USE OF AN INTERVENTIONAL PATIENT SKIN INTEGRITY CARE BUNDLE IN THE INTENSIVE CARE UNIT

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Keywords

Adult intensive care, barriers, care bundle, compliance, facilitators, implementation, incidence, intervention, medical devices related ulcer, Ottawa of Model Research Use, pressure ulcer, prevention, registered nurses’ attitude, and risk factors.
Abstract

**Background:** Pressure ulcers (PUs) have been identified as a worldwide problem that contribute significantly to increasing health care costs, compromise an individual’s health, and in some cases contribute to mortality. Generally, PUs are considered predictable and preventable, thus making them a priority patient safety and risk management issue. Despite a number of published guidelines for PU prevention in general healthcare contexts, PU prevention guidelines for the intensive care patient is not a well-defined area. The intensive care context poses special challenges to PU prevention due to the high acuity of patients and the highly invasive nature of interventions and therapies critically ill patients receive. Accordingly, PU prevalence and incidence rates reported in the adult critical care population are as high as 56%. However, no data is available for the Kingdom of Saudi Arabia (KSA) intensive care context. These high rates could reflect a gap between dissemination and implementation of evidence-based PU prevention approaches in intensive care. Importantly, this is an under-researched area of need in the KSA context.

In response to these challenges, this research proposed a comprehensive process, integrating a care bundle approach of best available evidence and a model of research implementation, the Ottawa Model of Research Use (OMRU). The care bundle approach provides a protocol of high quality evidence of PU prevention strategies, while the OMRU, a knowledge translation framework, can be used to guide the translation of the care bundle into action.

**Aim:** The overarching research aim guiding this study is to examine the effectiveness of an interventional patient skin integrity care bundle in the intensive care unit to best manage skin integrity in critically ill patients.
Design: In Phase One Part A, a prospective observation study was conducted to generate benchmark profiles of the problem (PU incidence). Phase One Part B used survey methods, (the Attitude towards Pressure ulcer Prevention instrument [APuP], and the modified PU prevention in the Paediatric Intensive Care Unit (PICU) "Barriers and Facilitators") to identify the barriers and facilitators to research use in the intensive care unit (ICU) context. Tailored research transfer strategies were enacted based on the findings. In Phase Two, a two-arm cluster randomised experimental control trial and observation design was used to monitor and evaluate the implementation of the PU prevention bundle.

Participants: Participants were recruited from the ICUs of two major tertiary care hospitals in KSA. In Phase One Part A, a total of 84 ICU patients were screened on a second daily basis until discharge or death, over a consecutive 30-day period. In Phase One Part B, 56 of the available 60 intensive care Registered Nurses (RNs) participated in the study. In Phase Two, a total of 140 ICU patients were recruited; 70 control participants (with a total of 728 days of observation) and 70 intervention participants (with a total of 784 days of observation).

Result: Phase One Part A identified a cumulative hospital-acquired PU incidence rate of 39.3% (33/84 participants). The incidence of medical device-related PUs was 8.3% (7/84). According to binary logistic regression analyses, age, longer stay in the ICU, and infrequent repositioning were significant predictors of all stages of PUs, while the length of stay in the ICU and infrequent repositioning were associated with the development of PUs staged II–IV.

Phase One Part B found no significant differences between the demographic characteristics of the participants with the RNs attitude subscale, and perceived barriers and facilitators towards PU prevention in the ICU. Several barriers influenced
RNs ability in PU prevention; including time demands ($\beta=0.388$, $p=0.011$), limitation of RNs knowledge ($\beta=-0.632$, $p=0.022$), and the current documentation format ($\beta=0.344$, $p=0.046$). Impact of workload and lack of education were also reported as barriers that impeded the implementation of high quality in PU prevention evidence in the ICU. However, there were some statistically significant facilitating factors that increased the RN’s ability to implement PU prevention strategies in the ICU, such as ease of obtaining pressure relieving support surfaces ($\beta=-0.388$, $p=0.007$), collaboration with interdisciplinary teams (nursing/medicine/pharmacy/dietary) ($\beta=0.37$, $p=0.02$), and availability of appropriate skin care products ($\beta=0.44$, $p=0.015$). Moreover, RNs showed a moderately positive attitude towards PU prevention ($\mu=38.19/52, 73.44\%$). However, two factors showed lower attitude scores; the impact of a PU on the patient and society ($\mu=8.19/12, 68\%$), and the priority of PU prevention ($\mu=8.28/12, 69\%$) in their daily routine work.

Phase Two revealed no significant differences between both groups (intervention and control) in all demographic characteristics and all clinical characteristics, except time in the operating room prior to ICU admission. Braden Scale data showed that a majority of the participants in both groups were at high risk of PU development. PU cumulative incidence was significantly lower in the intervention group (7.14%) compared to the control group (32.86%). Poisson regression modelling inferred that the rate of any new PUs in the intervention group was 70% lower in the intervention group than the control. The intervention, the PU prevention care bundle, contributed positively in lowering the severity of PU development between the intervention and control group, with significant differences in stage I and stage II PUs between the groups ($p=.001$ and $p=0.029$ respectively).
Conclusion: This the first study to examine the phenomena of PUs and PU prevention strategies in the KSA context. Further, this study was the first to determine the incidence of PU events in KSA ICUs and to test the effectiveness of a PU prevention bundle that comprises the best available evidence to improve skin integrity. The initial incidence rate of 39% was higher than that reported in other international studies. This indicates the importance of putting PU prevention strategies into practice in this setting. The PU prevention bundle, based on a tailored assessment of the health care setting (ICUs) and clinicians (RNs), and implemented effectively in practice had a significant effect in reducing PU development in critically ill patients in the ICU.
A Note Regarding Format

This dissertation is a thesis by publication. It contains six articles that have either been published or are under blind-peer review by refereed journals, therefore, the wording and spelling of the journals are as published and some contain American spelling. The logical flow of the thesis is maintained by introducing these articles where they fit most appropriately into the thesis structure. All articles have been reformatted using the APA referencing style and reconfigured to Word to provide consistent formatting throughout the thesis. Moreover, tables and figures have been numbered continuously throughout the thesis, for consistency.
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<td>EPUAP</td>
<td>European Pressure Ulcer Advisory Panel</td>
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<td>HAPU</td>
<td>Hospital-acquired pressure ulcer</td>
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<tr>
<td>ICU</td>
<td>Intensive care unit</td>
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<td>KSA</td>
<td>Kingdom of Saudi Arabia</td>
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<td>MDRU</td>
<td>Medical device-related ulcer</td>
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<td>NPUAP</td>
<td>National Pressure Ulcer Advisory Panel</td>
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<td>PPPIA</td>
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Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signature:

Date: ___05 October 2016________
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Finally, thanks to Umm Al-Qura University for offering me the scholarship to gain my postgraduate degree and to everyone at Queensland University of Technology for their cooperation and support.
Chapter 1: Introduction

Pressure ulcers (PUs) represent a common but potentially preventable condition seen most often in high-risk populations such as elderly persons, those with physical impairments, and the critically ill. Evidence suggests that PUs can be prevented with the implementation of PU prevention guidelines or a care bundle (Elliott, McKinley, & Fox, 2008; Gray-Siracusa & Schrier, 2011; Schindler, 2009). Care bundle approaches have been frequently used in clinical practice, and have been shown to provide improvement in the process of care and patient outcomes (Fulbrook & Mooney, 2003; Gray-Siracusa & Schrier, 2011; Kiernan & Downie, 2011; Pronovost et al., 2006; Schindler et al., 2013). While there is considerable evidence for PU prevention globally (Coyer et al., 2015; Dibsie, 2008; Elliott et al., 2008), a PU prevention bundle suited to the Kingdom of Saudi Arabia (KSA) intensive care unit (ICU) context has not been clearly defined, nor previously implemented and tested. Therefore, a new PU prevention bundle for the KSA ICU context is crucial to improve patients’ outcomes, decrease costs, and reduce the morbidity and mortality rates of ICU patients. This study evaluates the effectiveness of the PU prevention bundle in a KSA ICU context.

The term “pressure ulcer” is used throughout this document in lieu of “pressure injury”. There is a view that the term pressure injury is more realistic, as it denotes damage from pressure as an injury, possibly a preventable occurrence, whereas the term ulcer connotes a wound occurring as a complication of an event (Australian Wound Management Association (AWMA), 2012). This study was conducted in KSA, where the healthcare system is linked to Europe and the United States of America (USA). In Europe and the USA the term PU is used, accepted, and reported (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel [EPUAP.
& NPUAP], 2009). Therefore, in keeping with the convention where this study was conducted, the term “pressure ulcer” is used throughout this study.

This chapter outlines the background and significance of the research programme and presents the aims, research questions, and hypotheses. The provision of background information and significance of PUs and issues surrounding this phenomenon will highlight the importance of this study. This chapter concludes with the outline of the thesis document.

1.1 BACKGROUND

Critically ill patients managed in an ICU may experience multiple physiological changes directly related to their illness and possibly their care (Bouten, Oomens, Baaijens, & Bader, 2003; Brower, 2009; Clavet, Hébert, Fergusson, Doucette, & Trudel, 2008; Convertino, 1997; Fan, Zanni, Dennison, Lepre, & Needham, 2009; Hamburg et al., 2007; Morris, 2007; Truong, Fan, Brower, & Needham, 2009; Vollman, 2010; Winkelman, 2009; Youngman, 2008). The majority of ICU patients are ventilated and sedated and, therefore, unable to care for themselves, move or change position. Further, the patient’s critical illness may involve haemodynamic instability which potentially may complicate and accelerate the effects of prolonged immobility. Paradoxically, mobility is a natural defence to alleviate prolonged pressure on the skin (Shahin, Dassen, & Halfens, 2008). Extensive exposure to pressure, from lying or sitting, on a specific part of the body renders patients at greater risk of skin breakdown. Therefore, the vulnerability of these patients places them at high risk of impaired skin integrity, particularly PU development.
Pressure ulcers are one of the most common problems in health care settings. Hospital patients are often particularly vulnerable because of their illness. Literature suggests that PUs have devastating effects on patients’ care outcomes, either on an individual patient level (such as quality of life [Gorecki et al., 2009], pain [Günes, 2008], infection [Baranoski, 2006; Yoshikawa, Livesley, & Chow, 2002], length of stay [Graves, Birrell, & Whitby, 2005], and morbidity and mortality [Spear, 2013] or the healthcare system levels (such as quality of care [Vollman, 2010], and economic cost [Bennett, Dealey, & Posnett, 2004; Padula, Mishra, Makic, & Sullivan, 2011]).

Pressure ulcer rates are most frequently measured as either prevalence or incidence. Reports of prevalence and incidence fluctuate widely across different healthcare settings globally (Berlowitz, 2014). However, difficulties are apparent when reviewing or comparing PU studies due to different methodologies, differing patient populations in different health care settings, variance in the reporting of PU stages, underreporting of PU prevalence or incidence, different sample sizes, and insufficient control of data acquisition (Ikechukwu, 2012; Prentice, Stacey, & Lewin, 2003; Stotts, Brown, Donaldson, Aydin, & Fridman, 2013; Woodbury & Houghton, 2004). Moreover, the use of different PU classification systems (Bethell, 2002), and organisational considerations such as varied nurse/patient ratios and differing use of preventive devices all contribute to inherent difficulties in comparing PU incidence or prevalence studies (Benbow, 2004; Kaltenthaler, Whitfield, Walters, Akehurst, & Paisley, 2001; Meehan, 1990; Prentice, Stacey, & Lewin, 2003; Whittington, Patrick, & Roberts, 2000). Overall, all these studies highlight that the ICU context is the most common acute care setting for PU development. In KSA where this research was conducted there is no data reflecting the magnitude of the PU problems in the ICU.
context. Therefore, increased awareness of the scope of the problem and the importance of prevention is essential.

1.1.1 Brief Historical Prospective

The earliest examples of PUs have been found in Egyptian mummies, dated more than 5000 years old (Agrawal & Chauhan, 2012). In 1593, the clinical characteristics and causes of PUs were identified for the first time by Fabricius Hildanus, a “father of German surgery”, who hypothesised that the development of a PU was influenced by external and internal supernatural factors, and interruption of the blood and nutrient supply in the tissue (Defloor, 1999). During the sixteenth century, the first recommendations for PU prevention and treatment were developed, including good nutrition, debridement, and relief of pain and pressure (Agrawal & Chauhan, 2012). Interestingly, these recommendations are still relevant to recently published guidelines for PU prevention strategies (NPUAP, EPUAP, & Pan Pacific Pressure Injury Alliance (PPPIA), 2014). In 1722, PU development was positively associated with mechanical pressure and incontinence (Defloor, 1999). In the nineteenth-century, Charcot suggested “neurotropic theory” as the causation of ulcers, rather than pressure or local irritation (Levine, 2005). However, this theory was rejected and direct pressure was then understood to be the main contributing factor for PU development (Agrawal & Chauhan, 2012). In the twentieth century, shear and pressure forces were considered the fundamental factors for PU development; the same factors underlying the present understanding of PU aetiology (Agrawal & Chauhan, 2012; Defloor, 1999). In recent years, many clinicians and researchers have paid closer attention to the PU phenomena in order to identify pathophysiological sequale, associated risk factors, and different prevention and treatment strategies (AWMA, 2012; Kottner, Balzer, Dassen, &
1.1.2 Pressure Ulcers Defined

A PU, also known as pressure injury, pressure sore, decubitus ulcer, trophic ulcer, ischaemic ulcer, decubiti, or bed sore, results from a prolonged exposure to pressure from lying or sitting on a specific part of the body. This renders patients at greater risk of skin breakdown and delayed wound healing (Lyder, 2003; Vollman, 2010; Youngman, 2008). The NPUAP and EPUAP (2009) defined a PU as a lesion or trauma to the skin and underlying tissue resulting from unrelieved pressure, shear, friction, moisture, or a combination of these, usually over a bony prominence (EPUAP & NPUAP, 2009). Constant pressure to specific areas of the skin will impair blood circulation and disturb nerve impulses in the localised area, which in turn decreases supply of oxygen and essential nutrients to the part. Therefore, underlying tissue ischaemia occurs, leading to ulceration and necrosis (Black et al., 2007; Ousey, 2009). Moreover, there is emerging laboratory and animal evidence to show that high shear forces also contribute to cellular deformation which results in PU development (Bouten, Oomens, Baaijens, & Bader, 2003; Gefen, van Nierop, Bader, & Oomens, 2008; Stekelenburg et al., 2007). Bouten et al. (2003) suggests there are two types of PU based on the mechanism of PU development: superficial (which is a result of shear forces in the skin layers) and deep PUs (which occur due to sustained compression of the tissue). It could be assumed that a superficial PU could be a stage I or II ulcer, however Bouten et al. (2003) did not link this argument to PU staging.
Pressure ulcer development is a complex phenomenon. Understanding and increased awareness by all healthcare practitioners is required for all aspects of the PU phenomenon, including staging, common sites, risk factors, and prevention strategies. There are two categories of PU: hospital-acquired PU (HAPU), which is defined as a PU developed after 24 hours of hospital admission, and community-acquired PU (CAPU), defined as PU developed before hospital admission or with 24 hours of admission (Asimus & Li, 2011; Gibbons, Shanks, Kleinhelter, & Jones, 2006).

1.1.3 PU Staging

PU staging (grading/classification) refers to a recognised and established system to classify the level of tissue damage or depth of the ulcer observed. Such staging and determination of the magnitude of the problem is central to developing PU prevention programmes and treatment. Moreover, the use of a standardised staging system permits health care workers to be objective in their assessment of the depth of tissue ulcer. The NPUAP and EPUAP (2005) updated the definition of the staging system of PUs by adding two stages to the traditional classification, namely I to IV (see Appendix A).

The updated classification system has solved some of the limitations of the old staging system. For example, in the previous system, when an eschar (a slough of dead tissue cast off from the skin) was present, accurate determination of the stage of the PU was not possible until the eschar had sloughed or the wound had been debrided, as necrotic tissues could mask the true extent of the wound (Doughty et al., 2006). However, classification systems still have limitations, such as identifying stage one PUs and deep-tissue injury in dark-skinned people (Doughty et al., 2006). Defloor,
Schoonhoven, Katrien, Westrate and Myny (2006) suggested classifying stage I PUs (non-blanchable erythema) not as PUs, but as alarm signals. Despite the recent work on the staging system of PUs, which reflects the existing level of tissue damage as observed, the pathology or history of PUs in the patient needs to be considered in the management of PUs (Black et al., 2007).

Hart, Berquist, Gajewski and Dunton (2006) conducted a survey study that explored the inter-rater reliability to standard reliability of PU identification, staging, and source of PUs among 256 participants from 48 hospitals. The inter-rater reliability of the updated classification was substantially reliable, as shown by the Cohen's kappa coefficient (PU identification $\kappa = 0.56$; PU binary identification $\kappa = 0.84$; PU stage $\kappa = 0.65$; PU source $\kappa = 0.80$). However, the majority of participants (67%) were staff nurses and had received a higher level of education, and 17% of participants were certified in wound, incontinence, and ostomy care. This could have positively affected the accuracy of the results (Hart et al., 2006). A systematic review of the inter-rater reliability of the PU classification found that the classification reliability should be taken with caution because of identified limitations such as sample size and sample characteristics (Kottner, Raeder, Halfens, & Dassen, 2009). Accurate and standardised identification of PU staging is required to measure PUs as the primary outcome of prevention strategies and to reliably enhance comparison between studies (Kottner et al., 2009).

1.1.4 Common PU Sites

PUs commonly occur over bony prominence areas, as the soft tissue is compressed between two firm surfaces; the bone and the surface that the body part is
lying on or against. Approximately 95% of PUs occur in the lower part of the body (Thomas, 2007). Literature suggests that in the general clinical context, the sacral and coccygeal, ischial tuberosities, and greater trochanteric areas account for the majority of PU site occurrences (Amlung, Miller, & Bosley, 2001; Dealey, 1991; Peterson, 2009; Thomas, 2007). The most frequent site for PU development is the sacrum (36%), followed by the heel (30%), and other areas (6%), such as upper extremities and the head (Amlung et al., 2001; Meehan, 1990; Thomas, 2007). Similarly, the most common anatomical locations for PU development in ICU patients have been identified as the sacrum (24.3 - 45.2%), and heel area (22.6 - 29.2%) (Ahtiala, Soppi, Wiksten, Koskela, & Grönlund, 2014; Tayyib, Coyer, & Lewis, 2015a). However, evidence suggests that 20% - 34.5% of total PU incidence in the intensive care environment relates to medical devices (Black et al., 2010; Tayyib et al., 2015a).

1.1.5 International Guideline for PU Assessment and Prevention

Given the heightened risk ICU patients face in developing a PU, prevention strategies are paramount. For this to occur, the primary aim of PU prevention is to reduce, manage, and monitor risk factors. To achieve this aim, regular skin examination, relief of intensive and prolonged pressure, and assessment and management of factors such as malnutrition, faecal incontinence, and shear and friction forces should be considered. Several strategies can be used to prevent PU formation, such as the use of special skin care products, frequent patient repositioning, and pressure-relieving devices and support surfaces (Reilly, Karakousis, Schrag, & Stawicki, 2007). These strategies can be grouped together in a guideline to improve
Many guidelines have been published by world organisations such as the Australian Wound Management Association (AWMA) (2012), the NPAUP and the EPAUP (2009), and the Wound, Ostomy and Continence Nurses Society (2010). However, these are not specific to the ICU. The NPAUP and EPAUP collaborated to produce the international prevention of PUs guideline (EPUAP & NPUAP, 2009). This guideline is based on updated evidence-based recommendations for all patients in different health care settings. These include current definitions and the new classification of PUs, risk assessment scales, including the role of nutrition, skin assessment, and skin care, positioning and repositioning patients, evidence for the use of pressure relieving devices and protective devices used for PU prevention, and education and training for health care providers. The Wound, Ostomy and Continence Nurses Society (2010) suggested that the principles of PU prevention and treatment should contain risk assessment, systemic skin assessment, reduction of risk factors, patient, family, and staff education, and evaluation (Wound Ostomy and Continence Nurses Society, 2010). The Australian Wound Management Association (AWMA) (2012), as part of a collaboration between the AWMA, the New Zealand Wound Care Society, Hong Kong Enterostomal Therapists Association, and the Wound Healing Society of Singapore presented the Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injuries. This guideline includes the following components: identifying individuals ‘at risk’ and associated risk factors, implementing strategies aimed at eliminating risk factors and protecting the individual from potential further risk, and continually evaluating the effectiveness of the delivered care (AWMA, 2012). Despite some apparent variations noted in the
comparison of the above guidelines, the differences are not significant. The core components are identical, namely comprehensive skin assessment, assessment of risk factors, nutritional management, pressure relieving devices, strategies to reduce pressure, friction, shear and moisture, and education. Thus, the development of any comprehensive and effective PU prevention guideline or care bundle should be based on contemporaneous high quality evidence related to the core components of the aforementioned guidelines, as well as the use of advanced technological, contextually compatible techniques for decreasing the incidences of PU. For the purpose of this study, the NPAUP & the EPAUP (2009) guideline was followed, as this was the most current, widely accepted guideline published at the time the study was conducted.

1.2  RESEARCH AIM AND QUESTIONS

This research aims to address the gap in PU prevention practice for critically ill patients in KSA ICU. The overarching research aim guiding this study is to examine the effectiveness of an interventional patient skin integrity care bundle in the intensive care unit to best manage skin integrity in critically ill patients. A number of research questions addressing this aim underpin this study. These are:

1- What are the factors that accelerate PU development in adult ICUs?

2- What are the common risk assessments that are used and the most effective scales for identifying at risk patients to PU development in the ICU?

3- What are the effects of prevention strategies on the incidence/prevalence of pressure ulcers in adult ICUs?

4- What are the characteristics of ICU patients in the KSA?
5- What is the incidence of PU development in critically ill patients in the intensive care units of two tertiary referral hospitals in the KSA?

6- What are the factors associated with PU development in the ICU in the KSA?

7- What is the RNs attitude towards PUs prevention in a Saudi Arabian tertiary referral hospital ICU?

8- What are the facilitators and barriers for RNs in the adoption of PU prevention strategies in a Saudi Arabian tertiary referral hospital ICU?

9- Is there any association between participants’ characteristics and RNs’ attitude, or perceived barriers and facilitators to implement the PU prevention strategies?

10- Does a PU prevention bundle reduce the cumulative incidence of PU development in critically ill patients in the intensive care unit of a Saudi Arabian tertiary referral hospital?

