to the outcome when in fact they are not. Multivariate analysis techniques address this problem by keeping the type one error at a constant rate, regardless the number of comparisons (Tabachnick and Fidell, 2007, Field, 2009).

5.2.1 Strengths and weaknesses of the study design

This sub-section discusses the strengths and weaknesses of the design used in this study, and how they could affect the interpretation of the study results. Strengths of the current study were attributed to the inherent strengths of the study design, and to the data collection procedure implemented by the researcher.

One of the strengths in this study is related to collecting retrospective data. Nurses tend to record information concerning PUs due to the legal liability. When a complaint about skin integrity is made, medical records are the first source of data to be investigated (Russell, 1999). Nurses are more cautious in documenting when it comes to PUs. Therefore, existing medical records contain a large amount of medical information collected originally for other purposes than research. This forms a large repository of

routinely collected information, including PU risk assessment, prevention and management. Conducting a study using these already exacting data is less expensive and less time consuming. If the matched case-control design used in this study was to be conducted prospectively it would needed many data collectors. Those need time and money to be trained also the data collection procedure would be lengthy. Moreover, a prospective study will require long time to find matched pairs of patients in order to reach the same number of patients as in this study. This study reviewed almost four years of admissions to reach a reasonable number of patients.

Moreover, revising medical records in order to answer research questions resembles conducting an investigation about a real life situation. This reflects the real-world experience, without any manipulation of research variables (Clark, 2008). Biases that can result from a prospective study concerning Hawthorn effect were not present in current study (although this sort of bias may be present in prospective studies, they are considered more robust that retrospective studies). Nurses and other health care professionals recorded the care process of their patients without a previous knowledge that their recordings will be used in a future research study.

Mentioning the strengths that came from using retrospective data does not mean closing one's eyes to its weaknesses. The most important weaknesses in the study came from the use of retrospective data. Retrospective data relies on the accuracy of health care professional in recording information related to the care process (recall bias) (Garber and Rintala, 2003). If the information recorded were inaccurate, findings from the study will be inaccurate as well. Measures to insure data accuracy applied in this study can enhance the quality of data collected (see data collection procedure, section: 3.15). However, there is no way to insure retrospective data accuracy (Clark, 2008).

The presence of a matched control group is another strength attributed to the study design. Presence of this group facilitates the way to initiate a baseline comparison group. In this way, effectiveness of preventive interventions can be compared with a baseline control group. Likewise, risk factors can be compared between the control group and study group. Nevertheless, due to the retrospective nature of the study, variables collected could only be described in each group then statistically compared between the two groups. Comparison results does not show a cause and effect relation between variables. Instead, results from current retrospective study can be used to formulate a hypothesis about interventions and risk factors (Hess, 2004). This hypothesis can be tested later in a future prospective study to confirm which factors could be attributed to the occurrence of PUS, and also to confirm which preventive interventions were attributed to the prevention of PUs.

Another strength of collecting data from medical records relates to the data collection procedure. As mentioned earlier in the methodology chapter (see data collection procedure, section 3.15), a number of measures were integrated into the data collection procedure to ensure that more accurate and complete data were collected. These procedures were implemented to ensure that only accurate and complete information pertaining to study variables were collected. In addition, the use of operational definition for all the study variables minimized the chance of recording unrelated information that were not apple to answer the research questions, thus producing a biased results. Also in this context, sampling method (convenience sampling) was also strength to this study. Although a convenient sample is a non-probability sample that may not represent the whole population. In this study the term convenience was used to indicate that all available patients who matched the study criteria were selected. This

method of sampling was used in studies that aimed at including all available patients in order to identify PUs preventive interventions and risk factors (Lyder et al., 2002, Horn et al., 2004).

In a nutshell, the methodological approach used in this study tried to overcome some of the shortcomings reported in previous studies in the same area of research, and it tried to compensate as much as possible for the weaknesses of retrospective data through data collection procedure and variables' operational definitions. The retrospective nature of the study affected results' interpretation and usability. Preventive interventions that were shown to be associated with PUs prevention cannot be directly implemented in the clinical setting. Likewise risk factors that were associated with PUs cannot be directly used to assess risk. Results can be recommended as useful material for future prospective research. The effectiveness of preventive interventions shown to be significant in this study can be tested in a robust RCT. Validity of risk factors shown to be associated with PUs can be tested in a large prospective study.

5.3 Statistical considerations

As mentioned earlier in results chapter, a special algorithm (purposeful selection macro) for fitting the logistic regression model was used. This model has some advantages over the stepwise regression procedures available in SPSS and used in PU research. Stepwise regression depends merely on statistical criteria to fit the final model that contains only significant variables. Statistical criteria of inclusion and exclusion variables to reach the final model are dependent on statistics generated from the sample. Trivial differences in these statistics can have a profound effect on the final logistic model. As Tabachnick and Fidell (2007) argued, this could be hazardous when fitting the final model because

the main criterion for including variables is their statistical significance. There is no consideration for other parameters that could confound the final model.

The special algorithm used in this study uses different criteria for model fitting. It does not only depend on significant level of variables alone to decide which variables to be selected as in stepwise regression. An additional consideration for the model fitting is added. According to this model, when the non-significant variable is deleted, the parameter estimates (B estimates) of other variables in the model are observed. If the change in one of these estimates exceeds 20%, the deleted variable is retained back to the model. The change in other parameters estimates means there is a confounding effect between the deleted variable and other variables. Keeping the confounding variables may have an effect on other variables significant level. Therefore, the final set of variables may have differed if only significant level was used as the model refining criterion. Using this special algorithm can result in a more controlled model that contains significant variables in addition to confounders. Moreover, different steps of this algorithm depend on deleting, refining and verifying variables, with the analyst making the decision in each step (not a computer). As Bursac et al. (2008) argued, human decision making in logistic model fitting remains the most powerful; computer automated modelling algorithms cannot replace it

Using this modelling algorithm adds to the novelty in this study. This algorithm has been used in some studies in the health sector to reveal a more controlled statistical model (Conner et al., 2003, Gujral et al., 2007) but not in the PU research. This study is the first to use such algorithm in this area of inquiry.

5.4 Interpretations of the study's main results

5.4.1 Summary of the findings

This section summarizes the main findings generated from the statistical analysis of study variables. In order to discus results of related variables collectively; findings were summarized in three groups. Group one represents preventive interventions, group two represents variables related to physical activity and mobility and group three represents variables related to intrinsic risk factors.

In this study the key finding used to answer research questions were those of multivariate analysis. However, results of univariate analysis were also presented here to compare these results with those of multivariate for each group of variables. In this concern, some of the non-significant variables in univariate analysis turned to be significant in multivariate analysis. Conversely, some of the significant variables in the univariate analysis turned to be insignificant in multivariate analysis in this study.

In this context odds ratio reported with multivariate analysis was used as an indicator for the relation direction (does the predictor variable increase or decrease the outcome variable) between the outcome variable (PUs) and other predictor variables (risk factors and interventions). Odds ratio can indicate the relation direction between the outcome variable and predictor variables depending on how these variables were coded in SPSS and if the odds ratio was more than one or less than one. If the odds ratio for a significant predictor variable was greater than one this will indicate an increase in the odds of outcome variable coded one with a one-unit increase in the predictor variable. On the other hand, if the odds ratio was less than one this will indicate a decrease in the

odds of outcome variable coded one with a one unit decrees in the predictor variable (Tabachnick and Fidell, 2007).

For each group of variables, separate tables were used to summarize the results of significant and non-significant variables in univariate analysis. Each table contains variable name, categories of that variable and the category that had the highest proportion in contingency tables of being associated with PU prevention for group one variables. For groups two and three (risk factors) summary tables included the category with the highest proportion of being associated with developing PUs. This way the precise categories representing either preventive interventions or risk factors (whether significant or not) can be easily distinguished. Tables for significant variables had effect size as an additional column in order to give an indication of the influence of the independent variable in univariate analysis.

Three variables reported within univariate analysis were excluded from multivariate analysis: reason for hospitalization, second mattress used and binary CRP. Excluded variables had either large number of missing values or had large number of cases with low frequency (violated goodness of fit assumption in logistic regression). Including these variables in multivariate analysis would decrease the statistical power of the test.

- **Group One: Preventive interventions**

- **Univariate analysis results**

- Significant variables ($P \leq 0.05$) in univariate analysis associated with preventing PUs are presented in table 5.1.

Table 5.1: Significant PU preventive intervention in univariate analysis

Variable	Variable categories	Significant category associated with prevention	Effect size
Type of hospital bed	- Profiling bed - standard bed	Standard bed	Small
Seating cushion	- Using cushion - Not using cushion	Using cushion	Small
First mattress	- Alternating mattress - Static mattress	Static mattress	Small
Re-positioning frequency	- Not positioned - Every 2 hours - Every 4 hours	Every 4 hours	Medium
Sitting in chair	- Sits in chair - not sitting in chair	Sits in chair	Medium

- Non-significant variables ($P > 0.05$) in univariate analysis associated with PU prevention are presented in table 5.2.

Table 5.2: Non-significant PU preventive intervention in univariate analysis

Variable	Variable categories	Category associated with prevention
Using barrier cream	- Using barrier cream - Not using barrier cream	No category was associated with significance. Constant variable
Using moisturizing cream	- Using moisturizing cream - Not using moisturizing cream	No category was associated with significance. Constant variable
Using draw sheet	- Draw sheet used - Draw sheet not used	Draw sheet used
Dietician referral	- Referred to a dietician - Not referred to a dietician	Nearly similar proportion of acquiring PU between the two categories.
Physiotherapy referral	- Refereed to a physiotherapist - Not refereed to a physiotherapist	Nearly similar proportion of acquiring PU between the two categories.
Second mattress	- Alternating mattress - Static mattress	Static mattress

- **Multivariate analysis summary for group one**

In this group three variables were significant in logistic regression final model, namely:

- Using draw sheet: this variable had two categories (table 5.2). Using draw sheet was the significant category as a PU preventive intervention in this variable with an odds ratio of 0.24.

- Sitting in chair: this variable had two categories (table 5.1). Sitting in chair was the significant category as a PU preventive intervention in this variable, with an odds ratio of 0.13.

- Frequency of re-positioning: this variable had three categories (table 5.1). Only re-positioning every 4 hours was significantly associated with PU prevention, with an odds ratio of 0.06.

- **Group Two: Variables related to physical activity and mobility**

- **Univariate analysis results:**

- Significant variables ($P \leq 0.05$) associated with PU for variables representing physical activity and mobility are presented in table 5.3.

Table 5.3: Significant variables associated with PU for variables representing physical activity and mobility

Variable	Variable categories	Significant category associated with PUs	Effect size
Activity in bed	- Moves with help - Moves independently	Moves with help	Medium
Ability to do hygiene practices	- Shower or assisted bathing - Bed bath - Hoist bath	Bed bath	Large
Ability to do ADLs	- Needs one help - Needs two help - Independent or needs help in bathing only	Needs two help	Large
Activity outside bed	- Moved by hoist only - Moved with help or independently	Moved by hoist only	Medium

- Non-significant variable ($P > 0.05$) associated with PU for variables representing physical activity and mobility is presented in table 5.4.

Table 5.4: Non-significant variable associated with PU for variables representing physical activity and mobility

Variable	Variable categories	Category associated with PUs
Long surgical procedure	- Underwent long surgery - Patient had no surgery	Underwent long surgery

- **Multivariate analysis summary for group two**

In this group two variables were significant in logistic regression final model, namely:

- Activity in bed: this variable had two categories (table 5.3). Moving with help was the significant category associated with PU as a risk factor in this variable, with an odds ratio of 7.69.

- Ability to do hygiene practices: this variable had three categories (table 5.3). Bed bath was the significant category associated with PU as a risk factor in this variable, with an odds ratio of 3.67.

➢ **Group Three: Variables related to PU intrinsic risk factors**

- **Univariate analysis results:**

- Significant variables ($P \leq 0.05$) in univariate analysis associated with PU for variables related to intrinsic risk factors are presented in table 5.5.

Table 5.5: Significant variables in univariate analysis associated with PU for variables related to intrinsic risk factors

Variable	Variable categories	Significant category associated with PUs	Effect size
Number of underlying conditions	- Not present - One conditions - Two conditions - Three conditions	Three conditions	Large
Depression	- Suffering from depression - Not depressed	Suffering from depression	Small
Presence of dehydration	- Not present - Present	Presence of dehydration	Small
Blood transfusion	- Blood transfused - Blood not transfused	Blood transfused	Small
Binary albumin	- Albumin< 32 mg/dl[1] -Albumin ≥ 32 mg/dl	Albumin< 32 mg/dl	Large
Binary haemoglobin	- HB[4]<130 g/L[2] for males or <115 g/L for females - HB≥130 g/L for males or ≥115 g/L for females	HB<130 g/L for males or <115 g/L for females	Medium
Systolic B.P.	- < 113 mmHg[3] - ≥ 113 mmHg	Systolic BP<113 mmHg	Small

1: Milligrams per decilitre, 2: Gram per litre, 3: Millimetre of mercury, 4: Haemoglobin

- Non-significant variables (p>0.05) in univariate analysis associated with PU for variables related to intrinsic risk factors are presented in table 5.6.

Table 5.6: Non-significant variables in univariate analysis associated with PU for variables related to intrinsic risk factors

Variable	Variable categories	Category associated with PUs
Level of consciousness	- Conscious - Confused	Confused
Cognitive impairment	- With cognitive impairment - Without cognitive impairment	With cognitive impairment
Dysphagia	- Dysphagia present - Dysphagia not present	Dysphagia present
Denture or chewing problem	- problem with dentures or chewing present - problem with chewing or dentures not present	problem with dentures or chewing present
Binary sodium	- < 135 mmol/L [1] - ≥ 135 mmol/L	≥ 135 mmol/L
Binary potassium	- < 3.5 mmol/L - ≥ 3.5 mmol/L	No category was associated with significance. Constant variable
Binary urea	- ≤ 21 mg/dl [2] - > 21 mg/dl	≤ 21 mg/dl
Binary creatinine	- ≤ 120 µmol/L [3] for males or ≤ 110 µmol/L for females - > 120 µmol/L for males or > 110 µmol/L for females	> 120 µmol/L for males or > 110 µmol/L for females
WCC	- < 10×10^9 cells/L [4] - ≥ 10×10^9 cells/L	≥ 10×10^9 cells/L
Diastolic B.P.	- < 60 mmHg [5] - ≥ 60 mmHg	< 60 mmHg
CRP*	< 10 mg/L [6] ≥ 10 mg/L	≥ 10 mg/L

1: Millimoles per litre, 2: Milligrams per decilitre, 3: Micromoles per litre, 4: Cells per litre, 5: Millimetre of mercury, 6: Milligrams per litre. * Was not included in multivariate analysis

- **Multivariate analysis summary for group three**

In this group four variables were significant in logistic regression final model, namely:

- Number of underlying medical conditions: this variable contained four categories (table 5.5). Two categories were significantly associated with PUs, namely: presence of two underlying conditions and three underlying conditions, with an odds ratio of 13.3 and 143 respectively.

- Cognitive impairment: this variable had two categories (table 5.6). Presence of cognitive impairment was the significant category associated with developing PU, with an odds ratio of 4.3.

- Binary albumin: this variable had two categories (table 5.5). Albumin level < 32 mg/dl (hypoalbuminemia) was the significant category associated with PUs, with an odds ratio of 0.10.

- Binary haemoglobin: this variable had two categories (table 5.5). Haemoglobin < 130 g/L^2 for males or <115 g/L for females was the significant category associated with PUs, with an odds ratio of 0.14.

5.4.2 Discussion and interpretation of the study main findings

As it can be noticed from the study findings, the aforementioned method and the multivariate statistical procedures used, led to answering the two research questions and rejecting the two null study hypotheses. This means that there were a number of interventions and risk factors that contributed to the outcome (PU). This section discuses and interprets these findings. The discussion of findings is divided into three parts:

Part one: preventive interventions

Part two: risk factors related to physical activity and mobility

Part three: risk factors related to PUs intrinsic risk factors

Each part will be divided into sub-sections that discuss the results of different individual variables. In these sub-sections interpretations from the multivariate analysis were used to answer the research questions. As stated earlier, multivariate results will be used to answer the research questions. This is because multivariate analysis assumes that the outcome (PU) is influenced by a combination of factors. Therefore multivariate analysis controls the effect of other variables in the model when predicting which variables are associated with the outcome. Conversely, univariate analysis assumes that acquiring PU is only affected by the individual variable analysed regardless the effect of other variables in the data set. In case of PUs using multivariate analysis to answer research questions is more valid because PUs is a multifactorial problem. Results of univariate analysis are presented in this section to compare them with results from multivariate analysis, also variables that were significant in univariate analysis but not in multivariate analysis can increase the awareness for future research.

Results for all the variables entered into the three different logistic models were discussed. Additional results reported in findings chapter were also discussed in order to elaborate more on the results of the study.

5.4.2.1 Part one: preventive interventions

Multivariate analysis revealed three interventions that were significantly associated with PU prevention: using draw sheet to mobilize patient, sitting patient in chair and

changing patient position every four hours. Other interventions that were entered into the multivariate model turned to be insignificantly associated with PU prevention, these were: type of hospital bed, seating cushion, first mattress used, positioning every two hours, barrier creams, moisturizing cream, dietician referral and physiotherapy referral.

Each pair of patient in this study had an equal Waterlow total score (patients matched on sub-scores). However, results of the statistical analysis (whether descriptive or inferential) for preventive interventions showed that there was a difference in the type of preventive interventions used between each two paired patients. This may indicate that nurses used cues other than the total Waterlow score to allocate preventive interventions. These cues may include clinical judgment, personal experience, or the unavailability of particular preventive equipment in certain wards.

- **Draw sheets**

Draw sheets were investigated in this study to distinguish if their use as a patient lifting and handling technique could prevent PUs. Results from univariate analysis indicated that there was no significant difference in using draw sheets between the two study groups. But, when adjusting the effect of other preventive intervention through the multivariate model; draw sheets turned to be a significant variable. The odds ratio reported with this variable was 0.24, a value less than one. This indicate that patients who had draw sheet used to mobilize them were less likely to develop PUs compared to patients who were mobilized without a draw sheet with all other variables being controlled in this group.

Literature found in this area showed that there was no clear empirical evidence to supports the use of draw sheets in preventing PUs. All studies found in this area were in

form of recommendations or guidelines. No prospective or retrospective studies were found that investigated the role of draw sheets in PUs prevention. To the best of the researcher knowledge, this study is the first to examine the effectiveness of such intervention having PU as its outcome.

- **Sitting in chair**

The operational definition of this variable was designed to indicate if the patient sat in a chair on a regular basis during admission, whether assisted in doing so or just encouraged by the nursing team. Hypothetically, sitting in a chair is considered a preventive intervention because it can decrease the time of lying down in bed. Changing between lying in bed and sitting in a chair can relieve pressure on certain areas of the body and increase mobility level (Thomas, 2006). Sitting in chair was considered as a preventive intervention because nurses had an active role that led to its occurrence.

In the current study, this variable was significant in both univariate analysis and multivariate analysis. Univariate analysis showed a significantly higher number of patients used to sit regularly in a chair to be free of PUs. Interpretations from multivariate analysis suggest a significant association between sitting in chair and prevention of PUs. An odds ratio of 0.13 (a value of less than one) was reported in the multivariate model indicated that patients who sat regularly in a chair during hospitalization were less likely to develop PUs compared to patients who did not sit regularly in a chair during their hospitalization, with all other variables being controlled in this group.

Only one study was found during the literature search that investigated the relation between sitting in chair as a preventive intervention for PUs (Nijs et al., 2009). This study found a negative association between sitting in chair and PU grade 2-4. This result was consistent with the results of this study especially that most of the PUs in this study were grades three and four.

Apart from the ability of this intervention to relive pressure, another possible explanation for the negative association between PU and sitting in chair in current study could be attributed to the ward environment. Hospital wards that had nurses who encouraged or assisted sitting in chair may also encourage other activities of mobility or implement other interventions to prevent PUs that are not recorded in medical files. De Laat et al (2006b) conducted a one day survey to evaluate the effectiveness of a new PU prevention and treatment policy in a university hospital. In this study a significant decrease in hospital-acquired PUs after implementation the new policy had happened. As the author notes that this decrease may not as a result of implementing the new policy alone. In some occasions nurses tend to perform in-between interventions that are not recorded. These interventions can help in preventing more ulcers.

- **Re-positioning frequency**

Univariate analysis showed a significantly higher number of patients who were re-positioned every four hours to be free of PUs. In multivariate analyses re-positioning every four hours was the significant category with an odds ratio of 0.06 (a value less than one). This odds ratio indicates that patients positioned every four hours were less likely to develop PUs compared to patients who were not positioned at all with all other

variables being controlled in this group. Re-positioning every two hours was not significant in multivariate analysis.

In general, regular body re-positioning was supported in literature and described as the most promising intervention to prevent the occurrence of PUs (Duimel-Peeters et al., 2007). Results from the current study supported less frequent re-positioning (every four hours) but not more frequent positioning (every two hours). Theoretically , more frequent re-positioning can decrease the duration of interface pressure against certain body area, thus relief pressure more than less frequent re-positioning (Armstrong and Bortz, 2001).

In this area, most of the literature did not clearly support a specific turning frequency. There was not enough evidence to support a specific re-positioning regimen (Reddy et al., 2006, Vanderwee et al., 2007c) or it was just an anecdotal evidence based on intuition with no scientific position (Clark, 2004, Hagisawa and Ferguson-Pell, 2008). Still, in a clinical trial comparing the effect of different re-positioning frequencies, re-positioning every four hours on a pressure redistributing mattress was better than re-positioning every two hours on a standard mattress in terms of lowering PU incidence (Defloor et al., 2005). The results of Defloor's study are in line with the current study in terms of the effect of turning frequency on the incidence of PUs. However, the current study did not assign a different type of mattresses for each turning regimen, as Defloor did.

Although in the current study, re-positioning four hourly was significantly associated with prevention based on a statistical criteria; theoretical explanation could also be proposed. This explanation is related to the effect of shear and friction forces on living

tissue. More frequent positioning means more exposing the skin to shear and friction forces that can cause tissue break down (Ousey, 2010).

- **Type of hospital bed**

From a theoretical point of view, profiling beds (electrical moving beds) are superior to standard hospital beds (non-electrical moving beds) in preventing PUs. Profiling beds can relieve pressure more by helping the patient to re-position while lying in bed (Maklebust, 1997).

Univariate analysis showed significantly more patients were free of PUs who were laid in a standard hospital bed. However, when controlling the confounding effect of other interventions through multivariate analysis, there was no difference between the two types of beds in respect to PU prevention. This means that multivariate analysis did not support the use of profiling beds to prevent PUs. This does not suggest that using a standard hospital bed is more beneficial. In other words, multivariate model suggested no superiority of either type of bed in respect to PU prevention.

Contradictory evidence was found in the literature to support the use of profiling beds. In a contemporary systematic review, evidence to support the use of profiling beds or not was of low quality and unclear (Cullum and Petherick, 2008). However, evidence from an RCT was in agreement with this study, and found no significant evidence to support the use of profiling beds to prevent PUs (Keogh and Dealey, 2001). Other RCTs found the use of profiling beds to be significantly associated with prevention (Hampton, 1998). Regardless of the results of these two trials, they investigated the efficacy of profiling beds by only controlling limited numbers of other preventive interventions and risk factors. The current study addressed this through controlling a

larger number of confounding variables that can affect the result of the study. This does not suggest that this result is more accurate than the two mentioned RCTs due to retrospective data used, rather it suggests a new approach that could be used prospectively in future studies to resolve conflict in literature concerning this intervention.

- **Seating cushion**

Theoretically, seating cushions can help in protecting from PU by decreasing the intensity of pressure while seated (Maklebust, 1997). Based on this assumption, this variable was considered in this study to examine its association with PU prevention.

Univariate analysis showed significantly more patients were free of PUs if they had seating cushions. However, when controlling the confounding effect of other interventions through multivariate analysis, there was no difference between using seating cushions or not in respect to PU prevention. Literature showed that the evidence to support using seating cushions as a PU preventive measure was weak and lacking. Different studies that reported the efficacy of seating cushions showed unclear and contradictory evidence (McInnes, 2010).

In current study the largest numbers of PUs developed were on heels. Seating cushions are designed to protect only buttocks from pressure. Based on this, seating cushions cannot protect heels. This could give a possible explanation why this intervention was not significant in this study.

- **First mattress**

According to the operational definition of this variable, first mattress used was either a static pressure reducing mattress or an alternating reliving mattress. Theoretically, both types can decrease the intensity of pressure thus prevent PUs. The debate lies in which of these is more effective. A plethora of previous studies compared the efficacy of both mattress types. Literature reviews that compared the evidence in such studies found no clear (or sometimes contradictory) evidence to support the superiority of one type over another (Jones, 2005, Bell, 2005).

Univariate analysis for this variable showed that significantly more patients with PUs slept on alternating mattresses compared to patients who slept on static mattresses. However, when adjusting the effect of all other preventive interventions through multivariate analysis, there was no significant difference between the two types of mattresses in respect to PU prevention. This result was in agreement with a number of RCTs that compared both types of mattresses. These RCTs did not find any significant difference in PU incidence between the two static or alternating pressure mattresses (Russell et al., 2003, Vanderwee et al., 2005).