   \( H_0 \): There is no difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care.

11- Does a PU prevention bundle decrease the cumulative PU incidence by 25% or greater when compared to standard hospital care?

   \( H_0 \): The difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care was less than 25%.

12- Will patients who receive a PU prevention bundle develop PU later in their intensive care unit stay?
12 Chapter 1: Introduction

\( H_0: \) There is no significant difference in a delayed time to PU development with implement the PU prevention bundle.

13- Will patients who receive the PU prevention bundle have fewer numbers of PUs per patient during their ICU stay?

\( H_0: \) There is no significant difference in number of PU per patients with implement the PU prevention bundle during the ICU stay

14- Will patients who receive the PU prevention bundle have fewer full thickness PUs (Stage III and IV)?

\( H_0: \) There are no significant differences in full thicknesses PUs (Stage III and IV) with implement the PU prevention bundle.

15- Does the PU prevention bundle increase the adherence to the process of care in comparison to standard hospital skin care?

16- Does the OMRU model, as a framework, facilitate the implementation of the PU prevention bundle in the ICU context?

1.3 RESEARCH OUTLINE

In order to address the research questions this research was conducted in two phases, which were underpinned by a literature review of PU risk factors and common risk assessment scales in ICU contexts, and a systematic review of PU prevention strategies (Publications 1 and 2). This study was guided by an evidence translation model, the Ottawa Model of Research Use (OMRU). According to the OMRU model, Phase One consisted of two parts. Part A used a prospective observational design to measure the incidence of PU development in the ICUs of two KSA tertiary teaching
hospitals, the King Abdul-Aziz Hospital (KAAH) and the King Fasil Hospital (KFH) (Publication 3). Part B used a cross-sectional survey design to explore barriers and facilitators related to PU prevention strategies among KSA registered nurses (RNs) working in the intervention arm of the Phase Two (Publication 4). In this phase, RNs’ perceptions and the environment (ICU) were assessed to determine the barriers and facilitators for implementation of the PU prevention bundle. Consequently, comprehensive and supported strategies were designed for effective implementation and adoption of the PU prevention bundle. Phase Two used a two-arm cluster randomised control trail (cRCT) to monitor the implementation of a PU prevention bundle and evaluate the effectiveness of the bundle in reducing PU incidence of ICU patients (Publication 5). Finally, the validity of a study conceptual framework was assessed and presented in the last publication with the title “Translating pressure ulcer prevention bundle into intensive care practice; overlying a care bundle approach with a model of research implementation” (Publication 6).

1.4 SIGNIFICANCE OF THE STUDY

PUs are recognised as potentially preventable conditions; however, their epidemiological rate of occurrence is still alarming. Literature suggests that this problem is underreported, particularly in the KSA, and that there is a lack of awareness concerning PU prevention and management through the health care systems (Anthony, Parboteeah, Saleh, & Papanikolaou, 2008).

Several studies have measured the effectiveness of PU prevention using different methodological approaches and in different clinical settings (Turpin & Pemberton, 2006; Uzun, Aylaz, & Karadag, 2009; van Nieuwenhoven et al., 2006; Verbelen,
2007). The purpose of these studies was to improve the knowledge and awareness of healthcare providers and clinical decision makers regarding the effectiveness of different PU prevention strategies in reducing incidence/prevalence. However, reduction of HAPUs in health care systems has shown little improvement, as the prevalence of PUs worldwide, especially in the ICU, remains high, with up to 50% of ICU patients experiencing skin breakdown (Ballard et al., 2008; Berlowitz, 2014; Frankel, Sperry, & Kaplan, 2007; Shahin, Dassen, & Halfens, 2008). Possible explanations for this might be found in inconsistencies of methodology; different PU definitions, different PU staging systems (Keller, Wille, van Ramshorst, & van der Werken, 2002), as well as the factors that influence the adoption and the process of translation of research evidence to real clinical practice not being reported (Russell et al., 2003; Theaker, Kuper, & Soni, 2005; Verbel, 2007).

The present study was conducted in the ICU, which is a complex environment involving many factors that negatively affect fundamental care in improving skin integrity for critically ill patients. These include nursing workload, dependence on technological support, availability of effective devices, and critical illness. These alarming figures indicate that imperative change is required in the current practices for skin management for this patient population and complex practice environment. This research provided a novel approach to enhancing PU prevention in intensive care. This research aimed to develop, implement, and measure the effectiveness of a PU prevention bundle to reduce the incidence of PU development or delay the occurrence of PUs in the context of Saudi Arabian critically ill patients. This was firstly achieved by describing the PU problem in Saudi ICUs by calculating PU incidence and developing a PU prevention bundle that comprised the best available evidence to inform individual patient care and team approaches to patient skincare, within the
particular environment of the ICU. The PU prevention bundle was also focused upon organisational issues in order to develop a problem-solving approach that will lead to an improvement in the quality of skincare for patients. Secondly, the implementation of the PU prevention bundle was monitored. Finally, the effectiveness of the PU prevention bundle was evaluated for its efficacy in reducing the PU incidence.

This research is significant because it is the first study of its kind to test the effectiveness of a PU prevention bundle, combining the best available evidence to improve critically ill patients’ skin integrity in the KSA. This research identified the barriers and facilitators that affected the implementation of PU prevention bundle in the ICU. Further, this research increases knowledge and awareness of nurses regarding PU prevention and management to enable nurses to provide high quality nursing care. Moreover, this research can be considered a reliable benchmark that will enable comparison with other PU studies in ICU contexts.

Patient outcomes may potentially improve by reducing PU incidence rates through implementation of the PU prevention bundle. Further, patient’s morbidity and mortality, along with their pain level, and length of stay in ICU are all associated with PU incidence reduction (Bennett, Dealey, & Posnett, 2004; Brown, 2003; EPUAP, & NPUAP, 2009; Graves, Birrell, & Whitby, 2005). This reduction will contribute to lower costs and increased quality of care for healthcare organisations.

1.5 DEFINITION OF TERMS

**Intensive care unit** (ICU) defined as:

In the Australian context, an intensive/ critical care unit is:
A distinct unit within a hospital that has easy access to the emergency department, operating theatre, and medical imaging. It provides care to patients with a life-threatening illness or injury and concentrates the clinical expertise and technological and therapeutic resources required (Elliott, Aitken, Chaboyer, & Australian College of Critical Care Nurses, 2015).

In the American and also KSA context:

Intensive care units (ICUs) are specially equipped hospital units that provide highly specialised care to patients who suffer from a serious injury or illness. The ICU staff includes doctors, nurses, respiratory therapists, clinical nurse specialists, pharmacists, physical therapists, nurse practitioners, physician assistants, dietitians, social workers and chaplains. Three factors differentiate intensive care units from other units in the hospital: 1) a very high nurse-to-patient ratio, 2) the availability of invasive monitoring, 3) the use of mechanical and pharmacological life sustaining therapies (mechanical ventilation, vasopressors, continuous dialysis) (American Association of Critical-Care Nurses, n.d.).

**Critically ill patients:** Patients who are managed in the ICU for their illness or disease state are defined as critically ill (Estenssoro et al., 2006). Critical illness means the presence of actual and/or potentially life threatening health problems. However, all critically ill patients require continuous observation and intervention to restore and prevent complications (Moreno & Rhodes, 2011).

**Pressure ulcer:** Defined according to the NPUAP/EPUAP guideline (see Section 1.1.2 pressure ulcer definition).

**Hospital-acquired pressure ulcer:** See Section 1.1.2 pressure ulcer definition.
Community-acquired pressure ulcer: See Section 1.1.2 pressure ulcer definition.

Strategy: High level plan of evidence-based methods or actions designed to achieve one or more goals (for this study to prevent PU development), which is not systematically implemented. This term is usually used with quasi-experiential trial (Meinert, 2012; Mosby, 2013).

Intervention: A program, set of actions, or structured strategies specifically designed to address an identified deficiency (PU prevention), systematically implemented, monitored, and evaluated to ensure the effectiveness of this intervention in outcome (PU incidence). The term intervention is more commonly used with randomised control trials (Meinert, 2012; Porta et al., 2014).

1.6 THESIS OUTLINE

This thesis demonstrates the work undertaken in fulfilment of the Doctor of Philosophy degree and is presented as a series of publications. The document consists of 10 chapters. The publications framing this thesis are depicted in Figure 1.1. (See publication list, page xv)

Chapter 2 presents the first of two literature reviews that inform this thesis, and was published in the Journal of Nursing Education and Practice (Tayyib, Coyer, & Lewis, 2013). It provides a detailed explanation and critique of the literature that focuses on risk factors for PU development in critically ill patients and the utility of risk assessment scales in the intensive care setting.

Chapter 3 presents the second literature review. This chapter compromises a
systematic review that was submitted to the Worldview Evidence Based Nursing and is in press now (Tayyib & Coyer, in-press). This systematic review explored effective PU prevention strategies in the adult ICU context.

Chapter 4 presents the conceptual framework underpinning this research. The framework chosen guided and facilitated the implementation of the intervention (the PU prevention bundle) in an effective, efficient, and consistent manner, using a care bundle approach overlayed with a research implementation model (OMRU).

Chapter 5 presents the methodology of the two phases of this research and outlines the research design and justification, methodology, sampling strategies, recruitment process, instrument development, data collection methods, and analysis plan for the research. An overview of the ethical considerations pertinent to this research is also addressed.

Chapter 6 is one of three publications to address the findings of this thesis (see also Chapters 7 and 8). This chapter was published in the International Wound Journal (Tayyib, Coyer, & Lewis, 2015a). The publication identifies PU incidence in two Saudi ICUs.

Chapter 7 has been accepted for publication in the Journal of Wound Ostomy Continence Nursing (Tayyib, Coyer & Lewis, 2016). It provides an overview of assessment regarding the RNs who provide the intervention, and the ICU environment.

Chapter 8 addresses the effectiveness of the implementation of the PU prevention bundle in reducing PU incidences in the ICU. This article was published in the Journal of Nursing Scholarship (Tayyib, Coyer & Lewis, 2015b).
Chapter 1 - Introduction

Chapter 2 - Review of PU risk factors and risk assessment scales (Publication 1)

Chapter 3 - Review of evidence-based approaches to PU prevention in the ICU (Publication 2)

Chapter 4 - Conceptual framework

Chapter 5 - Research design

Phase One
Assessment (Problem, healthcare providers, and organisation)

Result Phase One
Chapter 6 - PU incidence (Publication 3)
Chapter 7 - Perceived facilitators and barriers factors

Phase Two
Translation and adoption of the intervention

Result Phase Two
Chapter 8 - A two–arm cluster randomised control trial (Publication 5)

Chapter 9 - Translating pressure ulcer prevention bundle into intensive care practice; using a care bundle approach with the OMRU model (Publication 6)

Chapter 10 - Conclusion, limitation, and implication

Figure 1.1 Detailed Schema of the Thesis
Chapter 9, the final publication of this research, addresses the importance of using a framework, such as the OMRU model, in the translation of evidence (the PU prevention bundle) to clinical practice (the ICU). This chapter comprises a manuscript that has been submitted to the Journal of Nursing Care Quality (Tayyib & Coyer, 2016b).

Chapter 10 concludes this thesis and summarises the research process undertaken to address the research aims and the conclusions drawn from this research study. Further, the strengths and limitations of the study, along with implications for clinical practice and further research are addressed.
Chapter 2: (Article 1) Pressure Ulcers in the Adult Intensive Care Unit: A Literature Review of Patient’s Risk Factors and Risk Assessment Scales

This chapter comprises the following published article:


Pressure ulcers (PUs) are a matter of significant concern for worldwide health organisations. Ischaemia or necrosis is considered the main reason for the development of ulceration in the skin. Different risk factors have been identified that accelerate the development of PU in ICU contexts and have an influence on the level and extent of tissue necrosis. This chapter presents the published article that summarised potential risk factors for PU development in adult critically ill patients. Identification of the main factors that enhance PU development in the ICU aids the design and development of PU prevention practice.

Moreover, this article reviewed the utility of risk assessment scales (RASs) in ICU settings and their possible limitations. Pressure ulcer RASs were evaluated through reliability, predictive validity, and choice of appropriate cut off points. While this review highlighted the fluctuation of reported predictive validity values of the RASs, all of the existing scales tended to over predict due to low identified scale specificity. The findings of this review were consistent with those of another
systematic review (García-Fernández, 2013), in that many RASs have been developed for ICU patients, but not validated. However, the Braden Scale score as RAS for ICU patients was recommended (García-Fernández, 2013; Tayyib, Coyer, & Lewis, 2013).

Recently, Richardson and Barrow (2015) developed a new risk assessment scale for critically ill patients (CALCULATE), which was not included in this review. This scale consists of seven items, including too unstable to turn, impaired circulation, dialysis, mechanical ventilation, long period of surgery > 4 hours, low protein and albumin serum (albumin below 35 g/l), and faecal incontinence. Each item is scored with a single point. Patients are classified based on the total score: four or more factors are classed as ‘very high’ risk and patients with three or less risk factors classed as ‘high’ risk. However, this scale has some noted limitations. There is a noted lack of refinement to the scale, as validity and reliability have not been measured. Some of the factors, such as age and longer length of stay in the ICU, identified in this review (Tayyib, Coyer, & Lewis, 2013) were not considered. Moreover, appropriate intervention plans for each at risk group were not included.

Achieving a valid PU RAS for ICUs requires identification of the underlying factors that accelerate PU development in critically ill patients, determination of appropriate scale cut off points, and preventive measures for each risk category. However, international best practice guidelines advocate the use of RASs as a fundamental component of a PU prevention and management strategy (Chou et al., 2013).

This article answers research questions one and two for this study.

**Research Question 1:** What are the factors that accelerate PU development in adult ICUs?
Research Question 2: What are the common risk assessments used and the most effective scales for identifying at risk patients for PU development in the ICU?

This article adds to existing literature by reviewing recent research published in the area of the PU risk factors and RASs. The last review conducted on PU risk factors and risk assessment scales in adult ICU was undertaken prior to 2000 (Keller et al, 2002). This review represents an update on current research. The article informed this study by identifying the main potential risk factors that needed to be considered during the planning of the PU prevention intervention. Moreover, it facilitated the selection of a reliable and valid RAS instrument for use in this research in the ICU, the Braden Scale score.

This article has been cited nine times in Google scholar.
Pressure ulcer in the adult intensive care unit: a literature review of patient risk factors and risk assessment scales


2.1 ABSTRACT

**Background:** Critically ill patients are at high risk for pressure ulcer (PU) development due to their high acuity and the invasive nature of the multiple interventions and therapies they receive. With reported incidence rates of PU development in the adult critical care population as high as 56%, the identification of patients at high risk of PU development is essential. This paper will explore the association between PU development and risk factors. It will also explore PU development and the use of risk assessment scales for critically ill patients in adult intensive care units.

**Method:** A literature search from 2000 to 2012 using the CINHAL, Cochrane Library, EBSCOHost, Medline (via EBSCOHost), PubMed, ProQuest, and Google Scholar databases was conducted. Key words used were: pressure ulcer/s, pressure sore/s, decubitus ulcer/s, bed sore/s, critical care, intensive care, critical illness, prevalence, incidence, prevention, management, risk factor, risk assessment scale.

**Results:** Nineteen articles were included in this review: eight studies addressing PU risk factors, eight studies addressing risk assessment scales, and three studies overlapping both. Results from the studies reviewed identified 28 intrinsic and extrinsic risk factors, which may lead to PU development. Development of a risk factor
prediction model in this patient population, although beneficial, appears problematic due to many issues such as diverse diagnoses and subsequent patient needs. Additionally, several risk assessment instruments have been developed for early screening of patients at higher risk of developing PU in the ICU. No existing risk assessment scales are valid for identification high-risk critically ill patient, with the majority of scales potentially over-predicting patients at risk for PU development.

**Conclusion:** Research studies to inform the risk factors for potential pressure ulcer development are inconsistent. Additionally, there is no consistent or clear evidence which demonstrates any scale to better or more effective than another when used to identify the patients at risk for PU development. Furthermore, robust research is needed to identify the risk factors and develop valid scales for measuring the risk of PU development in ICU.

**Keywords:** Pressure ulcer, pressure ulcer risk, risk factors, risk assessment, adult intensive care, literature review.
2.2 INTRODUCTION

A pressure ulcer (PU) can occur anywhere on the body where there is prolonged exposure to pressure. Prolonged pressure (from lying or sitting on a specific part of the body) will impede capillary blood supply to an area and thus limit the delivery of oxygen and nutrients to tissue, placing patients at risk for skin breakdown (Niezgoda & Mendez-Eastman, 2006). Expected capillary pressure ranges are between 10 and 30 mmHg (Guyton & Hall, 2006). Tissue hypo-perfusion occurs when the interface pressure exceeds capillary pressure (Bader, Oomens, Bouten, & Baaijens, 2003; Youngman, 2008), thus increasing the likelihood of PU development.

The epidemiology of PU varies appreciably by clinical setting. In acute care settings PU incidence ranges from 0.4% to 38%, in long term care setting from 2.2% to 39.4%, in the home care environment from 0% to 17%. According to the National Healing Corporation (2005), the worldwide incidence of PU in intensive care units (ICU) ranged widely from 1- 56% (Kaitani, Tokunaga, Matsui, & Sanada, 2010; Keller, Wille, van Ramshorst, & van der Werken, 2002). Further, there is wide variation reported in PU prevalence in ICUs between countries and continents: 49% across Western Europe (Shahin, Dassen, & Halfens, 2008), 22% in North America (Frankel, Sperry, & Kaplan, 2007; Shahin et al., 2008), 50% in Australia (Ballard et al., 2008; Elliott, McKinley, & Fox, 2008), and 29% in Jordan (Tubaishat, Anthony, & Saleh, 2011).

Prevalence is the most commonly reported measure of PU, largely because this is a simple and cost effective method of data collection. However, it has recognized that prevalence data is a snapshot and not a true reflection of the scope of a given problem (Baharestani et al., 2009). Incidence data provides a more accurate picture of the magnitude of a problem. However, incidence data presents problems with lengthy...
and time-consuming data collection (Baharestani et al., 2009). Critically ill patients in ICU are considered to be at greatest risk for PU development, as this patient group is likely to present with high acuity, may require mechanical ventilation and subsequent administration of sedation and pharmacological drugs potentially reducing peripheral circulation and be immobile (Johnson & Meyenburg, 2009; Vollman, 2010).

According to Vollman (2010), the negative impact of patient immobility is directly related to the adverse event of PU development and subsequent undesirable long-term implications, such as reduction in quality of life, pain, increased medical costs, and increased mortality and morbidity rates and increase in ICU length of stay. In addition to these consequences of PU, the financial impact of treatment should be considered, including cost to healthcare system and also personal costs to patients. Worldwide PU treatment costs to healthcare systems are a significant burden. The annual cost is approximately £1.4–£2.1 billion in the UK (Bennett, Dealey, & Posnett, 2004) and $1.6 billion in the US for the treatment of pressure ulcers (Whittington, Patrick, & Roberts, 2000). In Australia, pressure ulcer costs have been identified as $18,964 per each critically ill patient (Graves, Birrell, & Whitby, 2005). In the UK, the cost of PU was four per cent of total healthcare expenditure (Bennett et al., 2004). These adverse outcomes emphasize the importance of preventing PU. While PU has been extensively examined in the literature, only one review addresses this issue in the context of ICU. Given this paper was published in 2002 and the literature included in the review was published between 1980 and 1999; a further review of PU in the ICU environment is timely.
2.3 AIMS

The aim of this paper is to review existing literature to explore the association between PU development and risk factors. The paper also aims to examine PU risk assessment scales for critically ill patients managed in adult intensive care units.

2.4 METHOD

A comprehensive search of databases and Internet research engines holding information related to PU in intensive care units conducted. PU defined and classified according to NPUAP/EPUAP guidelines (National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009). The CINHAL; Cochrane Library; EBSCOHost; Medline (via EBSCOHost); PubMed; ProQuest databases were searched, along with Google Scholar search engine from 2000 to 2012. The key search terms entered into database searches were: pressure ulcer, pressure sore, decubitus ulcer, bed sore, critical care, intensive care, critical illness, prevalence and incidence, prevention, management, risk factor, risk assessment scale. Databases were searched for relevant information contained within journals, books, handbooks, and abstracts. Literature searches were limited by language (English). The criteria used for article selection were 1) quantitative studies, 2) studies related to risk factors of pressure ulcer development, 3) studies of adult patients. 4) studies specific to the intensive care environment, and 5) studies that contained a sub-analysis of results specific to the adult intensive care setting. The reference list of each selected article was also checked manually as a source of additional information. A total of 28 original studies were reviewed. Following this initial review, eight papers were excluded as they failed to
meet the above inclusion criteria. A total of 19 articles are included in this review (Figure 2.1).