- **Barrier creams**

Using barrier creams is supposed to protect the skin surface from irritants like moisture and provide a layer for protection against friction force that can causes skin breakdown (Nakagami et al., 2007). A literature review found evidence to support that using barrier creams was unclear (Ersser et al., 2005). In the current study there was not enough statistical evidence to support the use of barrier creams as a PU preventive measure. An equal number of patients had a barrier cream used on them in both of the two study

groups (five in each group). This means that this variable is a constant between the two groups. Such a constant variable should have been excluded from the data, because it would be worthless to analyse. The reason behind keeping this variable is to test its confounding effect on other variables in the logistic model.

Moreover, the number of patients who had barrier creams used on them was relatively small compared to other interventions (only 10 patients in the two study groups). As noted during data collection, barrier creams were more frequently used after the PU developed, or as a recommendation from the TVN. This may indicate that nurses did not realize the importance of the intervention in the prevention process, or they did not recognize which patients are in need of this intervention.

- **Moisturizing creams**

Moisturizing creams work by hydrating the skin surface in order to maintain tissue tolerance and prevent skin from breaking down (Frantz et al., 2004). The use of moisturizing creams has been indicated in many skin care regimens to maintain a health skin and prevent breakdown. Despite that, there is no clear empirical evidence to support their use (Voege, 2010). In the current study, an equal number of patients who had a moisturizing cream applied to their skin was found in both of the study groups (seven patients in each). This situation made this variable a constant between the two study groups. In this case, no statistical inference could be drawn. The reason behind keeping this variable was to test its confounding effect on other variables in the logistic model.

As in the previous variable, the number of patients who had moisturizing creams applied to their skin was relatively small compared to other interventions (only 14

patients in the two study groups). As noted during the revision of medical files, using moisturizing creams was initiated after the PU developed, or as a recommendation from the TVN. This may indicate that nurses did not recognize the role of this intervention in preventing skin break down or they did not recognize which patients are in need for this intervention.

- **Physiotherapy and dietician referrals**

The physiotherapist has a role in increasing patients' level of activity and decreasing the intensity and duration of compressive forces. This is accomplished by implementing different exercises and using the right lifting and handling techniques. The role of a dietician is to assess alterations in nutritional status and intervene to improve them. These interventions include adjusting dietary intake by giving different types of supplement or increasing calorie or fluid intake. Interventions implemented by these members of the caring team have a role in preventing PUs (Stirling, 2009). The current inquiry took into account these two roles and studied their association with PUs prevention. According to the operational definition of these two variables, only those patients who benefited from the physiotherapist or dietician interventions were sorted as referred.

Results of this study were not able to support either the role of dietician or the physiotherapist in preventing PUs. Approximately equal numbers of patients were found in the two study groups who were referred to dietician or physiotherapist. As a consequence both results of multivariate analysis and univariate analysis did not reveal any significant association between dietician or physiotherapist referral and PU prevention. However, both of these variables were retained in the final logistic model

as confounders. This means that these two variables must be statistically controlled because they affected parameters of other significant variables without being significant.

Studies found in this area showed a significant decrease in PU incidence after implementing prevention programmes through a multidisciplinary team (including dieticians and physiotherapists) (Baker, 1998, Harrison et al., 2008, Stirling, 2009). Comparing results from the current study with literature was difficult, because previous studies did not investigate the role of physiotherapist and dietician solely, whereas the current study did.

5.4.2.2 Part Two: Risk factors related to physical activity and mobility

Part two represents the first group of PU risk factors that are addressed in current study. This group of variables were abstracted from routine risk assessment and nursing notes. In this group there are five variables that were theoretically related to one of PU's well-known risk factors, namely immobility. Variables in this group meant to measures level of activity and mobility according to two criteria. These criteria are different than the criteria reported with Waterlow scale to measure risk of PUs through mobility. The first criterion was for the first four variables (table 5.3); the second one was for the fifth variable (table 5.4). According to the first criteria, the first four variables in this group depended on measuring the level of independency each patient had in performing certain tasks that needs a certain level of mobility. In these four variables, it is anticipated that patients who needed more help in doing certain activities are less active or less mobile, thus at a greater risk of acquiring PUs. According to second criterion, fifth variable (long surgical procedure) included patients who spent more than two

continuous hours on operation table. In this variable it is anticipated that patient who underwent surgeries that lasted two hours or more are at greater risk of acquiring PUs because of the long period of immobility they experienced during surgery.

In brief, the two mentioned criteria were targeted to measure levels of mobility during different situations. Lower level of immobility in all of these variables can cause less pressure relief, thus increasing tissue vulnerability to breakdown.

On the other hand, a number Waterlow sub-scores took into account different criteria than level of independency or long surgeries to assess risk of PUs through mobility level. Waterlow criteria depended on the presence of certain conditions that can hinder patient's mobility level or can cause friction or shear. These included the presence of particular physical disorders, psychological conditions , mechanical restrains or the administration of particular pharmacological agents (Waterlow, 2005b). As these conditions persist, the chance of pressure, shear or friction forces (or a combination of these) to cause tissue break down is increased. Using criteria other than Waterlow's was not undertaken arbitrarily. Patients in this study were identically matched for Waterlow mobility sub-scores. Using the same criteria to measure mobility level would be meaningless and no difference between groups could be detected. In addition, using a new criteria based on routine risk assessment can reveal further aspects of risk that could be associated with acquiring PUs.

Multivariate analysis for this group revealed that two variables out of the five entered into the logistic model turned to be significantly associated with developing PUs. These were activity in bed, and ability to undertake hygiene practices. The other three

variables were not significantly associated with acquiring PUs. However, the variables ADLs and long surgical procedure were retained in the final model as confounders.

- Activity in bed

This variable had two categories (table 5.3). In univariate analysis, a significantly higher number of patients who moved in bed with help had PUs. Multivariate analysis also showed that this category was significant, with an odds ratio of 7.69 (a value greater than one). This indicates that patients who were only able to move in bed with help were more likely to develop a PU compared to patients who moved independently, with all other variables in this group being controlled.

- Ability to maintain skin hygiene practices

This variable was significant in univariate analysis with the category “bed bath” to have significantly the highest number of patients with PUs. Multivariate analysis also showed this category to be significant with an odds ratio of 3.67 (a value larger than one). According to this odds ratio, patients who were only able to take their bath in bed were more likely to develop PUs compared to patients who were able to take their bath in shower independently or with help with other variables in this group being controlled.

- Ability to do ADLs

This variable was significant in univariate analysis but not in multivariate analysis. In univariate analysis the need for two help to do ADLs was the category with the highest number of patients who developed PUs. Multivariate analysis did not show any category of this variable to be associated with developing PUs.

- Activity outside bed

This variable was significant in univariate analysis but not in multivariate analysis. In univariate analysis significantly higher number of patients with PUs were only moved by hoist. Multivariate analysis did not show any category of this variable to be associated with developing PUs.

- Long surgical procedure

This variable was not significant in univariate analysis or multivariate analysis, although larger number of patient who underwent long surgeries acquired PU compared to patients who did not. This difference was not statistically significant in univariate analysis. Multivariate analysis did not show this variable to be associated with developing PUs.

Interpretations of univariate analysis results showed that patients who were more dependant in their mobility or needed more help in doing certain activities were at greater risk of acquiring PUs, and that being totally immobile for more than two hours during a surgery does not increase the risk of PUs. These interpretations could only be held true if PUs are assumed to be the result of one of these variables alone. However, clinically these interpretations are invalid because PU is a multifactorial problem. Therefore, interpretation of multivariate analysis could be held more accurate because it takes into account the influence of all variables in this group on the outcome. Multivariate analysis showed that PUs were only associated with moving in bed with help and being only bathed in bed. The need for two help in doing ADLs, being moved outside bed by a hoist and having a long surgery turned to be insignificant in multivariate analysis. This result could possibly suggest that patients who were more

dependent on nurses for activities that are only carried out in bed were at a greater risk for PUs. Such patients could have a much lower level of mobility and may even be frailer with poor level of health to be transferred out of bed.

This study constructed the five variables related to mobility and activity based on the way they were documented in medical files. Literature reported different ways to construct such variables and to define the degree of risk associated with these variables. For instance, one retrospective cohort study that investigated a number of risk factors considered patients to be at risk of PUs according to the number ADLs they needed assistance in doing; if this number exceeds seven, the patient is at risk of acquiring PUs (Horn et al., 2004). In the mentioned study, the concept of ADLs was expanded to include all patients' activities, including mobility in and outside bed, in addition to the ability to maintain skin hygiene. The current study differentiated between these last three factors and ADLs (table 5.3). Studies that did the same, and differentiated between the effects of these variables, were also reported in literature. In these studies, dependency in doing some ADLs, such as moving in bed and moving outside bed, were significantly associated with increased risk of PUs among other risk factors (Mino et al., 2001, Mertens et al., 2008). The main difference between those studies and this one is the different group of variables investigated and entered into the multivariate model. Other studies in this domain adopted different approach. The ability to perform all ADLs were represented by a numerical value through a score (Spector and Fortinsky, 1998, Capon et al., 2007). These studies found a significant association between the score, indicating a higher dependency level and increased risk of PUs.

Previous studies suggested an association between PUs and being dependant in doing all types of ADLs. Findings from literature did not fully match the current study's

results. In this study, only dependencies in moving in bed and in doing skin hygiene were significantly associated with PUs in the final multivariate model. Partial disagreement between the current study and literature could be explained by two reasons: firstly, the current study used a different set of variables that were entered into the multivariate model than studies reported in literature, which could have an effect of the final significant variables; and secondly, it used a different matched approach, which was not used in previous studies. Controlling certain risk factors through matching could have an effect on the final results.

Having a long surgical procedure was studied alone as a risk factor in literature. As shown previously, this variable was not significantly associated with PUs in current study. However, it was clinically proven that unrelieved pressure for two hours or more could result in tissue breakdown (Smith, 1995). Moreover, a number of studies (including literature reviews) found a positive relation between PU incidence and surgery duration (Keller et al., 2002, Baumgarten et al., 2003, De Laat et al., 2006a). Findings from the current study contradicted those of previous literature that investigated the relationship between surgery duration and PU. This contradiction could be due to different risk factors and/or different intraoperative PU preventive interventions between current study and studies reported in literature.

5.4.2.3 Part Three: Variables related to intrinsic risk factors

This part represents the interpretation of the statistical results for a number of variables that were theoretically linked to PU intrinsic risk factors. These factors are not directly related to the pathogenesis of PUs, like interface pressure, but they can increase tissue vulnerability to breakdown. Some of these factors can be clinically managed or

corrected, such as low haemoglobin or low serum albumin. Others are inevitable and cannot be managed (e.g. cognitive impairment), but their presence can give indications for nurses to implement appropriate PUs' prevention measures.

In this part, 17 variables related to intrinsic risk factors were entered into the third multivariate model. Only four of them turned to be significantly associated with PUs in the final multivariate model. These were: number of underlying medical conditions, binary albumin, binary haemoglobin and presence of cognitive impairment.

- Number of underlying medical conditions

Apart from the main reason for admission, this variable categorizes the number of comorbidities that were present on admission to hospital. These comorbidities can make patients more vulnerable to tissue breakdown by decreasing the amount of interface pressure needed to close blood capillaries. This can reduce oxygen supply to skin and delay reactive hyperaemia that is important to restore blood flow after pressure is relieved (Defloor, 1999, Lyder, 2003). Statistically, this variable was significant in both univariate analysis and multivariate analysis. Univariate analysis showed a significantly higher number of patients who had two or three underlying conditions to have PUs. In multivariate analysis two categories in this variable were significant in this variable, namely: presence of two underlying conditions and three underlying conditions with an odds ratio of 13.3 and 143 respectively (values larger than one). This indicates that patients who had two or three underlying medical conditions on admission were more likely to develop PUs compared to patients with no comorbidities with all other variables being controlled in this group.

Interpretations of the odds ratio suggest that the risk of PUs is increased with the increase in the number of comorbidities. As an implication of this result, nurses must be more cautious when caring for patients with multiple comorbidities. In this case, more comorbidity can carry more risk factors of PUs associated with these comorbidities, thus making tissue more vulnerable to breakdown.

Findings from the literature were in agreement with those of the current study. Previous studies for PU risk factors in different clinical setting supported the link between acquiring PUs and presence of underlying medical conditions. Different approaches were used in studies that investigated this risk factor. Some used a numerical scale to measure severity of illness and linked the score of this scale to PUs (Baumgarten et al., 2003, Horn et al., 2004). Other studies established a relation between the presence of certain underlying conditions e.g. DM, pulmonary disease and PUs (Lindholm et al., 2008). Also in this context, one study found a significant difference in the number of comorbidities (as a continuous variable) between patients who acquired PU and patients who did not through univariate analysis, but not in multivariate analysis (Baumgarten et al., 2004). Other risk factors or preventive interventions in this study were not controlled for through a multivariate model as in current one.

This study employed a different approach to study such risk factor which was to the best of the researcher knowledge not used in previous studies. This approach categorized the number of underlying conditions for easier interpretation and use within a clinical setting. Moreover, through multivariate analysis other risk factors were controlled for. This can produce more valid results through controlling other confounders that can affect the result.

- Presence of cognitive impairment

Cognitive impairment is one of the factors that may hinder patients' feelings of pain resultant from persistent pressure, thus increasing the chance of tissue breakdown (Burdette-Taylor and Kass, 2002). In this study, the presence of cognitive impairment was a significant risk factor associated with PUs in multivariate analysis, but not in univariate analysis. In the case of univariate analysis, cognitive impairment was not significant, when assuming that PU is an effect of cognitive impairment alone. In multivariate analyses it became significant when assuming that PU is a result of a combination of variables. As stated earlier, this is more theoretically valid, since PU is acknowledged as a multifactorial problem. An odds ratio of 4.3 (greater than one) reported with multivariate analysis means that patients with a cognitive impairment were more likely to develop PUs than patients with no cognitive impairment, with all other variables being controlled in this group.

In literature, some studies that investigated cognitive impairment as a PU risk factor were inconsistent, and some findings were merely based on clinical judgment and not on empirical evidence (Allman et al., 1995). However, those studies that used empirical evidence were in agreement with this one. These studies found cognitive impairment to be statistically significant in PUs, with some reservations. In a multi-centre prospective study a group of risk factors were investigated in their relation to PUs, cognitive impairment, advanced age, length of hospital stay and disability were found to be associated with PUs through multivariate analysis. This study was restricted to older age patients and included patients with PUs on admission (Mecocci et al., 2005). These limitations could limit the usability of these results. In the present study, all patients were free of PU on admission. Presence of PU on admission can increase the risk for

further ulcers to develop. Other studies also found cognitive impairment to be associated with PUs but not independently (Horn et al., 2002, Söderqvist et al., 2007). The effect of other variables was not controlled for through multivariate analysis. This study used multivariate analysis to ensure a more controlled analysis.

Addressing some of the shortcomings in previous studies does not necessarily make the current study superior, as this study used retrospective data, while previous studies used prospective data, the latter of which reflects a higher degree of accuracy. This study merely validates their results through using a different approach and controlling more confounding variables.

- **Biological measures**: binary albumin/ binary sodium/ binary potassium/ binary urea/ binary creatinine/ binary haemoglobin/ binary WCC / binary systolic B.P. / binary diastolic B.P.

This section discusses study results of some routinely measured biological factors on admission. Using these factors to identify risk has some advantages. Most of these measures are routinely done on admission for clinical purposes other than assessing risk of PUs, so they constitute readily available indicators that can help in spotting patients at risk of PUs. Also, these factors are more easily managed clinically than other risk factors relating to intrinsic environment. For instance, low albumin level can be clinically managed by improving nutritional status or by administering parenteral albumin. Other factors relating to intrinsic environment are not manageable like age or gender. Another advantage is the objectivity of these measures. Depending on an objective measures to assess risk can give more robustness than using subjective measures (e.g. clinical judgement).

As mentioned earlier in the study, in order to use these biological measures as a clinical indicator for risk, they must be categorized (Anthony et al., 2000b). Therefore, only binary variables were entered into the multivariate model. In this context, it was noticed that most of the studies investigated the role of biological measure used them as continuous variables. This can make their results less useful in the clinical settings.

Multivariate analysis for variables related to intrinsic risk factors revealed two variables to be associated with acquiring PUs, namely binary albumin and binary haemoglobin.

- Binary albumin

This variable had two categories (table 5.5). These two categories were to differentiate patients with normal albumin level and those with below normal level (hypoalbuminemia.) Albumin level ≥ 32 mg/dl indicate that patient has a normal serum albumin level, while albumin ≤ 32 mg/dl indicates that patient is hypoalbuminemic.

Univariate analysis for serum albumin as a continuous variable showed a significant difference in the mean of serum albumin between the two study groups. As a binary variable; significantly more patients in the PU grope had hypoalbuminemia compared to non-PU group. In multivariate analysis serum albumin < 32 mg/dl (hypoalbuminemia) was the significant category associated with PUs with an odds ratio of 0.10 (a value less than one). Interpretations of this odds ratio indicate that patients with hypoalbuminemia were more likely to develop PUs than patients with normal serum albumin, with all other variables being controlled in this group.

Result from multivariate analysis suggests that being hypoalbuminemic on admission is an independent risk factor of PUs. Low serum albumin with other risk factors can increase tissue vulnerability to ulceration by inducing cellular dehydration and oedema

(Allman et al., 1995). One problem with albumin as an indicator for PU risk is its long half life (from 19 to 21 days) (Sakka, 2007). This means that if nurses were to take action for low albumin by improving nutrition, it would take a long time before an improvement occurred, during which time patients could develop PUs. However, low serum albumin could be also an indicator for disease severity , which in turn can be a risk factor of PUs (Thompson and Fuhrman, 2005). Therefore, extra care should be provided for patients with low serum albumin.

Previous studies that investigated low albumin as a PU indicator were conducted in different settings using different patient groups and statistical analyses approaches. Some of these studies showed that low albumin as a significant predictor of PUs, others did not. Limitations were found in studies whether supported the role of low albumin as a predictor for PUs or not. However, studies found that did not support albumin as a predictor were generally underpowered. One of these had small sample number (Goode et al., 1992), others had a considerably small incidence of PUs (Kemp et al., 1990, Allman et al., 1995, Lindgren et al., 2004, Lindgren et al., 2005, Okuwa et al., 2006, Sayar et al., 2009) (see Appendix B for more details). One study was found to disrespect the role of low albumin as a PU predictor with moderate sample size and high incidence of PUs (Bergstrom and Braden, 1992). The mentioned study showed that patients who developed PUs had a low protein intake. Results from this study that did not show low albumin as a PU predictor over and above protein intake could be explained by the correlation between albumin and protein intake.

On the other hand, studies that found albumin to be a significant predictor of PUs had larger sample sizes than those showing no relation between low serum albumin and PUs (Allman et al., 1986, Anthony et al., 2000b, Bourdel-Marchasson et al., 2000, Mino et

al., 2001, Reed et al., 2003, Walsh and Plonczynski, 2007). One study was found with moderate sample size (Hatanaka et al., 2008), but with a higher incidence of PUs than all other studies, which did not find low albumin as a predictor of PUs (for more details, see Appendix B).

Comparing the current study to other studies that investigated the low albumin as a predictor of PUs, it can be noticed that current study had a smaller sample size (n=152) but had higher number of patients with PUs (50% of the sample had PUs).

- Binary haemoglobin

This variable was designed to catch patients with a low haemoglobin level (anaemia). Therefore it has two categories (binary). Haemoglobin level <130 g/L2 for males or <115 g/L for females represents patients with anaemia. Haemoglobin level >130 g/L for males or >115 g/L for females represents patients with normal haemoglobin level. This variable was not matched within the sub-scores in this study. Anaemia in Waterlow scale uses a different cut-off point of 70 g/L to indicate anaemic patients.

Univariate analysis for haemoglobin as a continuous variable showed a significant difference in the mean of haemoglobin level between the two study groups. As a binary variable; significantly more patients in the PU grope had anaemia compared to non-PU group. In multivariate analysis haemoglobin level <130 g/L for males or <115 g/L for females was the significant category associated with PUs with an odds ratio of 0.10 (a value less than one). This indicates that patients with anaemia were more likely to develop PUs than patients with normal haemoglobin level with all other variables being controlled in this group.

The main function of haemoglobin is to carry oxygen to tissue, thus decreased haemoglobin may induce tissue vulnerability to PUs (Hatanaka et al., 2008). A number of studies found low haemoglobin to be associated with developing PUs (Theaker et al., 2000, Hatanaka et al., 2008, Haleem et al., 2008). This was in agreement with current study results. In contrast, other studies did not find low haemoglobin to be associated with PUs (Cullum and Clark, 1992, Sayar et al., 2009, Nijs et al., 2009). All studies, whether they agreed or disagreed with the current study's findings, used different approaches. This study relatively controlled a larger number of confounders through matching on a number of Waterlow sub-score, though retrospectively. Using current study approach within a prospective conduct may result in more reliable results.

- Binary WCC

This variable was used in this study to investigate the association between increased WCC and developing PUs. From a physiological point of view, increased interface pressure can trigger an inflammatory response causing WCC to rise. WCC with lipids and other free radicals can accumulate in the fine blood capillaries causing it to close, hence leading to ischemia that can cause tissue break down (Sharp and McLaws, 2005, Fowler et al., 2008). Based on this explanation increased WCC can be considered as an early indicator for PUs.

Results of the study showed that elevated level of WCC was not associated with developing PUs, neither in univariate nor in multivariate analysis. This result was in agreement with studies that investigated the association between WCC and increased incidence of PU (Hatanaka et al., 2008, Sayar et al., 2009). One study was found to

disagree with this finding (Goode et al., 1992). Findings from this study were not statistically significant due to the small number of patients included (n=21).

Current study and a number of previous studies did not find that the increase in WCC is associated with PUs. This does not contradict with the physiological explanation mentioned earlier. One reason for this is that WCC can increase not just as a result of interface pressure. Other conditions can cause this increase (e.g. bacterial infection). Therefore, in order to validate this result, other factors (apart from interface pressure) that can cause increased WCC must also be controlled.

- Binary sodium and binary potassium

Low serum sodium and potassium could lead to cellular dehydration. In turn, cellular dehydration could increase the risk of PUs (Bourdel-Marchasson et al., 2000). In addition, low serum levels of these two biochemical factors may indicate malnutrition which is also a risk factor for PUs (Phillips, 2003). Based on this, these two variables were investigated in this study to study their association with PUs.

Findings from univariate and multivariate analysis suggest no significant association between these two variables and developing PUs. However, binary serum sodium was kept in the final multivariate model as a confounder. This means that even though binary sodium was not significant but adjusting its effect in multivariate analysis was important.

Very few studies found that studied the relation between these two factors and PUs. There was no clue in these studies that supported the association between these two factors and PUs (Cullum and Clark, 1992, Anthony et al., 2000b, Okuwa et al., 2006). This was in agreement with the current study's findings. In this context, more studies

are needed to validate this result, in the same time controlling more factors that can cause cellular dehydration and malnutrition.

- Binary urea and creatinine

The goal of including these two variables was to investigate if their increase above normal level can be associated with developing PUs. Physiologically, elevated serum urea and creatinine indicates a renal comorbidity. Kidneys are responsible for the production of vaso-active substances that help blood vessels to dilate after being suppressed by external pressure force (as in case of prolonged immobility). In the case of renal comorbidity; production of this substance is decreased leading to a delayed vasodilatation after the pressure is relieved. This could result in tissue ischemia thus, breaking down of the skin (van Marum et al., 2001).

Results from current study suggest no association between these two variables and PUs both in univariate and multivariate analysis. However, Binary urea was retained in the final logistic model as a confounder. Even though binary urea was not significant but adjusting its effect in the final logistic model was important for the statistical stability of the final model.

In previous literature, most of the studies found were consistent with current study findings. In these studies no association was found between PU and elevated serum levels of urea or creatinine (Allman et al., 1995, Hatanaka et al., 2008, Sayar et al., 2009, Manzano et al., 2010). However, one study was found that contradicted these findings. It found creatinine to be significantly associated with PU as an independent variable. This study used multivariate analysis and controlled a large number of risk factors and comorbidities that can increase the risk of PU. Nevertheless, in this study

was underpowered only 3% of patients developed PUs (Frankel et al., 2007). This small incidence of patients who developed PUs could limit the reliability of this finding.

Although there was a theoretical basis to support elevated urea and creatinine as an indicator for PU risk, this study and previous literature could not find clear empirical evidence to support this. Further studies controlling more confounding variables could be useful to clear the picture in this area.

- Binary systolic and diastolic B.P.

These two variables were designed to detect the association between low B.P. (systolic and diastolic) and developing PUs. This was based on the theoretical assumption that normal blood pressure is an important factor in tissue perfusion. Low blood pressure results in delayed reperfusion to the tissue after being exposed to interface pressure. Such a delay can result in tissue ischemia which can lead to tissue break down (Defloor, 1999). Cut-off points used in current study to indicate low systolic and diastolic blood pressure were based on a robust study that investigated a large number of PU risk factors. This study found through multiple regression that systolic blood pressure less than 113 mmHg and diastolic less than 60 mmHg is the best predictor of PU among other risk factors (Bergstrom and Braden, 1992).

In present study, low systolic blood pressure (< 113 mmHg) was significant in univariate analysis but not in multivariate analysis. Low diastolic blood pressure (< 60 mmHg) was not significant both in univariate or multivariate. These Findings does not support low systolic or diastolic blood pressure to be associated with PUs as independent risk factors.

Evidence in literature for the effect of low blood pressure on the development of PUs was unclear and contradicting. A number of studies were in line with current study findings. These studies found low systolic or diastolic blood pressure to be a significant risk factor for developing PUs (Bergstrom and Braden, 1992, Haleem et al., 2008, Vanderwee et al., 2009). On the contrast, other studies did not find these two factors as indicators for PUs development (Cullum and Clark, 1992, Lindgren et al., 2004, Lindgren et al., 2005, Lindholm et al., 2008, Nonnemacher et al., 2009). Comparisons between these mentioned studies and current one are difficult. Different studies in literature, whether or not they agreed with the current study's findings, used different methodologies and cut-off points; some used multivariate analysis while others used univariate, or controlled different groups of risk factors in different clinical settings.

However, findings from current study concerning the effect of low blood pressure had some shortcomings. Some factors that affected tissue perfusion were controlled like haemoglobin; others were not controlled (e.g. smoking, diabetes, medications, presence of vascular diseases). These factors should have been considered and controlled, but unfortunately were not available in medical files.

- Presence of dehydration

Dehydration can decrease the circulatory blood volume, thus decreasing the amount of oxygen and nutrients delivered to tissue. This can contribute for tissue breakdown and development of PUs (Ferguson et al., 2000). Based on this assumption; the association between dehydration and acquiring PUs was investigated.

In current study presence of dehydration was significant in univariate analysis. Significantly more patients in the PU group were dehydrated compared to non-PU

group. Though, when adjusting the effect of other variables thorough logistic regression it was not significant. This finding indicates that dehydration was not associated with developing PUs as an independent risk factor. This result was not in agreement with most of previous literature found (including literature reviews) that investigated dehydration as a risk factor for acquiring PUs (Bansal et al., 2005, Lindholm et al., 2008). Most studies that were found during the literature review supported the effect of dehydration on PU formation. Also prevention guidelines in this area indicated that dehydration is a risk factor for PUs and should be assessed (Lewis et al., 2003, Ayello and Lyder, 2009). However, one study did not find dehydration to be a predictor of PUs (Horn et al., 2004). In this study, the author noted that dehydration is a known risk factor for PUs, but because the whole of study population were at risk of PU, they may not have variations in some risk factors.

A possible explanation for the contradiction between current study findings and literature could be attributed to the degree and amount of time the patient was dehydrated for. Being mildly dehydrated for just a short period of time could have a small, easily reversible effect on tissue viability. In medical files there was not enough information about the degree of dehydration or for how long the patient was dehydrated. Patients found to be dehydrated on admission in this study may suffer from a mild type of dehydration, or they were not chronically dehydrated. Giving them fluid supplements on admission may improve their fluid status.

- Depression

Depression can have a negative effect on mobility level and appetite. Depressed patients may tend to demonstrate a lower level of mobility (Waterlow, 2005b). Additionally,

they may experience loss of appetite, which in turn can lead to malnutrition (Serpa and Santos, 2008). Immobility and malnutrition were shown in a number of studies to be associated with PUs. Building on this; association between depression and acquiring PUs was investigated in current inquiry.

Statistical analysis revealed that presence of depression was significant in univariate analysis. Significantly more patients in the PU grope were depressed compared to non-PU group. However, when adjusting the effect of other risk factors through multivariate analysis it turned to be insignificant. Statistical findings from multivariate analysis do not support depression to be an independent risk factor associated with PUs. In literature there was a controversy and weak evidence in studies that empirically addressed evidence regarding the effect of depression on acquiring PUs. Studies that agreed with current study finding were either restricted to a special group of patients (spinal cord injury patients) (Correa et al., 2006), or had a small number of patients who developed PUs (Berlowitz et al., 2001). On the other hand, one study was found that contradicted with current study finding was also restricted for patients with spinal cord injuries (Smith et al., 2008). Spinal cord injury patients may have different characteristics and risk factors than other patients. Weaknesses and different patients' characteristics reported in previous studies makes comparisons with the current one difficult.

Also in this context, literature reported that use of antidepressant medications has a role in decreasing the likelihood of acquiring PUs (Horn et al., 2004). In current study this factor was not controlled for in the multivariate model because data were not available in medical records concerning the use of antidepressants. Controlling for such factor can produce more reliable results.

- Blood transfusion

This variable was included to test if transfusing blood could be an indicator for PU development. In this context, it's true that transfusing blood increases the level of haemoglobin, which in turn can improves tissue perfusion and decrease the risk of PUs. Yet, the time period before transfusion when the haemoglobin level is very low could indicate deteriorated health and low nutritional status. This period could be a source of risk for the patient; also it could be an indicator for the nurse to predict PUs.

Transfusing blood was significant in univariate analysis to be associated with PUs development. Significantly more patients in the PU grope had blood transfusions compared to non-PU group. Thus, when adjusting the effect of other risk factors through the multivariate model, it turned to be insignificant. Statistical findings from multivariate analysis do not support blood transfusion to be an independent risk factor for predicting PUs. Searching literature, no studies were found that studied blood transfusion as a risk indicator for PUs. However, one study found blood transfusion to be an independent predictor of death and deteriorated health in long term care residents (Berlowitz et al., 1997).

Although this study did not find blood transfusion to be a risk factor for developing PUs, it can increase the awareness for future research to investigate this factor more thoroughly.

- Level of consciousness

From a clinical point of view, decreased level of consciousness can increase patient dependency in fulfilling their basic needs, such as moving, eating and hygiene.

Fulfilling these needs is essential in preventing tissue break down (Fernandes and Caliri, 2008).

In the current study, decreased levels of consciousness were not significantly associated with PUs both in univariate analysis and multivariate analysis. This finding does not support the clinical assumption behind this risk factor. Previous literature that investigated this variable showed contradictory evidence. Some studies were found to support decreased levels of consciousness as a risk factor for developing PUs (Boyle and Green, 2001, Reed et al., 2003). Other studies did not find it to be associated with PUs (Allman et al., 1995, Allman et al., 1986). Regardless of the different methodologies used in these studies (whether they supported level of consciousness as a risk factor or not), level of consciousness was defined according to different criteria.

The current study also had a different criterion for defining level of consciousness. According to their medical records, all patients in this study were either conscious or confused. This may limit this finding, particularly as other studies took a wider range of categories to describe level of consciousness (e.g. unconscious, unresponsive and apathetic).

- Dentures or chewing problems and presence of dysphagia

These two variables were included to indicate if the patient had any problems that can prevent eating or chewing food. Presence of eating problems could have a negative effect on the patients' nutritional status (Russell et al., 1998). Deteriorated nutritional status can decrease tissue tolerance for pressure, thus increase the likelihood of PUs development (Green and Watson, 2006, McGillivray and Considine, 2009).

These two variables were not significantly associated with PUs development either in univariate analysis or in multivariate analysis according to the current study findings. This finding does not support the clinical assumption mentioned earlier. Also, it disagreed with literature findings. Studies in this area found a positive association between the presence of eating problems (including dentures or chewing problems and dysphagia) and acquiring PUs (Westergren et al., 2001, Horn et al., 2004).

5.4.3 Interpretation of additional results

This section discusses the additional statistical results reported in the findings chapter. The aim of these additional findings was to further explore some of the study results.

- **Additional logistic model**

The presence of some PU risk factors could interfere with the effectiveness of some preventive interventions. For this reason, the current study controlled a number of risk factors (Waterlow sub-scores) to control their effect on the results accuracy regarding preventive interventions. Other risk factors that were significant in this study were not controlled for. For this reason an additional model that contained significant preventive interventions and significant risk factors was fitted. This will exclude the probability that these interventions turned to be significant because other significant risk factors were not controlled for. In other words, it will statistically control for additional risk factors in addition to those matched within Waterlow sub-scores.

After fitting this additional model, all preventive interventions that were significant in the first model remained significant when all other risk factors were controlled for. This suggests that each of these interventions was independently significant even when adjusting the effect of additional risk factors.

- **Difference in the number of preventive interventions between the two study groups**

The number of all preventive interventions each patient had was counted in both of the study groups. Interventions were counted regardless of being statistically significant in multivariate analysis or not. The reason for doing this is that of all these interventions have a theoretical background in literature that supported there effect in preventing PUs. The mean of interventions number was slightly higher for patients in the non-PU group. However, t-test showed that this difference was not statistically significant.

On the other hand, when only significant interventions in multivariate analysis were counted; non-PU group had more significant preventive interventions compared to PU group. According to Mann-Whitney U test this difference was statistically significant. These two results may suggest that the type of intervention (significant interventions) not the number of interventions was responsible for preventing PUs. These additional results confirm findings from the first logistic model that contained preventive interventions.

- **ROC curves**

Both albumin and haemoglobin were significant predictors of PUs in multivariate analysis with an odds ratio of 0.10 and 0.14 respectively. ROC curve was used to clarify which one of these two variables is better predictor of PUs (ROC curve enable to test the ability of a variable to predict a certain condition or disease). The area under the ROC curve is used to measure this ability. As the area under the curve increase the ability of variable to distinguish those with and without the disease or condition increases.

In this study, the area under the curve for serum albumin was bigger than area of haemoglobin. This suggests that albumin is a better predictor of PUs than haemoglobin.

5.5 Conceptual framework impact on findings interpretation

This section aims to clarify the impact of using web of causation model as a theoretical base for the conceptual framework used in this study. It suggests how web of causation model clarifies the multifactorial relation between different factors in current study.

PU is a multi-causal health problem. Web of causation is used to explain how a multifactorial problem like PUs can be prevented systematically in a scientific approach. It helps health care workers in thinking more deeply and try to connect different risk factors together. Knowing that multiple causes are related to each other and in turn related to PUs can aid health care workers to break this web of causation by applying the appropriate interventions on targeted risk factors. As a consequence, intervening to prevent one risk factor is not enough in the prevention process. The prevention process will be more effective if more numbers of risk factors are prevented through implementing more than one preventive intervention.

In light of that, each of the three significant interventions in multivariate analysis, namely sitting in a chair, using draw sheets, and turning every four hours is implemented to prevent particular risk factors. Sitting in a chair and turning every four hours are implemented to prevent interface pressure by relieving pressure over certain body areas. Using draw sheet to mobilize patient is implemented to prevent shear and friction forces that can cause tissue break down. According to the web of causation model, all of these risk factors (pressure shear and friction) interrelate with each other, and every one of them is related to developing PUs. For instance, immobile patients

who cannot relieve pressure are also susceptible to shear and friction forces if dragged to be lifted in bed. In order to prevent these three interrelated risk factors, all the preventive interventions mentioned here must be implemented. This means that preventive interventions are interrelated and must be implemented together because risk factor they prevent are interrelated.

Similarly, all the significant risk factors in multivariate analysis are also interrelated with each other and with PUs. For example, severity of illness (number of underlying medical conditions) can cause low haemoglobin level (Theaker et al., 2000). According to multivariate analysis, these last two are related to developing PUs. This also implies to other risk factors significant in multivariate analysis in this study, with many examples in literature supporting these interrelations. Again, these interrelations between risk factors and between PUs and risk factors form a multifactorial web that enhances the understanding of PU risk. In order to prevent PUs all risk factors with their interrelations must be taken into consideration. Intervening to prevent one risk factor is not enough.

Finally, it is important to note that significant interventions and risk factors in this study do not form all the web of causation. This study only analyzed variable that were available in medical files in a single clinical setting. Other risk factors or interventions that were not included may form a part in this web, therefore must also be considered.

5.6 Chapter summary

This chapter seeks to clarify the usefulness, strengths and weaknesses of the methodological approach used in this study, and to shed light on the novel contributions of this study to the body of knowledge in this area of inquiry. Interpretations of the

study's main findings in view of previous literature and the study's conceptual framework were also among the discussed issues in this chapter.

The present study was based on a retrospective matched case-control design that retrospectively described and compared two groups of patients through using data extracted from medical records. Strengths of the current study were attributed to the inherent strengths of the study design, also to data collection procedure implemented by the researcher. The most important strengths for using this design were the considerable saving in time and resources and eliminating the interference of Hawthorn effect. The most important weaknesses in the study came from the use of retrospective data which relies on the accuracy of health care professional in recording information related to the care process.

One of the novel contributions to the body of knowledge in this study is also designated to the methodological approach used. This approach is the first to be used in this area of inquiry. Another contribution of this study, that it tried to overcome some of the shortcomings present in previous studies in the same area of research. These shortcomings included: focusing only on a specific group of patients e.g. patients with restricted mobility, including only coded data from medical files, excluding grade one PU and including patients at risk according to a RAS. The special statistical algorithm (purposeful selection macro) which was used to fit the multivariate model is also another novel approach of this study. This study is the first to use such approach in this specific area of research. The use of this algorithm reflects more accuracy in reaching the final results because it uses criteria that does not only depend on significant level of the variables as other stepwise algorithms do.

Retrospective nature of the study affected results interpretation and usability. Preventive interventions that were shown to be associated with PUs prevention cannot be directly implemented in the clinical setting. Likewise risk factors that were associated with PUs cannot be directly used to assess risk. Results can be recommended as ammunition for future prospective research.

Chapter Six: Limitations, Recommendations and Conclusion

6.1 Introduction

This study used a new approach to investigate PU preventive interventions and risk factors. The aim of using this approach was to effectively answer the research questions and overcome a number of shortcomings that were present in previous literature in the same area of inquiry.

This chapter presents the limitations of the study that were evident during the course of the study in order to be overcome in future research. Also, this chapter presents recommendations for both health care practitioners and researchers in order to draw attention for a number of preventive interventions to be utilized in practice and future research. Contributions of this study to the body of knowledge in the area under investigation were also summarized.

A general conclusion of the study was provided at the end to give a clearer picture regarding the interpretation of the results.

6.2 Study limitations

Every research study tries to use the best available data to answer the research question(s) in terms of the research design used. However, some factors that can affect the research findings are inevitable, even though maximum effort is made to reduce the effect of such factors. These factors could be attributed to inherent limitations of the study design itself, or to other details within the study that can affect its findings. The

current study manifested a number of strengths through using a matched case-control design; nevertheless, a number of limitations are evident. These limitations should be considered in future research. Limitations of this study include:

- **Using a retrospective data**

Retrospective data is relatively easy and inexpensive to collect. Nevertheless, using retrospective data has some limitations in respect to its accuracy (Clark, 2008). The current study relied on retrospective data recorded by nurses and other health care professionals to draw results regarding preventive interventions and risk factors. As a consequence, the accuracy of the study results relied on the accuracy of the collected retrospective data. Measures applied during data collection procedure in addition to variables operational definitions can augment the accuracy of the results to an extent, but not completely.

In addition to inaccuracy, another limitation that is attributed to retrospective data in medical records that could affect the results is missing data. This limitation could be due to the nature of nursing care, which may sometimes include in-between activities that are not recorded. For instance, patients recorded to be positioned every four hours may have occasional turns in-between if the nurse noted that the patient was in an uncomfortable position (De Laat et al., 2006b). These two limitations attributed to the nature of retrospective data from medical records can affect the external validity of the study finding. Due to these limitations findings of the study could not be directly recommended to be used in clinical setting. Further validation through research should be sought first.

- **Data source**

This study used medical records as the source of data to answer research questions and test the hypotheses. One possible problem with using medical records as a source of data is that medical records tend only to record routinely occurring data (Reed et al., 2003).This may result in the omission of some important occasional data that is not routinely recorded, including some PU preventive interventions or other risk factors that can interfere with the study results.

- **Data collection site**

All the data in this study were collected from a single clinical setting. Other clinical settings may have different interventions used and different patients' characteristics. Therefore, other effective interventions or risk factors could be revealed.

- **Different products under one classification**

In this study some products that had different manufacturers with different compositions were grouped under one category. These were: alternating mattresses, static mattresses, barrier creams, moisturizing creams and seating cushions. Although these products were meant to prevent PUs using the same principle; but each product is made from different materials or have different compositions. As a result these products may have different effectiveness in protecting from PUs. If these products were evaluated separately they could have different effectiveness for protecting from PUs.

6.3 Recommendations

Results of the current study draw attention to the importance of a number of PU preventive interventions in addition to risk factors through using a new approach based

on matching a number of Waterlow sub-scores. In the same time, it addressed a number of shortcomings in previous studies in the same area of research through using a robust methodological approach both in data collection and analysis, though retrospectively. The present study supports the holistic approach in prevention and risk assessment through using a conceptual framework that supports multi-factorial causation.

Although some limitations were evident in the course of this study, it is nevertheless considered an innovative valuable work for both nursing practitioners and researchers. Findings from this study could be used as a base to draw some recommendations for practice and research.

6.3.1 Recommendations for nursing practitioners

This study created a number of recommendations that can improve nursing practice in the area of PU prevention and risk assessment. These recommendations include:

1- Documented preventive interventions in medical files did not include interventions to protect particular body areas from pressure (i.e. heels). In this context, nurses are recommended to implement interventions that can relieve pressure and protect from shear and friction to all body areas, not just concentrating on particular body areas.

2- In this study simple and easy preventive measures were significant in preventing PUs (i.e. sitting in a chair, using draw sheet to mobilize and turning every four hours). Other expensive and high tech interventions like using alternating mattresses and electric profiling bed were insignificant. This does not rule out their use, because they had some evidence in literature to support their use, nor that only significant interventions should be employed. The conceptual model

used in the study imposes that different risk factors that form the web of causation must be identified and appropriate interventions must be applied to break this web of causation. Accordingly, nurses are recommended to use a combination of preventive interventions that can break this web of causation in order to effectively prevent PUs.

3- The role of TVN was underestimated in this particular clinical setting. Patients were only referred to TVN only for advanced ulcers (grades three and four). Patient under risk and free of PU were not referred. In this domain nurses are recommended to refer patients under risk to TVN or at least consult her/him for proper prevention strategies.

4- A number of PUs risk factors that were significant in this study were found in routinely collected data (e.g. level of activity in bed). As a consequence, nurses are recommended not to ignore any piece of information related to patient assessment because it may relate in a way or another to PU risk factors.

Incomplete documentation of some information, especially in the area of PU prevention, was noticed. Some interventions have not been documented properly. This could affect the process of prevention. Other nurses revising the medical file could not continue implementing the same preventive interventions because they were not clearly documented. This in turn could debar the patient from this intervention. In this context, nurses are recommended to properly document their work, not just for liability reasons but to continue the care process or to replace ineffective intervention with other effective ones.

6.3.2 Recommendations for future research

Based on limitation of this study; some recommendation for future research could be produced in order to validate the results of this study. These recommendations include:

1- Depending on prospective data decrease the chance of inaccuracy compared to depending on retrospective data from medical records. Through using this study approach; data could be directly collected prospectively by a team of trained nurses or researchers in order to ensure a higher accuracy of data. In this situation the most reliable prospective study to identify preventive interventions or risk factors is an RCT. This can increase both reliability and external validity of the findings.

2- Increase the number of subjects recruited in similar studies. This could achieve a higher statistical power and increase reliability of the results.

3- Higher control of risk factors that can affect results of the study could be achieved by matching on all of the Waterlow sub-scores or the sub-scores of any other RAS.

4- Data in this study were collected from a single clinical site. Other clinical sites could have patients with different characteristics (different risk factors), also could be implementing different PUs preventive methods. A multisite study using the same matching approach could result in more validated findings.

5- Interventions that were found in this study to be associated with PU prevention could be investigated in future RCTs, especially that some of these interventions were under researched compared to other preventive interventions reported in literature.

6.4 Contribution to knowledge

This section demonstrates the unique contribution of this thesis to the body of knowledge in the area of PU prevention and risk assessment. These contributions include:

- Using a retrospective matched case-control design based on matching a number of pre-established risk factors (Waterlow RAS sub-scores) between two groups of patients, one with hospital- acquired PU the other with none. This risk adjusted approach to explore preventive interventions and risk factors is the first to be used in this area of inquiry.

- Another contribution of this study was that it overcomes some of the shortcomings present in previous studies in the same area of research. These shortcomings included: excluding PU stage one, focusing only on a specific group of patients, depending on an administrator to electronically extract specific data from electronic medical files, including only patients at risk of PUs and using univariate analysis instead of multivariate analysis to analyze the sum of risk factors or interventions.

- Using a special multivariate algorithm to analyze data (i.e. purposeful selection macro). This algorithm is the first to be used in the area of PU prevention and risk factors.

- The present study supports the role of a PU preventive intervention that was underestimated in literature (i.e. draw sheets), also it is the first study to purposely explore the role of dieticians and physiotherapists in PU prevention.

6.5 Conclusion

A plethora of studies were previously conducted that investigated PU's preventive interventions and risk factors, though through different methodological approaches. Current inquiry aims at investigating these two points in a new different approach, in an effort to add new evidence to the body of knowledge in this area of inquiry. The study worked to achieve its aims in exploring effective PU preventive interventions and associated risk factors in terms of acquiring PUs as an outcome. This could differentiate between effective and ineffective prevention measures, whilst simultaneously distinguishing which risk factors are associated with PU development.

The study concludes that the interventions most likely associated with PU prevention were those that decreased the duration of interface pressure or intensity of friction and shear forces. Changing patient position, albeit less frequently (every four hours instead of two) decreased interface pressure duration and spared patients extra friction and shear forces. Sitting imposes high contact pressure at buttocks, thighs and often sacrum. The duration of pressure application will be reduced mainly by getting out of chair (walking back to bed). Draw sheets used to mobilize patients were responsible for decreasing the intensity of shear and friction forces. Other preventive methods related to decreasing the intensity of interface pressure (e.g. mattresses), or those responsible for increasing tissue tolerance for pressure (e.g. dietician referral) were not associated with prevention in this study. This does not prove the ineffectiveness of these interventions, but supports other interventions as more effective within this study's data set.

In the area of risk factors, this study found a number of risk factors that were independently associated with developing PUs. Again, this does not prove that these are

the only risk factors that can be associated with PUs, but emphasizes that these factors were particularly associated with PUs within the study data set.

Findings from this study suggest a number of interventions to be effective in PU prevention, and a number of risk factors that can predict risk of PUs. Findings were based on statistical association between acquiring PUs and the independent variables (preventive interventions and risk factors). This cannot constitute a cause and effect relationship, due to the retrospective nature of data analyzed. It only supports the association between a number of interventions and risk factors in preventing or predicting PUs. This can help in opening new doors for further research to investigate these interventions and risk factors employing the same approach used, but in a prospective manner.

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Appendices

Appendix: A

Hawker's Assessment Tool*

Author and title:					
Date:					
	Good (4)	Fair (3)	Poor (2)	Very poor (1)	Comment
1. Abstract and title					
2. Introduction and aims					
3. Method and data					
4. Sampling					
5. Data analysis					
6. Ethics and bias					
7. Findings/results					
8. Transferability/generalizability					
9. Implications and usefulness					
Total score*					

***Total score interpretations:**

< 10: Very poor

10-19: Poor

20-29: Fair

30-40: Good

1. Abstract and title: Did they provide a clear description of the study?

Good	Structured abstract with full information and clear title.
Fair	Abstract with most of the information.
Poor	Inadequate abstract
Very Poor	No abstract

2. Introduction and aims: Was there a good background and clear statement of the aims of the research?

Good	Full but concise background to discussion/study containing up-to date literature review and highlighting gaps in knowledge. Clear statement of aim AND objectives including research questions
Fair	Some background and literature review. Research questions outlined.
Poor	Some background but no aim/objectives/questions, OR Aims/objectives but inadequate background
Very Poor	No mention of aims/objectives No background or literature review.

3. Method and data: Is the method appropriate and clearly explained?

Good	Method is appropriate and described clearly. Clear details of the data collection and recording
Fair	Method appropriate, description could be better. Data described.
Poor	Questionable whether method is appropriate Method described inadequately. Little description of data
Very Poor	No mention of method, AND/OR Method inappropriate, AND/OR No details of data.

4. Sampling: Was the sampling strategy appropriate to address the aims?

Good	Details (age/gender/race/context) of who was studied and how they were recruited. Why this group was targeted. The sample size was justified for the study. Response rates shown and explained
Fair	Sample size justified. Most information given, but some missing
Poor	Sampling mentioned but few descriptive details.
Very Poor	No details of sample

5. Data analysis: Was the description of the data analysis sufficiently rigorous?

Good	Clear description of how analysis was done. Qualitative studies: Description of how themes derived/respondent validation or triangulation. Quantitative studies: Reasons for tests selected hypothesis driven/ numbers add up/statistical significance discussed.
Fair	Qualitative: Descriptive discussion of analysis. Quantitative
Poor	Minimal details about analysis
Very Poor	No discussion of analysis

6. Ethics and bias: Have ethical issues been addressed, and what has necessary ethical approval gained? Has the relationship between researchers and participants been adequately considered?

Good	Ethics: Where necessary issues of confidentiality, sensitivity, and consent were addressed. Bias: Researcher was reflexive and/or aware of own bias.
Fair	Lip service was paid to above
Poor	Brief mention of issues
Very Poor	No mention of issues

7. Results: Is there a clear statement of the findings?

Good	Findings explicit, easy to understand, and in logical progression. Tables, if present, are explained in text. Results relate directly to aims. Sufficient data are presented to support findings.
Fair	Findings mentioned but more explanation could be given. Data presented relate directly to results.
Poor	Findings presented haphazardly, not explained, and do not progress logically from results.
Very Poor	Findings not mentioned or do not relate to aims.