![Flow Diagram: Selection Process for Literature Review](Moher, D., et al., 2009)

Figure 2.1 Flow Diagram: Selection Process for Literature Review (Moher, D., et al., 2009)
2.5 RESULTS

2.5.1 Risk Factors for PU Development

Among the 19 articles that met the inclusion criteria, 11 studies identified risk factors that may accelerate the development of PU in the critically ill patient population (Table 2.1). Table 2.1 provides an overview of the year of publication, setting, population, study method, measures, and results of each study. The studies presented in Table 2.1 will be discussed under relevant risk factors below.
<table>
<thead>
<tr>
<th>Author, year of publication</th>
<th>Sample</th>
<th>Setting</th>
<th>Study method</th>
<th>Potential predictor variable</th>
<th>Result (Risk factors associated with PU development)</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theaker et al (2000)</td>
<td>286</td>
<td>Medical &amp; Surgical ICU, UK</td>
<td>Prospective</td>
<td>22 Factors including demographic and clinical variables</td>
<td>norepinephrine infusions, APACHE II scores of 13 or above, fecal incontinence, anemia and length of stay in ICU of &gt; 3 days coma/unresponsiveness and paralysis sedation cardiovascular instability</td>
<td>Unmeasured factors such as BMI could be significant.</td>
</tr>
<tr>
<td>Boyle and Green (2001)</td>
<td>534</td>
<td>ICU, Australia</td>
<td>Prospective observational</td>
<td>Waterlow scale Jackson/Cubbin scale</td>
<td>coma/unresponsiveness and paralysis sedation cardiovascular instability</td>
<td>Inter-rater reliability of the two scales is not measured.</td>
</tr>
<tr>
<td>Eachempati et al (2001)</td>
<td>3027</td>
<td>Surgical ICU, USA</td>
<td>Prospective</td>
<td>Cornell ulcer risk score APACH II Systemic inflammatory Multiple organ dysfunction Demographic data</td>
<td>Emergency ICU admission ICU LOS &gt; 7 days Older age Prolonged time without nutrition Non-ambulatory status</td>
<td>Stage 1 PU excluded</td>
</tr>
<tr>
<td>Fife et al (2001)</td>
<td>186</td>
<td>Neurological ICU, USA</td>
<td>Prospective cohort</td>
<td>Demographic and clinical data</td>
<td>Braden scale ≤ 13 Low BMI on admission</td>
<td>Stage I PU excluded.</td>
</tr>
<tr>
<td>Frankel et al (2007)</td>
<td>820</td>
<td>Surgical ICU, USA</td>
<td>Retrospective analysis</td>
<td>Demographic and laboratory data LOS APACHE II</td>
<td>History of diabetes, spinal cord injury, renal insufficiency, and older age &gt; 60 years</td>
<td>The incidence of PU was low (3%). Excluded Stage I. Difficulties acknowledged in measurement of incidence and prevalence rate.</td>
</tr>
<tr>
<td>Author, year of publication</td>
<td>Sample</td>
<td>Setting</td>
<td>Study method</td>
<td>Potential predictor variable</td>
<td>Result (Risk factors associated with PU development)</td>
<td>Limitations</td>
</tr>
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</tr>
<tr>
<td>Suriadi et al. (2007)</td>
<td>105 ICUs, Indonesia</td>
<td>Prospective cohort study</td>
<td>Interface pressure, Skin moisture, Body temperature, Smoking, Diastolic blood pressure, Fecal incontinence, Nutrition</td>
<td>Increase interface pressure, Skin moisture, Increase body temperature, Smoking</td>
<td>Authors disregard the underlying patient's condition and treatment. Many instruments to measure interface pressure, moisture and temperature. Cigarette composition may different from other countries.</td>
<td></td>
</tr>
<tr>
<td>Nijis et al. (2008)</td>
<td>520 Surgical ICU, Belgium</td>
<td>Prospective descriptive research</td>
<td>Demographic, clinical data. Other preventive measures such as (frequent turning, floating heels, alternating mattresses and sitting in chair)</td>
<td>Vascular disease, Uses of Dopamine or Dobutamine medication, Intermittent hemodialysis or continuous veno-venous hemofiltration (renal insufficiency), Mechanical ventilation, Infrequent turning, Adequate prevention measures, Alternating mattresses, Floating heels, No association between the uses of sedatives, patient's body temperature above 38.5°C, and sitting in chair and PU formation grade 2-4 in ICU.</td>
<td>Stage 1 PU excluded.</td>
<td></td>
</tr>
<tr>
<td>Author, year of publication</td>
<td>Sample</td>
<td>Setting</td>
<td>Study method</td>
<td>Potential predictor variable</td>
<td>Result (Risk factors associated with PU development)</td>
<td>Limitations</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>---------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Shahin et al (2009)</td>
<td>121</td>
<td>Nephrology, surgical and cardiology ICUs, Germany</td>
<td>Longitudinal study</td>
<td>Assess demographic and clinical data such as (length of stay, unconsciousness, urinary catheter at admission and existing of pressure ulcer in admission) with Braden scale and APACHE II</td>
<td>APACHE II score above 14.</td>
<td>Small sample size</td>
</tr>
<tr>
<td>Kaitani et al. (2010)</td>
<td>606</td>
<td>ICU, Japan</td>
<td>Prospective</td>
<td>Severity of illness and pressure ulcer development</td>
<td>Emergency ICU/HCU admission.</td>
<td>Infrequent turning; The lower APACH II score is 19.9</td>
</tr>
<tr>
<td>Slowikowski &amp; Funk (2010)</td>
<td>230</td>
<td>Surgical ICU, USA</td>
<td>Prospective</td>
<td>Demographic and clinical data</td>
<td>History of diabetes.</td>
<td>Age &gt; 70 years; Low Braden scale</td>
</tr>
<tr>
<td>Cox (2011)</td>
<td>347</td>
<td>Medical &amp; Surgical ICU, USA</td>
<td>Retrospective analysis</td>
<td>Braden score, mobilization, activity, sensory perception, moisture, nutrition, friction/shear, length of stay, age, arteriolar pressure, vasopressor administration, APACHE II score and comorbid conditions</td>
<td>Older age; length of stay more than 3.3 days; mobility; and cardiovascular disease. Additionally, this study identified the predictive factors which were significantly associated with PU stage II and greater. They were friction/shear; norepinephrine infusion; length of stay and cardiovascular disease.</td>
<td>Retrospective analysis affects accuracy of identification of stage development and assessment. Measure risk factors with Braden scale in the first 24 hours of patient's admission.</td>
</tr>
</tbody>
</table>
A total of 28 factors were identified as risk factors for PU development in ICU patients. These are conceptualized and labeled as intrinsic (inherent factors of critical illness) and extrinsic (related to external forces) factors (Table 2.2). The main risk factors identified or evidenced as enhancing PU development in ICU setting by two or more studies will discussed below. Intrinsic factors identified in two or more studies were older age, increased length of stay in ICU and history of cardiovascular disease. Extrinsic factors identified in two or more studies were the administration of norepinephrine and patient repositioning (turning).

Older age usually involves skin alterations, including a thinning of the epidermis, a 20% loss of dermal thickness, and the loss of elastin fibers (Baranoski, 2001). Eachempati, Hydo, and Barie (2001) examined age factors by multivariate analysis, and found that age was significantly associated with PU development (OR 1.08, 95% CI 0.0026–0.0131, p= 0.003). Frankel, Sperry, and Kaplan, (2007) reported that older age was significantly associated with PU development for surgical ICU (SICU) patients (OR 2.9, 95% CI 1.2-7.1, p= 0.022). Slowikowski and Funk (2010) using logistic regression analysis, also found that patients aged over 70 who were admitted to ICU had a significantly higher incidence of PU development (OR 2.14, 95% CI 1.27-3.62, p= 0.004). Recently, this result was confirmed by Cox (2010) who identified that age was a predictive factor for PU development in ICU (OR 1.033, 95% CI 1.003-1.064, p= 0.03). It appears clear that the older critically ill adult patient is vulnerable for PU development.

Length of stay (LOS) in ICU is another commonly identified risk factor for PU development. In three studies (Cox, 2010; Eachempati et al., 2001; Theaker, Mannan, Ives, & Soni, 2000), it was found that patients with an ICU LOS of greater than three days were at increased risk for PU development. Eachempati and team (2001), using
univariate analysis, found that ICU patients with LOS of seven days or more were at high risk for PU development (p = 0.0288). Theaker and associates (2000) showed that a longer stay in ICU for three days or more was significantly associated with PU development (OR 2.76, 95% CI 1.08-7.05, p = 0.034). Cox (2010) found a significant association between LOS and PU development (OR 1.008, 95% CI 1.004-1.012, p < 0.001). Significantly, Fife and colleagues (2001) argued, by correlation or logistic regression analysis, that LOS did not predict PU development in a neurological ICU (p = 0.31). However, the authors conducted this study in a special population which included adults with spinal cord or closed head injuries who were more susceptible to PU development because of prolonged immobility, also the authors did not acknowledge a reason for this association. Further research will be essential to clarify this association. While these papers clearly indicate a longer LOS increases the likelihood of an increased incidence of PU development, it should also be considered that a longer LOS would logically correlate with an increased patient acuity.

Comorbidities including cardiovascular disease and diabetes can be one of the prognostic indicators for PU development in ICU. Cardiovascular disease was found in several studies to be significantly associated with PU development (Boyle & Green, 2001; Cox, 2010; Nijs et al., 2009). Boyle and Green (2001) reported that patients with cardiovascular instability were at higher risk of PU occurrence ($\chi^2$ = 6.850, p = 0.009). Using logistic regression Cox (2010) found that a history of cardiovascular disease was a significant predictor of PU (OR 2.952, 95% CI 1.3-6.4, p = 0.007). Similarly, Nijs et al. (2009), found a positive association between vascular disease and 24 hours before PU occurrence (OR 4.51, 95% CI 1.99-10.24, p = 0.001) or 48 hours before PU occurrence (OR 2.85, 95% CI 1.29-6.30, p = 0.001). A possible explanation for this association is that cardiovascular disease predisposes patients to ischemia or reduced
peripheral blood flow (Nijs et al., 2009). Patients with a compromised cardiac pump and vasculature disease are likely to exhibit lower capillary perfusion pressures which can be overcome with lower interface pressures. Thus, cardiovascular disease should be considered as a predictive factor for PU development.
<table>
<thead>
<tr>
<th>Cluster</th>
<th>Factor</th>
<th>Reference</th>
<th>Statistical test, p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrinsic factors - inherent factors of critical illness</td>
<td>Age</td>
<td>Eachempati et al (2001) Slowikowski &amp; Funk (2010) Frankel et al (2007) Cox (2011)</td>
<td>$\chi^2$, $p=0.0030$ LRA†, $p=0.004$ Stepwise LRA†, $p=0.022$ LRA†, $p=0.03$</td>
</tr>
<tr>
<td></td>
<td>Low BMI</td>
<td>Fife et al (2001)</td>
<td>MLRA‡, $p=0.0133$</td>
</tr>
<tr>
<td></td>
<td>Smoking</td>
<td>Suriadi et al(2007)</td>
<td>MLRA‡, $p=0.001$</td>
</tr>
<tr>
<td></td>
<td>Body temperature</td>
<td>Suriadi et al(2007)</td>
<td>MLRA‡, $p=0.001$</td>
</tr>
<tr>
<td></td>
<td>Emergency ICU/HCU admission</td>
<td>Eachempati et al (2001) Kaitani et al (2010)</td>
<td>$\chi^2$, $p=0.0001$ LRA†, $p &lt; 0.01$</td>
</tr>
<tr>
<td></td>
<td>Days without nutrition</td>
<td>Eachempati et al (2001)</td>
<td>$\chi^2$, $p=0.0014$</td>
</tr>
<tr>
<td></td>
<td>Immobility status</td>
<td>Eachempati et al (2001) Cox (2011)</td>
<td>$\chi^2$, $p=0.0064$ LRA†, $p=0.04$</td>
</tr>
<tr>
<td></td>
<td>Coma/unresponsiveness/paralysis &amp; sedation</td>
<td>Boyle and Green (2001)</td>
<td>$\chi^2$, $p=0.001$</td>
</tr>
<tr>
<td></td>
<td>Anemia</td>
<td>Theaker et al (2000) Slowikowski &amp; Funk (2010)</td>
<td>MA§, $p=0.013$ LRA†, $p=0.019$</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>Funk (2010) Frankel et al (2007)</td>
<td>Stepwise LRA†, $p=0.023$</td>
</tr>
<tr>
<td></td>
<td>Spinal cord injury</td>
<td>Frankel et al (2007)</td>
<td>Stepwise LRA†, $p=0.021$</td>
</tr>
<tr>
<td></td>
<td>Cardiovascular disease</td>
<td>Boyle and Green (2001) Cox (2011)</td>
<td>MLRA‡, $p=0.001$ $\chi^2$, $p=0.009$ LRA†, $p=0.007$</td>
</tr>
<tr>
<td>Cluster</td>
<td>Factor</td>
<td>Reference</td>
<td>Statistical test, p value</td>
</tr>
<tr>
<td>---------------------------------</td>
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<td>---------------------------</td>
</tr>
<tr>
<td>Extrinsic factors - external</td>
<td>Norepinephrine medication</td>
<td>Cox (2011)</td>
<td>LRA†, p= 0.04</td>
</tr>
<tr>
<td>forces</td>
<td></td>
<td>Theaker et al (2000)</td>
<td>MA§, p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Dopamine or Dobutamine medication</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p= 0.003</td>
</tr>
<tr>
<td></td>
<td>Sedation</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p= 0.004</td>
</tr>
<tr>
<td></td>
<td>Fecal incontinence</td>
<td>Theaker et al (2000)</td>
<td>MA§, p=0.010</td>
</tr>
<tr>
<td></td>
<td>Interface pressure</td>
<td>Suriadi et al (2007)</td>
<td>MLRA‡, p=0.001</td>
</tr>
<tr>
<td></td>
<td>Skin moisture</td>
<td>Suriadi et al (2007)</td>
<td>MLRA‡, p= 0.002</td>
</tr>
<tr>
<td></td>
<td>Friction/shear</td>
<td>Cox (2011)</td>
<td>LRA†, p= 0.01</td>
</tr>
<tr>
<td></td>
<td>Mechanical ventilation</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p= 0.003</td>
</tr>
<tr>
<td></td>
<td>Intermittent hemodialysis/Continuous</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p= 0.001</td>
</tr>
<tr>
<td></td>
<td>veno-venous hemofiltration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infrequent turning</td>
<td>Kaitani et al (2010)</td>
<td>LRA†, p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Floating heels</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p = 0.002</td>
</tr>
<tr>
<td></td>
<td>Alternating mattresses</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Adequate prevention</td>
<td>Nijis et al (2008)</td>
<td>MLRA‡, p &lt; 0.001</td>
</tr>
</tbody>
</table>

* Chi-square; † Logistic regression analysis; ‡ Multivariate Logistic regression analysis; § Multivariate analysis

Diabetes is a common disorder which effects vascular perfusion and may predispose patients to PU development (Frankel et al., 2007; Slowikowski & Funk, 2010). Frankel and team (2007) also reported that diabetes has positive association with PU occurrence in SICU (OR 2.7, 95% CI 1.1-6.4, p= 0.023). More recently, Slowikowski and Funk (2010) using logistic regression analysis found that diabetes significantly predicted PU development in critically ill patients (OR 1.93, 95% CI
1.11-3.35, p= 0.019). Therefore, a history of diabetes has been found to be an indicator for developing pressure ulcers in ICU.

Hemodynamic instability in critically ill patients leads to tissue hypoxia (Keller et al., 2002). These patients also require vasoactive drugs, such as norepinephrine, to treat hypotension and maintain organ perfusion. Theaker and co-workers (2009) used a multivariate analysis to reveal that norepinephrine perfusion was positively associated with PU occurrence (OR 8.11, 95% CI 3.64-18.0, p= 0.001). Cox (2010) also found that norepinephrine perfusion was a significant predictor of stage II, or greater, PU development (OR 1.017, 95% CI 1.001-1.033, p= 0.04). It might also be considered that the use of norepinephrine while stabilizing hemodynamic function in optimal circumstances will also simultaneously reduce tissue perfusion. This too may potentially increase the risk of PU.

While having many contributing factors, PU occurrence is also dependent on the length of time an area is exposed to pressure. Patient's immobility is considered a preeminent factor for PU development. In the ICU this could be a direct result of uses of sedation or patient's status—not simply patient acuity. Nijis and team (2009) showed a significant association between frequent of repositioning and time, with a period of 24 hours before PU development (OR 6.66, 95% CI 2.70-16.44, p= 0.001) being particularly relevant. Recently, Kaitani and colleagues (2010) demonstrated that PU development in an ICU could be predicted by analyzing the frequent of repositioning patient (OR 0.452, 95% CI 0.004-0.470, p< 0.01). Therefore, critically ill patients are at a greater risk of experiencing PU due to their poor mobility.
2.5.2 Pressure Ulcer Risk Assessment Scales

Eleven articles were identified that examined PU risk assessment scales in ICUs. Several risk assessment instruments have been developed for early screening of patients at higher risk of developing PU in the ICU. Table 2.3 provides a summary of the year of publication, setting, population, study method, scale, cut-off point, sensitivity, and results of each study. Table 2.4 provides background information and overviews of each risk assessment scale used in ICU including items of assessment, score and total score, and determination of ‘at risk’ category.

The Braden scale, utilized in nine studies was the most commonly applied risk assessment scale in research studies included in this review. Recently, Gomes, Bastos, Matozinhos, Temponi, and Velásquez-Meléndez (2011) in an across-sectional analytic study of 22 ICUs, found the moderate and high risk categories of the Braden Scale to be highly predictive for PU development (OR 5.54, 95% CI 1.36-22.49, p= 0.017), (OR 11.60, 95% CI 3.56-37.74, p= 0.000) respectively. Lewicki, Mion, and Secic (2000) in a descriptive study in 337 cardiothoracic ICU patients examined the sensitivity and specificity of the Braden Scale using different cut-off points at various days of hospitalization to determine the optimal cut-off point in a cardiac surgical population. The author recommended that several cut-off scores corresponding with day of hospitalization exist in populations whose conditions change greatly over the course of their hospital stay. Ongoing assessment is always required as the clinical status of patients is liable to change (Lewicki, et al., 2000).

Other scales used in the ICU setting include the Jackson/Cubbin (Hunt, 1993; Seongsook, Ihnsook, & Younghee, 2004; Kim, S. M. Lee, E. Lee, & Eom, 2009), Waterlow (Boyle & Green, 2001; de Araujo, M. F. de Araujo, & Caetano, 2011; Kottner & Dassen, 2010), Modified Norton (Feuchtinger, Halfens, & Dassen, 2007),
Suriadi and Sanda (Sanada, Sugama, Thigpen, & Subuh, 2008), and Douglas (Seongsook et al., 2004). T. M. De Araujo and collaborators found the Waterlow scale to be significantly predictive for patients at risk for PU development (p=0.005) in comparison with the Braden or Norton scales (de Araujo et al., 2011). Boyle and Green (2001) meanwhile argue that the Waterlow scale and Jackson/Cubbin scale are not predictive for patients at risk for PU development in ICU (p= 0.92, p=0.47 respectively). Using Chi square analysis Boyle and Green (2001), found that the "high risk" category only in Jackson/Cubbin scale was positively associated with PU development (p=0.0005).

The Jackson/Cubbin scale was a modification of the Norton scale which was developed and revised specifically for ICU patients. Seongsook and coworkers (2004) tested the sensitivity and specificity of three risk assessment scales in ICU, the Braden, Jackson/Cubbin, and Douglas scale, and found that Jackson/Cubbin scale was more valid as its sensitivity was 89% and specificity 61% in comparison with the two other scales. Also Kim et al. (2009) prospectively examined different risk assessment scales, namely Braden, Song and Choi, and Jackson/Cubbin scale and found that Jackson/Cubbin was higher predictor for PU than the two scales, with a sensitivity of 95% and specificity of 81.5%. However, the reliability of these scales were not reported.
### Table 2.3 Studies Examined the Effectiveness of Risk Assessment Scales for PU Development

<table>
<thead>
<tr>
<th>Author, year of publication</th>
<th>Sample</th>
<th>Setting</th>
<th>Study method</th>
<th>Scale/Assessment</th>
<th>Cut-off point*</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lewicki et al. (2000)</td>
<td>337</td>
<td>Cardiac surgical ICU</td>
<td>Prospective cohort</td>
<td>Braden scale</td>
<td>Cutoff Braden scale score varied by hospital day</td>
<td>1st day (13)=50% 3rd days (14)=57.1 5th days (20)=50</td>
<td>1st day (13)=45.7 3rd days (14)=92 5th days (20)=70.9</td>
<td>On 1st day postoperative, 67% of patients were identified as PU positive with cut-off 13 On 3rd day, 57% with cut-off 14 On 5th day, 50% with cut-off 20 Waterlow scale (all categories) is not significantly predictive for PU occurrence. High risk category of Jackson/Cubbin scale is significantly predictive for PU development. Braden scale ≤ 13 score predicting to PU development.</td>
</tr>
<tr>
<td>Boyle &amp; Green (2001)</td>
<td>314 188</td>
<td>ICU</td>
<td>Prospective observational</td>
<td>Waterlow scale Jackson/cubbin scale</td>
<td>≥10 ≤29</td>
<td>Not reported</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>Fife et al. (2001)</td>
<td>186</td>
<td>ICU (Neurological)</td>
<td>Prospective cohort</td>
<td>Braden scale</td>
<td>≤13</td>
<td>91.4</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>Author, year of publication</td>
<td>Sample</td>
<td>Setting</td>
<td>Study method</td>
<td>Scale/Assessment</td>
<td>Cut-off point*</td>
<td>Sensitivity (%)</td>
<td>Specificity (%)</td>
<td>Result</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------</td>
<td>---------</td>
<td>--------------</td>
<td>-----------------</td>
<td>---------------</td>
<td>----------------</td>
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<td>--------</td>
</tr>
<tr>
<td>Seongsook et al. (2004)</td>
<td>112</td>
<td>ICU</td>
<td>Longitudinal study</td>
<td>Braden Jackson/Cubbin Douglas</td>
<td>≤ 16</td>
<td>79</td>
<td>26</td>
<td>Jackson/Cubbin scale has higher validity</td>
</tr>
<tr>
<td>Feuchtinger et al. (2007)</td>
<td>53</td>
<td>ICU (cardiac surgery)</td>
<td>Explorative prospective study</td>
<td>Braden Modified Norton 4-factor model Suriadi and Sanada scale</td>
<td>≤ 20</td>
<td>97</td>
<td>5</td>
<td>Braden scale has higher validity for cardiac surgery ICU</td>
</tr>
<tr>
<td>Suriadi et al. (2007)</td>
<td>253</td>
<td>ICU in Indonesia</td>
<td>Prospective cohort</td>
<td>S.S &gt; 4</td>
<td></td>
<td>81</td>
<td>83</td>
<td>PU incidence in first ICU: 27% Second ICU: 31%</td>
</tr>
<tr>
<td>Kottner &amp; Dassen (2009)</td>
<td>45</td>
<td>ICU</td>
<td>Observational</td>
<td>Braden scale Waterlow scale Subjective scale</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>The three scales are not recommended in ICU. Braden scale was more reliable in comparison.</td>
</tr>
<tr>
<td>Kim (2009)</td>
<td>219</td>
<td>ICU (Surgical) In Korea</td>
<td>Non-experimental prospective study</td>
<td>Braden scale Song and Choi scale Jackson/cubbin</td>
<td>Braden ≤ 24 Song and Choi ≤ 21 Jackson/Cubbin ≤ 28</td>
<td>92.5</td>
<td>95</td>
<td>92.5</td>
</tr>
<tr>
<td>Slowikowski &amp; Funk (2010)</td>
<td>230</td>
<td>Surgical ICU in USA</td>
<td>Prospective</td>
<td>Braden scale</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Braden scale was effective scale in prediction PrU patients</td>
</tr>
<tr>
<td>de Araujo et al. (2011)</td>
<td>42</td>
<td>ICU In Brazil</td>
<td>Exploratory and Longitudinal study</td>
<td>Norton scale Braden scale Waterlow scale</td>
<td>Norton ≤ 14 Braden ≤ 16 Waterlow ≥ 10</td>
<td>Not reported</td>
<td>Not reported</td>
<td>The Waterlow scale has higher score in PrU risk assessment in comparison to Norton and Braden scales</td>
</tr>
<tr>
<td>Gomes et al. (2011)</td>
<td>140</td>
<td>ICU</td>
<td>A crosssectional and analytic study</td>
<td>Braden scale</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Braden scale was high predictive for PU</td>
</tr>
</tbody>
</table>

*Cut-off point divides the sample into two groups. One group has significantly risk for developing pressure ulcer, while the other group no significantly risk.
The Suriadi and Sanda scale was developed for ICU patients in Indonesia. This scale produced a balance between sensitivity (81%) and specificity (83%) (Sanada et al., 2008). However, the author noted several limitations with this scale including; specific factors that may be unique on Indonesian populations and the influence of cigarette composition of nicotine and tar which may differ from other countries. To confirm this result, a longitudinal study in different populations is essential.

Table 2.4 Comparison of the Concepts of the Risk Assessment Instruments

<table>
<thead>
<tr>
<th>Scale</th>
<th>Item</th>
<th>Score</th>
<th>Total (min, max)</th>
<th>At risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norton</td>
<td>Physical condition, Level of consciousness, Activity, Mobility, Incontinence, Skin condition, Cooperation/motivation</td>
<td>Each subscale rated from 1 to 4</td>
<td>5 to 20</td>
<td>Lower score, higher risk of pressure ulcer formation the score ≤ 14 for patients at risk.</td>
</tr>
<tr>
<td>Modified Norton</td>
<td>Skin condition, Cooperation/motivation, Physical condition, Additional diseases, Mental state, Incontinence, Activity, Mobility, Age, Sensory perception</td>
<td>Each subscale rated from 1 to 4</td>
<td>≤ 25</td>
<td>Lower score, higher risk of pressure ulcer formation</td>
</tr>
<tr>
<td>4-factor model</td>
<td>Moisture, Friction and shear, Age</td>
<td>1</td>
<td>&gt; 2</td>
<td>Higher score, higher risk of pressure ulcer formation</td>
</tr>
<tr>
<td>Braden</td>
<td>Sensory perception, activity and mobility; moisture, nutritional status, friction/shear</td>
<td>Each subscale rated from 1 to 3 or 4</td>
<td>6 to 23</td>
<td>The score for mild-risk patients is 15–16, for moderate risk is 12–14 and for high risk is 11 or below. Thus, lower score, a higher risk of PrU development</td>
</tr>
<tr>
<td>Scale</td>
<td>Item</td>
<td>Score</td>
<td>Total (min,max)</td>
<td>At risk</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------</td>
<td>----------------------------</td>
<td>-----------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Waterlow</td>
<td>Build/weight, continence, skin type, mobility, gender, age, appetite, tissue malnutrition, neurological deficit, surgery/trauma and specific medications</td>
<td>Each subscale rate from 0 to 3 or 5 or 8</td>
<td>&lt; 10 to &gt;20</td>
<td>Scores between 10 and 14 is in the ‘at-risk group’, between 15 and 19 in the ‘high-risk group’, and 20 or above in the ‘very high-risk group’. Higher score, higher risk of pressure ulcer formation</td>
</tr>
<tr>
<td>Suriadi and Sanada (S.S)</td>
<td>Interface pressure, in mmHg, (3 and 0) Body temperature (4 and 0) Cigarette smoking (2 and 0)</td>
<td>Each subscale rate from 0 to 3 or 5 or 8</td>
<td>0-9</td>
<td>Higher score, higher risk of pressure ulcer formation</td>
</tr>
<tr>
<td>Douglas scale (adapter of Norton)</td>
<td>Pain Activity Physical condition Incontinence Steroid therapy Diabetes Cytotoxic therapy Dyspnea Age Weight General skin Mental condition Mobility Hemodynamic status Respiration Nutrition Incontinence Hygiene Body temperature Amount of medication (analgesics, sedation and anticoagulants) Sensory perception, activity and mobility moisture, nutritional status and friction/shear</td>
<td>Each subscale is rated from 1-4</td>
<td>8 to 24</td>
<td>Lower score, a higher risk of PU development</td>
</tr>
<tr>
<td>Jackson/Cubbins (adaption of the Norton scale)</td>
<td>Each subscale is rated from 1-3 or 4</td>
<td>10 to 40</td>
<td>Lower score, a higher risk of PU development</td>
<td></td>
</tr>
<tr>
<td>Song and Choi (adapter of Braden)</td>
<td>Each subscale is rated from 1-3 or 4</td>
<td>8 to 31</td>
<td>Lower score, a higher risk of PU development</td>
<td></td>
</tr>
</tbody>
</table>
Considering the review of these PU risk assessment tools, there appears a lack of consistency regarding the appropriate risk assessment scale in ICU settings. It would appear further research to clarify a valid and reliable PU risk assessment tool for the ICU setting is needed.

2.6 DISCUSSION

2.6.1 Risk Factors for PU Development

The first aim of this review was to identify factors or risks that contribute to PU development in ICU. Schoonhoven, Bousema and Buskens (2007) argues that the cornerstone of PU prevention is to identify, assess, and manage potential risk before an injury occurs. Identification of potential risk is important; however, results from this review suggest that PU formation is enhanced by presence of multiple, rather than single, risk factors in the one critically ill individual (Theaker et al., 2000). Sound evidence demonstrates that older age (Cox, 2010; Eachempati et al., 2001; Frankel et al., 2007a; Slowikowski & Funk, 2010), length of stay (Cox, 2010; Eachempati et al., 2001; Theaker et al., 2000), norepinephrine infusion (Cox, 2010; Theaker et al., 2000) and prolonged immobility (Kaitani et al., 2010; Nijs et al., 2009) were significantly associated with PU development in ICU patients. These risk factors will each be discussed.

Age

Patient age was evidenced by literature to be a predictive variable for PU development in ICU patients. While critical illness has a significant impact on the older adult, older people are at high risk for skin breakdown also because of limitations in their mobility. Additionally, their skin becomes fragile and thin and they have a
predisposition to degenerative and other diseases (Finch, 2003). These considerations suggest the effects of ageing on skin integrity cannot be preventable, but rather need to be managed more carefully. Aggressive implementation of preventative measures in this patient group such as use of appropriate pressure relieving mattresses and other support surfaces, frequent turning, regular bathing and the prevention of skin tears will greatly reduce the risk of PU.

**Length of stay**

As evidenced by numerous studies in this review (Cox, 2010; Eachempati et al., 2001; Theaker et al., 2000), the longer the patient remains in ICU, the greater the risk of PU development. This would be viewed as a logical conclusion as higher acuity patients may have a longer length of stay and are consequently at a greater potential for risk of complications, such as PU development.

**Norepinephrine**

The nature of critical illness often results in the majority of ICU patients presenting with impaired ventilation and circulation, which affects body tissue oxygenation. This issue may be ameliorated by special medications such as norepinephrine. Norepinephrine acts via the binding to adrenergic receptors, which causes peripheral vasoconstriction, and may further impair peripheral tissue perfusion leading to peripheral cellular hypoxia (Offermanns & Rosenthal, 2008), which causes ischemia. Thus, profound peripheral vasoconstriction with norepinephrine administration leads to reduced local circulation and increased risk of PU development. Bedside nurses need to be cognizant of the patient’s medication regime
and its potential effects when implementing PU reduction measures, i.e., such patients may require higher level pressure relieving mattresses and more frequent turning.

**Prolonged immobility**

Infrequent turning for ICU patients has a significant impact on PU development. Infrequent turning will result in increased pressure on one point for prolonged periods of time. However, there is no evidence for the optimum frequency for repositioning the critically ill ICU patients. Two-hourly repositioning of patients is accepted as standard practice on the basis of anecdotal data (Hagisawa & Ferguson-Pell, 2008). Goldhill, Badacsonyi, Goldhill and Waldmann (2008) undertook a prospective observational study to examine ICU patient position and frequency of turning. They identified the mean time between turning for patients in over 50 ICUs in the United Kingdom was 4.88 hours (Goldhill, Badacsonyi, Goldhill, & Waldmann, 2008). Tayyib, Lewis and Coyer (2011) found the mean time between patient repositioning in a Saudi Arabian ICU to be two hours. The reviewed studies described the mean time to reposition an ICU patient were between two (Kaitani et al., 2010) and four hours (Nijs et al., 2009). Therefore, while the mean time for repositioning critically ill patients will vary across countries and even individual ICUs within a country, it should still be recognised that, for the most part, turning regimes in ICU aim to reposition patients within time frames of two to four hours. As such repositioning practices should be sensitive to individual patient needs.
Summary

It should be noted that a risk factor prediction model for critically ill patients has yet to be developed. Development of a model is, however, problematic as there are a multiple risk factors to be considered. Further contributing to this, the studies reviewed have utilized different methodologies, different measures of analyses, varying PU definitions and PU classifications, and examined PU across a diverse ICU population. Consequently, development of a risk factor prediction model would be difficult. Further, these complexities have limited the translation and implementation of this research into clinical practice (Keller et al., 2002). Ideally, to examine the association between risk factors and PU development a multicentre longitudinal prospective observational study is needed.

2.6.2 Pressure Ulcer Risk Assessment Scales

The second aim of this review was to examine published studies exploring risk assessment scales that predict PU development in critically ill patients in ICU settings. In this section, discussion of the reviewed studies will focus on reported reliability, validity measures, and sensitivity and specificity of the instruments (Pancorbo-Hidalgo et al., 2006).

Reliability

Reliability concerns a measure’s accuracy, and for the purpose of this review relates to the frequency with which the risk assessment tool produces similar results in the absence of change in the patient’s status (inter-rater reliability), and stability of the
instrument over period of time (test-retest reliability). Only three studies included this review assessed inter-rater reliability of the following scales; Braden scale (Lewicki et al., 2000), Braden and Waterlow scale (Kottner & Dassen, 2010), and Suriadi and Sanada scale (Sanada et al., 2008). The Braden scale demonstrated high reliability (Pearson’s r: 0.83 – 0.99) (Lewicki et al., 2000). Kottner & Dassen (2009) confirmed that the Braden scale has high inter-rater reliability value compared to Waterlow scale (Kottner & Dassen, 2010). However, Pancorbo-Hidalgo et al. (2006) demonstrated that the Braden scale is reliable in terms of inter-rater reliability compared to other risk assessment scales for prediction patient who are at risk for PU development such as Norton, Waterlow and Cubbin/Jacksoon scale (Pancorbo-Hidalgo et al., 2006). The Suriadi and Sanada scale showed high inter-rater reliability (r = 1), but this scale was examined in a single study for a specific population (Sanada et al., 2008). No studies included in this review reported test-retest reliability. Further, reliability of the scales may influenced by many factors, such as training on the use of the risk assessment scale, and competence of individual nurses who assessing patients at risk (Kottner & Dassen, 2010).

**Validity**

Validity refers to the accuracy of the scale. In terms of predictive validity three types of validity exist; content, construct, and criterion validity (Tappen, 2011). Predictive validity refers to the ability of an instrument to consistently identify those patients who are at risk for developing PU (Keller et al., 2002). The National Pressure Ulcer Advisory Panel examined predictive validity of numerous risk assessment scales, for example; Braden scale (Tappen, 2011). The majority of the studies included in this review examined predictive validity through sensitivity and specificity, and the
Sensitivity, specificity and ROC

Sensitivity is defined as the proportion of true positives for patients at risk of PU development who are correctly identified by the scale as at risk. Specificity is defined as the proportion of patients who did not develop PU and were correctly identified by the scale as not at risk (Burns & Grove, 2005; Polit & Beck, 2004). Further to this, the appropriate cut-off point for determination of ‘at risk’ status for the PU risk scale is an important consideration. Investigators often use appropriate statistical analysis to detect cut-off points such as receiver operating curve (ROC) (Burns & Grove, 2005). The ROC also measures the association between predictive validity and the scale (Burns & Grove, 2005).

This review has highlighted that existing risk assessment scales may potentially over-predict patients at risk for PU development (as the sensitivity of the existing scales was reported as acceptable but the specificity reported was low, i.e., the scales failed to identify patients who are not risk for PU development (Seongsook et al., 2004; Kim et al., 2009; Kottner & Dassen, 2010; Lewicki et al., 2000). The risk associated with an overly sensitive risk assessment scale is that patients may receive prevention measures that they do not need resulting in increased costs for the health care facility. Although, the Suriadi and Sanda scale achieved a sound sensitivity and specificity for an Indonesian population (Sanada et al., 2008), a quasi-experimental trial is needed to clarify this result in different countries.
The review also highlighted fluctuations of reported specificity and sensitivity values between different studies (Seongsook et al., 2004; Kim et al., 2009; Kottner & Dassen, 2010; Lewicki et al., 2000; Sanada et al., 2008). These varying results may arise from differences among study settings, populations, PU definition, outcome measures, patient's demographic data, sample sizes and preventive measures which have been implemented. Additionally, performance of risk assessment scales depends on the competence of individual nurses who assess risk in different ways (Flanagan, 1995).

However, Defloor and Grypdonck (2004) suggest that the comparison between risk assessment scales using specificity and sensitivity is meaningless, and the differences between the scales is doubtful. Defloor and Grypdonck (2004) argue that scale items do not consider preventative measures which can impact the PU outcome and thus their value cannot be generalized (Scott, 2000). This poses the question as to whether or not the validity of the scales can be measured through sensitivity, specificity and predictive values (Defloor & Grypdonck, 2005). Since the ideal scale has yet to be developed, these measures should be calculated to test risk assessment scales.

Further, debate continues regarding the use of risk assessment scales for critically ill patients in the ICU. Seongsook et al. (2004) stated that the identification of patients who are at risk for PU would increase nursing care efficiency and be more cost effective, while Pender and Frazier (2005) state that almost all ICU patients are almost at risk for PU development. Similarly, Webster, Gavin, Nicholas, Coleman and Gardner (2010) stated that patients who are unable to reposition themselves independently should be automatically considered as at high risk for PU development. It is timely to consider this argument for ICU patients who are largely immobile, and
by the nature of their critical illness, at high risk for PU development. The current international NPUAP/EPUAP guidelines recommend that risk assessment scales should be used in conjunction with the implementation of preventative PU measures and a clear evaluative framework, which examines all factors influencing the PU risk scale (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009).

2.6.3 Limitations

This review is limited by a number of factors: Firstly, the review was based on specific exclusion and inclusion criteria. Consequently, this yielded a smaller number of studies. However, as the last previous work in this field was published in 2002 (Keller et al., 2002), the intent of this study was to review studies published after this date contributing to the body of knowledge in this area. Secondly, the inclusion of studies only published in the English language may have introduced a risk of language bias. However, it was beyond the financial scope of this review to include studies requiring translation into English. Consequently, it is acknowledged that this review does not include a potential body of work in this field. Finally, the 19 studies reviewed demonstrated inconsistency in methodological approaches and quality making in-depth synthesis and generalization of results across ICU population difficult.

2.6.4 Conclusion

This review identified 28 intrinsic (inherent factors of critical illness related) and extrinsic (external forces related) risk factors for PU development in the adult ICU.
patient population. While ICU patients are confronted with multiple factors for potential PU development, there is inconsistency specific to how these factors are measured. Furthermore, several risk assessment scales have been examined in many studies in terms of predictive performance. There is no consistent or clear evidence which demonstrates any scale to better or more effective than another when used to identify the patients at risk for PU development. Many scales were found to have problems with validity or to be over predictive. There is therefore, a strong need to undertake well designed prospective studies to identify the risk factors and develop valid scales for measuring the risk of PU development in ICU.
2.6.5 References


Chapter 3: (Article 2) Effectiveness of Pressure Ulcer Prevention Strategies for Adult Patients in Intensive Care Units: A Systematic Review

As identified in Chapter Two, PU development is a complex phenomenon, dependent on a wide variety of extrinsic and intrinsic risk factors. Thus, preventing the development of PUs requires multiple strategies aimed at ameliorating known risk factors associated with PU development in intensive care units (ICU). Initial searching identified that the National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP), which are professional associations in the field of PU prevention and treatment, collaborated to produce a free comprehensive guideline that provides brief summaries of evidence-based recommendations for the PU prevention (NPUAP, EPUAP, & PPPIA, 2014). However, at the time of the study (2012-2013) the critically ill patient population was not acknowledged in this or other published guidelines. This omission is of note, as critically ill patients in the ICU present the highest risk for PU development (EPUAP, & NPUAP, 2009).

Recently, the NPUAP & EPUAP collaborated with the Pan Pacific Pressure Injury Prevention Alliance (2014) to produce comprehensive global prevention guidelines. The main recommendations of the NPUAP, EPUAP and PPPIA prevention guidelines include risk factors and risk assessment (RAS), skin and tissue assessment and preventative skin care, nutrition, repositioning and early mobilisation, repositioning to prevent heel PUs, use of support surfaces, medical device management, and recommendations for special populations, such as bariatric patients,
the critically ill, older adults, adults with spinal cord injury, paediatric patients, and the operating room. Both guidelines addressed the main area that should be considered during the prevention plan in general, and neither guideline focused on education and training as the main recommendation. However, the updated guideline includes specialist groups, such as critically ill patients in the ICU. In addition, the recent guideline presents an increased focus on skin care, medical device-related PUs, and new intervention strategies, such as dressings. Therefore, the updated guideline could be considered more current, more applicable, and containing readily available information on the practice guidelines, which could assist and guide the health care clinician in preventing PU development.

This chapter contains the following article:


This publication presents the review and appraisal of the quality of existing up-to-date literature relevant to PU prevention and the management of risk factors identified in the previous chapter, that relate specifically to critically ill patients. The protocol for this systematic review is published on the JBI Database of Systematic Reviews and Implementation Reports (Tayyib & Coyer, 2016a).

This chapter answers research question three in this study.

**Research Question 3:** What are the effects of prevention strategies on the incidence/prevalence of pressure ulcers in adult ICUs?

This review provides an update on current research on PU prevention in adult ICUs. This will inform healthcare practitioners about the best available current evidence in preventing PU development in ICUs.
The Journal of Worldviews of Evidence Based Nursing was the journal chosen for submission, as the journal attracts a wide international readership and the results of the review highlighted the available current evidence base related to PU prevention in the ICU which would be of interest to an international audience.
Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: A systematic review


3.1 ABSTRACT

**Background:** Pressure ulcers are associated with substantial health burden, but could be preventable. Prevention of hospital acquired pressure ulcers (HAPUs) has become a priority for all healthcare settings, as it considered a sign of the provision of quality of care. Critically ill patients in the intensive care unit (ICU) are at higher risk for HAPU development. Incidence of HAPUs in the ICU ranges from 22-49%. Despite the availability of published prevention strategies, there is a little evidence to support which strategies have impact on HAPUs prevention and can be safely integrated into routine standard care.

**Aims:** The aim of this systematic review was to synthesize the best available evidence regarding the effectiveness of single strategies designed to reduce the incidence and prevalence of HAPU development in critically ill patients in the ICU.

**Methods:** The search strategy was designed to retrieve studies published between 2000 and 2015 in English language. All adult ICU participants were aged 18 years or over. This review included randomized controlled trials, quasi-experimental and comparative studies. The studies that were selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical-appraisal instruments.
**Results:** The review included 25 studies and meta-analysis revealed a statistically significant effect of a silicon foam dressing strategy in reducing sacral and heel HAPU incidence (effect size = 4.62; 95% CI: 0.05-0.29; p < 0.00001, effect size = 4.50; 95% CI: 0.05-0.31; p= 0.00001 respectively) in critically ill patients. Evidence of the effectiveness of nutritional interventions, skin care regimens, positioning and repositioning schedules, support surfaces, and the role education in prevention HAPUs development in ICU were limited, which precludes significant conclusions.

**Conclusions and Implication:** The review provides an evidence-based guide to future priorities for clinical practice. A silicone foam dressing has a demonstrated positive impact in reducing the incidence of sacral and heel HAPUs in the ICU.

**Keywords:** pressure ulcer, intensive care, prevention, intervention, strategy, adult, and systematic review.
3.2 INTRODUCTION

Skin injury or ulceration as a result of pressure and shear forces is increasingly being viewed as an indicator of the quality of care given to patients. Therefore, the testing of strategies to prevent the development of hospital acquired pressure ulcers (HAPUs) has been of growing interest in all health-care settings. Nevertheless, PUs are still a common problem in healthcare settings (Berlowitz, 2014), especially in intensive care (ICU), with approximately 22-49% of critically ill patients affected (Berlowitz, 2014).

The development of PUs is a complex process, dependent on a wide variety of extrinsic and intrinsic risk factors (Tayyib, Coyer, & Lewis, 2013). Various strategies have been examined in the prevention of PUs with different methodological approaches and in different clinical settings (Behrendt, Ghaznavi, Mahan, Craft, & Siddiqui, 2014; Girard et al., 2014; Park & Kim, 2014; Theaker, 2003; van Nieuwenhoven et al., 2006; Verbelen, 2007). These studies aimed to inform the clinical decision making of healthcare workers of the best predictors and prevention strategies for HAPUs. However, these studies have limitations, such as lack uniformity in defining and staging of HAPUs and study power. It is argued that providing concise summaries of the supporting evidence, in terms of a systematic review, increases healthcare practitioners’ satisfaction with, acceptance of, and level of implementation of specific strategies (Dobbins, Rosenbaum, Plews, Law, & Fysh, 2007).

The National Pressure Ulcer Advisory Panel (NPUAP), the European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Prevention Alliance (PPPIA) collaborated to produce a comprehensive guideline that provides brief summaries of evidence-based recommendations for the prevention and treatment of HAPUs (NPUAP, EPUAP, & PPPIA, 2014). The NPUAP, EPUAP, and PPPIA
guideline is framed in two sections; prevention of PUs and interventions for prevention and treatment. Prevention is summarized through the topics of risk factors and the use of a risk assessment scale (RAS), skin and tissue assessment, and preventative skin care. Interventions for prevention and treatment of PUs are addressed in sections covering nutrition, repositioning and early mobilization, repositioning to prevent heel PUs, support surfaces, medical device management, and recommendations for special populations such as bariatric, critically ill, older adult, with spinal cord injury, paediatric, and in the operating room. While the intensive care critically ill patient population was acknowledged in this international guideline, this document failed to address PU prevention in ICU from strong evidence based perspective (NPUAP, EPUAP, & PPPIA, 2014). This is significant as ICU patients present the highest risk of HAPU development.