8. Transferability or generalizability: Are the findings of this study transferable to a wider population?

Good	Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high level in Question 4 (sampling).
Fair	Some context and setting described, but more needed to replicate or compare the study with others, PLUS fair or higher level in Question 4.
Poor	Minimal description of context/setting
Very Poor	No description of context/setting

9. Implications and usefulness: How important are these findings to policy and practice?

Good	Contributes something new and/or different in terms of understanding/insight or perspective. Suggests ideas for further research Suggests implications for policy and/or practice
Fair	Two of the above (state what is missing in comments).
Poor	Only one of the above
Very Poor	None of the above

***Source: Hawker et al. (2002)**

Appendix: B

Summary of PU risk factors studies

Study/setting	Design	Variables analyzed	Limitations	Significant risk factors	Remarks	Hawker et al. (2002) Quality score
- (Schoonhoven et al., 2005) - Acute care	Prospective cohort	Demographics, medical speciality, Mobility, activity, incontinence Skin condition, history of PUs Friction and shear, diagnosis,	No power analysis, Univariate analysis used, Didn't include PU grade one	Friction and shear, Long surgeries, Presence of malignant condition	All patients had standard PU prevention care.	33: Good brief mention about statistical procedure
- (Perneger et al., 2002) - Acute care	Prospective	Age, gender, activity, mobility Physical status, mental status, incontinence, friction and shear, skin moisture, dietary intake, sensory perception	Patients followed up for only five days	Age, mobility, mental status, friction and shear	Mental status belongs to Norton scale, friction and shear and mobility belongs to Braden scale. Multivariate analysis used.	32: Good No mention of ethical issue

- (Jones et al., 2005) - Community	Survey	Demographics, weight, hours out of bed, alcohol consumption, tobacco use, employment status, incontinence, physical activity	Small sample (86), used univariate analysis.	Incontinence, male gender, increased body weight, use of alcohol and tobacco, unemployment, incontinence problems, decreased physical activity	This study included spinal injury patients living at home.	32: Good Findings not clear
- (Anthony et al., 2000b) - Acute care	Observational retrospective	Serum albumin, serum sodium, Waterlow scale total score	Study limited to older patients.	Serum albumin and water low total score	Multivariate analysis used. Large sample size (n=733)	33: Good Minimal description of setting
- (Fogerty et al., 2008b) - Acute care	Retrospective survey	Age, race, gender medical diagnosis	Depending on retrospective data. Not all patients were free of PUs on admission.	African American race, advanced age, disorders of skin, organ failure, infection	Multivariate analysis used.	29: Fair No ideas for future work mentioned
- (Capon et al., 2007) - Long term care	Cross sectional survey	Age, gender, blood pressure, history of trauma, history of stroke, psychiatric illness, neurological disease, DM, respiratory diseases, cardio vascular disease, medications used, length of stay, previous care setting, mental status, Alzheimer's disease, activity of daily living.	PU prevalence instead of incidence was used to evaluate risk factors.	Cardio vascular disease, decreased ability to do activity of daily living.	Patients not followed in this study, risk factors and PU status were cross sectional. Activities of daily livings were measured through a total score.	28: Fair Sample not well described

- (Wann-Hansson et al., 2008) - Acute care	Cross sectional survey.	Age, gender, hospital unit, length of stay, friction and shear, sensory perception, activity, mobility, moisture, nutrition, incontinence.	Patients with acquired PU were compared to patients with pre-admission PU instead of patients free of PUs.	Older age, decreased level of activity, friction and shear,	Level of activity and friction and shear were defined as in Braden scale.	28: Fair Ethical issues not well described
- (Horn et al., 2004) - Long term care	Retrospective cohort	Age, dehydration, diet type, DM, tobacco use, incontinence, previous PU, deterioration in activities of daily livings, requiring assistance with activity of daily living, mobility, new resident, weight loss, oral eating problems, poor meal intake, gender, severity of illness, anti depressants, cognitive ability catheter use, nurse staffing characteristics.	Not all patients were free of PUs on admission. PU grade one not included. Univariate analysis used.	Increased severity of illness, previous PU, new resident, weight loss, oral eating problems, antidepressants use, registered nurse time > 15 minutes/day per patient, nurses turnover, assistant nurse time > 2 hours/day per patient	All patients were at risk of PUs according to Braden scale. Severity of illness was measured through a scale.	32: Good Not all components clear to replicate the study
- (Ash, 2002) - Spinal cord injury unit	Retrospective records review	Age, gender, place of spinal cord injury, length of hospital stay. Severity of spinal cord injury, presence of additional injuries e.g. hip fracture, surgical stabilization of the neck, presence of tracheotomy on admission, time between injury and admission to the spinal unit	Using retrospective data, using univariate analysis Resulted restricted to spinal cord injury patients	Increased length of hospital stay, sever spinal cord injury, neck stabilization surgery, tracheotomy on admission, delay in transferring to spinal cord unit.		32: Good No clear concideration for ethical issues

- (Papanikolaou et al., 2003) - Acute care	Retrospective records review	Incontinence, body mass index, appetite, mobility, skin condition, tissue malnutrition, socio demographics, neurological deficits, malignancy, kidney disease, Cerebrovascular disease , hospital transfers	Retrospective data used, level of care was not assessed for the patients.	Poor appetite, occasional incontinence, discoloured skin, broken skin, decreased mobility level, female gender, hospital transfers.	Multivariate analysis used. Risk factors studied were those defined by Waterlow scale.	28: Fair Sampling method not clear
- (Nijs et al., 2009) - Intensive care	Prospective descriptive	Demographics, reason for admission, body mass index, immobility, time of surgery, activity, physical restraints, body temperature, skin humidity, medications, consciousness, haemoglobin, creatinine, bilirubin, platelets , sitting in chair, haemodialysis.	Patients followed only during their stay in intensive care. PU grade one not included.	Previous vascular disease, using Dopamine or Dobutamine, intermittent haemodialysis, mechanical ventilation	Multivariate analysis used.	30: Good Discussion of ethical considerations not clear
- (Theaker et al., 2000) - High dependence unit	Prospective	Anaemia, coagulopathy, DM, dopamine, Dobutamine, Epinephrine, incontinence, length of stay at hospital, moisture, norepinephrine, oedema, pain, peripheral vascular disease, pain, low nutritional intake, APACHE (score of deteriorated health) smoking, inability to turn, steroids, albumin.	Large number of factors studied with no calculation of power of analysis.	Norepinephrine infusion, increased length of stay, faecal incontinence, anaemia, high APACHE score indicating a deteriorated health.	Risk factors were assessed every 8 hours. Multivariate analysis used.	31: Good No clear description of variables

- (Lindgren et al., 2004) - Acute care	Prospective comparative	Age, gender, general physical condition, mobility, activity, moisture, food and fluid intake, sensory perception, friction and shear, body temperature, serum albumin, length of stay at hospital, weight, blood pressure, surgical treatment	Prevention was not standardized for patients in the study. Univariate analysis used. Low incidence of PUs (62 out of 530 developed PUs).	Immobility, increased length of stay at hospital, lower systolic blood pressure, older age, undergoing surgery, lower weight.	Multivariate analysis used.	32: Good No discussion of ethical issues
- (Nonnemacher et al., 2009) - Acute care	Retrospective survey for medical records	Smoking, malignancy, pain, hydration, nutrition, weight, night sweat, fever, metabolic diseases, inflammatory bowel disease, vasoconstrictive drugs, sedative drugs, heart failure, hypertension, inhibited pain, temperature or pressure sensation, incontinence, arterial disease, skin problems, history of PUs, friction or shear	Only 1.8% of patients developed PUs.	Limited mobility, malignant condition, pain, dehydration, impaired nutrition, sedative drugs, arterial disease, history of PUs, skin problems, friction and shear.	Multivariate analysis used.	29: Fair No clear description od data collection procedure

- (Baumgarten et al., 2003) - Acute care for patients undergoing hip surgery	Retrospective records review	Age, gender, race, preadmission residence, type of hip fracture, type of surgical procedure, type of anaesthesia, stay in the intensive care unit, comorbidity index (to indicate severity of illness), time before surgery, lab results, malnutrition or cachexia, medications, patients ability to do activities of daily livings,	Results restricted to older patients admitted with hip fracture and undergoing hip surgery.	Stay in intensive care unit, long wait before hip surgery, long surgery, use of general anaesthesia, impairment in doing activities of daily livings, stay in intensive care, and presence of malnutrition or cachexia.	Multivariate analysis used. Activities of daily livings were assessed through using a scale.	30: Good Sample size not justified
- (Kwong et al., 2009) - Older residents living in nursing homes	Prospective cohort	Demographics, smoking, mode of feeding, using sedatives, activities of daily livings, comorbidities, sensory perception, mobility, moisture, activity, friction and shear, body built, skin type, nutrition.	Nurses were aware of this study taking place; consequently this can decrease the incidence of PUs and reduce biased results. Results restricted to older age patients.	Immobility, presence of kidney impairment and stroke	Multivariate analysis used.	30: Good No clear description of variables

- (Reed et al., 2003) - Acute care	Multisite Longitudinal cohort	Serum albumin, faecal incontinence, confusion, age, sex, race, skin integrity, nutritional status, incontinence, medical diagnosis, fever, hypotension, haemoglobin, tachycardia, tachypnea, increased white blood cells.	Results restricted to patients with activity limitations. Grade one PU was excluded.	Low albumin, presence of confusion, having a do not resuscitate order, malnourishment, requiring a urinary catheter.	Multivariate analysis used. Large sample size (n=2771)	29: Fair No clear description of data collection procedure
- (Allman et al., 1986) - Acute care	Cross sectional survey	Demographics, lab results, medical diagnosis, level of consciousness, mobility, activity level, faecal and urinary incontinence, nutritional status.	Patients with risk for PUs were compared to patients with acquired PUs at a cross sectional point in time and not followed from admission.	Hypoalbuminemia, faecal incontinence, presence of fractures.	Multivariate analysis used. Norton scale was used to define level of consciousness, activity and mobility. Large sample size(n=634)	28: Fair Not enough details about ethical issues
- (Hatanaka et al., 2008) - Acute care for patients with respiratory disorders	Prospective	Demographics, Braden scale items, complete blood count with differential, albumin, c-reactive protein, urea, creatinine, liver function test.	Focused on a particular group of patients with deteriorated health.	Low albumin, low haemoglobin, elevated C-reactive protein, older age, gender (female).	Multivariate analysis used. 38 patients out of 149 developed PUs.	32: Good Some findings were not clearly explained

- (Kemp et al., 1990) - Acute care for surgical patients	Prospective	Time spent in surgery, hypotensive episodes during surgery, age, serum albumin, total protein level, preoperative Braden score, using extracorporeal circulation during surgery	Results restricted to patients undergoing surgery. Low incidence of PUs, only 15 patients out of 125 developed PUs.	Using extracorporeal circulation during surgery, longer time spent on operation table, older age.	Multivariate analysis used.	28: Fair No clear description for future work
- (Halfens et al., 2000) - Acute care	Prospective multi-centre study	Braden score items, incontinence, extreme sweating, smoking, mental health, physical health, body mass index, history of PUs, DM	Not sufficient prevention as the author notes were used with patients in the study.	Older age, friction and shear, sensory perception, moisture	Multivariate analysis used.	31: Good Data collection procedure not clear
-(Lindholm et al., 2008) - Acute care for patients undergoing hip surgery	prospective	Braden scale items, demographics, type of fracture, pain on admission, smoking, blood pressure, haemoglobin, dehydration and hunger on admission, body mass index, comorbidity, time waiting for surgery, use of traction, type of anaesthesia, duration of surgery.	Not all patients followed until discharge. Correlation statistics used only. Results restricted to hip fracture patients undergoing surgery.	Older age ($\geq$ 71 years), dehydration, moist skin, total score of Braden, presence of friction, decreased sensory perception) impaired nutrition, pulmonary, presence of comorbidities i.e. pulmonary disease and DM.	Presence of friction and sensory perception were defined according to Braden scale. Dehydration was diagnosed through skin fold test, dray lips and thirst.	29: Fair No clear considerations for sample size

- (Haleem et al., 2008) - Acute care for patients undergoing hip surgery.	Retrospective survey	Age, sex, residence before admission, mobility, mental status, physical status, comorbidities, using steroids, smoking, haemoglobin, type of hip fracture, time waiting for surgery, length of surgery, type of anaesthesia, falling blood pressure Intraoperetively,	Using retrospective data. Using univariate analysis. Low period prevalence of PUs (3.8%).	Older age, impaired mental status, DM, low haemoglobin, decreased mobility, low blood pressure Intraoperetively, fracture for extra-capsular neck of femur, increased time waiting before surgery, impaired physical status.	Mobility, physical status and mental status were measured using scales from literature.	27: Fair Data collection procedure not clear
- (Sayar et al., 2009) - Intensive care	Prospective descriptive	Age, gender, types of paralysis, mechanical ventilation, deformities, contractures, amputations, chronic diseases, oedema, surgery, incontinence, use of steroids or diuretics, level of consciousness, level of activity, level of cooperation, method of nutrition, body mass index, history of PUs, haemoglobin, albumin, total protein, c-reactive protein, urea, creatinine, leucocytes.	Note all variables analyzed were measured adequately as the author notes. Small incidence of PUs (20 out of 140 developed PUs).	Increased length of hospital stay, decreased level of activity.	All patients in the study were at risk according to Waterlow scale. All patients had adequate PUs preventive measures. Multivariate analysis used.	30: Good No clear description of how analysis was done

- (Allman et al., 1995) - Acute care	Prospective cohort	Age, race, skin condition, smoking, history of PUs, comorbidity, blood pressure, albumin, creatinine, lymphocyte count, haemoglobin, diarrhea, mobility, mental status, level of consciousness, functional status, disease severity incontinence, body weight, triceps skin fold, food intake.	PU grade one was not included. Results restricted to patients with activity limitations. Only 37 out of 286 patients developed PUs.	Nonblanchable erythema, lymphopenia, immobility, dry skin, decreased body weight.	Multivariate analysis used. Mobility and mental status measured according to Norton scale. Level of consciousness was measured as alert vs. others.	28: Fair Sample size not justified
- (Manzano et al., 2010) - Intensive care for mechanically ventilated patients.	Prospective cohort	Age, sex, study period, body weight , type of intensive care unit, length of hospital stay, severity of illness, diagnosis, organ failure, presence of septic shock or respiratory distress syndrome, pneumonia, total time for mechanical ventilation, total time in intensive care.	Results restricted to mechanically ventilated patients. PU grade one was not included.	Respiratory failure, cardiovascular failure, increased length of mechanical ventilation, winter period, older age.	Multivariate analysis used.	30: Good No clear description for future work

- (Rademakers et al., 2007) - Acute care for older patient undergoing hip surgery	Retrospective review of medical files.	Age, sex, severity of illness score, type of hip fracture, length of hospitalization, time waiting before surgery, time to mobilization after surgery, type of anaesthesia, post operative hospital stay, underlying comorbidities, post operative complications,	Results restricted to older patient with hip fracture undergoing surgery. Using retrospective data.	Presence of urinary tract infection, DM, post operative hip dislocation, increased severity of illness, increased time waiting for surgery.	Multivariate analysis used.	26: Fair No clear description of data collection procedure
- (Vanderwee et al., 2009) - Nursing homes	Retrospective (secondary data analysed from previous study).	Age, sex, dm, history of stroke, body mass index, incontinence, using sleeping medications, presence of contractures, body temperature, blood pressure, Braden scale items.	Results restricted to older patients in nursing homes.	Hypotension, presence of contractures, previous stroke.	All patients in the study had grade one PU (study was to identify risk factors of deteriorating PU grade one). Multivariate analysis used.	34: Good More details of future work could be provided
- (Takahashi et al., 2011) - Older adults in community	Retrospective cohort	Demographics, underlying comorbidities	Retrospective data used. Incidence of PUs is low in the study (2.9%). Results restricted to older adults living in community	Older age, male gender, long term care facility admission, history of PUs, DM, cataracts, kidney insufficiency, falls, peripheral vascular disease.	Multivariate analysis used.	28: Fair Setting of the study is not enough described

- (Westergren et al., 2001) - Stroke rehabilitation unit	Prospective observational	Sitting position, manipulate food on plate, transfer food to mouth, can open or close mouth, can manipulate food in mouth, swallowing difficulties, eats less than three quarters of meal, alertness, apparent eating speed, number of eating difficulties.	Results restricted to patients with stroke.	Alertness, swallowing difficulties, eats less than three quarters of served food, apparent slow eating.	Eating difficulties were related to malnutrition thus to developing PUs in this study. Multivariate used.	30: Good Variables could be better described
- (Banks et al., 2009) - Acute care	Multicentre cross sectional audit	Presence of malnutrition	Using convenience sampling.	Presence of malnutrition was associated with acquiring PU.	Age, sex, medical speciality and facility location were controlled using multivariate model.	29: Fair No justification for sample size
- (Iizaka et al., 2010) - Community	Prospective	Malnutrition determined by the presence of at least one of the following: body mass index < 18.5, serum albumin less than 3g/dl, haemoglobin < 11 g/dl.	Malnutrition assessment is restricted to a limited number of factors.	Presence of malnutrition according to mentioned criteria.	Other PUs risk factors in this study were controlled through a multivariate model.	30: Good Data collection procedure not well described

- (Boyle and Green, 2001) - Intensive care	Multi-centre prospective observational	Level of consciousness (coma, unresponsiveness, paralyzed and sedated), cardio vascular instability, obesity or under weight, faecal incontinence, gender, hospital was the study conducted.	Not all patients were free of PUs on admission (this can increase their PU risk)	Decreased level of consciousness cardio vascular instability.	Used multivariate analysis. Level of consciousness was defined as: coma, unresponsiveness, paralyzed and sedated.	28: Fair Aims of the study not clearly stated
- (Fernandes and Caliri, 2008) - Intensive care	Exploratory descriptive	Total Braden score, Glasgow comma scale, age, gender, skin colour (white, brown, black), body mass index, length of stay at hospital	Small sample (48 patients. Using univariate analysis.	Increased length of stay at hospital, lower Braden scores (indicating increased risk of PUs), lower Glasgow comma scale (indicating decreased level of consciousness).		29: Fair Not enough description of study variables
- (Martz et al., 2010) - Community for spinal cord injury patients.	Self report questionnaire	Age, gender, spinal cord injury level, anxiety, depression, engagement, disengagement-coping, social support.	Using a self report questionnaire, the researcher didn't examine patients PUs. Results restricted to spinal cord injury patients.	Disengagement-coping was associated with less PU occurrence.	Multivariate analysis used. Depression predicted more severity of PU but not occurrence.	24: Fair Data collection procedure not clear

- (Correa et al., 2006) - Acute care for ambulatory spinal cord injury patients	Retrospective Case control study	Age (> 40 years), time since spinal injury (> 5 years), body type (thin, obese), complete spinal lesion, complete paraplegia, incontinence, smoking, presence of spasticity, ability to regularly stand up, presence of a life partner, employment, problems in social interaction, sexuality, anxiety, depression, personal disorder, poor family relations, addiction on alcohol, brain damage.	Small sample number (41 patients). Using multivariate analysis. Results restricted to spinal cord injury patients.	Time since injury (> 5 years, presence of complete spinal lesion, presence of complete paraplegia, inability to practice regular standing.		26: Fair No consideration of sample size
- (Smith et al., 2008) - Community	Survey using self report questionnaire.	Gender, age, race, place of residence, level of spinal cord injury, level of spinal cord injury, frequency of depressive symptoms, asthma, DM, stroke, coronary heart disease, blood pressure, smoking, alcohol use.	Researcher didn't personally examine patients for presence of PUs (a self assessment questionnaire was used instead).	Presence of DM, smoking, increased spinal injury duration, reporting depressive symptoms.	Multivariate analysis used.	26: Fair Data collection procedure not described

- (Mertens et al., 2008) - Nursing homes and hospitals	Cross sectional	Age, sex, items of the care dependency scale (eating, drinking, body posture, day/night pattern, getting dressed, body temperature, hygiene, avoidance of danger, communication, contact with others, since of rules, daily activities, recreational activities, learning ability)	Using a cross sectional design impair reaching a case and effect relation between PUs and risk factors.	Inability to obtain body posture, impaired mobility, increased body temperature, impaired learning ability, inability to do recreational activities.	Multivariate analysis used.	30: Good No consideration for sample size
- (Bergquist, 2001) - Nursing homes	Retrospective cohort	Demographics, Braden scale sub-items (sensory perception, activity, mobility, nutrition, friction and shear)	Using retrospective data.	Very limited mobility, presence of skin moisture, presence of friction and shear.	Multivariate analysis used.	30: Good More explanation of the findings needed
- (Mino et al., 2001) - Acute care for older patients.	Case control	Sub-items of Braden scale, continence, turning in bed, oral intake, setting up, DM, stroke, albumin level, cholesterol level, lymphocytes count, haemoglobin level.	Results restricted to older patients group.	Impaired self positioning in bed, decreased serum albumin level.	Age and sex were matched between the study and control groups. Multivariate analysis used. Large sample size (n=468)	29: Fair Aims of the study not clearly stated

- (Anthony et al., 2002) - Acute care	Retrospective for medical records	Ethnic groups, age, gender	Other confounding factors related to ethnicity were not controlled e.g. religion, country of origin	Older age.	Multivariate analysis used.	33: Good More details of the study setting is needed
- (Baumgarten et al., 2004) - Nursing homes	Prospective cohort	Race (black or white), age, sex, number of dependencies in daily activities, bedridden, PU on admission, incontinence, dementia, health insurance (is the patient on Medicaid), facility characteristics (beds number, profit or non-profit facility, facility in urban or rural area).	Results restricted to older people. PUs frequency was obtained from medical records which creates some uncertainty about the accuracy of data.	Black race, increase dependency doing activity of daily living, presence of PU on admission.	Multivariate analysis used. Dependency in daily living was assessed using a scale ranging from 0 to 6.	30: Good No discussion for future work
- (Mecocci et al., 2005) - Hospitals and community hospitals.	Multicentre prospective observational	Demographics, objective diagnostic measures (including laboratory results), medications, medical diagnosis on admission and discharge, comorbidity, cognitive status, functional status (activity of daily livings), quality of care, history of falls.	Results restricted for older age. Study included patients with PUs on admission.	Cognitive impairment, advanced age (> 85 years), length of stay (> 3 weeks), severe disability.	Multivariate analysis used.	32: Good Ethical considerations not clearly discussed

- (Horn et al., 2002) - Long term care facilities	Multicentre retrospective cohort.	Age, gender, severity of illness score, Braden score, activity of daily livings, cognitive ability, mobility, incontinence, laboratory tests, nutritional status, PU on admission, medical diagnosis,	Using univariate analysis. Comparisons for PU risk factors were made between patients who developed a new PU and patients who had an existing PU on admission.	Gender (female), decreased mobility, cognitive impairment, older age.	All patients in the study were at risk for PU according to Braden score or had an existing PU on admission.	30: Good No clear description of all variables in the study was provided
- (Söderqvist et al., 2007) - Acute care for patients with hip fracture	Prospective	Presence of cognitive impairment through using a cognitive dysfunction scale.	Comparing cognitive impairment only as a PU risk factor in univariate analysis. Other risk factors were not taken into considerations.	Acquiring PU is associated with sever cognitive dysfunction.		30: Good No clear description for future work was given

- (Bourdel-Marchasson et al., 2000) - Acute care for older patients	Prospective multicentre	Age, sex, Norton score, activity of daily living, albumin, weight, c-reactive protein, medical diagnosis and comorbidities.	A nutritional intervention was implemented in this study. Some patient had nutritional supplements, others didn't. This could affect significant risk factors.	Low serum albumin at baseline, decreased ability to do activities of daily livings, fracture in lower limb, not receiving a nutritional supplement, Norton score < 10.	Patients unable to move or eat independently were included in study. Multivariate analysis used. Activity of daily living was assessed through a scale. Large sample size (n=672).	29: Fair No clear description for future work was given
- (Lindgren et al., 2004) - Acute care	Prospective comparative	General physical condition, physical activity, moisture, food intake, fluid intake, sensory perception, temperature, albumin, friction and shear, time of hospitalization, gender, age, weight, body mass index, blood pressure, surgical treatment, medical diagnosis, drug treatment, smoking,	Study results restricted to older people. Small incidence of PUs (62 patients out of 530 developed PUs)	Immobility, older age, increase time of hospitalization, surgical treatment, lower weight.	Multivariate analysis used. General physical condition, physical activity, moisture, food intake, fluid intake, sensory perception, temperature, albumin, friction and shear were defined according to risk assessment pressure sore scale.	29: Fair No clear description of the study setting

- (Lindgren et al., 2005) - Acute care for patient undergoing surgery	Prospective comparative	General physical condition, physical activity, moisture, food intake, fluid intake, sensory perception, blood pressure, temperature, albumin, friction and shear, drug treatment, smoking, weight, height, American Society of Anaesthesiologists (ASA) classification or New York Heart Association (NYHA) classification to assess physical status of patient preoperatively.	Results restricted to patients undergoing surgery. Small incidence of PUs (41 out of 286 patients developed PUs).	Gender (female), decreased food intake, deteriorated physical status measured using American Society of Anaesthesiologists (ASA) classification or New York Heart Association (NYHA) classification.	Multivariate analysis used. General physical condition, physical activity, moisture, food intake, fluid intake, sensory perception, temperature, albumin, friction and shear were defined according to risk assessment pressure sore scale.	33: Good Sample size not justified
- (Bergstrom and Braden, 1992) - Nursing facility	Cohort prospective	Braden score, blood pressure, body temperature, anthropometrics, dietary intake, complete blood count, serum albumin, serum total protein, serum iron, iron binding capacity, serum zinc, copper, vitamin C.	Results restricted to older patients.	Lower systolic blood pressure, older age, Lower Braden score (indicating risk), lower body temperature, lower dietary protein intake.	Multivariate analysis used.	34: Good More discussion for future work could be provided

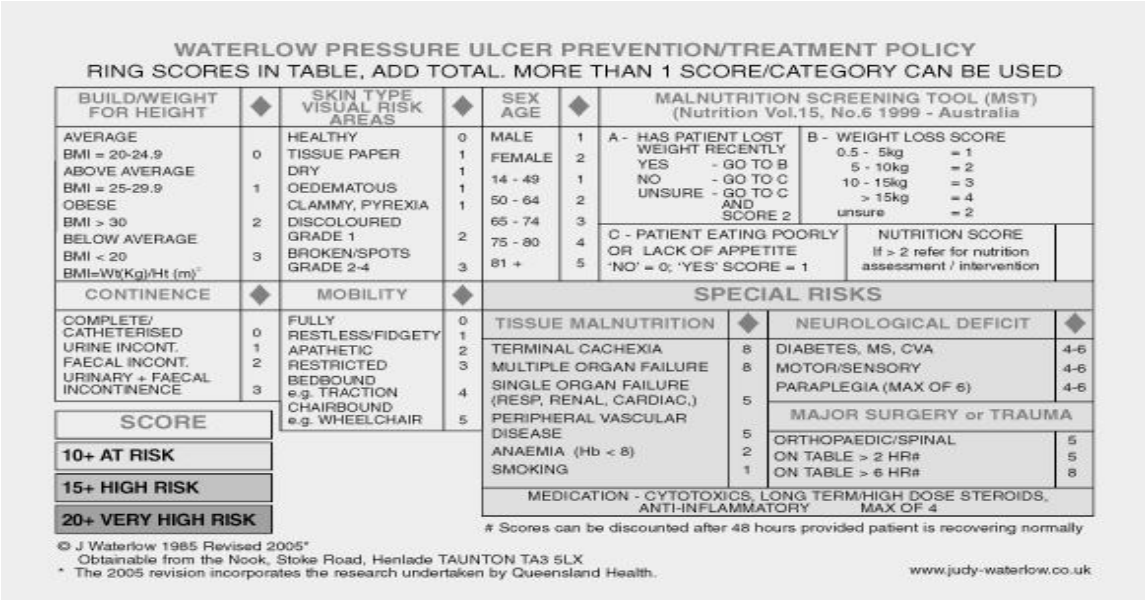
- (Frankel et al., 2007) - Surgical intensive care unit	Retrospective for medical records	Demographics, severity of illness, length of hospital stay, serum creatinine, serum urea, DM, vascular disease, spinal cord injury, paralysis, use of vasopressor medications,	Using retrospective data. Only 3% of patients developed PUs in this study. PU grade was excluded.	DM, spinal cord injury, creatinine >3mg/dl, age > 60 years.	Severity of illness was defined using APACHE scale. Age defined as: > 60 or ≤ 60 years. Creatinine defined as: <3 vs. ≤ 3 mg/dl. Urea defined as: <30 vs. ≤ 30 mg/dl. Multivariate analysis used.	30: Good Description of the study variables could be enhanced
- (Okuwa et al., 2006) - Long term care facility	Prospective cohort	Gender, age, ankle-brachial index (measures blood flow in legs), length of bed confinement, Braden total score, cerebrovascular disease, hypertension, heart disease, DM, respiratory disease, arteriosclerosis, contractures in lower legs, contractures in toe, interface pressure on heel, complete blood count, albumin, c-reactive protein, urea, creatinine, sodium potassium, chloride.	Results restricted to patients confined to bed and older age population. Risk factors investigated are only related to lower extremity PUs. Small incidence of PUs (33 out of 159 developed PUs).	Gender (male), length of confinement to bed, low ankle-brachial index value (indicating a week blood flow in lower extremity).	Multivariate analysis used. Outcome in this study was lower extremity PUs only	30: Good Description of the study setting could be enhanced

- (Gomes et al., 2010). - Intensive care units.	Cross sectional	Gender, age, smoking, skin colour, body mass index, length of hospital stay, length of stay at intensive care unit. Underlying medical condition, medications used, total Braden score	Using a cross sectional design impair reaching a cause and effect relation between PUs and risk factors.	Presence of sepsis, length of hospital stay ≥ 10 days, being at risk according to Braden scale	Multivariate analysis used.	30: Good More description of study setting needed
- (Goode et al., 1992). - Acute care	Observational cohort	Serum albumin, haemoglobin, zinc, vitamins A, C and E., WCC	Small sample number (n=21)	Low concentration of WCC and vitamin C		29: Fair No clear description of all of the study variables
- (Walsh and Plonczynski, 2007). - Community hospital.	Retrospective chart review and prospective patients follow up	Comorbidities, Braden RAS	Identification of risk factors depended on retrospectively reviewing medical files.	Low serum albumin, type two DM, peripheral vascular disease, Braden RAS.	Large sample (n=242).	28: Fair Variables could be better described

Appendix: C

Waterlow, Braden and Norton pressure ulcer risk assessment scales

Front side of Waterlow risk assessment card*



WATERLOW PRESSURE ULCER PREVENTION/TREATMENT POLICY

RING SCORES IN TABLE, ADD TOTAL. MORE THAN 1 SCORE/CATEGORY CAN BE USED

BUILD/WEIGHT FOR HEIGHT		SKIN TYPE VISUAL RISK AREAS		SEX AGE		MALNUTRITION SCREENING TOOL (MST) (Nutrition Vol.15, No.6 1999 - Australia
AVERAGE		HEALTHY	0	MALE	1	A - HAS PATIENT LOST WEIGHT RECENTLY YES - GO TO B NO - GO TO C UNSURE - GO TO C AND SCORE 2
BMI = 20-24.9	0	TISSUE PAPER	1	FEMALE	2	B - WEIGHT LOSS SCORE 0.5 - 5kg = 1 5 - 10kg = 2 10 - 15kg = 3 > 15kg = 4 unsure = 2
ABOVE AVERAGE		DRY	1	14 - 49	1	
BMI = 25-29.9	1	OEDEMATOUS	1	50 - 64	2	
OBESE		CLAMMY, PYREXIA	1	65 - 74	3	
BMI > 30	2	DISCOLOURED GRADE 1	2	75 - 80	4	C - PATIENT EATING POORLY OR LACK OF APPETITE 'NO' = 0; 'YES' SCORE = 1
BELOW AVERAGE						NUTRITION SCORE If > 2 refer for nutrition assessment / intervention
BMI < 20	3	BROKEN/SPOTS GRADE 2-4	3	81 +	5	
BMI=Wt(Kg)/Ht (m)²						

CONTINENCE		MOBILITY	
COMPLETE/ CATHETERISED	0	FULLY	0
URINE INCONT.	1	RESTLESS/FIDGETY	1
FAECAL INCONT.	2	APATHETIC	2
URINARY + FAECAL INCONTINENCE	3	RESTRICTED	3
		BEDBOUND e.g. TRACTION	4
		CHAIRBOUND e.g. WHEELCHAIR	5

SCORE
10+ AT RISK
15+ HIGH RISK
20+ VERY HIGH RISK

SPECIAL RISKS

TISSUE MALNUTRITION		NEUROLOGICAL DEFICIT	
TERMINAL CACHEXIA	8	DIABETES, MS, CVA	4-6
MULTIPLE ORGAN FAILURE	8	MOTOR/SENSORY	4-6
SINGLE ORGAN FAILURE (RESP, RENAL, CARDIAC,)	5	PARAPLEGIA (MAX OF 6)	4-6
PERIPHERAL VASCULAR DISEASE	5	MAJOR SURGERY or TRAUMA	
ANAEMIA (Hb < 8)	2	ORTHOPAEDIC/SPINAL	5
SMOKING	1	ON TABLE > 2 HR#	5
		ON TABLE > 6 HR#	8

MEDICATION - CYTOTOXICS, LONG TERM/HIGH DOSE STEROIDS, ANTI-INFLAMMATORY MAX OF 4

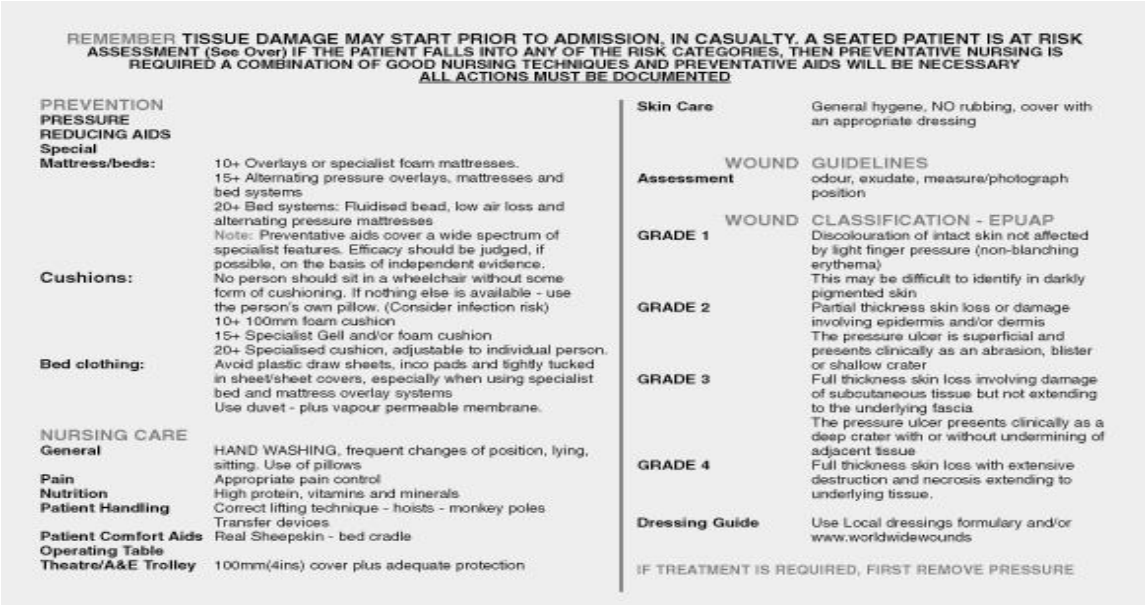
Scores can be discounted after 48 hours provided patient is recovering normally

Obtainable from the Nook, Stoke Road, Henlade TAUNTON TA3 5LX

* The 2005 revision incorporates the research undertaken by Queensland Health.

www.judy-waterlow.co.uk

Back side of Waterlow risk assessment card*



REMEMBER **TISSUE DAMAGE MAY START PRIOR TO ADMISSION, IN CASUALTY, A SEATED PATIENT IS AT RISK**
ASSESSMENT (See Over) IF THE PATIENT FALLS INTO ANY OF THE RISK CATEGORIES, THEN PREVENTATIVE NURSING IS REQUIRED A COMBINATION OF GOOD NURSING TECHNIQUES AND PREVENTATIVE AIDS WILL BE NECESSARY
ALL ACTIONS MUST BE DOCUMENTED

PREVENTION

PRESSURE REDUCING AIDS

Special Mattress/beds:
10+ Overlays or specialist foam mattresses.
15+ Alternating pressure overlays, mattresses and bed systems
20+ Bed systems: Fluidised bead, low air loss and alternating pressure mattresses
Note: Preventative aids cover a wide spectrum of specialist features. Efficacy should be judged, if possible, on the basis of independent evidence.

Cushions:
No person should sit in a wheelchair without some form of cushioning. If nothing else is available - use the person's own pillow. (Consider infection risk)
10+ 100mm foam cushion
15+ Specialist Gell and/or foam cushion
20+ Specialised cushion, adjustable to individual person.

Bed clothing:
Avoid plastic draw sheets, inco pads and tightly tucked in sheet/sheet covers, especially when using specialist bed and mattress overlay systems
Use duvet - plus vapour permeable membrane.

NURSING CARE

General HAND WASHING, frequent changes of position, lying, sitting. Use of pillows
Pain Appropriate pain control
Nutrition High protein, vitamins and minerals
Patient Handling Correct lifting technique - hoists - monkey poles Transfer devices
Patient Comfort Aids Real Sheepskin - bed cradle
Operating Table
Theatre/A&E Trolley 100mm(4ins) cover plus adequate protection

Skin Care General hygene, NO rubbing, cover with an appropriate dressing

WOUND GUIDELINES

Assessment odour, exudate, measure/photograph position

WOUND CLASSIFICATION - EPUAP

GRADE 1 Discolouration of intact skin not affected by light finger pressure (non-blanching erythema)
This may be difficult to identify in darkly pigmented skin

GRADE 2 Partial thickness skin loss or damage involving epidermis and/or dermis
The pressure ulcer is superficial and presents clinically as an abrasion, blister or shallow crater

GRADE 3 Full thickness skin loss involving damage of subcutaneous tissue but not extending to the underlying fascia
The pressure ulcer presents clinically as a deep crater with or without undermining of adjacent tissue

GRADE 4 Full thickness skin loss with extensive destruction and necrosis extending to underlying tissue.

Dressing Guide Use Local dressings formulary and/or www.worldwidewounds

IF TREATMENT IS REQUIRED, FIRST REMOVE PRESSURE

***Source: (Waterlow, 2005b)**

Braden Pressure Ulcer Risk Assessment scale*

Patient's Name _____ Evaluator's Name_____ Date of Assessment

SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort	**1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of con-sciousness or sedation. OR limited ability to feel pain over most of body	**2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly Limited** Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort..				
MOISTURE degree to which skin is exposed to moisture	**1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift.	**3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals.				
ACTIVITY degree of physical activity	**1. Bedfast** Confined to bed.	**2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	**4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours				
MOBILITY ability to change and control body position	**1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance	**2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently.	**4. No Limitation** Makes major and frequent changes in position without assistance.				
NUTRITION usual food intake pattern	**1. Very Poor** Never eats a complete meal. Rarely eats more than ⅓ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	**2. Probably Inadequate** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	**3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	**4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION & SHEAR	**1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	**2. Potential Problem** Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.					
				Total Score				

***Source: (Bergstrom et al., 1998)**

Norton Pressure Ulcer Risk Assessment Scale*

Norton Scale

		Physical condition	Mental condition	Activity	Mobility	Incontinent	Total score
		Good 4 Fair 3 Poor 2 Very bad 1	Alert 4 Apathetic 3 confused 2 Stupor 1	Ambulant 4 Walk/help 3 Chairbound 2 Bed 1	Full 4 Slightly limited 3 Very limited 2 Immobile 1	Not 4 Occasional 3 Usually/urine 2 Doubly 1	
Name	Date						

***Source: (Lindgren et al., 2002)**

Appendix: D

Pressure ulcer grading systems (Torrance, Stirling, EPUAP and NPUAP)

Torrance Grading System*

Stage 1

Blanching hyperaemia: Reactive hyperaemia is a temporary dilation of the capillaries which bring oxygen to the area and remove accumulated carbon dioxide and other waste products.[26] It causes a distinct erythema after pressure is released. Light finger pressure is said to cause blanching of this erythema, indicating that the microcirculation is intact

Stage 2

Non-blanching hyperaemia: The erythema remains when light pressure is applied, indicating a degree of microcirculatory disruption and inflammation. Oedema distorts and thickens all tissues compressed between the bone and the support surface. Superficial damage may present as swelling, induration, blistering or epidermal ulceration, which might expose the dermis

Stage 3

Ulceration progresses through the dermis to the junction with subcutaneous tissue. The ulcer edges are distinct but it is surrounded by erythema and induration. At this stage the damage is still reversible

Stage 4

Ulceration extends into the subcutaneous fat. Small-vessel thrombosis and infection compound fat necrosis. Underlying muscle is swollen and inflamed, and undergoes pathological changes. The relatively avascular deep fascia temporarily impedes downward progress of the damage but promotes lateral extension, causing undermining of the skin. Epidermal thickening creates a distinct ulcer margin but inflammation, fibrosis and retraction distort the deeper areas of the sore

Stage 5

Infective necrosis penetrates the deep fascia, and muscle destruction progresses rapidly. The wound spreads along the fascial planes and bursae, and may even reach the joints and body cavities. Osteomyelitis can easily develop. Multiple pressure ulcers may join, resulting in massive areas of tissue destruction

***Source: (Russell, 2002)**

Stirling Grading System*

Grade	Definition
Stage 0	No clinical evidence of a pressure ulcer
0.0	Normal appearance, intact skin
0.1	Healed with scarring
0.2	Tissue damage but not assessed as a pressure ulcer
Stage 1	Discoloration of intact skin (light finger pressure applied to the site does not alter the discoloration)
1.1	Non-blanchable erythema with increased local heat
1.2	Blue/purple/black discoloration. The ulcer is at least stage 1
Stage 2	Partial-thickness skin loss or damage involving epidermis and/or dermis
2.1	Blister
2.2	Abrasion
2.3	Shallow ulcer, without undermining of adjacent tissue
2.4	Any of these with underlying blue-purpose-black discoloration or induration. The ulcer is at least stage 2
Stage 3	Full-thickness skin loss involving damage or necrosis of subcutaneous tissue but not extending to underlying bone, tendon or joint capsule
3.1	Crater, without undermining of adjacent tissue
3.2	Crater, with undermining
3.3	Sinus, the full extent of which is not certain
3.4	Full-thickness skin loss but wound bed covered with necrotic tissue (hard or leathery black-brown tissue or softer yellow-cream-grey slough) which masks the true extent of tissue damage. The ulcer is at least stage 3. Until debrided it is not possible to observe whether damage exceeds into muscle or involves damage to bone or supporting structures
Stage 4	Full-thickness skin loss with extensive destruction and tissue necrosis extending to underlying bone, tendon or joint capsule
4.1	Visible exposure of bone, tendon or capsule
4.2	Sinus assessed as extending to bone, tendon or capsule
Third-digit classification —	for the nature of the wound bed
x.x0	Not applicable
x.x1	Clean, with partial epithelialization
x.x2	Clean, with or without granulation, but no obvious epithelialization
x.x3	Soft slough, cream-yellow-green in color
x.x4	Hard or leathery black-brown necrotic (dead/avascular) tissue
Fourth-digit classification for	infective complications
x xx0	No inflammation surrounding the wound bed
x.xx1	Inflammation surrounding the wound bed
x.xx2	Cellulitis bacteriologically confirmed

***Source: (Pedley, 2004)**

European Pressure Ulcer Advisory Panel (EPUAP) Grading System*

Grade	Short description	Definition
1	Nonblanchable erythema of intact skin	Nonblanchable erythema of intact skin. Discoloration of the skin, warmth, edema, induration, or hardness may also be used as indicators, particularly on individuals with darker skin.
2	Blister	Partial-thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
3	Superficial ulcer	Full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
4	Deep ulcer	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full-thickness skin loss.

***Source: (Russell, 2002)**

National Pressure Ulcer Advisory Panel (NPUAP) Grading System*

Grade	Definition
1	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.
2	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.
3	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
4	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

***Source: (Black et al., 2007)**

Appendix: E

Summary of studies reported the effectiveness of support surfaces

Study/setting/design	Intervention	Results	limitations	Category of comparison	Hawker et al. (2002) Quality score
- (Still et al., 2003) - Acute care (burn patients) - Retrospective	Pressure alternating mattress vs. standard hospital mattress.	Patients on alternating mattress developed no PUs.	Only descriptive statistics used to compare incidence rate between patients.	Dynamic mattress vs. standard mattress.	22: Fair No clear aim Data analysis not appropriate
- (Russell and Lichtenstein, 2000) - Acute care (surgical patients. - RCT	Multi-cell dynamic mattress vs. standard hospital mattress.	Significantly less PUs developed in patients having the dynamic mattress compared to patient on standard mattress.	Results restricted to patients undergoing cardiac surgery.	Dynamic mattress vs. standard mattress.	30: Good Finding mentioned but more analysis could be conducted to meet the aims.
- (Chalian and Kagan, 2001) - Acute care (operation room) - Descriptive	Fluid mattress vs. standard mattress	Fluid mattress deceased the incidence of PU significantly compared to standard mattress.	Results restricted to operation room prevention. Patients followed only for 3 days Small sample (n= 36)	Static mattress vs. standard mattress.	28: Fair Aims of the study not clear

- (Goldstone et al., 1982) - Acute care (orthopedics) - RCT	Polystyrene mattresses, cushions and heel protectors vs. standard mattresses, cushions and heel protectors	Polyester surfaces decreased PU incidence significantly compared to standard surfaces	Results restricted to older people with femur fractures	Static mattresses and cushions vs. standard mattresses and cushions	24: Fair Aim not clear Ethical consideration were not clearly discussed
- (De Laat et al., 2006b) - Acute care - Descriptive comparative	Viscoelastic foam mattress and PU prevention guidelines vs. standard mattress	Introducing the new guidelines and the foam mattress decreased PU prevalence.	Prevalence of PU instead of incidence used. It's not known for sure if the new mattress decreased PU prevalence or the new preventive guidelines.	Static mattress vs. standard mattress	29: Fair Variables of the study could be better described
-(Gray and Smith, 2000) - Acute care - RCT	Static special foam mattress vs. standard hospital mattress	No significant difference between the two	Over all low PU incidence in the study population (incidence = 2%)	Static mattress vs. standard mattress	26: Fair Method not clearly stated
-(Gunningberg et al., 2000b) - Acute care (orthopedic) - RCT	Viscoelastic static foam mattress vs. standard hospital mattress.	No significant difference between the two	Results restricted to older patients.	Static mattress vs. standard mattress	30: Good Description of future work not clear.