To date, most systematic reviews have investigated the effectiveness of prevention strategies in general ward or healthcare settings. Because there are significant differences in patient acuity and diagnoses, care provided, and environmental factors between ICU and general wards or units, it is inappropriate to extrapolate general care-related results to the intensive care setting. Further, no systematic review of PU prevention strategies in ICU has been conducted since 2000 (Keller, Wille, van Ramshorst, & van der Werken, 2002).

There is evidence that PU prevention is more effective with multiple prevention strategies. However, many studies employ single intervention measured against standard care. Therefore, this systematic review examined the effectiveness of single prevention strategies on HAPUs in ICU patients with the goal of gathering scientific evidence to support or refute the benefit of using such strategies for critically ill patients. The NPUAP, EPUAP, & PPPIA prevention guideline (2014) was utilised as
the framework for this systematic review. The results of this study may serve as a reference for professional caregivers and the information provided could be put into practice during the clinical skin care of ICU patients. The methods of this review were specified in advance in a previously published protocol (Tayyib, & Coyer, 2016).

3.3 OBJECTIVE

The objective of this review was to identify the effectiveness of single strategies designed to reduce the incidence and prevalence of HAPUs development in ICUs in comparison to no strategy, other strategies, or usual practice. The review question was: what is the effectiveness of implementing single PU prevention strategies to reduce the incidence/prevalence of HAPUs compared to different PU prevention strategies, standard/usual care, or no strategies in the adult intensive/critical care environment?

3.4 METHOD

3.4.1 Search Strategy

The search strategy used a three-step search strategy to identify both published and unpublished studies. An initial limited search of MEDLINE (PubMed) and CINAHL was undertaken, followed by analysis of the keywords and index terms contained in the title and abstract. A second search using all identified keywords and index terms was then undertaken across all included databases. Thirdly, the reference list of all identified reports and articles was searched for additional studies. Studies published in non-English language were not considered for inclusion in this review due to lack of available resources for translation. Studies published from 2000 to 2015 were considered for inclusion in this review.
All databases were searched from 2000 to week 30 (26 July) 2015 included: CINAHL, Medline, Cochrane Central Register of Controlled Trials, Web of Science, Embase, ERIC, Scopus, and Mednar. The search for unpublished studies included New York Academy of Medicine Library Gray Literature Report, Google, National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearing House, Centers for Disease Control and Prevention (CDC), and Dissertation/Thesis Abstracts International.

Initial keywords used were: "pressure ulcer\*", "pressure injury", "pressure sore", "bed sore", "critical care", "intensive care", "prevent\*", "reduc\*", "incid\*", and "preval\*".

3.4.2 Selection Criteria

This review considered quantitative experimental studies (randomized controlled trials [RCT]), non-randomized controlled trials, quasi-experimental, before and after, and comparative studies, published in English, with adult participants who were aged 18 years or over and managed in intensive or critical care units. Studies where the results for adult intensive care were unclearly separated from general data were excluded.

This review considered studies that included the following primary outcome measures: HAPU incidence, HAPU prevalence, PU severity, time to occurrence, and number of PUs per patients. The Secondary outcome measure was any adverse effect caused by, or associated with, the use of the prevention strategy.
3.4.3 Quality Assessment

Papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Joanna Briggs Institute, 2014). The JBI-MAStARI tool is a standardized appraisal tool encompassing an assessment checklist of the risk of bias in study selection, performance, detection, attrition and reporting. Studies that met 50% of the JBI-MAStARI checklist tool were included in this review. Any disagreements that arose between the reviewers were resolved through referring the study for the adjudication of a third reviewer.

3.4.4 Data Abstraction

Data were abstracted from papers included in the review using the standard data extraction tool from JBI-MAStARI. The data abstracted included specific details about the strategies, populations, study methods, and outcomes of significance to the review question and specific objectives.

3.4.5 Data Synthesis

Quantitative data was intended to be pooled in statistical meta-analysis as planned in the published protocol (Tayyib & Coyer, 2016). The heterogeneity of the studies was assessed by considering their population, intervention, and outcome. Where possible, odds ratios with 95% confidence interval (CI) were calculated for
binary outcomes. As statistical pooling was not possible the findings are presented in narrative form.

3.5 CHARACTERISTICS OF INCLUDED STUDIES

Searching identified 675 potentially relevant papers, and after sifting of titles and abstracts according to the above inclusion criteria, 78 papers were selected for retrieval. When the full text versions of the papers were examined, 35 of the 78 retrieved papers were found to fully meet the inclusion criteria. These 35 studies were critically appraised by two independent reviewers using the Joanna Briggs Institute Meta-Analysis of Statistics and Review Instrument (JBI-MAStARI) critical appraisal tools. Only 24 were found to be of sufficient quality to include. The flowchart (see Figure 3.1) presents further details of the search results and study selection process.
Chapter 3: (Article 2) Effectiveness of Pressure Ulcer Prevention Strategies for Adult Patients in Intensive Care Units: A Systematic Review

Figure 3.1 Flow Diagram: Selection Process for Systematic Review

Records identified through database and other sources searching (n = 675)

Records after duplicates removed (n = 132)

Records excluded (n = 465)
- Non-English language
- Over 15 years full text
- Review studies
- More than one prevention strategy
- Different study outcome

Records screened (n = 543)

Records excluded (n = 52)
- Non-English language
- Over 15 years full text
- Review studies
- More than one prevention strategy
- Different study outcome

Full-text articles assessed for eligibility (n=78)

Full-text articles assessed for methodology quality (n=35)

Studies included in synthesis (n = 24)

Full-text articles excluded, with reasons (n = 11)
- Unclear if both groups were comparable ……………….8
- Different measurement between both groups ……………….1
- Un-comparable sample size………1
- Unclear findings…………………1

Not ICU specific………………23
- Literature reviews…………………9
- No method design…………………3
- Different outcome measures …....4
- Descriptive study…………………4
The level of evidence overall was moderate to strength or levels II to III-2 according to the National Health and Medical Research Council (NHMRC) evidence hierarchy (NHMRC, 2009). The majority of included studies were RCT designs (n=14). One was a post-test only design with three-group comparisons, three were pre-post experimental studies, and six were two-group quasi-experimental studies. Included studies were conducted worldwide and participants were all intensive care patients (n=6642). Studies details are described further in Tables 3.1.
Table 3.1 Strategies for Pressure Ulcer Prevention in Intensive Care Units

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Author (year of publication)</th>
<th>Design/ level of evidence</th>
<th>Sample</th>
<th>Setting</th>
<th>Intervention measure</th>
<th>Outcome/ recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Care</td>
<td>Pittman, et al (2012)</td>
<td>RCT/ II</td>
<td>59</td>
<td>ICU (USA)</td>
<td>To compare (1) bowel management system (BMS) catheter; (2) Rectal trumpet RT utilized as a rectal fecal incontinence device, and (3) usual care (UC) consisting of barrier creams and/or a fecal pouch collector.</td>
<td>No significant difference in HAPU prevalence (P =0.63)</td>
</tr>
<tr>
<td></td>
<td>Brindle &amp; Wegelin (2012)</td>
<td>Two group quasi-experimental/III-1</td>
<td>100</td>
<td>CSICU (USA)</td>
<td>To evaluate the silicone border foam dressing in the sacrum area</td>
<td>No significant differences in the incidence between both groups (P = 0.3)</td>
</tr>
<tr>
<td></td>
<td>Park (2014)</td>
<td>Quasi-experimental/III-1</td>
<td>102</td>
<td>ICU (South Korea)</td>
<td>To evaluate the silicone foam dressing in the sacrum area</td>
<td>Significant decrease in HAPUs incidence (P &lt; 0.001)</td>
</tr>
</tbody>
</table>
|           | Santamaria N, et al. (2015)   | RCT/ II                   | 313 | ICU (Australia) | To evaluate silicone foam dressings when applied to the sacrum and heel in the emergency department and maintained throughout their ICU stay | Significant decrease:  
- Overall incidence of HAPUs (P =0.001).  
- Sacral event (P =0.05)  
- Heel event (P =0.002) |
|           | Santamaria N, et al. (2015)   | Pre-post quasi-experimental/III-1 | 341 | ICU (Australia) | To evaluate silicone foam dressings when applied on heel in the emergency department and maintained in ICU | Significant decrease heel HAPUs incidence (P <0.001) |
|           | Verbelen J (2007)             | RCT/II                    | 23    | ICU (Belgium) | To examine the polarised light (once a day) on the sacrum and heel in preventing HAPUs grade II or above | Significant decrease in HAPUs incidence (P = 0.019) |
|           | Theilla, et al (2007)         | RCT/II                    | 100   | ICU (Israel) | To compare a diet enriched in lipids and vitamins A, C and E with a diet similar in macronutrient composition | The intervention diet significantly decreased the incidence of HAPUs (P<0.05) |

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<table>
<thead>
<tr>
<th>Guideline Elements*</th>
<th>Author (year of publication)</th>
<th>Design/level of evidence</th>
<th>Sample</th>
<th>Setting</th>
<th>Intervention measure</th>
<th>Outcome/ recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repositioning and early mobility</td>
<td>Still, et al. (2013)</td>
<td>Pre-post experimental trial/ III-1</td>
<td>1112</td>
<td>SICU (USA)</td>
<td>To evaluate a turn team with a 2 hours repositioning schedule</td>
<td>A turn team strategy significantly decreased HAPUs incidence (P &lt; 0.0001)</td>
</tr>
<tr>
<td></td>
<td>Behrendt, et al. (2014)</td>
<td>RCT/II</td>
<td>422</td>
<td>MICU (USA)</td>
<td>To evaluate a continuous bedside pressure mapping (CBPM) device with 2-hour repositioning</td>
<td>HAPUs incidence was significantly lower in the CBPM group (P=0.02).</td>
</tr>
<tr>
<td></td>
<td>Manzano, et al. (2014)</td>
<td>RCT/II</td>
<td>329</td>
<td>ICU (Spain)</td>
<td>To compare 2 and 4 hours repositioning with alternating pressure air mattresses</td>
<td>No significant difference between both repositioning regimen (P=0.73)</td>
</tr>
<tr>
<td></td>
<td>van Nieuwenhoven, et al (2006)</td>
<td>RCT/II</td>
<td>255</td>
<td>ICU (Netherlands)</td>
<td>To compare 45° with 10° head of bed (HOB) elevation</td>
<td>The authors compared between the achieved angles of HOB (28° vs. 10°), and no significant differences were found between groups (28% vs 30% respectively)</td>
</tr>
<tr>
<td></td>
<td>Girard, et al. (2014)</td>
<td>RCT/II</td>
<td>466</td>
<td>ICU (France)</td>
<td>To compare prone with supine positioning.</td>
<td>Supine positioning significantly decreased HAPUs incidence of (P =0.005) after seven days of ICU stay</td>
</tr>
<tr>
<td></td>
<td>Schallom et al. (2015)</td>
<td>RCT/II</td>
<td>15</td>
<td>ICU (USA)</td>
<td>To compare between 30o and 45o HOB elevation</td>
<td>No HAPUs developed in either group.</td>
</tr>
<tr>
<td></td>
<td>Theaker, Kuper, &amp; Soni (2005)</td>
<td>RCT/II</td>
<td>62</td>
<td>ICU (UK)</td>
<td>To compare an alternating pressure mattresses with a low air loss mattress</td>
<td>No significant difference between both groups (P=0.35)</td>
</tr>
<tr>
<td></td>
<td>Malbrain M, et al. (2010)</td>
<td>RCT/II</td>
<td>16</td>
<td>MICU (Belgium)</td>
<td>To compare an active alternating pressure mattress with a reactive mattress overlay</td>
<td>No difference in incidence (1 vs. 2, respectively)</td>
</tr>
<tr>
<td></td>
<td>Jackson, et al. (2011)</td>
<td>Pre-post experimental trial/ III-1</td>
<td>53</td>
<td>CTV ICU (USA)</td>
<td>To evaluate the effect of air fluidized therapy beds</td>
<td>Incidence decreased after strategy (40% pre. vs 15% post)</td>
</tr>
<tr>
<td>Support surfaces</td>
<td>Black, Berke, Urzendowski (2012)</td>
<td>Two group comparative study/ III-2</td>
<td>52</td>
<td>SICU (USA)</td>
<td>To compare a low air loss with microclimate management bed to the integrated powered air pressure redistribution bed</td>
<td>Incidence was significantly lower with the low air loss bed (P = 0.046)</td>
</tr>
<tr>
<td></td>
<td>Manzano F, et al. (2013)</td>
<td>Two group quasi-experimental/III-1</td>
<td>221</td>
<td>ICU (Spain)</td>
<td>To compare an alternating pressure mattress with a foam overlay mattress</td>
<td>Incidence was significantly lower with an alternating pressure mattress (P = 0.038)</td>
</tr>
<tr>
<td></td>
<td>Ozürek &amp; Yavuz (2015)</td>
<td>RCT/II</td>
<td>105</td>
<td>ICU (Turkey)</td>
<td>To compare two types of viscoelastic mattresses</td>
<td>No significant difference between both groups (P=0.44)</td>
</tr>
</tbody>
</table>

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### Medical Devices Related PUs

<table>
<thead>
<tr>
<th>Guideline Elements*</th>
<th>Author (year of publication)</th>
<th>Design/ level of evidence</th>
<th>Sample</th>
<th>Setting</th>
<th>Intervention measure</th>
<th>Outcome/ recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gregoretti, C., et al. (2002)</td>
<td>RCT/II</td>
<td>194</td>
<td>ICU (Italy)</td>
<td>To compare prototype face masks (PMs) with conventional face masks (CMs)</td>
<td>The PMs significantly decrease the incidence of MDRPU ($P &lt; 0.001$). The protective dressings significantly decrease the HAPUs incidence ($P &lt; 0.001$). However, no significant different was reported between both dressings.</td>
</tr>
<tr>
<td></td>
<td>Weng (2008)</td>
<td>Three group quasiexperimental/III-1</td>
<td>60</td>
<td>ICU (Taiwan)</td>
<td>To compare HAPUs incidence related to face-mask when using a protective dressing (hydrocolloid, or transparent film) with nothing applied with face-mask</td>
<td>Phase I: No significant differences between both groups in the incidence (intervention= 24.1% vs control= 28.6%) Phase II: the intervention Significantly decrease the incidence ($P = 0.002$). Early tracheostomy was significantly decreased the incidence of HAPUs ($P = 0.001$)</td>
</tr>
<tr>
<td></td>
<td>Rassin et al. (2013)</td>
<td>Three group RCT/II</td>
<td>Phase I: 57 PhaseII: 112</td>
<td>ICU (Israel)</td>
<td>Phase I: to compare urinary catheter skin care regimen of once every 24 hours to standard care on the incidence of HAPUs related to urethral catheterization Phase II: to compare urinary catheter three times daily skin regimen to standard care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alali, et al. (2013)</td>
<td>Two group comparative study/III-2</td>
<td>1811</td>
<td>ICU (Canada)</td>
<td>To evaluate early tracheostomy ($\leq$ 8 days) in trauma brain injury</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uzun, Aylaz, Karadag (2009)</td>
<td>Two group comparative study/III-2</td>
<td>186</td>
<td>ICU (Turkey)</td>
<td>To evaluate the impact of an educational strategy (2 seminars for 2 hours) on the incidence of stage II or greater PUs</td>
<td>Significantly lower the incidence with educational strategy ($P &lt; 0.01$)</td>
</tr>
</tbody>
</table>

*National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance, 2014*
3.6 FINDINGS

The results will be reported according to the NPUAP, EPUAP, and PPPIA guideline (2014) and framed in two sections; prevention of PUs and interventions for prevention and treatment.

3.6.1 Effectiveness of Risk Assessment/Skin and Tissue Assessment

No studies were found that examined the contribution of RASs as a strategy to reducing HAPUs in ICU.

3.6.2 Preventive Skin Care

One study evaluated the impact of a strategy for faecal incontinence on the rate of PU development (Pittman, Beeson, Terry, Kessler, & Kirk, 2012). The study compared three strategies of bowel management to control fecal incontinence on the prevalence of HAPUs with no significant difference found in the prevalence rate of HAPUs ($p=0.63$) in either group.

3.6.3 Emerging Therapies for Hapu Prevention

*Polarised light.*

One study investigated the efficacy of polarised light once/day for 10 minutes in preventing the incidence of HAPUs on the sacral and heel area (Verbelen, 2007). The study showed no significant difference in the development of all stages of PUs with the use of polarised light on the sacrum and heels ($p = 0.196$), despite there a significant
decrease in the incidence of HAPUs when stage I PUs were excluded (p= 0.019). However, the control group had more assessed areas of skin at risk for PUs (39 areas/13 participants) compared to the intervention group (28 areas/10 participants). Additionally, a small sample size of 23 participants limited the study’s findings.

**Dressings.**

Three studies reported the effectiveness of the application of prophylactic silicone foam dressings in decreasing the incidence of sacral HAPUs (Brindle & Wegelin, 2012; Park, 2014; Santamaria et al., 2015b). The overall effect size across studies was 0.12 (95% confidence interval [CI]: 0.05-0.29; p < 0.00001), the result indicating that HAPU incidence of sacral area decreased after the application the dressing (see Figure 3.2).

Two studies examined the effectiveness of similar dressings in reducing the incidence of heel HAPUs (Santamaria et al., 2015a; Santamaria et al., 2015b). These two studies demonstrated that heel HAPU incidence significantly decreased after implementation of the dressing. The first trial’s result demonstrated a significant reduction of heel HAPU incidence in the intervention group (5 vs. 19, p = 0.002) compared to the control group (Santamaria et al., 2015b). The result was confirmed with a subsequent study that evaluated the dressing on heel HAPU incidence. No PU was reported on heels following the implementation of the dressing strategy (0 vs. 19, p < 0.001) (Santamaria et al., 2015a). Both studies used the same control group where the second study (Santamaria et al., 2015a) recruited a new intervention group and measured against a historical control group (Santamaria et al., 2015b).
3.6.4 Nutrition

Only one study examined specific nutritional strategies to prevent HAPUs in critically ill patients with acute lung injuries (Theilla, Singer, Cohen, & Dekeyser, 2007), reporting that the intervention diet was significantly associated with reduction of HAPU incidence (p=0.05). However, more participants were recruited with existing PUs in the control group, and so were more likely to develop subsequent PUs, therefore biasing the results.

3.6.5 Repositioning and Early Mobilization

Repositioning frequency

Two studies supported two-hour repositioning intervals in reducing the incidence of HAPUs through different interventions (Behrendt et al., 2014; Still et al., 2013). The first study investigated the efficacy of using continuous bed pressure...
mapping (CBPM) with a 2-hourly repositioning regimen (Behrendt et al., 2014). Results showed a significant difference in the incidence of HAPUs, stage II or greater, between groups (p=0.02). The second study showed improvements with two-hour repositioning using a turn team strategy (Still et al., 2013). A turn team composed of two trained patient care assistants showed significant improvement in the incidence of HAPUs between pre and post implementation (p < 0.0001) (Still et al., 2013). However, these two studies pose a number of limitations, such as the compliance to turn team to the strategy (Still et al., 2013), other prevention strategies employed at the time of the study (Behrendt et al., 2014; Still et al., 2013), and the duration of time to reach peak interface pressure were not reported (Behrendt et al., 2014).

Only one cluster RCT study investigated the efficacy of different patients repositioning regimens (2 versus 4 h) in mechanically ventilated patients who were managed on an alternating pressure air mattress (Manzano et al., 2014). No significant differences in reduction of HAPUs of stage II or greater were found between groups (p = 0.73). However, the compliance to both repositioning regimens was not reported.

**Positioning the patient in bed**

Three studies examined the effectiveness of a variety of patient positioning strategies and the impact on PU development (Girard et al., 2014; Schallom, Dykeman, Metheny, Kirby, & Pierce, 2015; van Nieuwenhoven et al., 2006). Strategies trialled were diverse: one study compared the effectiveness of the backrest elevation of 28° vs 10° for semi recumbent positioning with findings revealing no differences between each position (28° vs. 10°) groups in developing HAPUs (28% vs. 30% respectively) (van Nieuwenhoven et al., 2006). The second study compared the effectiveness of a
backrest elevation of 45° vs. 30°. No HAPUs developed for both groups (Schallom et al., 2015). The third study compared prone vs. supine position in HAPU development with severe acute respiratory distress syndrome (ARDS) (Girard et al., 2014). Results suggested that the prone position was associated with significantly greater HAPU development compared to a supine position in the first seven days of patient admission (p=0.05). However, these three studies did not address the frequency of repositioning patients, other supportive PU prevention strategies, and the angle of lower part of the body.

**Repositioning the patient out of bed**

No studies were identified that investigated the strategy of positioning the patient out of bed in a chair, the types of surfaces to seat ICU patients out of bed, or the frequency and or duration of sitting out of bed to reduce the incidence of HAPUs.

**3.6.6 Support Surfaces**

Six studies investigated the efficacy of a variety of pressure-relieving support surfaces (Black, Berke, & Urzendowski, 2012; Jackson et al., 2011; Malbrain et al., 2010; Manzano et al., 2013; Ozyurek & Yavuz, 2015; Theaker, Kuper, & Soni, 2005). Two of these studies investigated the efficacy of using an active alternating pressure mattress in preventing PU development in the ICU setting in comparison to a mattress overlay. A small pilot trial demonstrated similar impact of two support surfaces on prevention of HAPUs (1/8 in active alternating pressure mattress vs. 2/8 in reactive mattress overlay (Malbrain et al., 2010). In contrast, Manzano and colleagues suggested that the alternating pressure mattress can significantly lower the incidence
of HAPUs, stage II or greater, in comparison with the foam overlay mattress (p=0.038) (Manzano et al., 2013). However, these studies have limitations, notably, small sample sizes (n=16), the compliance to other prevention strategies were not declared, and the heterogeneity of the outcome measures.

The efficacy of using an alternating pressure mattresses compared to a low air loss mattress on reducing the HAPU in ICU was investigated in a single study with no significant difference found between the groups (p=0.35). This study was limited by retrospective data collection, small sample size, lack of reporting of other PU preventive care strategies in place and compliance to the intervention (Theaker et al., 2005). A low air loss with microclimate management bed (LAL-MCM) was compared to integrated powered air pressure redistribution bed (IP-AR) (Black et al., 2012). The LAL-MCM significantly decreased the incidence of HAPUs compared to IP-AR (p = 0.046) (Black et al., 2012).