- (Hofman et al., 1994) - Acute care (orthopaedics) - RCT	Special foam static mattress vs. standard hospital mattress	Patients on special foam mattress had significantly lower number of developed PUs.	No blinding for PU assessors.	Static mattress vs. standard mattress	34: Good More details could be added to the method section
- (Berthe et al., 2007) - Acute care - RCT	Foamy-block static mattress vs. standard hospital mattress	No significant difference between the two.	Over all low PU incidence in the study population (incidence = 2.4%)	Static mattress vs. standard mattress	29: Fair Aim not clearly stated
- (Vyhlidal et al., 1997) - Acute care - RCT	Static foam mattress vs. static foam overlay	Significant decrease in PU incidence when using foam mattress compared to using foam overlay	Small sample number (n= 40). All patients were at risk according to Braden scale.	Static mattress vs. static overlay	30: Good No clear recommendation for future research
- (van Leen et al., 2010) - Nursing home - RCT	Static cold foam mattress vs. static air overlay.	Patients on static air overlay had significantly lower incidence of PU compared to patients on static foam mattress.	Results restricted to older people population.	Static mattress vs. static overlay	28: Fair Data analysis method could be better explained

- (Vanderwee et al., 2005) - Acute care (geriatric wards) - RCT	Pressure alternating mattress vs. static foam mattress	No significant difference between the two	Results restricted to older patients. Study excluded grade one PU. Duration of patient sitting was not standardized.	Dynamic mattress vs. static mattress.	31: Good No calculation for sample size
- (Cavicchioli and Carella, 2007) - Acute care - RCT	High tech alternating pressure mattress vs. high specification foam mattress	Significant lower pressure incidence for patient on alternating pressure mattress compared on foam mattress	Small number for patients in the foam mattress group (n= 33).	Dynamic mattress vs. static mattress.	30: Good More description of the statistical analysis procedure needed.
- (Economides et al., 1995) - Acute care - RCT	Dynamic air fluidized bed vs. static air mattress	No difference between the two	Small sample (n= 12). Inferential statistics not used to calculate significant level.	Dynamic mattress vs. static mattress.	26: Fair Abstract not adequate
- (Price et al., 1999) - Acute care (orthopaedics) - RCT	Dynamic pressure alternating mattress and cushion vs. static inflatable mattress	No difference between the two	Results restricted to older patients with neck of femur fracture.	Dynamic mattress vs. static mattress.	28: Fair No clear aims

- (Nixon et al., 2006a) - Acute care - RCT	Alternating pressure overlay vs. alternating pressure mattress	No significant difference between the two	Excluding PU grade one from analysis. No blinding for PU assessors.	Dynamic mattress vs. dynamic overlay	31: Good More details could be provided about data collection procedure
- (Nixon et al., 2006b) - Acute care - RCT	Alternating pressure overlay vs. alternating mattress	No significant difference between the two	Excluding PU grade one from analysis. Results restricted to older patients.	Dynamic mattress vs. dynamic overlay.	30: Good Future work not clearly stated
- (Jolley et al., 2004) - Acute care - RCT	Static sheep skin overlay vs. standard hospital mattress	Significantly lower incidence of PU for patient on sheepskin overlay.	As author notes a caring bias may be present: patient on sheepskin overlay may have better PU prevention.	Standard mattress vs. static overlay.	28: Fair Ethical consideration could be better stated
- (Schultz et al., 1999) - Acute care (operation room) - RCT	Special operation table foam overlay vs. standard operation table	No significant difference between the two	Results restricted to PU prevention during surgery.	Standard mattress vs. static overlay.	30: Good Some variables need s to be better described
- (Nixon et al., 1998) - Acute care (operation room) - RCT	dry viscoelastic polymer operation table overlay vs. standard operation table mattress	Significant reduction in PUs for patient on viscoelastic polymer operation table overlay.	Results restricted to PU prevention during surgery.	Standard mattress vs. static overlay.	31: Good Future work not clearly stated

- (Mistiaen et al., 2010) - nursing homes - RCT	Static sheepskin overlay vs. standard hospital mattress	Patients on sheep skin overlay had significantly lower number of sacral PUs compared to patients on standard mattress	Study focused only on sacral PUs.	Standard mattress vs. static overlay.	30: Good Some variables need s to be better described
- (Feuchtinger et al., 2006) - Acute care (operation room) - RCT	Thermoactive viscoelastic foam overlay on operation table vs. standard operation table mattress	No significant difference in reducing incidence of PU post operatively	Using of additional warming source which could affected the ability of viscoelastic foam to reduce pressure.	Standard mattress vs. static overlay	32: Good No calculation of sample size
- (Theaker et al., 2005) - Acute care (intensive care unit) - RCT	Low air loss dynamic mattress vs. alternating pressure mattress	No significant difference between the two	No blinding in randomization of interventions. Patients not followed until discharge.	Dynamic mattress vs. dynamic mattress	29: Fair Aims not clearly stated
- (Exton-Smith et al., 1982) - Acute care (geriatric) - RCT	Dynamic air wave system mattress vs. dynamic large-cell ripple mattress.	Air wave system was significantly more effective in prevention of PUs.	No blinding for PU assessors.	Dynamic mattress vs. dynamic mattress	30: Good Method could be enhanced to measure the outcome accurately

- (Johnson et al., 2011) - Acute care - prospective, comparative cohort	Low air loss dynamic mattress vs. alternating pressure mattress	No significant difference between the two	Prevalence of PU instead of incidence used.	Dynamic mattress vs. dynamic mattress	29: Fair More details about ethical considerations needed
- (Geyer et al., 2001) - Nursing home (geriatrics) - RCT	standard cushion vs. convoluted foam cushion	no significant difference between the two	Small sample number (n=32). Results restricted to older population.	Static cushion vs. standard hospital cushion.	28: Fair No clear description of future work
- (Conine et al., 1994) - long term care - RCT	Polyurethane foam cushion vs. gel and foam cushion	Patients on gel and foam cushion had significantly lower incidence of PUs.	More patients refused gel and foam cushion because of discomfort.	Static cushion vs. static cushion.	29: Fair Data analysis procedure not clearly stated
- (Lim et al., 1988) - Long term care - RCT	Polyurethane slab foam cushion vs. polyurethane contoured foam cushion	No significant difference between the two.	Results restricted to older patients.	Static cushion vs. static cushion.	28: Fair No enough description of the study setting
- (Brienza et al., 2011) - nursing home - RCT	Air, fluid and foam cushion vs. gel and foam cushion	No significant difference between the two.	Results restricted to older patients.	Static cushion vs. static cushion.	30: Good Ethical issues not fully discussed

Appendix: F

Summary of studies reporting the effectiveness of topical skin care

Study/setting/design	Intervention	Result	Limitations	Category of skin care	Hawker et al. (2002) Quality score
- (Lewis-Byers et al., 2002) - Long term care - prospective descriptive	Non rinse liquid followed by moisture barrier cream vs. soap and water followed by a moisturizing cream only after incontinence	No significant difference	More time was given to the soap-water group when care was provided. All patients were females.	- Skin care for incontinence. - Barrier creams - Moisturizing creams	29: Fair Sample size was not justified
- (Bou et al., 2005) - Acute care - Multi-centre RCT	Barrier cream with moisturizing and anti-oxidant properties vs. placebo cream	Incidence of PUs decreased significantly in patient receiving the barrier moisturizing cream.	Not all patients in this study were free initially of PUs which may increase their risk of acquiring new ulcers.	-Barrier cream	28: Fair More description of the study variables needed
- (Clever et al., 2002) - Long term care - Retrospective case control	Special skin cleansing liquid vs. soap and water after incontinence	Decreased incidence of PUs in the cleansing group compared to soap and water.	Introducing skin cleanser was associated with educational programme for PU prevention	Skin care for incontinence	29: Fair Aim of the study not clear

- (Cooper and Gray, 2001) - Long term care - Multi-centre RCT	Special foam cleanser vs. soap and water after incontinence	No significant difference	No calculation of sample size to detect statistical difference	Skin care for incontinence	30: Good Findings mentioned but more explanation could be given
- (Bale et al., 2004) - Pre and post intervention study - Nursing home	Skin cleanser with barrier cream vs. soap and water after incontinence	PUs incidence decreased with using skin cleanser with barrier cream compared to soap and water only	Introducing skin cleanser was associated with educational programme for PU prevention which may improve prevention.	-Skin care for incontinence and Barrier cream	29: Fair Context of the study could be better explained
- (Hunter et al., 2003) - Quasi-experimental pretest-posttest - Two nursing homes	Special body cleanser and skin protectant vs. soap and water after incontinence	PU incidence significantly decreased after using the special body wash and skin protectant.	Introducing skin cleanser and protectant was associated with educational programme for PU prevention which may improve prevention.	-Skin care for incontinence and Barrier cream	30: Good No justifying for the sample number
- (Whittingham and May, 1998) - Nursing care facility - RCT	Aerosol mousse vs. soap and water after incontinence.	No clear result about the incidence of PUs.	Small sample number (n=29). The amount and duration of cleaning the skin varied between groups	Skin care for incontinence	28: Fair Sampling procedure not clearly explained
- (Thompson et al., 2005) - Long term care - Quasi experimental	Special body wash vs. soap and water after incontinence.	Significant decrease in PU incidence after using body wash.	Study observed PU grade two or more.	Skin care for incontinence	30: Good More details are needed to explain why this study design chosed.

- (Dealey, 1995) - Nursing home - Repeated measure	Skin cleanser followed by a barrier cream vs. soap and water alone after incontinence	Decrease in PU incidence after using the cleanser and barrier cream	Small sample number (n=22)	- Skin care for incontinence. - Barrier cream.	27: Fair Future work not clearly stated
- (Bates-Jensen et al., 2003) - nursing homes - Multi-centre RCT	Incontinence and exercise (mobilization) interventions every two hours vs. standard care	No significant difference between two regiments on PU incidence	Nurses in standard care group knew about the implementation of the trial (Hawthorn effect), as a result nurses in this group may improve their caring activities.	Skin care for incontinence	30: Good Study variables could be better defined
- (Meaume et al., 2005) - Acute care (geriatric wards) - Prospective observational survey	Topical barrier agent with standard care vs. standard care without the topical barrier	PU incidence significantly decreased in patient who had a barrier agent.	Patients' characteristics and medical condition was not controlled between the two groups.	Barrier creams	31: Good Ethicalissues need to be more discussed
- (Nakagami et al., 2007) - Acute care (geriatric wards) - Experimental bilateral comparison.	Low frictional barrier dressing on side of each patient's trochanter vs. nothing on other trochanter	Significantly decrease in PU incidence in the side cover with the barrier dressing.	Small sample size (n=37)	Barrier creams	29: Fair Data analysis procedure needs to be better explained

Appendix: G

Medical records data extraction sheet

Patient data - Pressure ulcer developed: Yes/No

-Case number:

-Date of birth:

-Gender:

-Ethnic group:

-Occupation: past/present:

-Living arrangements: with family or friend, alone at home, care home, others:….

-Marital status:

- Changes of wards during hospitalization and admission information table:

Medical speciality	Patient-Nurse ratio
Admission:	
Chang:	
Chang:	
Chang:	
Total number of changes	
Time spent in emergency department	Hour
Date off admission/discharge	From: to:
Total period of hospitalization	Days

Severity of illness:

- Reason for admission to hospital: (e.g.: chest pain, anaemia, asthma)

-Chronic illness:

-Organ failure:

-Allergies:

-Disabilities (e.g. paralysis):

- Neurological deficits

-Injuries that can cause immobility or decrease mobility (e.g. spinal cord injury, fractures)

-Episodes of bleeding during hospitalization: Yes /No, (if yes: specify timing and amount):

-History of healed pressure ulcers: Yes/No

-Any metabolic disorders:

-Level of consciousness:

Mental status

- Presence of cognitive impairment: Yes/ No, specify (e.g. Alzheimer's Disease, dementia, traumatic brain injury)

- Presence of psychological problems: Yes/No

- Interventions to resolve mental status problems:

Medications

Medication & dose	Classification	Duration

Activity:

Bed fast, chair fast, walks with assistance, walks without assistance (specify):

Physical measures

-Height:

-Weight on admission:

-Body mass index on admission:

-Weight changes during hospitalization (timing & amount):

Vital signs:

- Blood pressure (systolic/diastolic):

- Episodes of high temperature: frequency/duration:

Pain

- Episodes of pain for any reason (specify: duration, frequency, intensity, treatment)

Activities of daily living during hospitalization: (e.g. feeding, grooming)

Totally dependent/ partially dependent/ independent

Lab results during hospitalization

Lab test	Result	Normal range	Interpretation
Serum albumin			
Serum sodium			
Serum potassium			
urea			
Creatinine			
C-reactive protein			
Haemoglobin			
WCC			

- Blood transfusion during hospitalization: Yes/NO, Amount:

Skin integrity assessment

No.	Timing of assessment	Result (Including any wounds or skin insults)	Presence of PUs (location &stage)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

***indicate if PUs developed after significant event e.g. surgery**

- Comments on skin assessment:

Nutrition status

- Type of diet:

- Identifying sign of malnutrition/ dehydration:

- Identifying of any eating difficulties (e.g. difficulty in swallowing, missing teeth, using dentures):

- Feeding route: oral, Nasogastric tube, PEG (percutaneous endoscopic gastrostomy) tube, total parenteral nutrition, mix rotes (specify):

Surgery

(If patient had any surgeries during hospitalization period)

Surgery type	Total days preoperative	Total days postoperative

- Preventive interventions for PUs during surgery time and in recovery room (specify type):

- Complications post surgery (excluding pressure ulcers):

Protective interventions for pressure ulcer

Surfaces patient placed on (including mattresses and overlays)

No.	Surface & cushions	Duration (days)	Type of surface*
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

* including standard surfaces& pressure redistributing

- Comments on surfaces and additional details if any present

Turning and positioning

- Any restrains for repositioning: Yes/ NO, If yes specify:

- **In bed:**

-Self positioning: Yes/no, frequency/day:

- Positioning with assistance: Yes/no, frequency/day:

- Dependent positioning (manually): Yes/no, frequency/day:

- Dependent positioning (electrical bed): Yes/no, frequency/day:

- Use of positioning devices (type& frequency):

- **In chair**

-Self: Yes/no, frequency/day:

-Assisted: Yes/no, frequency/day:

Use of any seating devices (type/frequency):

- **Elevation of head of bed**

Bed angle used (specify timing and frequency):

Use of draw sheets for tilting and transfer: yes/ no, if yes frequency:

Heal protection:

- Elevation with pillow: Yes/no, frequency/day:

- Lift heals while moving to prevent shear: Yes/no

- Apply barrier moisture cream or other materials to prevent friction: Yes/no, specify:

- **Referral to tissue viability nurse: Yes/ No, if yes specify frequency and duration:**

- **Special interventions implemented by tissue viability nurse (specify type & frequency):**----------
  ----

Incontinence and skin care:

-Use of skin barrier creams: Yes/NO, frequency

-Use of skin moisture creams: Yes/NO, frequency

-Care of incontinence (specify timing and frequency

Materials used to care of incontinence (e.g. diapers, absorbent pads) specify type and frequency:

Skin hygiene

-Hygiene measures where carried out through: bed bath, assisted bath, showers bath, other: specify

-Frequency and timing of the hygiene measure:

-Substances used during hygiene practices: soap and water, non-rinsing cleaners, others:……

Nutritional interventions

-Nutritional supplements:

-Dietician referral (frequency):

-Interventions implemented to support patients nutritional statues:

Referrals

Referral to other health care professionals e.g. physiotherapy (specify duration &frequency):

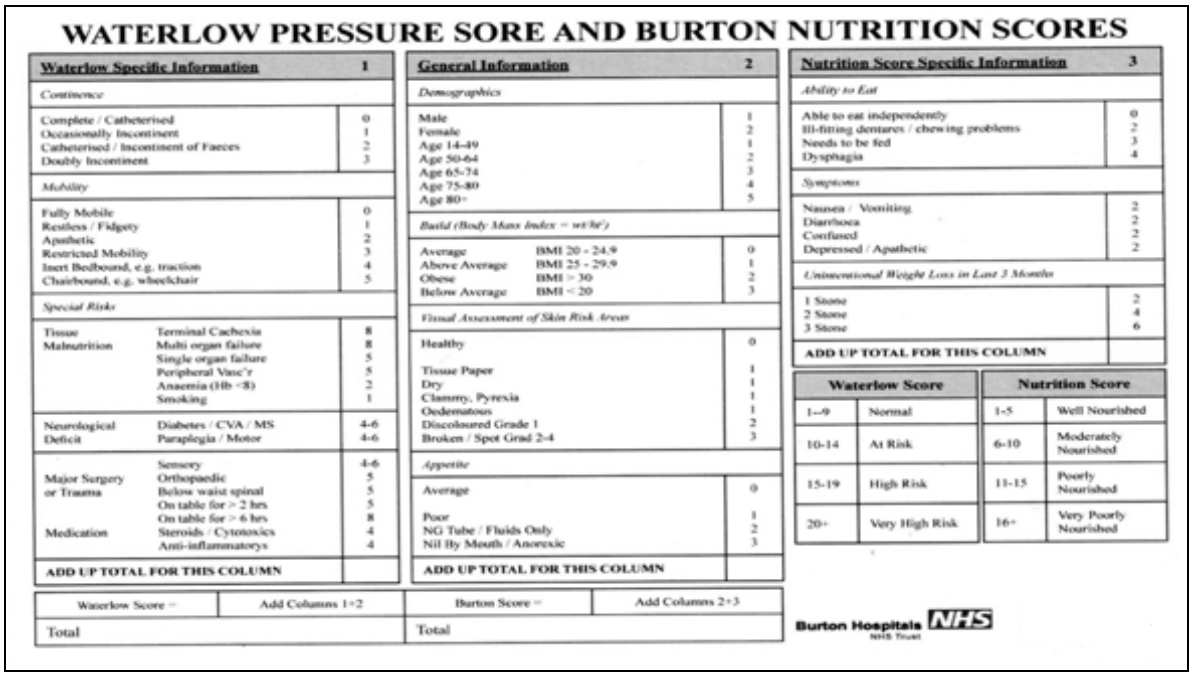
Additional comments on the patient data

Notes

Appendix: H

Waterlow pressure ulcer risk assessment scale used at Burton Hospital

Front side of Waterlow risk assessment card



WATERLOW PRESSURE SORE AND BURTON NUTRITION SCORES

Waterlow Specific Information		1
Continence		
Complete / Catheterised		0
Occasionally Incontinent		1
Catheterised / Incontinent of Faeces		2
Doubly Incontinent		3
Mobility		
Fully Mobile		0
Restless / Fidgety		1
Apathetic		2
Restricted Mobility		3
Inert Bedbound, e.g. traction		4
Chairbound, e.g. wheelchair		5
Special Risks		
Tissue Malnutrition	Terminal Cachexia	8
	Multi organ failure	8
	Single organ failure	5
	Peripheral Vasc'r	5
	Anaemia (Hb <8)	2
	Smoking	1
Neurological Deficit	Diabetes / CVA / MS	4-6
	Paraplegia / Motor	4-6
Major Surgery or Trauma	Sensory	4-6
	Orthopaedic	5
	Below waist spinal	5
	On table for > 2 hrs	5
	On table for > 6 hrs	8
Medication	Steroids / Cytotoxics	4
	Anti-inflammatorys	4
ADD UP TOTAL FOR THIS COLUMN		

General Information		2
Demographics		
Male		1
Female		2
Age 14-49		1
Age 50-64		2
Age 65-74		3
Age 75-80		4
Age 80+		5
Build (Body Mass Index = wt/ht²)		
Average	BMI 20 - 24.9	0
Above Average	BMI 25 - 29.9	1
Obese	BMI > 30	2
Below Average	BMI < 20	3
Visual Assessment of Skin Risk Areas		
Healthy		0
Tissue Paper		1
Dry		1
Clammy, Pyrexia		1
Oedematous		1
Discoloured Grade 1		2
Broken / Spot Grad 2-4		3
Appetite		
Average		0
Poor		1
NG Tube / Fluids Only		2
Nil By Mouth / Anorexic		3
ADD UP TOTAL FOR THIS COLUMN		

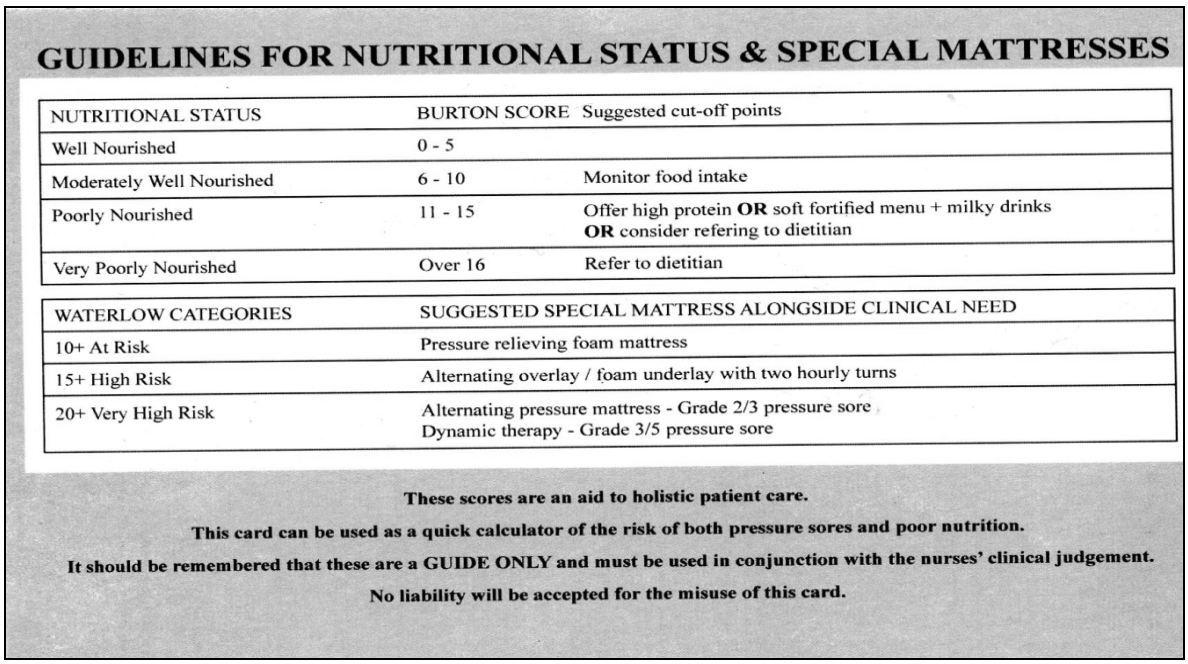
Nutrition Score Specific Information	3
Ability to Eat	
Able to eat independently	0
Ill-fitting dentures / chewing problems	2
Needs to be fed	3
Dysphagia	4
Symptoms	
Nausea / Vomiting	2
Diarrhoea	2
Confused	2
Depressed / Apathetic	2
Unintentional Weight Loss in Last 3 Months	
1 Stone	2
2 Stone	4
3 Stone	6
ADD UP TOTAL FOR THIS COLUMN	

Waterlow Score		Nutrition Score	
1--9	Normal	1-5	Well Nourished
10-14	At Risk	6-10	Moderately Nourished
15-19	High Risk	11-15	Poorly Nourished
20+	Very High Risk	16+	Very Poorly Nourished

Waterlow Score =	Add Columns 1+2	Burton Score =	Add Columns 2+3
Total		Total	

Burton Hospitals NHS NHS Trust

Back side of Waterlow risk assessment scale



GUIDELINES FOR NUTRITIONAL STATUS & SPECIAL MATTRESSES

NUTRITIONAL STATUS	BURTON SCORE	Suggested cut-off points
Well Nourished	0 - 5	
Moderately Well Nourished	6 - 10	Monitor food intake
Poorly Nourished	11 - 15	Offer high protein **OR** soft fortified menu + milky drinks **OR** consider refering to dietitian
Very Poorly Nourished	Over 16	Refer to dietitian

WATERLOW CATEGORIES	SUGGESTED SPECIAL MATTRESS ALONGSIDE CLINICAL NEED
10+ At Risk	Pressure relieving foam mattress
15+ High Risk	Alternating overlay / foam underlay with two hourly turns
20+ Very High Risk	Alternating pressure mattress - Grade 2/3 pressure sore Dynamic therapy - Grade 3/5 pressure sore

These scores are an aid to holistic patient care.

This card can be used as a quick calculator of the risk of both pressure sores and poor nutrition.

It should be remembered that these are a GUIDE ONLY and must be used in conjunction with the nurses' clinical judgement.

No liability will be accepted for the misuse of this card.

Appendix: I

De Montfort University Ethical Approval

dmu.ac.uk
DE MONTFORT UNIVERSITY
LEICESTER

5th March 2009

Ma'en Aljezawi
PhD Candidate
Flat BO1 Room 2
Benjamin Russell Court
35 Grassmere St,
Leicester, LE2 7PT

Dear Ma'en,

Re: Ethics application – What are the nursing caring modalities that prevented pressure ulcers in high risk patients (ref: 443)

I am writing regarding your application for ethical approval for a research project titled to the above project. This project has been reviewed in accordance with the Operational Procedures for De Montfort University Faculty of Health and Life Sciences Research Ethics Committee. These procedures are available from the Faculty Research and Commercial Office upon your request.

I am pleased to inform you that ethical approval has been granted by Chair's Action for your application. This will be reported at the next Faculty Research Committee, which is being held on 26th March 2009.

Should there be any amendments to the research methods or persons involved with this project you must notify the Chair of the Faculty Research Ethics Committee immediately in writing. Serious or adverse events related to the conduct of the study need to be reported immediately to your Supervisor and the Chair of this Committee. Also, The Faculty Research Ethics Committee should be notified by e-mail to HLSFRO@dmu.ac.uk when your research project has been completed.

Yours sincerely,

Professor Paul Whiting
Chair
Faculty of Health and Life Sciences
Research Ethics Committee

Faculty of Health and Life Sciences, The Gateway, Leicester LE1 9BH.
Tel: (0116) 255 1551 / **Fax:** (0116) 257 7135

Appendix: J

National Health Services (NHS) research passport

Research passport page 1 of 2

Burton Hospitals NHS
NHS Foundation Trust

Queen's Hospital
Belvedere Road
Burton Upon Trent
Staffordshire
DE13 0RB

Telephone: 01283 566333

Human Resources Directorate

Mr Ma'en Aljezawi
Flat BD01
Room 2
Benjamin Russell Court
35 Grassmere Street
Leicester
LE2 7PT

9 April 2009

Dear Mr Aljezawi

Letter of access for research project: What are the nursing caring modalities that prevented pressure ulcers in high-riske patients?