A single study trialled the effectiveness of air fluidized therapy support surface beds on preventing PU development (Jackson et al., 2011) reporting that the air fluidized therapy bed was more effective in reducing the incidence of HAPUs development in a cardiothoracic vascular ICU (40% pre-implementation vs 15% post-implementation) (Jackson et al., 2011). The characteristics of standards beds were not reported.

Recently, one trial compared the efficacy of two viscoelastic mattresses (Ozyurek & Yavuz, 2015), one composed of two layers, while the second was composed of three layers. No significant differences were found in the incidence of HAPUS between groups (p=0.44) (Ozyurek & Yavuz, 2015).
3.6.7 Medical Devices-Related PUs

One study with a 2-phase design addressed the effectiveness of a strategy to prevent HAPUs in the critically ill male’s urinary meatus (Rassin, Markovski, Fishlov, & Naveh, 2013). Each phase evaluated different intervention strategies compared to usual standard care. The standard care was washing the area around the catheter entry point once/day. The findings for Phase I (daily washing the area around the catheter entry point) showed no significant difference in the incidence of urinary catheter related PUs between groups (7/29 intervention vs. 8/28 control). In Phase II (three times daily washing the area around the catheter entry point) showed a significant difference between groups (p=0.002).

Two studies evaluated different strategies to reduce device-related PUs with non-invasive ventilation (Gregoretti et al., 2002; Weng, 2008). One study investigated the effectiveness of prototype face masks (PMs) compared to conventional face masks (CMs) and found significant improvement in device-related PUs using PMs (p<0.001). Another study investigated the effectiveness of using different protective dressings (hydrocolloid, and transparent film) with CM to prevent device-related PU (Weng, 2008). The findings showed a significant difference in the incidence of device-related PUs between groups (p=0.001) (Weng, 2008). However, no significant difference was found with using different types of protective dressings (Weng, 2008).

Only one trial examined the timing of a tracheostomy procedure for traumatic brain injury patients in reducing the incidence of HAPUs in ICU (Alali et al., 2014). The findings showed that early tracheostomy, ≤ 8 days of the patient’s admission, significantly lowered the incidence of HAPUs (p=0.001) (Alali et al., 2014). However, the study was limited as it was retrospective study, unclear that the outcomes were
measured based on objective criteria and in reliable way, and no other PU preventive strategies for both groups were mentioned (Alali et al., 2014).

3.6.8 Educational Strategies

A single study examined the effectiveness of educational strategies on the reduction of HAPU incidence in ICU settings (Uzun, Aylaz, & Karadağ, 2009). This study aimed to increase understanding and knowledge of PU prevention strategies through two 2-hour seminars for ICU nursing staff. A significant reduction of the HAPUs incidence was reported after implementation of the educational strategy (p <0.01) (Uzun et al., 2009).

3.7 DISCUSSION

Using the NHMRC (2009) evidence hierarchy for study design, this review found 24 studies in level II to III-2 evidence categories that evaluated different PU prevention strategies in the ICU. However, uncertainty in interpretation of these studies results exists due to small underpowered sample sizes with wide confidence intervals, and intention to treat was calculated (Gregoretti et al., 2002; Jackson et al., 2011; Malbrain et al., 2010; Schallom et al., 2015; Theaker et al., 2005; Verbelen, 2007).

There was no evidence that use of a RAS, with or without a protocol intervention strategy, could reduce the incidence of HAPUs in ICU. Tayyib and colleagues (2013) recommended developing a RAS specifically for ICU, as most common RASs appear to be unreliable in prioritizing the higher risk patients in ICU,
possibly affecting deployment of available resources. Risk and skin assessment are not stand-alone events, nor are interventions. Thus no studies have, or can, examine the association between risk or skin assessment by itself and PU development. However, risk and skin assessments are recommended to always be incorporated into study protocols (NPUAP, EPUAP & PPPIA, 2014) to identify the patient at risk and guide the implementation of appropriate strategies. A gap remains as what intensive care clinicians could provide for specific patient’s condition (e.g. sepsis, hypotension, and multi-organ failure)

Evidence was inadequate to determine the effectiveness strategies for controlling faecal incontinence, and keeping patients’ skin dry and clean but not excessively dry in impeding overall HAPU development specifically in the sacral area of ICU patients. To develop a full picture of effective skin care strategies additional studies will be needed that aim to manage skin moisture, skin hygiene, skin dehydration, and the maintenance of natural skin pH.

A few studies demonstrated the effectiveness of supine positioning with different elevation angles of backrest on preventing HAPUs development. Defloor (2000) reported that the supine position has the lowest interface pressure (Defloor, 2000). Frequent repositioning, “two-hour repositioning”, is considered to be standard care to prevent PUs development (Behrendt et al., 2014) and is reported in this review to be effective in reducing the incidence of HAPUs, which is often not achieved. Goldhill and colleagues found that the average time for repositioning the ICU patients was 4.85 hours (Goldhill, Badacsonyi, Goldhill, & Waldmann, 2008). However, four-hour repositioning using alternating pressure air mattress showed similar impact on HAPUs. This finding reveals a possible interaction between positioning, turning and using a support-surfaces strategy. In this review, different types of support surfaces.
were evaluated and compared. However, the most effective support surfaces are
difficult to ascertain in the absence of effective sample sizes, huge variety of support
surface products availability/ choice, and inconsistency in the use of PU staging
systems as an outcome measure (Black et al., 2012; Jackson et al., 2011; Malbrain et
al., 2010; Manzano et al., 2013; Ozyurek & Yavuz, 2015; Theaker et al., 2005). Further
evaluations are therefore required between different support-surfaces with sufficient
power to identify the most effective surfaces on the reduction of HAPU incidence in
ICU.

Moreover, different prevention strategies were implemented, such as high
protein diet with multivitamins, polarised light, timing of a tracheostomy, and different
education and training strategies. These studies overall, have yielded improved results
in preventing PU development, however, more research is required to validate these
finding.

Medical devices could increase risk for developing HAPUs in areas such as the
face, neck and inner thigh. Few trials with small sample sizes compared and evaluated
the efficacy of different devices and different types of dressing for securement for non-
invasive ventilation devices, as well as the efficacy of frequently cleaning the area
underneath devices and changing positioning. The resulting of sample size trial could
affect the reliability of the outcome.

All studies which examined the application of prophylactic silicon border foam
dressings suggested statistically significant decrease in the incidence of sacral and heel
HAPUs in ICU. Using a prophylactic silicon border foam dressing on the sacrum was
confirmed by a meta-analysis which demonstrated a statistically significant decrease
in the incidence of sacral HAPUs. In regards heel HAPUs and prophylactic silicon
border foam dressings, statistical pooling was not conducted as both studies had same
control group. Further, standard care is to offload pressure on heels. A comparison study is required to determine if the outcomes with the use of dressings are better than the outcomes of heel offloading devices.

In this review it was found that authors of most PUs prevention strategy trials did not acknowledge or monitor the degree of compliance to either the strategy itself or other PU prevention strategies, which may have affected the trials’ results. Moreover, the measurement tools in the study (the assessment and staging of PUs) were based on different definitions. Therefore, standardized PU definition and tools of measurement, monitoring the intervention compliance, and the reporting other prevention strategies are required to increase the understanding of these strategies. Consequently, a more systematic meta-analysis could be developed and more effective PUs prevention guideline could be generated.

3.8 CONCLUSION

The present review demonstrated different prevention strategies with positive impact that reduces the incidence of HAPUs in ICUs. A meta-analysis of this review reveals the effectiveness of using silicon foam dressing for preventing sacral HAPUs in ICU settings. However, pooled data from studies with different research designs and settings could be potential sources of heterogeneity and could affect this review’s findings. Moreover, the included studies pose many limitations such as different PU staging systems, small sample size, lack of randomisation, heterogeneity of these studies and compliance to intervention or other prevention strategies. Thus, no conclusions can be reached regarding the effectiveness of these strategies over another to prevent HAPUs in the intensive care context.
Further rigorous-designed RCTs that follow standardised criteria for reporting intervention are required. The criteria should consider multiple factors including a standard PU definition, staging systems, the degree of compliance to the intervention and other PUs prevention care, and characteristics of both groups either related to participants, and other PUs prevention care. This will promote the understanding and generalizability of these interventions’ effectiveness to different patient populations and settings.
3.9 REFERENCES


Chapter 4: Conceptual Framework

4.1 INTRODUCTION

The previous chapters demonstrated that while several studies have addressed pressure ulcer (PU) prevention strategies in the ICU, PU incidence and prevalence in this setting remains high globally (Ballard et al., 2008; Coyer et al., 2015; Frankel et al., 2007). This suggests a lack of translation of best available evidence in real clinical settings. A possible explanation for this phenomenon could be related to the factors influencing the implementation of strategies, and possibly the validity of the studies’ findings themselves. It could be argued that a lack of comprehensive processes exist to guide the application of PU prevention strategies in the clinical setting, particularly the ICU. As the objective of this study was to develop, implement, and evaluate a PU prevention strategy in the intensive care setting, a comprehensive framework was required to effectively guide the implementation of PU prevention evidence in the ICU. This chapter provides an outline and justification for the conceptual framework used to inform this study, a care bundle approach combined with a research implementation framework.

4.2 CARE BUNDLE APPROACH

All critically ill patients in intensive care units are at risk for PU development due to their high acuity, physiological responses to critical illness, and subsequent length of stay in the ICU. Therefore, it is important to implement strategies that prevent PU development in critically ill patients. Evidence reveals that PU incidence can be reduced through the implementation of a PU prevention care bundle (or practice
The term “care bundle approach” refers to a set of three to six treatment interventions targeted towards a specific procedure, symptom, or treatment (Cinel & Dellinger, 2006; Frantz, 2004; Fulbrook & Mooney, 2003; Marwick & Davey, 2009; Robb et al., 2010). Robb et al. (2010) argued that the care bundle approach is more effective than simply following clinical guidelines. This may be due to the mandatory and audited nature of care bundles, whilst clinical guidelines are regarded as advisory. The main concept of the care bundle approach is to group best evidence together, implemented at the same time, and then audited regularly. Such interventions can increase compliance and produce greater positive outcomes for patients than when carried out individually (Crunden, Boyce, Woodman, & Bray, 2005; Fulbrook & Mooney, 2003; Gillespie, 2007; Griffin et al., 2007; Lawrence & Fulbrook, 2011; Marwick & Davey, 2009; Pronovost, Nolan, Zeger, Miller, & Rubin, 2011; Robb et al., 2010; Thomson, Angus, & Scott, 2000). There is an emphasis on the importance of all elements of the “all or nothing” care within the care bundle approach, rather than the traditional audit approach, whereby each element is considered individually (Robb et al., 2010). The philosophy behind the practice is the combined use of evidence that has been accumulated.

This approach has been shown to be effective in many clinical areas such as PU prevention (Cherry & Midyette, 2011), reduction in ventilator-associated pneumonia (Crunden et al., 2005), antibiotic management (Toth, Chambers, & Davis, 2010), and increased compliance for hand hygiene (Pincock, Bernstein, Warthman, & Holst, 2012). Therefore, mounting evidence supports that bundling or grouping of high

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quality evidence into one intervention is more effective in achieving the desired outcome, reduced PU incidence, in critically ill patients.

However, some healthcare practitioners have voiced opposition to care bundle approaches for a variety of reasons, namely: deprivation of the autonomy to make other clinical decisions, perceived inefficiencies (similar outcomes may be achieved with fewer elements), or ineffectiveness (the bundle may not be up to date with the most recent effective interventions) (Amerling, Winchester, & Ronco, 2008). Further, the risk of over or under-treatment could be increased, as not all patients may need all elements of the bundle. Finally, the care bundle approach does not address the process of translation of knowledge and evidence into the real clinical setting (Camporota & Brett, 2011).

Despite these acknowledged limitations, the care bundle approach has proven to be effective through its all-inclusive nature. Namely, it promotes standardised care grounded in current evidence, which is more effective than single symptom management in complex areas (Fulbrook & Mooney, 2003). This standardisation helps to increase clinician compliance to adopt effective, evidence-based strategies to prevent, manage, and treat health problems. Thus, this research used a care bundle approach to guide the development of PU prevention strategies.

4.3 RESEARCH IMPLEMENTATION FRAMEWORKS

A care bundle itself is insufficient to implement evidence based practice; a systematic and dynamic model is required to guide the implementation and consequent adoption of a PU prevention bundle. There are a range of valid, effective, context-focused models/or frameworks that have been used across numerous clinical settings.
to promote research uptake by health care practitioners. These frameworks include: the Promoting Action on Research Implementation in Health Services Framework (PARIHS) (Kitson, Harvey, & McCormack, 1998; Kitson et al., 2008; Rycroft-Malone, 2004), the Johns Hopkins Nursing EBP model (JHNEBP) (Newhouse, Dearholt, Poe, Pugh, & White, 2005; Newhouse, Dearholt, Poe, Pugh, & White, 2007), the Iowa model (Cullen & Titler, 2004; Titler et al., 1994), and the Ottawa Model for Research Use (OMRU) (Graham & Logan, 2004). A brief overview of these models/frameworks is discussed in the next section.

4.3.1 Promoting Action on Research Implementation in Health Services Framework (PARIHS)

The PARIHS is a conceptual model for translating research evidence into clinical practice and assessing components that could facilitate the implementation of an intervention. It was originally developed in 1998 (Kitson et al., 1998), and refined over time based on concept analyses and exploratory research (Kitson et al., 2008). According to this model, successful implementation of evidence is based on three core elements: evidence, context, and the facilitator. These three elements are ranked on a low-to high continuum, and the framework predicts successful intervention implementation when each element falls within the high continuum (see Figure 4.1).
The first element, evidence, includes propositional and non-propositional knowledge (research, clinical experience, patient and carers' experience, and local information). Each piece of evidence is considered and ranked as low or high on the continuum according to the criteria to be met. Research evidence within PARIHS is one of the sources of knowledge that facilitates decision making for specific topics, especially when the research is well-conceived and conducted, and judged to be reliable. Clinical experiences are another source of evidence, therefore, these experiences should be verified and critiqued with other community practices to be considered effective sources for making a decision. Patient experience could also
influence decision making through individual interaction, and perception and appropriateness of patient care. Moreover, local information such as audit and quality measurement and evaluation could contribute positively to making a decision regarding evidence, which could be translated to a clinical setting (Kitson et al., 2008; Rycroft-Malone, 2004).

The second element of context refers to the setting or environment in which the practice change will be applied. This includes three sub-elements, which are culture, leaders, and evaluation. Culture is defined as a “learning organisation”, which includes leaders’ management styles and the relationship between the workers in a specific organisation. Leaders play an important role in transforming culture to create a context more conducive to translating evidence to practice. Evaluation reflects on whether the change of practice was appropriate, effective, and efficient (Kitson et al., 2008; McCormack et al., 2002; Rycroft-Malone, 2004).

The final element is facilitation, which reflects the strategies or techniques that allow the implementation of research evidence into clinical practice. The role of the facilitator is to help the individual, team, and organisation to understand how, when, and what strategies they need to translate the evidence to practice. Therefore, facilitators need to have appropriate information and skills (Harvey et al., 2002; Kitson et al., 2008).

While the PARHIS framework (see Figure 4.1) provides a comprehensive process to explore the factors and barriers that contribute to the successful implementation of research, there remains a lack of knowledge regarding how this framework could be applied in real clinical practice (Sudsawad, 2007). In addition, this framework neglects to outline or explain how the core elements interrelate and interact with each other (Rycroft-Malone & Bucknall, 2011).
4.3.2 The Johns Hopkins Nursing EBP Model (JHNEBP)

The Johns Hopkins Nursing EBP model and guidelines were the result of collaboration between the Johns Hopkins Hospital Department of Nursing and the Johns Hopkins University School of Nursing in 2002 (Newhouse et al., 2005; Newhouse et al., 2007). The healthcare setting is a dynamic environment where nurses cannot achieve expertise without maintaining continual awareness of the entire realm of recent knowledge and how this can be utilised in practice (Pape, 2003). The expertise of both hospital nursing staff and school of nursing staff was derived to develop and test the EBP process. The Johns Hopkins Hospital identified the development of an EBP model as a strategic initiative (Newhouse et al., 2007).

The JHNEBP model assists nursing clinicians to translate research evidence into practice whilst considering the impact of internal and external factors. External factors in this model include quality measures, standards, and professional regulatory and accreditation bodies. Internal factors include the organisational culture, which comprises values and beliefs; and the environment; leadership support; resource allocation; patient services; organisational mission or value statement; organisational priorities; availability of technology; library support; and finance (Newhouse et al., 2007) (see Figure 4.2).
Figure 4.2 The John Hopkins Nursing Process for Evidence-Based Practice

(Adapted from Newhouse et al., 2007)
The processes of this model are depicted by the essential cornerstone of the profession of nursing practice education and research, practice questions; evidence; and translation (PET) (see Figure 4.2). The practice question is the first phase; the process of generating a research question. The question is designed and refined, the scope of the question is determined, and an interdisciplinary team is formed. Evidence is the second phase of the PET process, and deals with the search for, and appraisal of, the best available evidence. Based on the results of this appraisal, recommendations are made by the team regarding identified practice changes. Translation is the third phase of the process, the EBP team determines if the changes to practice are feasible given the target setting. If so, an action plan is created. The change is then implemented and evaluated and the results are communicated to appropriate individuals both internal and external to the organisation. Each element of the process has many aspects that should be considered in assessing the success of the implementation, as shown in Figure 4.2.

However, the nature of the process should be not presented as unidirectional, as elements could be influenced by each other. As with any research translation model, emphasis should be on the implementation component within the translation process; however, a major criticism of the JHNEBP model is that the degree of adoption of evidence is not monitored (Newhouse et al., 2007). Therefore, a true translation of research findings would be lost.

4.3.3 The Iowa Model

This model was established from 1994 to 2001 by staff nurses of the University of Iowa Hospital and Clinics. It aimed to demonstrate the process of utilising research
to improve healthcare outcome in clinical practice (Rycroft-Malone & Bucknall, 2011; Titler et al., 2002). This model focuses on knowledge and problem-focused triggers, leading staff to question existing health care practices and whether care can be improved through the implementation of up-to-date research results (Titler, 2007; Titler et al., 2002). This model was developed and tested, firstly in acute care setting (Titler et al., 2002), then adopted widely in academic and acute care settings (Aitken et al., 2011; Bowman et al., 2005; M. Gordon, Bartruff, S. Gordon, Lofgren, & Widness, 2008; Haxton, Doering, Gingras, & Kelly, 2012; Ong, Miller, Appleby, Allegretto, & Gawlinski, 2009; Van Waning, Kleiber, & Freyenberger, 2005; Witzke et al., 2008). Moreover, it is applicable for all health care disciplines (see Figure 4.3).
Chapter 4: Conceptual Framework

Problem-focused triggers
1. Risk management data
2. Process improvement data
3. Internal/external benchmarking data
4. Financial data
5. Identification of clinical problem

Knowledge-focused triggers
1. New research or other literature
2. National agencies or organizational standards and guidelines
3. Philosophies of care
4. Questions from institutional standards committee

Is this topic a priority for the organization?

Form a team

Assemble relevant research and related literature

Critique and synthesize research for use in practice

Is there a sufficient research base?

Pilot the Change in Practice
1. Select outcomes to be achieved
2. Collect baseline data
3. Design evidence-based practice (EBP) guideline(s)
4. Implement EBP on pilot units
5. Evaluate the process and outcomes
6. Modify the practice guidelines

Base Practice on Other Types of Evidence
1. Case reports
2. Expert opinion
3. Scientific principles
4. Theory

Conduct research

Is change appropriate for adoption in practice?

Institute the change in practice

Monitor and Analyze Structure, Process, and Outcome Data
- Environment
- Staff
- Cost
- Patient and family

Disseminate results

Continue to evaluate quality of care and new knowledge

No

Yes

Yes

No

Figure 4.3 The Iowa Model of Evidence-Based Practice to Promote Quality of Care
(Adapted from Titler et al., 2002)
Many studies, guided by the Iowa model, suggest that this model facilitated the implementation of evidence based practice in real settings (Bowman et al., 2005; Brown, 2014; M. Gordon et al., 2008). The Iowa model uses a seven step process: selecting a topic, forming a team, evidence retrieval, grading the evidence, developing an EBP standard, implementing the EBP, and evaluation (see Figure 4.3).

Although it is evident that the Iowa model is an effective model for translating knowledge into practice, there are some notable limitations. For example, the Iowa model was criticised as the process of informing the individual practitioner about the outcome of change practices is not addressed (Rycroft-Malone & Bucknall, 2011; Schaffer, Sandau, & Diedrick, 2013), thus, there is no continuous feedback from the practitioners during the implementation period. Furthermore, there are questions regarding the fidelity of the implementation of this model in relation to adoption of critical and relevant evidence (Aitken et al., 2011).

4.3.4 The Ottawa Model of Research Use (OMRU)

The OMRU, designed by Logan and Graham (1998), is a dynamic, interactive model used to apply knowledge in clinical practice (Logan, Harrison, Graham, Dunn, & Bissonnette, 1999). As OMRU processes interconnected decisions and actions by different individuals related to each of the model’s elements (Buxton & Hanney, 1996), this means that the process can be repeated at any stage of the implementation. Many studies have applied the OMRU model to facilitate transfer of knowledge in real practice contexts (Hogan & Logan, 2004; Logan et al., 1999; Stacey, Pomey, O'Connor, & Graham, 2006).

The OMRU consists of six phases framed by assessment, monitoring, and evaluation: 1) research-based innovation, 2) the practice environment, 3) potential
adopters, 4) implementation of the intervention, 5) adoption, and 6) outcomes (see Figure 4.4) (Logan et al., 1999).