This letter confirms your right of access to conduct research through Burton Hospitals NHS Trust for the purpose and on the terms and conditions set out below. This right of access commences 09 April 2009 and ends on 01 January 2012 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at Burton Hospitals NHS Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Burton Hospitals NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Burton Hospitals NHS Trust, you will remain accountable to your employer, the De Montfort University of Leicester, but you are required to follow the reasonable instructions of Professor T Reynolds in this NHS organisation, or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Burton Hospitals NHS Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Burton Hospitals NHS Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Burton Hospitals NHS Trust premises. You must

observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (htto://www.dh.gov.uk/assetRoot/O4/06/92/54/04069254.pdf and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Burton Hospitals NHS Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

C. L. Roberts

Claire Roberts
Medical Staffing Manager
Burton Hospitals NHS Foundation Trust

cc:

R&D office at Burton Hospitals NHS Trust

Ms Z Glover
HR department at De Montfort University
The Gateway
Leicester
LE1 9BH

Appendix: K

Contingency tables (crosstabulation) for different study variables

➢ Group two: Variables representing preventive interventions

- Contingency table for using barrier creams

Hospital acquired PU developed vs.Using of barrier creams Crosstabulation

			Using barrier creams		
			no	yes	Total
Hospital acquired PU developed	no	Count	71	5	76
		% within Hospital acquired PU developed	93.4%	6.6%	100.0%
		% within Using of barrier creams	50.0%	50.0%	50.0%
	yes	Count	71	5	76
		% within Hospital acquired PU developed	93.4%	6.6%	100.0%
		% within Using of barrier creams	50.0%	50.0%	50.0%
Total		Count	142	10	152
		% within Hospital acquired PU developed	93.4%	6.6%	100.0%
		% within Using of barrier creams	100.0%	100.0%	100.0%

- Contingency table for using moisturizing cream

Hospital acquired PU developed vs.Using moisturising creams Crosstabulation

			Using moisturising creams		
			no	yes	Total
Hospital acquired PU developed	no	Count	69	7	76
		% within Hospital acquired PU developed	90.8%	9.2%	100.0%
		% within Using moisturising creams	50.0%	50.0%	50.0%
	yes	Count	69	7	76
		% within Hospital acquired PU developed	90.8%	9.2%	100.0%
		% within Using moisturising creams	50.0%	50.0%	50.0%
Total		Count	138	14	152
		% within Hospital acquired PU developed	90.8%	9.2%	100.0%
		% within Using moisturising creams	100.0%	100.0%	100.0%

- Contingency table for using type of hospital bed

Hospital acquired PU developed vs. Type of hospital bed Crosstabulation

			Type of bed		
			Standard	Profiling	Total
Hospital acquired PU developed	no	Count	72	2	74
		% within Hospital acquired PU developed	97.3%	2.7%	100.0%
		% within type of bed	52.9%	14.3%	49.3%
	yes	Count	64	12	76
		% within Hospital acquired PU developed	84.2%	15.8%	100.0%
		% within type of bed	47.1%	85.7%	50.7%
Total		Count	136	14	150
		% within Hospital acquired PU developed	90.7%	9.3%	100.0%
		% within type of bed	100.0%	100.0%	100.0%

- Contingency table for using seating cushion

Hospital acquired PU developed vs.Seating cushions Crosstabulation

			Seating cushions		
			no	yes	Total
Hospital acquired PU developed	no	Count	63	13	76
		% within Hospital acquired PU developed	82.9%	17.1%	100.0%
		% within Seating cushions	46.0%	86.7%	50.0%
	yes	Count	74	2	76
		% within Hospital acquired PU developed	97.4%	2.6%	100.0%
		% within Seating cushions	54.0%	13.3%	50.0%
Total		Count	137	15	152
		% within Hospital acquired PU developed	90.1%	9.9%	100.0%
		% within Seating cushions	100.0%	100.0%	100.0%

- Contingency table for using first mattress used

Hospital acquired PU developed vs.1st mattress Crosstabulation

			1st mattress used		
			Static	Alternating	Total
Hospital acquired PU developed	no	Count	61	15	76
		% within Hospital acquired PU developed	80.3%	19.7%	100.0%
		% within 1st mattress	55.5%	35.7%	50.0%
	yes	Count	49	27	76
		% within Hospital acquired PU developed	64.5%	35.5%	100.0%
		% within 1st mattress	44.5%	64.3%	50.0%
Total		Count	110	42	152
		% within Hospital acquired PU developed	72.4%	27.6%	100.0%
		% within 1st mattress	100.0%	100.0%	100.0%

- Contingency table for using second mattress used

Hospital acquired PU developed vs.2nd mattress Crosstabulation

			2nd mattress used		
			static	alternating	Total
Hospital acquired PU developed	no	Count	3	6	9
		% within Hospital acquired PU developed	33.3%	66.7%	100.0%
		% within 2nd matt	50.0%	18.8%	23.7%
	yes	Count	3	26	29
		% within Hospital acquired PU developed	10.3%	89.7%	100.0%
		% within 2nd mattress	50.0%	81.3%	76.3%
Total		Count	6	32	38
		% within Hospital acquired PU developed	15.8%	84.2%	100.0%
		% within 2nd mattress	100.0%	100.0%	100.0%

- Contingency table for positioning patient in bed

Hospital acquired PU developed vs.Positioning in bed Crosstabulation

			positioning in bed			
			Not positioned	2 hourly	4 hourly	Total
Hospital acquired PU developed	no	Count	10	52	14	76
		% within Hospital acquired PU developed	13.2%	68.4%	18.4%	100.0%
		% within positioning in bed	45.5%	45.2%	93.3%	50.0%
	yes	Count	12	63	1	76
		% within Hospital acquired PU developed	15.8%	82.9%	1.3%	100.0%
		% within positioning in bed	54.5%	54.8%	6.7%	50.0%
Total		Count	22	115	15	152
		% within Hospital acquired PU developed	14.5%	75.7%	9.9%	100.0%
		% within positioning in bed	100.0%	100.0%	100.0%	100.0%

- Contingency table for sitting in chair

Hospital acquired PU developed vs.Sitting in chair Crosstabulation

			Sitting on chair		
			no	yes	Total
Hospital acquired PU developed	no	Count	15	61	76
		% within Hospital acquired PU developed	19.7%	80.3%	100.0%
		% within Sitting in chair	25.4%	65.6%	50.0%
	yes	Count	44	32	76
		% within Hospital acquired PU developed	57.9%	42.1%	100.0%
		% within Sitting in chair	74.6%	34.4%	50.0%
Total		Count	59	93	152
		% within Hospital acquired PU developed	38.8%	61.2%	100.0%
		% within Sitting in chair	100.0%	100.0%	100.0%

- Contingency table for using draw sheet

Hospital acquired PU developed vs.Using draw sheets to move patient Crosstabulation

			Using draw sheets to move patient		
			no	yes	Total
Hospital acquired PU developed	no	Count	16	59	75
		% within Hospital acquired PU developed	21.3%	78.7%	100.0%
		% within Using draw sheets to move patient	37.2%	54.6%	49.7%
	yes	Count	27	49	76
		% within Hospital acquired PU developed	35.5%	64.5%	100.0%
		% within Using draw sheets to move patient	62.8%	45.4%	50.3%
Total		Count	43	108	151
		% within Hospital acquired PU developed	28.5%	71.5%	100.0%
		% within Using draw sheets to move patient	100.0%	100.0%	100.0%

- Contingency table for dietician referral

Hospital acquired PU developed vs Dietician referral Crosstabulation

			Dietician referral		
			no	yes	Total
Hospital acquired PU developed	no	Count	59	17	76
		% within Hospital acquired PU developed	77.6%	22.4%	100.0%
		% within Dietician referral	50.4%	48.6%	50.0%
	yes	Count	58	18	76
		% within Hospital acquired PU developed	76.3%	23.7%	100.0%
		% within Dietician referral	49.6%	51.4%	50.0%
Total		Count	117	35	152
		% within Hospital acquired PU developed	77.0%	23.0%	100.0%
		% within Dietician referral	100.0%	100.0%	100.0%

- Contingency table for physiotherapy referral

Hospital acquired PU developed vs. Physiotherapy referral Crosstabulation

			Physiotherapy referral		
			no	yes	Total
Hospital acquired PU developed	no	Count	54	22	76
		% within Hospital acquired PU developed	71.1%	28.9%	100.0%
		% within Physiotherapy referral	50.9%	47.8%	50.0%
	yes	Count	52	24	76
		% within Hospital acquired PU developed	68.4%	31.6%	100.0%
		% within Physiotherapy referral	49.1%	52.2%	50.0%
Total		Count	106	46	152
		% within Hospital acquired PU developed	69.7%	30.3%	100.0%
		% within Physiotherapy referral	100.0%	100.0%	100.0%

- **Group three: Variables representing factors related to physical activity and mobility**

- Contingency table for activity in bed

Hospital acquired PU developed vs. activity in bed Crosstabulation

			Activity in bed		
			Moves independently	Moves with help	Total
Hospital acquired PU developed	no	Count	24	52	76
		% within Hospital acquired PU developed	31.6%	68.4%	100.0%
		% within activity in bed	88.9%	41.6%	50.0%
	yes	Count	3	73	76
		% within Hospital acquired PU developed	3.9%	96.1%	100.0%
		% within activity in bed	11.1%	58.4%	50.0%
Total		Count	27	125	152
		% within Hospital acquired PU developed	17.8%	82.2%	100.0%
		% within activity in bed	100.0%	100.0%	100.0%

- Contingency table for activity outside bed

Hospital acquired PU developed vs. activity outside bed Crosstabulation

			Activity outside bed		
			Walks alone or with help	Unable or moved by hoist	Total
Hospital acquired PU developed	no	Count	59	17	76
		% within Hospital acquired PU developed	77.6%	22.4%	100.0%
		% within activity outside bed	64.8%	27.9%	50.0%
	yes	Count	32	44	76
		% within Hospital acquired PU developed	42.1%	57.9%	100.0%
		% within activity outside bed	35.2%	72.1%	50.0%
Total		Count	91	61	152
		% within Hospital acquired PU developed	59.9%	40.1%	100.0%
		% within activity outside bed	100.0%	100.0%	100.0%

- Contingency table for long surgical procedure

Hospital acquired PU developed vs. Long surgical procedure Crosstabulation

			Long surgical procedure		
			No	Yes	Total
Hospital acquired PU developed	no	Count	59	17	76
		% within Hospital acquired PU developed	77.6%	22.4%	100.0%
		% within long surgical procedure	51.8%	44.7%	50.0%
	yes	Count	55	21	76
		% within Hospital acquired PU developed	72.4%	27.6%	100.0%
		% within long surgical procedure	48.2%	55.3%	50.0%
Total		Count	114	38	152
		% within Hospital acquired PU developed	75.0%	25.0%	100.0%
		% within long surgical procedure	100.0%	100.0%	100.0%

- Contingency table for ability to do hygiene practices

Hospital acquired PU developed vs. ability to do hygiene practices Crosstabulation

			Ability to do			
			shower bathing/assisted	bed bath	hoist bath	Total
Hospital acquired PU developed	no	Count	50	19	7	76
		% within Hospital acquired PU developed	65.8%	25.0%	9.2%	100.0%
		% within hygiene practices	73.5%	30.2%	33.3%	50.0%
	yes	Count	18	44	14	76
		% within Hospital acquired PU developed	23.7%	57.9%	18.4%	100.0%
		% within hygiene practices	26.5%	69.8%	66.7%	50.0%
Total		Count	68	63	21	152
		% within Hospital acquired PU developed	44.7%	41.4%	13.8%	100.0%
		% within hygiene practices	100.0%	100.0%	100.0%	100.0%

- Contingency table for Ability to do ADLS

Hospital acquired PU developed vs. Ability to do ADLS Crosstabulation

			Ability to do ADLS			
			needs help in bathing only	needs one help	needs two help	Total
Hospital acquired PU developed	no	Count	16	51	9	76
		% within Hospital acquired PU developed	21.1%	67.1%	11.8%	100.0%
		% within ability to do ADLS	84.2%	60.0%	18.8%	50.0%
	yes	Count	3	34	39	76
		% within Hospital acquired PU developed	3.9%	44.7%	51.3%	100.0%
		% within ability to do ADLS	15.8%	40.0%	81.3%	50.0%
Total		Count	19	85	48	152
		% within Hospital acquired PU developed	12.5%	55.9%	31.6%	100.0%
		% within ability to do ADLS	100.0%	100.0%	100.0%	100.0%

- **Group four: Variables related to PUs intrinsic risk factors**

- Contingency table for the variable reason of hospitalization

(Table too large to display)

- Contingency tables and testing for significance for number of underlying medical conditions

Hospital acquired PU developed vs. Number of underlying medical disorders Crosstabulation

			Number of underlying medical disorders				
			Not present	one disorder	two disorders	three disorders	Total
Hospital acquired PU developed	no	Count	31	29	12	4	76
		% within Hospital acquired PU developed	40.8%	38.2%	15.8%	5.3%	100.0%
		% within Number of underlying medical disorders	81.6%	64.4%	35.3%	11.4%	50.0%
	yes	Count	7	16	22	31	76
		% within Hospital acquired PU developed	9.2%	21.1%	28.9%	40.8%	100.0%
		% within Number of underlying medical disorders	18.4%	35.6%	64.7%	88.6%	50.0%
Total		Count	38	45	34	35	152
		% within Hospital acquired PU developed	25.0%	29.6%	22.4%	23.0%	100.0%
		% within Number of underlying medical disorders	100.0%	100.0%	100.0%	100.0%	100.0%

- Contingency table and testing for significance for level of consciousness

Hospital acquired PU developed vs. Level of consciousness Crosstabulation

			Level of consciousness		
			Conscious	Confused	Total
Hospital acquired PU developed	no	Count	57	19	76
		% within Hospital acquired PU developed	75.0%	25.0%	100.0%
		% within level of consciousness	54.8%	40.4%	50.3%
	yes	Count	47	28	75
		% within Hospital acquired PU developed	62.7%	37.3%	100.0%
		% within level of consciousness	45.2%	59.6%	49.7%
Total		Count	104	47	151
		% within Hospital acquired PU developed	68.9%	31.1%	100.0%
		% within level of consciousness	100.0%	100.0%	100.0%

- Contingency table for presence of cognitive impairment

Hospital acquired PU developed vs. Presence of cognitive impairment Crosstabulation

			Presence of cognitive impairment		
			no	yes	Total
Hospital acquired PU developed	no	Count	66	10	76
		% within Hospital acquired PU developed	86.8%	13.2%	100.0%
		% within Presence of cognitive impairment	53.2%	35.7%	50.0%
	yes	Count	58	18	76
		% within Hospital acquired PU developed	76.3%	23.7%	100.0%
		% within Presence of cognitive impairment	46.8%	64.3%	50.0%
Total		Count	124	28	152
		% within Hospital acquired PU developed	81.6%	18.4%	100.0%
		% within Presence of cognitive impairment	100.0%	100.0%	100.0%

- Contingency table for the presence of depression

Hospital acquired PU developed vs. Depression Crosstabulation

			Depression		
			no	yes	Total
Hospital acquired PU developed	no	Count	72	4	76
		% within Hospital acquired PU developed	94.7%	5.3%	100.0%
		% within Depression	53.3%	23.5%	50.0%
	yes	Count	63	13	76
		% within Hospital acquired PU developed	82.9%	17.1%	100.0%
		% within Depression	46.7%	76.5%	50.0%
Total		Count	135	17	152
		% within Hospital acquired PU developed	88.8%	11.2%	100.0%
		% within Depression	100.0%	100.0%	100.0%

- Contingency table for presence of dehydration

Hospital acquired PU developed vs. Presence of dehydration Crosstabulation

			Presence of dehydration		
			No	Yes	Total
Hospital acquired PU developed	no	Count	17	59	76
		% within Hospital acquired PU developed	22.4%	77.6%	100.0%
		% within Presence of dehydration	70.8%	46.1%	50.0%
	yes	Count	7	69	76
		% within Hospital acquired PU developed	9.2%	90.8%	100.0%
		% within Presence of dehydration	29.2%	53.9%	50.0%
Total		Count	24	128	152
		% within Hospital acquired PU developed	15.8%	84.2%	100.0%
		% within Presence of dehydration	100.0%	100.0%	100.0%

- Contingency tables for Dysphagia

Hospital acquired PU developed vs. Presence of dysphagia Crosstabulation

			Presence of dysphagia		
			no	yes	Total
Hospital acquired PU developed	no	Count	70	6	76
		% within Hospital acquired PU developed	92.1%	7.9%	100.0%
		% within Presence of dysphagia	53.0%	30.0%	50.0%
	yes	Count	62	14	76
		% within Hospital acquired PU developed	81.6%	18.4%	100.0%
		% within Presence of dysphagia	47.0%	70.0%	50.0%
Total		Count	132	20	152
		% within Hospital acquired PU developed	86.8%	13.2%	100.0%
		% within Presence of dysphagia	100.0%	100.0%	100.0%

- Contingency table for blood transfusion

Hospital acquired PU developed vs. Blood transfusion Crosstabulation

			Blood transfusion		
			no	yes	Total
Hospital acquired PU developed	no	Count	62	14	76
		% within Hospital acquired PU developed	81.6%	18.4%	100.0%
		% within Blood transfusion	55.4%	35.0%	50.0%
	yes	Count	50	26	76
		% within Hospital acquired PU developed	65.8%	34.2%	100.0%
		% within Blood transfusion	44.6%	65.0%	50.0%
Total		Count	112	40	152
		% within Hospital acquired PU developed	73.7%	26.3%	100.0%
		% within Blood transfusion	100.0%	100.0%	100.0%

- Contingency table for presence of denture or chewing problems

Hospital acquired PU developed vs. presence of denture or chewing problems Crosstabulation

			presence of denture or chewing problems		
			no	yes	Total
Hospital acquired PU developed	no	Count	53	23	76
		% within Hospital acquired PU developed	69.7%	30.3%	100.0%
		% within presence of denture or chewing problems	55.8%	40.4%	50.0%
	yes	Count	42	34	76
		% within Hospital acquired PU developed	55.3%	44.7%	100.0%
		% within presence of denture or chewing problems	44.2%	59.6%	50.0%
Total		Count	95	57	152
		% within Hospital acquired PU developed	62.5%	37.5%	100.0%
		% within presence of denture or chewing problems	100.0%	100.0%	100.0%

- Contingency table and significance for binary biological risk factors

- Binary serum albumin

Hospital acquired PU developed vs. Binary albumin Crosstabulation

			Binary albumin		
			<32	>=32	Total
Hospital acquired PU developed	no	Count	13	63	76
		% within Hospital acquired PU developed	17.1%	82.9%	100.0%
		% within Binary albumin	20.6%	71.6%	50.3%
	yes	Count	50	25	75
		% within Hospital acquired PU developed	66.7%	33.3%	100.0%
		% within Binary albumin	79.4%	28.4%	49.7%
Total		Count	63	88	151
		% within Hospital acquired PU developed	41.7%	58.3%	100.0%
		% within Binary albumin	100.0%	100.0%	100.0%

- Binary serum sodium

Hospital acquired PU developed vs. Binary sodium Crosstabulation

			Binary sodium		
			<135	>=135	Total
Hospital acquired PU developed	no	Count	26	50	76
		% within Hospital acquired PU developed	34.2%	65.8%	100.0%
		% within Binary sodium	57.8%	46.7%	50.0%
	yes	Count	19	57	76
		% within Hospital acquired PU developed	25.0%	75.0%	100.0%
		% within Binary sodium	42.2%	53.3%	50.0%
Total		Count	45	107	152
		% within Hospital acquired PU developed	29.6%	70.4%	100.0%
		% within Binary sodium	100.0%	100.0%	100.0%

- Binary serum potassium

Hospital acquired PU developed vs. Binary potassium Crosstabulation

			Binary potassium		
			<3.5	>=3.5	Total
Hospital acquired PU developed	no	Count	7	69	76
		% within Hospital acquired PU developed	9.2%	90.8%	100.0%
		% within Binary potassium	50.0%	50.0%	50.0%
	yes	Count	7	69	76
		% within Hospital acquired PU developed	9.2%	90.8%	100.0%
		% within Binary potassium	50.0%	50.0%	50.0%
Total		Count	14	138	152
		% within Hospital acquired PU developed	9.2%	90.8%	100.0%
		% within Binary potassium	100.0%	100.0%	100.0%

- Binary serum urea

Hospital acquired PU developed vs. Binary urea Crosstabulation

			Binary urea		
			<=21	>21	Total
Hospital acquired PU developed	no	Count	70	5	75
		% within Hospital acquired PU developed	93.3%	6.7%	100.0%
		% within Binary urea	49.6%	50.0%	49.7%
	yes	Count	71	5	76
		% within Hospital acquired PU developed	93.4%	6.6%	100.0%
		% within Binary urea	50.4%	50.0%	50.3%
Total		Count	141	10	151
		% within Hospital acquired PU developed	93.4%	6.6%	100.0%
		% within Binary urea	100.0%	100.0%	100.0%

- Binary serum creatinine

Hospital acquired PU developed vs. Binary creatinine Crosstabulation

			Binary creatinine		
			<=120M, <=110F	>120 M, >110 F	Total
Hospital acquired PU developed	no	Count	56	20	76
		% within Hospital acquired PU developed	73.7%	26.3%	100.0%
		% within Binary creatinine	51.9%	45.5%	50.0%
	yes	Count	52	24	76
		% within Hospital acquired PU developed	68.4%	31.6%	100.0%
		% within Binary creatinine	48.1%	54.5%	50.0%
Total		Count	108	44	152
		% within Hospital acquired PU developed	71.1%	28.9%	100.0%
		% within Binary creatinine	100.0%	100.0%	100.0%

- Binary CRP

Hospital acquired PU developed vs. Binary CRP Crosstabulation

			Binary CRP		
			<10	>=10	Total
Hospital acquired PU developed	no	Count	8	39	47
		% within Hospital acquired PU developed	17.0%	83.0%	100.0%
		% within Binary CRP	66.7%	39.4%	42.3%
	yes	Count	4	60	64
		% within Hospital acquired PU developed	6.3%	93.8%	100.0%
		% within Binary CRP	33.3%	60.6%	57.7%
Total		Count	12	99	111
		% within Hospital acquired PU developed	10.8%	89.2%	100.0%
		% within Binary CRP	100.0%	100.0%	100.0%

- Binary haemoglobin

Hospital acquired PU developed vs. Binary HB Crosstabulation

			Binary HB		
			<130 M, <115 F	>=130 M, >=115 F	Total
Hospital acquired PU developed	no	Count	31	45	76
		% within Hospital acquired PU developed	40.8%	59.2%	100.0%
		% within Binary HB	35.2%	70.3%	50.0%
	yes	Count	57	19	76
		% within Hospital acquired PU developed	75.0%	25.0%	100.0%
		% within Binary HB	64.8%	29.7%	50.0%
Total		Count	88	64	152
		% within Hospital acquired PU developed	57.9%	42.1%	100.0%
		% within Binary HB	100.0%	100.0%	100.0%

- Binary WCC

Hospital acquired PU developed vs. Binary WBC Crosstabulation

			Binary WCC		
			<10	>=10	Total
Hospital acquired PU developed	no	Count	36	40	76
		% within Hospital acquired PU developed	47.4%	52.6%	100.0%
		% within Binary WCC	52.9%	48.2%	50.3%
	yes	Count	32	43	75
		% within Hospital acquired PU developed	42.7%	57.3%	100.0%
		% within Binary WCC	47.1%	51.8%	49.7%
Total		Count	68	83	151
		% within Hospital acquired PU developed	45.0%	55.0%	100.0%
		% within Binary WCC	100.0%	100.0%	100.0%

- Binary systolic B.P.

Hospital acquired PU developed vs. Binary systolic BP Crosstabulation

			Binary systolic B.P.		
			sys<113	sys>=113	Total
Hospital acquired PU developed	no	Count	9	60	69
		% within Hospital acquired PU developed	13.0%	87.0%	100.0%
		% within Binary systolic B.P.	25.0%	55.0%	47.6%
	yes	Count	27	49	76
		% within Hospital acquired PU developed	35.5%	64.5%	100.0%
		% within Binary systolic B.P.	75.0%	45.0%	52.4%
Total		Count	36	109	145
		% within Hospital acquired PU developed	24.8%	75.2%	100.0%
		% within Binary systolic B.P.	100.0%	100.0%	100.0%

- Binary diastolic B.P.

Hospital acquired PU developed vs. Binary Diastolic BP Crosstabulation

			Binary Diastolic B.P.		
			Diastolic < 60	Diastolic >= 60	Total
Hospital acquired PU developed	no	Count	6	63	69
		% within Hospital acquired PU developed	8.7%	91.3%	100.0%
		% within Binary Diastolic B.P.	30.0%	50.4%	47.6%
	yes	Count	14	62	76
		% within Hospital acquired PU developed	18.4%	81.6%	100.0%
		% within Binary Diastolic B.P.	70.0%	49.6%	52.4%
Total		Count	20	125	145
		% within Hospital acquired PU developed	13.8%	86.2%	100.0%
		% within Binary Diastolic BP	100.0%	100.0%	100.0%

Appendix: L

Detailed steps for fitting the three logistic models in the study using purposeful selection macro algorithm

- **Logistic regression for preventive interventions using purposeful selection macro modeling algorithm**

Variables fitted into the preliminary model ($P \leq 0.25$ in univariate analysis) and didn't violate goodness of fit assumption in logistic regression.

1- Sitting in chair

2- Draw sheets

3- Type of hospital bed

4- Seating cushion

5- First mattress

6- Re-positioning frequency

Variables tested as confounders ($P > 0.25$ in univariate analysis)

1- Barrier creams

2- Moisturizing cream

3- Dietician referral

4- Physiotherapy referral

Step 1: All interventions with $P \leq 0.25$ in univariate analysis were entered to this model using default enter method.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting on chair	-1.620	.443	13.360	1	.000	.198	.083	.472
Draw sheet	-1.530	.490	9.747	1	.002	.216	.083	.566
Type of hospital bed	1.199	.845	2.016	1	.156	3.318	.634	17.367
Seating cushion	-1.340	.880	2.317	1	.128	.262	.047	1.470
first mattress	.384	.472	.664	1	.415	1.468	.583	3.701
Positioning frequency			6.544	2	.038			
Re-positioning 2 hourly	.256	.560	.208	1	.648	1.291	.431	3.871
Re-positioning 4 hourly	-2.538	1.163	4.761	1	.029	.079	.008	.772
Constant	2.006	.665	9.102	1	.003	7.430		

Step 2: Variable first mattress was removed (largest *P* value). Removal of it did not change B estimates for any of the covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting on chair	-1.699	.435	15.291	1	.000	.183	.078	.428
Draw sheet	-1.469	.484	9.206	1	.002	.230	.089	.594
Type of hospital bed	1.311	.832	2.481	1	.115	3.711	.726	18.968
Seating cushion	-1.353	.880	2.366	1	.124	.258	.046	1.449
Positioning frequency			6.407	2	.041			
Positioning 2 hourly	.191	.554	.119	1	.730	1.211	.409	3.588
Positioning 4 hourly	-2.564	1.162	4.871	1	.027	.077	.008	.750
Constant	2.165	.642	11.369	1	.001	8.713		

Step 3: Removal of seating cushion (largest *P* value). Removal of it did not change B estimates for any of other covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting on chair	-1.827	.427	18.314	1	.000	.161	.070	.372
Draw sheet	-1.361	.465	8.564	1	.003	.256	.103	.638
Type of hospital bed	1.405	.834	2.839	1	.092	4.073	.795	20.866
Positioning frequency			6.540	2	.038			
Positioning 2 hourly	.022	.544	.002	1	.967	1.023	.352	2.971
Positioning 4 hourly	-2.726	1.155	5.568	1	.018	.065	.007	.630
Constant	2.205	.639	11.913	1	.001	9.068		

Step 4: Removal of type of hospital bed (largest *P* value). Removal of it didn't change B estimates for any of the other covariates by more than 20%. This model represents the semi-final model before testing for the confounding variables.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting on chair	-1.994	.422	22.321	1	.000	.136	.060	.311
Draw sheet	-1.421	.466	9.314	1	.002	.241	.097	.601
Positioning frequency			7.194	2	.027			
Positioning 2 hourly	.211	.534	.156	1	.693	1.235	.434	3.514
Positioning 4 hourly	-2.682	1.155	5.389	1	.020	.068	.007	.659
Constant	2.297	.640	12.869	1	.000	9.944		

The final model

Confounder variables (P>0.25) not initially tested with the model were entered once at a time to see if they were significant or changed B estimates by more than 20%. These confounders were: barrier creams, moisturizing cream, dietician referral and physiotherapy referral. All of them when entered one at a time to the model, were not significant. However, referral to physiotherapy was retained in the final model as confounder because it changed B estimates of other covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P value*	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Sitting on chair	-2.070	.431	23.054	1	.000	.126	.054	.294
Draw sheet	-1.416	.478	8.782	1	.003	.243	.095	.619
Positioning frequency			7.293	2	.026			
Positioning 2 hourly	.121	.548	.049	1	.825	1.129	.386	3.303
Positioning 4 hourly	-2.800	1.168	5.751	1	.016	.061	.006	.600
Physiotherapy referral	.561	.433	1.676	1	.195	1.752	.750	4.094
Dietician referral	.146	.468	.097	1	.756	1.157	.462	2.896
Constant	2.216	.646	11.773	1	.001	9.172		

- **Logistic regression for variables related to physical activity and mobility using purposeful selection macro modeling algorithm**

Variables fitted into the preliminary model ($P \leq 0.25$ in univariate analysis) and didn't violate goodness of fit assumption in logistic regression.

1- Activity in bed

2- Activity outside bed

3- Ability to do skin hygiene practices

4- Ability to do ADLs

Variables tested with the model as confounder ($p>0.25$ in univariate analysis)

1- Long surgical procedure ($\geq$ 2 hours)

Step 1: All interventions with $P \leq 0.25$ in univariate analysis were entered into this model using default enter method.

variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Activity in bed	1.688	.742	5.175	1	.023	5.411	1.263	23.174
Activity outside bed	.000	.522	.000	1	1.000	1.000	.359	2.785
Skin hygiene			5.528	2	.063			
Bed bath	1.236	.527	5.494	1	.019	3.440	1.224	9.668
Hoist bath	.804	.680	1.399	1	.237	2.234	.590	8.464
ADLs			7.335	2	.026			
Need one help	-.162	.805	.040	1	.841	.851	.176	4.121
Need two help	1.140	.925	1.520	1	.218	3.126	.511	19.144
Constant	-2.315	.758	9.320	1	.002	.099		

Step 2: Removal of activity outside bed (largest *P* value). Not significant and did not change B estimates for any of the covariates by more than 20%.
This is the semi-final model before testing for the confounding variables.

variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Activity in bed	1.688	.729	5.359	1	.021	5.411	1.295	22.601
Skin hygiene			7.417	2	.025			
Bed bath	1.236	.454	7.398	1	.007	3.441	1.412	8.383
Hoist bath	.804	.606	1.759	1	.185	2.234	.681	7.329
ADLs			7.742	2	.021			
Need one help	-.162	.804	.040	1	.841	.851	.176	4.114
Need two help	1.140	.922	1.529	1	.216	3.127	.513	19.043
Constant	-2.315	.755	9.396	1	.002	.099		

The final model

Long surgical procedure was tested with the semi-final model as a confounder. This variable changed B estimates by more than 20% for the covariate of activity in bed and ADLs but was not significant.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Activity in bed	2.039	.780	6.844	1	.009	7.687	1.668	35.425
Skin hygiene			7.857	2	.020			
Bed bath	1.301	.465	7.823	1	.005	3.674	1.476	9.146
Hoist bath	.883	.618	2.042	1	.153	2.418	.720	8.120
ADLs			8.658	2	.013			
Need one help	-.450	.831	.293	1	.588	.637	.125	3.252
Need two help	.937	.940	.994	1	.319	2.554	.404	16.126
Long Surgical procedure	.904	.483	3.505	1	.061	2.469	.958	6.361
Constant	-2.656	.797	11.114	1	.001	.070		

- **Logistic regression for variables related to intrinsic risk factors using purposeful selection macro modeling algorithm**

- Variables fitted into the preliminary model ($p \leq 0.25$ in univariate analysis) and didn't violate goodness of fit assumption in logistic regression.

1- Presence of dehydration

2- Binary systolic BP

3- Binary diastolic BP

4- Binary serum albumin

5- Binary Haemoglobin

6- Blood transfusion

7- Cognitive impairment

8- Depression

9- Number of underlying medical condition

10- Denture or chewing problem

11- Presence of dysphasia

12- Level of consciousness

- Variables tested as confounders (p>0.25) and didn't violate goodness of fit assumption in logistic regression.

1- Binary serum sodium

2- Binary serum creatinine

3- Binary WCC

4- Binary serum potassium

5- Binary serum urea

Step 1: All eligible variables with $P \leq 0.25$ entered to the model using default entering method.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Dehydration	-.227	.801	.080	1	.777	.797	.166	3.834
Binary systolic BP	-.674	.643	1.099	1	.294	.509	.144	1.797
Binary diastolic BP	-.236	.901	.069	1	.793	.790	.135	4.622
Binary serum Albumin	-1.737	.576	9.107	1	.003	.176	.057	.544
Binary Haemoglobin	-2.112	.638	10.938	1	.001	.121	.035	.423
Blood transfusion	-.448	.643	.486	1	.486	.639	.181	2.252
Cognitive impairment	1.777	.809	4.819	1	.028	5.910	1.210	28.875
Depression	.784	.858	.835	1	.361	2.191	.408	11.776
Underlying medical conditions			27.167	3	.000			
One condition	.826	.750	1.210	1	.271	2.283	.525	9.936
Two conditions	2.527	.830	9.267	1	.002	12.514	2.460	63.673
Three conditions	4.858	1.012	23.066	1	.000	128.804	17.737	935.382
Dentures/ chewing problem	.535	.563	.903	1	.342	1.707	.566	5.145
Dysphagia	.267	.840	.101	1	.751	1.306	.252	6.776
level of consciousness	.268	.612	.192	1	.661	1.307	.394	4.337
Constant	.329	1.089	.091	1	.762	1.390		

Step 2: Binary diastolic BP (largest p) value was deleted from the model. No change for B estimates for the rest of covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Dehydration	-.209	.800	.068	1	.794	.812	.169	3.893
Binary systolic BP	-.738	.597	1.528	1	.216	.478	.148	1.541
Binary serum Albumin	-1.774	.560	10.049	1	.002	.170	.057	.508
Binary haemoglobin	-2.121	.637	11.103	1	.001	.120	.034	.417
Blood transfusion	-.430	.639	.453	1	.501	.650	.186	2.276
Cognitive impairment	1.755	.802	4.789	1	.029	5.782	1.201	27.840
Depression	.747	.844	.785	1	.376	2.112	.404	11.032
Underlying medical conditions			27.629	3	.000			
One condition	.810	.745	1.182	1	.277	2.249	.522	9.693
Two conditions	2.472	.799	9.558	1	.002	11.842	2.471	56.750
Three conditions	4.825	1.001	23.225	1	.000	124.606	17.510	886.738
Dentures/ chewing problem	.528	.561	.886	1	.346	1.696	.565	5.092
Dysphagia	.289	.839	.118	1	.731	1.335	.258	6.906
Level of consciousness	.261	.611	.183	1	.669	1.299	.392	4.304
Constant	.214	.993	.047	1	.829	1.239		

Step 3: Presence of dehydration (largest *p* value) was deleted from the model. No change for B estimates for the rest of covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary systolic BP	-.729	.595	1.500	1	.221	.483	.150	1.548
Binary serum Albumin	-1.768	.558	10.030	1	.002	.171	.057	.510
Binary Haemoglobin	-2.092	.626	11.186	1	.001	.123	.036	.421
Blood transfusion	-.459	.629	.532	1	.466	.632	.184	2.170
Cognitive impairment	1.747	.799	4.787	1	.029	5.738	1.200	27.444
Depression	.770	.844	.834	1	.361	2.160	.413	11.289
Underlying medical conditions			27.761	3	.000			
One condition	.779	.733	1.128	1	.288	2.179	.518	9.175
Two conditions	2.446	.791	9.570	1	.002	11.540	2.450	54.349
Three conditions	4.788	.988	23.499	1	.000	120.119	17.329	832.597
Dentures/ chewing problem	.508	.555	.835	1	.361	1.661	.559	4.934
Dysphagia	.254	.825	.095	1	.758	1.289	.256	6.488
Level of consciousness	.233	.600	.151	1	.698	1.263	.389	4.094
Constant	.065	.811	.006	1	.936	1.067		

Step 4: Dysphasia (largest *p* value) value was deleted from the model. No change for B estimates of other covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary systolic BP	-.716	.592	1.467	1	.226	.489	.153	1.557
Binary serum Albumin	-1.772	.557	10.106	1	.001	.170	.057	.507
Binary haemoglobin	-2.099	.625	11.294	1	.001	.123	.036	.417
Blood transfusion	-.504	.613	.675	1	.411	.604	.182	2.009
Cognitive impairment	1.766	.798	4.889	1	.027	5.845	1.222	27.950
Depression	.792	.846	.875	1	.350	2.207	.420	11.591
Underlying medical conditions			28.038	3	.000			
One condition	.816	.724	1.272	1	.259	2.262	.548	9.338
Two conditions	2.472	.786	9.882	1	.002	11.842	2.536	55.299
Three conditions	4.790	.983	23.754	1	.000	120.284	17.526	825.553
Dentures/ chewing problem	.528	.552	.916	1	.338	1.695	.575	4.997
Level of consciousness	.224	.601	.139	1	.709	1.251	.385	4.063
Constant	.073	.812	.008	1	.929	1.075		

Step 5: Level of consciousness (largest *p* value) was deleted from the model. No change for B estimates for the rest of covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary systolic BP	-.766	.591	1.683	1	.195	.465	.146	1.479
Binary serum Albumin	-1.805	.551	10.722	1	.001	.164	.056	.484
Binary Haemoglobin	-2.080	.620	11.249	1	.001	.125	.037	.421
Blood transfusion	-.508	.603	.712	1	.399	.601	.185	1.960
Cognitive impairment	1.850	.744	6.179	1	.013	6.359	1.479	27.345
Depression	.915	.824	1.232	1	.267	2.496	.496	12.552
Underlying medical conditions			28.066	3	.000			
One condition	.751	.706	1.130	1	.288	2.118	.531	8.457
Two conditions	2.429	.767	10.025	1	.002	11.353	2.523	51.081
Three conditions	4.739	.970	23.855	1	.000	114.311	17.069	765.545
Dentures/ chewing problem	.597	.542	1.212	1	.271	1.817	.628	5.261
Constant	.197	.792	.062	1	.804	1.217		

Step6: Blood transfusion **(**largest *p* value) was deleted from the model. No change for B estimates of other covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary systolic BP	-.718	.586	1.500	1	.221	.488	.154	1.539
Binary serum Albumin	-1.703	.533	10.224	1	.001	.182	.064	.517
Binary Haemoglobin	-1.937	.591	10.752	1	.001	.144	.045	.459
Cognitive impairment	1.723	.719	5.747	1	.017	5.599	1.369	22.898
Depression	.833	.829	1.009	1	.315	2.300	.453	11.682
Underlying medical conditions			27.462	3	.000			
One condition	.751	.710	1.120	1	.290	2.120	.527	8.520
Two conditions	2.416	.767	9.917	1	.002	11.197	2.490	50.360
Three conditions	4.679	.971	23.219	1	.000	107.680	16.053	722.283
Dentures/ chewing problem	.630	.538	1.370	1	.242	1.877	.654	5.389
Constant	-.074	.723	.011	1	.918	.928		

Step7: Depression **(**largest p value) was deleted from model (largest *p* value). No change of B estimates for the rest for covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary systolic BP	-.730	.587	1.549	1	.213	.482	.153	1.522
Binary serum Albumin	-1.767	.528	11.195	1	.001	.171	.061	.481
Binary Haemoglobin	-2.004	.590	11.544	1	.001	.135	.042	.428
Cognitive impairment	1.823	.714	6.520	1	.011	6.188	1.527	25.067
Underlying medical conditions			27.271	3	.000			
One disorder	.742	.705	1.107	1	.293	2.099	.527	8.355
Two conditions	2.435	.763	10.177	1	.001	11.415	2.557	50.950
Three conditions	4.662	.975	22.866	1	.000	105.844	15.660	715.367
Dentures/ chewing problem	.724	.527	1.882	1	.170	2.062	.733	5.797
Constant	.038	.711	.003	1	.957	1.039		

Step8: Binary systolic BP **(**largest p value) was deleted from model. No change for B estimates for the rest of covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary serum Albumin	-2.001	.511	15.328	1	.000	.135	.050	.368
Binary Haemoglobin	-2.025	.582	12.106	1	.001	.132	.042	.413
Cognitive impairment	1.813	.705	6.609	1	.010	6.127	1.538	24.406
Underlying medical conditions			29.219	3	.000			
One condition	.713	.680	1.099	1	.294	2.040	.538	7.732
Two conditions	2.419	.743	10.601	1	.001	11.237	2.619	48.207
Three conditions	4.725	.946	24.943	1	.000	112.747	17.651	720.159
Dentures/ chewing problem	.723	.518	1.949	1	.163	2.060	.747	5.685
Constant	-.384	.643	.357	1	.550	.681		

Step 9: The variable dentures/ chewing problem was removed from the model (largest *p* value). Moving it didn't change B estimates of other covariates by more than 20%. All variables remained in the model were significant. This model represents the stage where confounders (P>0.25) were not yet tested with this model to see if any of them will turn significant or change B estimates of any of the covariates by more than 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary serum Albumin	-2.112	.504	17.573	1	.000	.121	.045	.325
Binary Haemoglobin	-1.949	.571	11.630	1	.001	.142	.046	.437
Cognitive impairment	1.575	.673	5.484	1	.019	4.831	1.293	18.053
Underlying medical conditions			29.332	3	.000			
One condition	.795	.673	1.395	1	.238	2.214	.592	8.277
Two conditions	2.398	.740	10.493	1	.001	11.003	2.578	46.956
Three conditions	4.734	.938	25.488	1	.000	113.732	18.102	714.538
Constant	-.051	.591	.007	1	.931	.950		

The final model

Confounder variables (P>0.25) were entered to the semi-final model one at a time. None of these confounders turned to be significant within the logistic model. However, two confounder variables, namely: binary serum sodium and binary serum urea were kept in the final model because they changed B estimates for the category (one underlying medical disorder) in the underlying medical disorder variable by more the 20%.

Variable	B	S.E.	Wald	d.f.	*P* value	Odds Ratio	95.0% C.I. for Odds Ratio	
							Lower	Upper
Binary serum Albumin	-2.269	.544	17.407	1	.000	.103	.036	.300
Binary Haemoglobin	-1.977	.586	11.386	1	.001	.139	.044	.437
Cognitive impairment	1.469	.691	4.514	1	.034	4.344	1.121	16.841
Underlying medical conditions			30.273	3	.000			
One disorder	.776	.703	1.220	1	.269	2.174	.548	8.620
Two conditions	2.588	.768	11.348	1	.001	13.307	2.952	59.995
Three conditions	4.963	.965	26.424	1	.000	143.008	21.556	948.773
Binary serum urea	-1.315	.938	1.965	1	.161	.268	.043	1.688
Binary serum sodium	1.026	.598	2.942	1	.086	2.789	.864	9.003
Constant	-.635	.711	.798	1	.372	.530		

Appendix M

(Abstract from the 29th Tissue Viability Society Annual Conference: Looking at things differently: collaboration, evidence and innovation for practice. April 13-14, Telford, UK.)

A retrospective approach to explore effective nursing interventions that prevented hospital acquired pressure ulcers in a Waterlow sub-scores matched cohort

Ma'en Aljezawi, Denis Anthony

Abstract

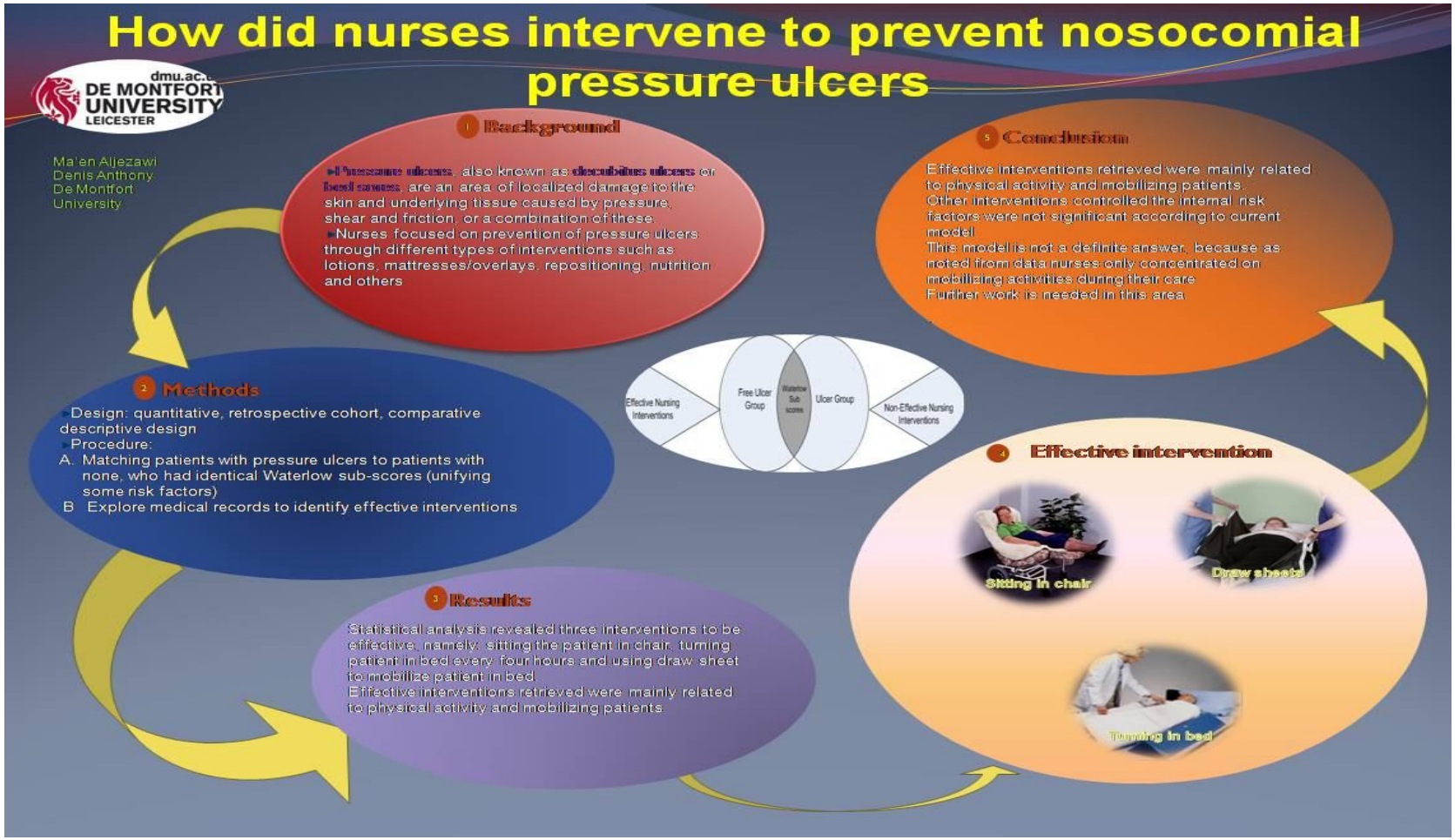
This study explores effective interventions in the area of pressure ulcer. A retrospective approach was used in this study to explore such interventions in a more natural clinical environment than found in a prospective study. While retrospective studies have their limitations, one problem of prospective studies, the Hawthorn effect, is not present.

A matched design was employed. The first group developed pressure ulcer during hospitalization, the other did not. In order to have a sound and robust comparison, patients from the two groups were matched or nearly matched on a number of Waterlow sub-scores, though further criteria for selection were carried out. These included: a minimum of three days total length of stay in hospital and being initially free of any pressure ulcer on admission for both groups. Electronic medical records for the two groups were revised and multidimensional data were extracted.

Data analyses were carried out using univariate analysis and multivariate analysis. In univariate analysis, the following interventions were significantly associated with pressure ulcer prevention ($P \leq 0.05$): standard hospital bed, seating cushion, static pressure redistributing mattress, positioning every four hours and helping the patient to sit regularly in a chair. When the effect of all interventions was adjusted through the multivariate model, the following interventions were independently associated with prevention: draw sheet, re-positioning every four hours and helping patient to sit regularly in chair (odds ratio = 0.24, 0.06 and 0.13 respectively).

Appendix N

(Poster presented in the Research Degree Student's Poster Competition, De Montfort University, Leicester, UK, April 2010)



Appendix O

Fitting the three logistic models in the study using stepwise regression

- Logistic regression for preventive interventions

Variable	B	S.E.	Wald	d.f.	*P* value	Odds ratio
Sitting on chair	-1.671	.371	20.247	1	.000	.188
Constant	1.076	.299	12.955	1	.000	2.933
Sitting on chair	-1.974	.404	23.898	1	.000	.139
Draw sheet	-1.217	.424	8.247	1	.004	.296
Constant	2.122	.488	18.892	1	.000	8.346
Sitting on chair	-1.950	.423	21.287	1	.000	.142
Draw sheet	-1.367	.467	8.564	1	.003	.255
Positioning frequency			7.193	2	.027	
Re-positioning 2 hourly	.154	.544	.080	1	.777	1.166
Re-positioning 4 hourly	-2.740	1.159	5.587	1	.018	.065
Constant	2.297	.643	12.777	1	.000	9.942

- Logistic regression for variables related to physical activity and mobility

Variable	B	S.E.	Wald	d.f.	*P* value	Odds ratio
ADLs			26.051	2	.000	
Need one help	1.269	.667	3.617	1	.057	3.556
Need two help	3.140	.730	18.516	1	.000	23.111
Constant	-1.674	.629	7.079	1	.008	.188
Activity in bed	1.667	.715	5.429	1	.020	5.295
ADLs			15.561	2	.000	
Need one help	.430	.763	.317	1	.574	1.537
Need two help	2.104	.839	6.280	1	.012	8.197
Constant	-2.304	.750	9.438	1	.002	.100
Activity in bed	1.688	.729	5.359	1	.021	5.411
Skin hygiene			7.417	2	.025	
Bed bath	1.236	.454	7.398	1	.007	3.441
Hoist bath	.804	.606	1.759	1	.185	2.234
ADLs			7.742	2	.021	
Need one help	-.162	.804	.040	1	.841	.851
Need two help	1.140	.922	1.529	1	.216	3.127
Constant	-2.315	.755	9.396	1	.002	.099

- Logistic regression for variables related to intrinsic risk factors

variables	B	S.E.	Wald	d.f.	*P* value	Odds ratio
Binary albumin	-2.156	.396	29.578	1	.000	.116
Constant	1.327	.312	18.089	1	.000	3.769
Binary albumin	-2.410	.483	24.871	1	.000	.090
Underlying medical conditions			27.164	3	.000	
One condition	.796	.637	1.560	1	.212	2.216
Two conditions	2.038	.672	9.186	1	.002	7.674
Three conditions	3.773	.786	23.066	1	.000	43.527
Constant	-.101	.548	.034	1	.854	.904
Binary albumin	-2.138	.504	17.987	1	.000	.118
Binary haemoglobin	-1.635	.538	9.233	1	.002	.195
Underlying medical conditions			27.270	3	.000	
One condition	.880	.674	1.703	1	.192	2.410
Two conditions	2.244	.726	9.543	1	.002	9.430
Three conditions	4.303	.888	23.464	1	.000	73.889
Constant	.198	.579	.117	1	.733	1.219
Binary albumin	-2.044	.514	15.819	1	.000	.129
Binary haemoglobin	-1.840	.572	10.354	1	.001	.159
Cognitive impairment	1.387	.678	4.183	1	.041	4.004
Underlying medical conditions			27.868	3	.000	
One condition	.847	.706	1.440	1	.230	2.333
Two conditions	2.419	.768	9.930	1	.002	11.232
Three conditions	4.679	.959	23.801	1	.000	107.614
Constant	-.139	.630	.049	1	.825	.870