The model is classified as a planned action model, as it provides direction for the issues that should be addressed and the activities that change agents should undertake (Logan & Graham, 1998). When knowledge transfer is being planned, the model relies on a process of assessing, monitoring, and evaluating each element before, during, and after the decision is made to promote the innovation (Rycroft-Malone & Bucknall, 2011). The OMRU directs change agents through assessment of the barriers and facilitators to research use related to the practice environment (in this instance the ICU), adopter characteristics (in this instance intensive care specialist registered nurses), and the clinical innovation (PU prevention bundle). These three phases result in the identification of factors that could hinder or assist the implementation of evidence-based innovation. An implementation plan is then tailored to overcome the identified facilitators and barriers. The strategies to deliver the intervention are based on the situational assessment and the transfer of the strategies with the ongoing evaluation. How the evidence-based research is transferred to clinical practice is then monitored. Finally, the intervention is evaluated by assessing the effect on patients, practitioners, and the system to conclude the effectiveness of the intervention.
Chapter 4: Conceptual Framework

Assess barriers and support + Monitor intervention and degree of use + Evaluation outcomes

Research-based innovation
- Development process
- Innovation attributes

Potential adopters
- Awareness
- Attitudes
- Knowledge/skill
- Concerns
- Current practices

Practice environment
- Patients
- Culture/social
- Structural
- Economic
- Uncontrolled events

Implementation intervention strategies
- Barrier management
- Transfer
- Follow up

Adoption
- Intention
- Use

Outcomes
- Patient
- Practitioner
- System

Figure 4.4 The Ottawa Model of Research Use (Adapted from Graham & Logan, 2004)
4.3.5 Summary of Research Implementation Frameworks

In comparing previous models/frameworks, it could be suggested that the OMRU model translated the evidence to the real clinical setting most effectively, and consequently, increased the validity of the research findings. In addition, it has previously been adopted in the translation of evidence to improve skin integrity (Graham & Logan, 2004). In response to the research questions, this study required a comprehensive framework to develop, effectively implement, and evaluate the PU prevention intervention in the critical care context. Thus, combining a care bundle approach of best available evidence with a complementary model of research implementation, the OMRU has provided a novel comprehensive framework for this study. The care bundle approach provides a protocol of high quality evidence toward PU prevention, while the OMRU, a knowledge translation framework, is used to guide the transformation of the care bundle into action.

4.4 APPLYING THE OMRU MODEL TO THIS STUDY

This section illustrates how the OMRU was used to theoretically direct the implementation of a PU prevention bundle within the intensive care environment to reduce PU incidence. Further, this section provides insight into this novel and comprehensive vehicle for using high quality evidence to improve skin integrity within an ICU practice setting. Each phase of the OMRU process as applied to this study is represented in Figure 4.5 and discussed below:
Chapter 4: Conceptual Framework

Assess barriers and support + Monitor intervention and degree of use + Evaluation outcomes

Research-based innovation (PU prevention bundle)
- Development process
- Innovation attributes

Potential adopters (ICU RNs)
- Awareness
- Attitudes
- Knowledge/skill
- Concerns
- Current practices

Practice environment (ICU)
- Patients
- Culture/social
- Structural
- Economic
- Uncontrolled events

Implementation intervention strategies (Education and training, and process of care)
- Barrier management
- Transfer
- Follow up

Adoption (implement effectively)
- Intention
- Use

Outcomes (PU incidence in ICU)
- Patient
- Practitioner
- System

Note: *Italic, and underline = Study specific information*

Figure 4.5 The Ottawa Model of Research Use for Implementing a PU Prevention bundle in ICU
(Adapted from Graham & Logan, 2004)
4.4.1 Assessment

**Phase 1: Research-based innovation (PU prevention bundle)**

Innovations within a hospital setting are defined as representing new things based on current knowledge and current research data, which may be in the form of procedures, policy practice guidelines, or a care bundle. These innovations should be of low complexity, compatible with the context (including current practice and value), clear, noncontroverisal, and cost effective (Khosrowpour, 2009).

Whenever an innovative care bundle is planned, the following steps should be considered: a review of the relevant literature and a synthesis of the best evidence along with the contextual demands and formation of an integrated bundle of care. However, the bundle approach is based upon holistic principles, whereby the whole is greater than the sum of its parts, and is an approach with which most nurses are familiar. The advantage of the care bundle approach is the provision of quality measurement indicators, which allows targeted interventions and the performance of care providers to be evaluated. Cinel and Dellinger (2006) commented that using indicators such as a care bundle approach would facilitate hospitals to use a quality of care assessment instrument that is objective. Such objective information would assist care providers and clinicians to be more effective in their work (Cinel & Dellinger, 2006). A panel of international experts, constituting the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP), as an international consensus committee (2009) reviewed evidence on PU prevention strategies and found consensus in the following guidelines for the general context. These guidelines were contextualised to the ICU context and presented as a care bundle (presented in Table 4.1)(EPUAP & NPUAP, 2009).
### Table 4.1 The PU Prevention Bundle for Critically Ill Patients

<table>
<thead>
<tr>
<th>Intervention</th>
<th>The PU prevention bundle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk assessment</td>
<td>Completion and documentation of Braden risk assessment scale within 24 hours of ICU admission and daily thereafter.</td>
</tr>
<tr>
<td>Skin assessment</td>
<td>Physical assessment of the patient’s skin is undertaken and documented within 4 hours of admission and every 8 hours thereafter.</td>
</tr>
<tr>
<td></td>
<td>Loss of skin integrity assessed (and documented) using the PU staging tool, noting site, size, depth, and whether any exudates are present.</td>
</tr>
<tr>
<td>Skin care:</td>
<td>Patients bed-bathed once per day using a pH balanced cleansing agent (pre-package washcloth). Skin treated with a topical moisturiser.</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Nutritional status assessment is undertaken by the clinical nutritionist upon admission.</td>
</tr>
<tr>
<td>Repositioning</td>
<td>Patients repositioned using a three hourly turning schedule using a ‘turn clock’. Foot of the bed elevated by 20 degrees if clinically permitted.</td>
</tr>
<tr>
<td></td>
<td>Patient's heels are elevated and supported. Drawsheets used to transfer and lift patients. Where clinically possible, patients are mobilised daily to sit out of bed on a chair. Position documented, including the time of repositioning and position adopted</td>
</tr>
<tr>
<td>Support surface</td>
<td>All ICU patients managed on air mattresses.</td>
</tr>
<tr>
<td>Education and training</td>
<td>RNs educated in the conduct of accurate and reliable Braden Scale score risk assessment. All ICU health practitioners, especially RNs, educated on targeted bundle elements of PU prevention (e.g., risk assessment, the role of repositioning in PU prevention, correct methods for patient repositioning and use of equipment in reducing pressure, friction and shear forces).</td>
</tr>
<tr>
<td>MDRPU</td>
<td>Assessment of skin around/underneath medical devices every 12 hours. Securement and repositioning of nasogastric tubes (NGT) and endotracheal tubes (ETT) as per techniques outlined in the study bundle.</td>
</tr>
</tbody>
</table>

The PU prevention bundle to improve the skin integrity of critically ill patients was based on the international guidelines for general settings, with up to date evidence of PU prevention injected to make the bundle compatible with the ICU context.
However, the bundle should also be tailored to each individual practice environment (ICU) and the potential adopters or users (RNs).

**Phase 2: Practice environment (ICU)**

The importance of organisational characteristics, such as leadership, culture, mechanisms for evaluation and feedback, and management support, together with the presence of champions to implement change in healthcare settings has been identified in a considerable volume of research (Bradley et al., 2005; Stetler, 2003; West, 2001). Many essential features of healthcare systems, which include the diversity and range of stakeholders, governance, and resource arrangements, together with autonomy and specialisation of professional staff, may result in varying cultures and norms, as well as high levels of interdependency amongst professionals in the system (Urquhart, Porter, Grunfeld, & Sargeant, 2012). These factors can promote or inhibit adoption of the PU prevention bundle (Logan & Graham, 1998). Interventions at an individual-level are important when changing clinical practice, yet the complex nature of healthcare organisations means that interventions delivered only at an individual level cannot result in a change in clinical practice in a sustained manner (Urquhart et al., 2012).

The ICU is a complex setting for the translation of knowledge into practice due to many aspects, such as nursing workload, dependence on technological support, critical illness trajectory, and information overload (Asadoorian, Hearson, Satyanarayana, & Ursel, 2010; Hogan & Logan, 2004; Hutchinson & Johnston, 2004; Pogorzelska & Larson, 2008; Sinuff et al., 2007; Stacey et al., 2006). Furthermore, the severity of illness of patients or patients’ resistance and their family may reduce
adherence to a PU prevention bundle (Abrahamson, Fox, & Doebbeling, 2012; Koh, Manias, Hutchinson, Donath, & Johnston, 2008; Sinuff et al., 2007). A lack of resources has been given as the reason for hindering clinician’s ability to carry out a PU prevention bundle (Abrahamson et al., 2012). The acceptance and use of a PU prevention bundle may be negatively affected by a lack of endorsement by a champion (Marchionni & Ritchie, 2008; Sinuff et al., 2007) or inadequate support from peers or administrators (Goossens, Bossuyt, & de Haan, 2008). However, peer practitioner support is also one of the major influencing factors within practice settings, as many practitioners report relying on colleagues to support their decisions (Gaddis, Greenwald, & Huckson, 2007). This practice may reduce with the increased use of a PU prevention bundle, thereby reducing the reliance upon experience-based decision making (Gaddis et al., 2007).

Poor skin care is not an individual problem, but a reflection of a failure of the health care setting, which may be the result of inadequately organised care processes, together with a practice culture that is not based upon evidence based practice, collaboration, and the improvement of care. A discussion regarding how the care bundle and the OMRU model informed the study is provided in Chapter 5, Section 5.3.3. Furthermore, an overall summary of the study’s conceptual framework (the care bundle and OMRU model) is presented in Chapter 9.

Phase 3: Potential adopters (specialist RNs)

Potential adopter refers to practitioners, such as registered nurses (RNs), who implement the PU prevention bundle (Graham & Logan, 2004). Assessment of RNs for their willingness to implement a PU prevention bundle is comprised of three
concepts: awareness of the problem and the PU prevention bundle innovation, the intention of RNs to change current practice, and concern regarding the PU problem (Rycroft-Malone & Bucknall, 2011). Understanding adopters’ perceptions of these three concepts is essential to understanding both potential barriers and facilitators in implementation of the bundle. Grol & Grimshaw (2003) stressed the importance of requesting support from health care providers in order to encourage the use of evidence by practitioners (Grol & Grimshaw, 2003). There are many factors affecting changes in the practice of ICU RNs, such as workload, no time in the workplace to update their knowledge in respect to PU prevention, lack of staffing, fear of the time needed to implement the new PU prevention bundle, and fear of overlooking the patient’s conditions (Baker et al., 2010; Brown, Wickline, Ecoff, & Glaser, 2009; Strand et al., 2010). Considering, assessing, and managing all of these factors, both individually or organisationally, before planning and implementing PU prevention bundle is crucial.

4.4.2 Monitoring

**Phase 4: Intervention Implementation (education and training of the PU prevention bundle)**

It is necessary for the intervention to be tailored to the specific health care setting based upon the assessment of the previous three fundamental elements of OMRU: barrier management strategies, passive and active implementation strategies, and follow-up activities. Therefore, the PU prevention bundle was designed along with the latest international guideline and up to date evidence, then tailored to the KSA ICU context. Close monitoring of all intervention strategies is required, including the implementation and utilisation of research findings, assisted by strategies designed to
meet the specific needs of target adopters, which should involve education, training, individual audit, and feedback (Logan et al., 1999).

Generally, the three fundamental research transfer categories are: passive diffusion, targeted dissemination, and active implementation (Rycroft-Malone & Bucknall, 2011). These implementation strategies require both voluntary and non-voluntary approaches (Rycroft-Malone & Bucknall, 2011). Non-voluntary approaches include developing a PU prevention bundle for the ICU, whereas a voluntary approach includes education and physical changes to the ICU. Multiple intervention approaches are related to the innovation adoption process.

Knowledge about the prevention of PU prevention should be assessed and, when insufficient, enriched before barriers may be dealt with effectively. Education is a key requirement, but a strategy that is in itself insufficient will fail to effect lasting changes in practice. The introduction of practice innovation for ICU RNs is suggested, using the resources of the ICU in order to identify the problem, create awareness, and persuade clinicians of the need to change practice and examine how this change may be achieved. This would be enhanced by the provision of brochures explaining the elements of the PU prevention bundle, as well as presenting evidence to support the PU prevention bundle. The education and training will empower ICU RNs and enhance their confidence in accurately identifying and staging PUs, thus affecting a positive change in practice.

It is important to create an environment that will make it easy for clinicians to provide the best care. This is achieved by ensuring that embedding the PU prevention bundle into daily practice provides the most appropriate conditions for effective change. Regular ICU audits should be performed to ensure compliance with the PU prevention bundle. When noncompliance of staff was noted, identification of the
barriers and mechanisms to overcome these are required. Support and encouragement of ICU RNs can be achieved by informing them of the progress in performance improvements. Finally, on-going assessment strategies should be implemented, which would explore the effectiveness of the PU prevention bundle, as well as identifying barriers and facilitators for its use.

**Phase 5: Adoption**

Adoption means action sequences of research evidence innovation (PU prevention bundle) represented as behaviour changes in potential adopters, which includes starting to implement and continuing to use the PU prevention bundle (Rycroft-Malone & Bucknall, 2011). A care bundle monitoring cycle is necessary to determine the extent to which the PU prevention bundle has diffused throughout ICU RNs and affected the process of care. It can also be used to determine whether the PU prevention bundle has been sufficient in bringing about the desired change, which is the reduce incidence of PUs, or whether more of the same, or a modification of the protocol is required. If the degree of adoption is less than expected, it may be useful at this stage to assess the ICU RNs’ perceptions, to determine whether the absence of change is related to a lack of interest on their part to reduce PU incidence for ICU patients, or whether it is related to other barriers that may be beyond their control.
4.4.3 Evaluation

*Phase 6: Outcomes*

Outcome refers to the effect and impact of the implementation of the PU prevention bundle on patients, practitioners, and the healthcare system (Rycroft-Malone & Bucknall, 2011). The purpose of this phase is to determine whether promotion of adoption is of value or not; fidelity of ICU RNs to comply with the PU prevention bundle, which is monitoring during implementation; and whether the PU prevention bundle has achieved the desired patient outcomes in term of reduction of incidence or prevalence of PU in critically ill patients in the ICU.

4.5 CONCLUSION

Despite a significant amount of evidence for PU prevention (Girard et al., 2014; Park & Kim, 2014; Theaker, 2003; van Nieuwenhoven et al., 2006; Verbelen, 2007), the delivery of quality patient care to prevent PU occurrences remains a challenge in the ICU. It is argued that bundling the best available evidence appropriate for critically ill patients will be more effective in reducing PU development in patients in the ICU. However, the ICU is a complex environment, and to implement high quality evidence for PU prevention requires a systematic, methodical approach. For effective implementation of the PU prevention bundle, a practical systemic and dynamic model is needed to guide the implementation process. The OMRU framework, as a knowledge translation model, has proven to be effective and efficient in sustaining changes of care in the ICU. Thus, the novel connection between a care bundle approach and the use of the best evidence facilitated by this dynamic model provided a logical framework to guide this research.
Chapter 5: Research Design

5.1 INTRODUCTION

Building on the conceptual framework presented in the previous chapter, a care bundle in combination with the OMRLU approach, this chapter details the methodology used to address the research questions for this study. This chapter outlines the research design, sample, population and setting, data collection method, instrument, data analysis, and ethical considerations for each phase of the study. The rationale for the research design and methods are provided in order to justify relevant decisions made.

5.2 RESEARCH DESIGN

The research aims and questions of this study dictated the quantitative methodological approach taken. As previously discussed (see Section 4.4) this research design was underpinned by the conceptual framework, which is the care bundle approach and OMRLU model. The first step of the OMRLU model was the assessment, including evidence, practice environment (Phase One, Part A), and potential adoptors (Phase One, Part B). Implementation and evaluation steps were then undertaken in Phase Two. Thus, the study consisted of two phases (see Figure 5.1). Phase One was comprised of two parts. Part A used a prospective observational study to determine the incidence of PUs at selected tertiary hospitals in the Kingdom of Saudi Arabia (KSA). The incidence data informed the sample size calculation for Phase Two (a two–arm cluster RCT). Part B used a cross-sectional survey design to explore barriers and facilitators related to PU prevention strategies among intensive care registered nurses (RNs) working in the intervention arm of the Phase Two study. This data assisted with tailoring of the training protocol for the Phase Two intervention.
Phase One of this study addressed the key assessment components of the OMRU model, and specifically the three elements of assessment of barriers and supports, assessment of the RNs as potential adoptors, and assessment of the intensive care practice clinical environment (see Figure 5.2). Following this, Phase Two, a two-arm cluster randomised control trial (cRCT), evaluated the effectiveness of a care bundle guided by a research implementation model in reducing the incidence of PU development in the ICU. Each phase of this study is presented according to the specific research design, sample, population and setting, data collection method, instrument, data analysis, and ethical considerations.
Phase Two: A Two-Arm Cluster RCT

Aim: to evaluate the effectiveness of a care bundle in reducing the incidence of PU in the ICU

Design: A two-arm cluster RCT

Sample: all ICU patients who met the inclusion and exclusion criteria. The sample size will be calculated based on incidence study.

Instrument: specifically designed data collection form including PU incidence form, Braden risk assessment scale, and checklist for care bundle performance.

Phase One, Part A: Incidence Study

Aim: to calculate the incidence of PU in the ICUs of two KSA hospitals. The incidence data will inform the sample size calculation for Phase Two.

Design: prospective cohort study

Sample: all ICU patients of two KSA hospitals admitted during consecutive 4 weeks

Instrument: data records designed to calculate PrU incidence, additionally SOFA, and PU grading tool.

Phase One, Part B: OMRU assessment

Aim: to identify barriers and facilitators as perceived by RNs to the adoption of evidence to reduce PU development. This data will assist with tailoring of the training protocol for the Phase Two intervention.

Design: descriptive cross-sectional study

Sample: all convenience RNs in intervention group

Instrument: RNs survey "Barriers and Facilitators"

Figure 5.1 Research Phases and Methodology
Chapter 5: Research Design

Figure 5.1 Research Phases and Methodology

1. **Assess** barriers and support
2. **Monitor** intervention and degree of use
3. **Evaluate** outcomes

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**Assess**
1. **1 - Research-based innovation**
   (PU prevention bundle)

2. **2 - Potential adopters**
   (Intensive care RNs)
   “Phase One, Part B”

3. **3 - Practice environment**
   (KSA ICU)
   “Phase One, Part B”

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**Monitor**
4. **4 - Implementation intervention strategies**
   (Education and training, and process of care)
   “Phase Two”

5. **5 - Adoption**
   (Implementation of the PU prevention bundle)
   “Phase Two”

6. **6 - Outcomes**
   (ICU PU incidence & RN compliance to the bundle)
   “Phase Two”

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Source: Graham & Logan (2004)

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Figure 5.2 Ottawa Model of Research Use Adapted and Applied to this Study
5.3 PHASE ONE, PART A

5.3.1 Research Design

This study used a multicentre prospective cohort observational design to calculate the new cases of an event (PUs) occurring in a group of people who share similar experiences and characteristics (critically ill patients in the ICU) over a specific period of time (four weeks) (Healy & Devane, 2011; Hood, 2009; Levin, 2006b; Melnyk & Fineout-Overholt, 2011; Simpson & Hannafor, 2002; Soh & Saw, 2010; Tay & Tinmouth, 2007; Wood & Kerr, 2011). An observational cohort study is a common quantitative study design used for intensive care patient research because it examines the correlation between variables and describes a specific group who share the same experience within a defined period (Boyle & Green, 2001; Eachempati et al., 2001; Sanada et al., 2007; Slowikowski & Funk, 2010). Furthermore, many studies examining incidence utilise a prospective design, as a new occurrence of an outcome of interest can be monitored and calculated within a specified time interval (Fife et al., 2001; Kaitani et al., 2010; Nijs et al., 2009; Sayar et al., 2009). A prospective observational design enabled the researcher to answer the research questions in this study, as it provided descriptions and exploration of PU incidence (Aschengrau & Seage, 2008; Bhopal, 2008; Friis & Sellers, 2009; Soh & Saw, 2010) in the ICU setting. Additionally, this design allowed the determination of PU incidence required to calculate the sample size required for Phase Two (RCT).

5.3.2 Research Questions

4- What are the characteristics of the ICU patients in KSA?
5- What is the incidence of PU development in critically ill patients in the intensive care units of two tertiary referral hospitals in the KSA?

6- What are the factors associated with PU development in the ICU in the KSA?

### 5.3.3 Study Setting and Population

The study was conducted in the intensive care units at King Abdulaziz Hospital (KAAH) and King Fasil Hospital (KFH), Makkah, KSA. Both hospitals are operated by the Ministry of Health, KSA and are major and large tertiary care hospitals, each with over 400 beds and ambulatory services. Further, both KSA facilities are accredited as meeting the national standards of excellence in quality and patient safety care and health services by the KSA National Accreditation program, as determined by the Central Board of Accreditation for Healthcare Institution (CBAHI).

At the time of the study, the ICU at KAAH had 24 beds, while the ICU at KFH has 20 beds, each in a single room. These two facilities provide services to patients of the western region of Saudi Arabia and from neighbouring regions. According to both hospitals’ annual reports, the ICUs admit between 2000 (KFH) and 2500 (KAAH) patients annually and approximately 70 to 80% of the ICU patients admitted each year require mechanical ventilation. A diverse number of complex treatments and advanced technological equipment are provided for ICU patients to support their body system functions during critical illness. The ICUs also provide continuous intensive monitoring for patients who have life-threatening illness or after major surgery. Both ICUs are specialist areas that deliver complex multi-system support for adults requiring comprehensive intensive care and monitoring by specialists.
Patients admitted to KAAH and KFH ICUs have similar high acuity and medical diagnoses. Patient’s diagnoses in both ICUs include cardiovascular illness, respiratory disease, cancer, renal dysfunction, sepsis, and multi-trauma injury such as head injury. According to the 2012 KAAH ICU portfolio, the average length of patient stay was 10 days. Similarly, for the KFH, the average length of stay was approximately 9 days.

Both ICUs have approximately 60 RNs working in the department. RNs providing care for ICU patients have tertiary qualifications, such as a Bachelor of Nursing or Diploma in Nursing, and relevant clinical experience. For both hospitals, the ICU staffing ratio is one nurse to two patients and one charge nurse per shift for each of the three shifts per day. In both hospitals, the RN in-charge of the ICU is not always supernumerary, and is sometimes rostered to provide care for two patients. At the time of the study there were no assistant practitioners or care assistants working in the unit. Furthermore, there are no dedicated clinical instructors or nurse educators in the units.

Additionally, both facilities have policies related to the prevention of PU development, such as a positioning policy where the patients’ position is rotated every two hours through right side, back, and then left side or vice versa. Additionally, routine historical skin hygiene practice for ICU patients in both units is a bed-bath at 6:00am using a ‘scrub-stat’ containing hydrogen peroxide. Physical examination and assessment of the patient’s skin is recommended three times per day; once per nurses’ shift. Moreover, all ICU patients are managed on air mattresses, as a pressure reducing mattress and repositioned using draw sheets with the latter being historical practice in KSA. Thus, prevention of PU for patients is part of fundamental nursing care in intensive care units at KAAH and KFH.
5.3.4 Sampling Strategy and Size

The sample for Phase One, Part A was all patients admitted to the KAAH and KFH ICUs who met the inclusion criteria over a consecutive four-week period. Patients were included if they were to be managed in the ICUs during the period of collection data and were aged 18 years or more.

The sampling framework consisted of a time period of four consecutive weeks and the inclusion criteria. Four weeks was selected as a representative timeframe to calculate the incidence of both community-acquired PUs (CAPU) and hospital-acquired PUs (HAPU) in relation to PU stage, type, or site of injury (e.g., medical device-related PU), and ICU length of stay. A consecutive sample was recruited to the study to minimise the risk of selection bias (Hulley, 2001). As this included all accessible participants over specific time period, this could provide a reasonable representation for the entire population (Lunsford & Lunsford, 1995).

5.3.5 Data Collection

Data was collected on three levels: baseline ICU survey, baseline patient survey, and second daily patient data collection. The data collection processes were piloted with validated instruments where available including SOFA score (Vincent et al., 1998), and PU grading scales (EPUAP & NPUAP, 2009b).

A data extraction form, specifically designed for this study, was used to calculate PU incidence in ICUs and describe the sample. This form recorded each participant’s demographic characteristics (age, sex, weight, height, body mass index (BMI), primary diagnosis, co-morbidities, ventilation status, the Sequential Organ Failure
Assessment (SOFA) score, reason for or type of admission, date of admission to the hospital and ICU, and length of stay in ICU before the occurrence of a PU).

Second daily data of the patient's skin assessment, any changes of skin integrity, PU site and stage, relationship to medical devices, and whether community acquired or hospital was also recorded. Pressure ulcers were staged according to the EPUAP and NPUAP criteria current at the time of the study. All instruments are discussed below:

**Baseline ICU data**

The system level data current at the time of commencement of data collection for each ICU was collected, including total bed capacity, ratio of ventilator/non-ventilator beds, annual number of patient admissions, average length of patient stay, number of patient mechanical ventilation days, nurse:patient ratios, years of RN nursing and critical care experience, and the number of RNs with a critical care qualification. Baseline ICU data also included the existence of specific policies regarding skin care, the existence of potential adopters such as ‘PU Prevention Champions’, and the existence or implementation of unit based preventative strategies for PU.

**Baseline patient data**

Patient level data was collected upon admission for all patients including demographics such as age; sex; nationality; BMI; and clinical data including diagnosis on admission, comorbidities, emergency or elective admission, length of time in operating theatre or emergency department or to ICU admission in hours if applicable, SOFA score, presence or absence of PU on admission (yes/no), mechanical ventilation
(yes/no), duration of mechanical ventilation in days if applicable, ICU length of stay in days, and ICU outcome (discharge to ward or death).

Second daily patient data collection

Data was collected over a consecutive 48-day period (four weeks) on all patients admitted to the ICUs on a second daily basis until patient discharge. This data included the presence or absence of PU, PU staging and site, and SOFA score.

Sequential Organ Failure Assessment (SOFA)

The SOFA was designed by the European Society of Intensive Care Medicine in 1994 and revised in 1996. The SOFA score is a scoring system used to determine the extent of a person's organ function or rate of failure in the ICU (Ferreira, Bota, Bross, Mélot, & Vincent, 2001). The score is based on a six-organ dysfunction/failure score: the respiratory, cardiovascular, hepatic, coagulation, renal, and neurological systems. Each organ is graded from 0 (normal) to 4 (the most abnormal), providing a daily score of 0 to 24 points. The purpose of the development the SOFA score was to create a reliable, simple, and continuous score that could be easily applied in all institutions.

The SOFA score is an indicator of prognosis when applied during the first few days of admission to the ICU. The SOFA mean and highest scores are very useful outcome predictors, whereby an increase in score during the first 24 to 48 hours in the ICU predicts where a mortality rate of at least 50% and up to 95% is predicted. When the SOFA scores are less than nine a predictive mortality is 33%, whilst 11 and above can be close to or above 95% predictive mortality rate (Ferreira et al., 2001). SOFA score demonstrates organ function progress during a period spend in ICU stay (KM,
2007). Although APACHE II offers greater discriminative power than the SOFA score during the first 24 hours of a patient's admission, a more sensitive approach to daily changes in the condition of patients is provided by the SOFA score, which provides an instrument to determine when organ dysfunction could develop after admission to ICU (Qiao, Lu, Li, Shen, & Xu, 2012) (see appendix A).

**PU staging tool**

PU staging refers to the level of tissue damage or depth of the injury observed, and is central to developing PU prevention programs and treatment. Moreover, staging permits health care workers to be objective in their assessment of the depth of tissue injury. The NPUAP and EPUAP (2005) updated the definition of the staging system of PUs by adding two stages to the traditional classification, which included stages I to IV. NPUAP & EPUAP (2009) provide a clear definition of each PU stage (see Appendix A).

For this study, a record form was designed for each patient to identify the PU staging according to EPUAP and NPUAP criteria (2009). Additionally, the PU site was identified on the data collection form by drawing a circle over the relevant area in the body figure (see Appendix A).

**Braden Scale score**

The Braden Scale score for predicting PU risk (see Appendix A), was designed in 1987 (Smith et al., 1995). The Braden Scale reflects the conceptualisation of the physiological sequale of PU development and formation. Accordingly, it consists of six elements: *sensory perception* (which measures an individual's ability to feel,
identify, and respond to pain or discomfort that is related to pressure on any part of their body; moisture (which measures the degree of moisture the skin is exposed to); activity (which measures the individual level of physical activity); mobility (which measures the physical competency of the individual for moving and change position); nutrition (which reflects the normal pattern of food and fluid intake); and friction and shear (which assesses the individual's ability to keep the skin safe from any force that could be generated through movement and positioning). While the first five elements are rated from 1 (most impaired) to 4 (least impaired), the last item "friction and shear" is rated from 1 (problem) to 3 (no problem). The total score then ranges from 6 to 23, with a higher score meaning a lower risk of developing a PU and vice-versa. When using this scale, all patients are divided into four subcategories: at mild risk (those with sum sores ranging from 15 to 18), moderate risk (those with sum scores ranging from 13 to 14), high risk (those with sum scores ranging from 10 to 12), and very high risk (those with sum scores of 9 or below). The Braden Scale has been validated for the identification of patients who are at risk of PU development in the ICU (Pancorbo-Hidalgo et al., 2006).

5.3.6 Procedure

Following ethical approval from the university and both KAAH and KFH hospitals, the researcher liaised with the medical staff and nursing unit manager (NUM) to negotiate the commencement of the study, and specifically, a convenient time to collect the local unit data. Following this, the researcher visited each ICU every other day for four weeks (alternating days in each ICU) to liaise with the NUM to identify those patients who met the study inclusion criteria and to recruit patients to
the study. Patient demographic data and the complete second daily patient data collection was collected as per the data collection tool for all included patients.

All patients were assigned a study number. A study enrolment log was maintained to correlate basic patient information (patient initials, bed number, hospital number) and the patient study number data collection form (see Appendix A). Re-identified participant information (the enrolment log) was only kept during the period of data collection. At the conclusion of the study, after the data collection period, the enrolment log sheet was shredded to ensure all data was de-identified.

5.3.7 Data Management

The data collected was entered into the Statistical Package for Social Sciences (SPSS) program, version 21.0. The researcher entered all data to decrease any potential data entry error. The data was checked before any statistical analysis was undertaken to ensure the reliability and accuracy of data entry (Kirkwood & Sterne, 2003; Tabachnick & Fidell, 2007) by randomly re-entering 10% of the collected data and comparing the two files. To check any invalid response codes, missing data and duplicates were run for a frequency distribution statistical analysis. All hard copy data was kept in a locked filing cabinet accessible only to the research team. Electronic data was stored on password protected files. All data will be maintained for seven years after the completion of the study. Following this time, data will be destroyed in accordance with the ethics research policies at KAAH and KFH.
5.3.8 Data Analysis

Descriptive and correlation statistical methods were used to answer the research questions. Statistical analysis was performed using SPSS version 21.0. The level of statistical significance was set at a p-value less than or equal to 0.05 (p ≤ 0.05), to reduce the risk of type 1 errors (Kirkwood & Sterne, 2003). This level of significance was applied to all analyses.

For Phase One Part A, incidence was calculated as cumulative incidence. Cumulative incidence is defined as the proportion of participants that develop a new PU within a specific time (Baharestani et al., 2009). Demographic and other data was also analysed using descriptive statistics (frequencies and means where appropriate) to describe the sample. Moreover, the normality of distribution for the data was measured. Bivariate analyses using chi-square, in-dependent t-test, and Mann-Whitney U were performed to identify variables associated with PU development. A binary logistic regression model was used to develop the best model for predicting PU occurrence in the ICU. It also explored the direction of the relationship between the predictive variables and PU occurrence. Further details of data analysis are presented in the publication in Chapter 6.

5.3.9 Ethical Consideration

Ethical approval to conduct this study was obtained from the Unit of Ethics of King Abdul-Aziz Hospital and King Fasil Hospital, Ministry of Health, Makkah, Saudi Arabia and the Queensland University of Technology (QUT) Human Research Ethics Committees (1300000341), Australia (see appendix C, D). This part of the study received approval with waiver of consent.
5.4 PHASE ONE, PART B

The purpose of Phase One, Part B was to assess the barriers and facilitators related to the practice context and the adopters of the intervention. Findings from this phase assisted in customising the intervention and the intervention training protocol to the RNs and the practice context.

5.4.1 Research Design

For Phase One Part B, a cross sectional descriptive survey was used to describe RNs perceptions regarding factors that hinder and/or assist them in the implementation of best available evidence to reduce PU occurrence in critically ill patients. Cross-sectional studies are observational in nature and known as descriptive research, not causal or relational research (Levin, 2006a). Researchers record the information that is present in a population, but they do not manipulate variables. This type of research can be used to describe characteristics that exist in a population, but not to determine cause-and-effect relationships between different variables. These methods are often used to make inferences about possible relationships, or to gather preliminary data to support further research and experimentation. (Oleckno, 2008).

A disadvantage of a cross-sectional survey is selection bias, i.e., non-response. Non-response is a particular problem affecting cross-sectional survey studies and bias can result when the characteristics or perceptions of non-responders differ from responding participants (Barriball & While, 1999; Rupp et al., 2002). In order to minimise this potential problem, all RNs who were working in the ICU of the
intervention site (KAAH) were invited to participate in the survey. Effort was made to approach each potential RN participant individually to explain the study. Counterbalancing these weaknesses are the strengths of cross section descriptive survey designs. This is the most widely used data gathering technique in research. It is also less costly compared with other methods, as it is easy to obtain rapid data acquisition from a sample (Neuman & Kreuger, 2003). Other strengths of this design include a single point of data collection (i.e., a survey) and the ability to describe characteristics of the participants and their perceptions (Burns & Grove, 2005). The latter is particularly important, as results from this study were used to inform the intervention implementation strategies used for the Phase Two, a two-arm cluster RCT study.

5.4.2 Research Question

7- What is the RNs’ attitude towards PUs prevention in a KSA tertiary referral hospital ICU?

8- What are the facilitators and barriers for RNs in the adoption of PU prevention strategies in a KSA tertiary referral hospital ICU?

9- Is there any association between participants characteristic and RNs’ attitude, or perceived barriers and facilitators to implement the PU prevention strategies?
5.4.3 Sampling Strategy and Size

This phase used a convenience sample of all RNs working in the intervention arm of the Phase Two study. There were approximately 60 RNs working in the ICU.

5.4.4 Data Collection

Data was collected using a survey method. The survey included a total of 42 items (38 items from the original instruments and four items added based on the literature) that were incorporated into four parts: demographic information, potential barriers to optimal skin care, potential facilitators to skin care, and RNs’ attitude towards PU care and prevention in ICU (see Appendix A).

Items for the first three parts of the survey were modified from the PUPrevention in the PICU "Barriers and Facilitators" questionnaire (see Appendix B) (Schindler, 2009). The purpose of the original survey was to determine the barriers and facilitators that RNs could encounter in a paediatric intensive care unit (PICU), that affected the implementation of the S.K.I.N. bundle. Therefore, this survey was adopted, with modification to be compatible for RNs in an adult ICU. The original survey consisted of three dimensions: demographic information about the RNs, and barriers and facilitators for the bundle implementation in the PICU. The survey comprised a total of 25 items; 19 questions where participants rated their response using a 10 point Likert scale (0 being to no extent to 10 being to a great extent), two open ended questions, and four items for participant demographic information. The advantage of using open-ended questions is that they provide an opportunity for participants to raise issues with no restriction, thus providing the participant with the opportunity to elaborate their response (Polit & Beck, 2004). This assists the researcher to acquire in-depth
information (Kumar, 2005). The survey is an established tool used in the PICU in the Children's Hospital of Wisconsin in Milwaukee (Schindler, 2009), but has no reported validity or reliability testing.

The fourth part of the survey was adopted from the Attitude towards Pressure ulcer Prevention instrument (APuP) (Beeckman, Defloor, Demarré, Van Hecke, & Vanderwee, 2010). This instrument was designed to measure the attitudes of nurses towards PU prevention. This instrument includes 13 items and covers five dimensions of RNs’ attitude towards personal competency to prevent PU, the priority of PU prevention, the impact of PUs, personal responsibility in PU prevention, and confidence in the effectiveness of prevention. The original instrument validation reported a Cronbach’s alpha of 0.79 (Beeckman et al., 2010).

Permission was sought and obtained from the original authors of the instruments, Dr. Christine A. Schindler and Dr. Dimitri Beeckman, via email (see Appendix B).

5.4.5 Survey Validity and Reliability

The survey for this study required content validity testing in order to assure the instrument’s structure and consistency were valid to the study context. To measure content validity, the survey was reviewed by a panel of five local expert nursing members (Netemeyer, Bearden, & Sharma, 2003), as the OMRU model assesses the local context. The panel included two nursing educators (one from each hospital) and two critical care nursing supervisors (one from each hospital), and one adult care RN.

The process of inferring content validity for this research survey included providing the participants with an overview of the research and a copy of a survey. The panel were asked to evaluate the relevancy of the items to intensive care nursing practice and management of critically ill patients. The relevancy of the survey items
was measured using a five point Likert scale for each item (1=irrelevant to 4=highly relevant). The result of the content validity was defined by the proportion of experts’ responses for these items (Polit & Beck, 2010). The internal reliability for the study survey items were measured by finding the Cronbach’s alpha of the completed survey. Additional detail of validity assessment is presented in the publication in Chapter 7.

5.4.6 Procedure

The researcher liaised with the nursing unit manager (NUM) of the ICU, randomised to receive the intervention, to determine a strategy to inform RNs about the study. All RNs working in the intervention arm of the Phase Two study were provided with a copy of the information sheet detailing the overview and purpose of the study. The survey was distributed to RNs in person by the researcher. Participation was voluntary. Completion and return of the survey were signified consent to participate. Participants were asked to deposit the completed survey in a marked, sealed mailbox placed at the nurses’ station in the ICU. A reminder message was posted to all RNs to complete the survey through staff communication books. Encouragement to complete and return the survey was given at relevant unit meetings. The survey was confidential and did not include personal information. Consequently, having completed and deposited the survey, the participant was unable to withdraw from the study, as their survey was not able to be identified. The survey data was collected over a one-week period.

5.4.7 Data Management

Data was managed in the same manner as for Phase One, Part A
5.4.8 Data Analysis

Descriptive statistics (i.e., frequencies and means) were used to analyse the results of the survey data, which included demographic data about participants and data from barrier-facilitator scales. Data was analysed using SPSS version (21.0). Correlation statistical methods were used to determine differences between both groups by comparing a mean with an independent t-test, Mann-Whitney tests, or ANOVA for continuous variables, and Chi-square test of independence between categorical variables. The level of statistical significance was set at a p-value less than or equal to 0.05 (p≤0.05). Multiple regression analysis was used to predict any barriers or facilitators that influenced RNs’ ability in PU preventive care. Negative statements in the APuP instrument were scored in reverse to obtain the total sum score. A total sum score is recommended to measure the total RNs attitude toward PU prevention. In addition, multinominal regression and correlation analyses were used to detect any association between the demographic variable and RNs attitude subscale. The participants' narrative responses in the two open-ended questions were analysed and reviewed using thematic analysis and linked with the quantitative data. This approach comprised of six steps: familiarisation with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report (Braun, & Clarke, 2006).

5.4.9 Ethical Consideration

Ethical approval to conduct this study was obtained from the Unit of Ethics of the King Abdulaziz Hospital, Makkah, Saudi Arabia, as well as the Queensland
5.5 PHASE TWO

5.5.1 Research Design

The second phase of the study used a two-arm cluster randomised control trial (cRCT) design that followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines. A two-arm cRCT study design was selected in order to assess the effect of the interventions and to identify the causal relationships between the variables (Oleckno, 2008). The study examined the influence of the demographic characteristics of the participants (age, sex, weight, height, primary diagnosis, ventilation status, SOFA score, Braden Scale score, reason for or type of admission, co-morbidities, and length of stay in intensive care) and organisational considerations (type of bed and mattress, and nurse/patient ratio) on PU incidence.

The two-arm cRCT provided the researcher with the ability to control the exposure of the intervention, thus permitting evaluation of the effectiveness of the prevention strategies in a group of people who share the same characteristics or experience in a specific period (Akobeng, 2005; Duffy, 2006; Oleckno, 2008; Salmond, 2008; Stolberg, Norman, & Trop, 2004). Moreover, a cRCT was the design of choice, as a controlled trial avoids overestimation of the effectiveness of an intervention (Grimshaw, Campbell, Eccles, & Steen, 2000). The efficacy of implementing the PU prevention bundle in the critically ill population in the intensive care unit of a KSA tertiary referral hospital in this research was measured in relation to the primary outcome; incidence of PUs. While the two-arm cRCT design offers
numerous merits, some disadvantages exist. A cRCT may be time consuming to conduct, costly, and may require a large participant number for an effective sample size (Polit & Beck, 2004). Further details of the methodology are presented in the publication in Chapter 9.

5.5.2 Research Questions

10- Does a PU prevention bundle reduce the cumulative incidence of PU development in critically ill patients in the intensive care unit of a KSA tertiary referral hospital?

\( H_0: \) There is no difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care.

11- Dose a PU prevention bundle decrease the cumulative PU incidence by 25% or greater when compared to standard hospital care?

\( H_0: \) The difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care was less than 25%.

12- Will patients who receive a PU prevention bundle develop PU later in their intensive care unit stay?

\( H_0: \) There is no significant difference in a delayed time to PU development with implement the PU prevention bundle.

13- Will patients who receive the PU prevention bundle have fewer numbers of PUs/patients during their ICU stay?
14- Will patients who receive the PU prevention bundle have fewer full thicknesses PUs (Stage III and IV)?

\(^{H_0}\): There are no significant differences in full thicknesses PUs (Stage III and IV) with implement the PU prevention bundle.

15- Does the PU prevention bundle increase the adherence to the process of care in comparison to standard hospital skin care?

5.5.3 Study Setting

The study setting was the same for Phase One Part A, the ICUs at KAAH and KFH. The characteristics of the two hospitals and ICUs were previously presented under Phase One, Part A.

5.5.4 Population and Sample

The population was all critically ill patients admitted to the ICUs at the KAAH and KFH. The general characteristics of these patients were presented in Phase One, Part A.

All ICU patients at KAAH and KFH during data collection who met the inclusion criteria were recruited to participate in this study. The inclusion criteria were:

- patients admitted to the ICU during the study period,
- expected to stay more than 24 hours, and
• 18 years of age or over.

• For the intervention arm, potential participants were excluded if they:
  
  o were admitted to the ICU with a community-acquired PU,

  o had any medical contraindications for the implementation of the care bundle intervention (e.g., patients with a fractured pelvis or burns whose care could not follow the repositioning schedule), and

  o were diagnosed with any stage of PU in the first 24 hours of admission to ICU.

5.5.5 Sample Size

The sample size to determine a clinically significant difference was calculated using the PU incidence in the KAAH and KFH ICUs (determined from Phase One Part A), which was 39.3%. Eighty percent statistical power was required to detect the 25-50% difference between the comparative groups. Therefore, the required sample size under individual randomisation was 48 participants per group. As a two-arm cluster randomised control design was taken for this study with the intra-cluster correlation (ICC = 0.05), to adjust the sample calculation (Hemming, Girling, Sitch, Marsh, & Lilford, 2011; van Breukelen, & Candel, 2012), giving an effective sample size of 70 per group, inclusive of a 20% allowance for patient attrition.
5.5.6 Randomisation

The research sites (the ICUs of the KAAH and KFH), not individual patients, were randomised to either the intervention or control arm of the study by a computer generated randomisation, where one hospital ICU was the intervention arm (KAAH) and the other the control arm (KFH). This is a commonly used and intuitive procedure, similar to "repeated fair coin-tossing", also known as “unrestricted" or "complete" randomisation, it is essential to avoid both selection and accidental biases.

The KAAH ICU was randomly selected to receive the intervention, the PU prevention bundle. Recruitment and enrolment of participants is illustrated in a CONSORT flow diagram in the publication in Chapter 9.

5.5.7 Intervention

As the intervention was a bundle of best available evidence it required a ‘whole of intensive care unit’ adoption. Therefore, the intervention was delivered at the unit level. The PU prevention bundle was specifically designed so that it was able to target the area of interest (i.e., the impact of the PU prevention bundle in incidences of PU), be suitable for RNs to deliver, and to fit within the structure of the ICUs in KSA. The intensive care RNs working in the intervention arm ICU were trained in the PU prevention bundle and delivered the intervention. The PU prevention bundle was based on the latest international guideline at the time of the study (2009), which comprised evidence-based recommendations incorporated from the results of RCTs and systematic reviews for the general hospital context, but was not specific to the ICU context (EPUAP & NPUAP, 2009b). This guideline was therefore modified and interpreted for the ICU setting and presented as a care bundle. The key aspects of the
PU prevention bundle were: risk assessment, skin assessment, skin care, nutrition, repositioning, support surface, education and training, and medical devices related PU as presented in Table 8.1 (See page 219). The contents of a PU prevention bundle were then reviewed by a panel of five local (KSA) expert nursing members with more than seven years of clinical experience, and accepted for implementation.

5.5.8 Data Collection

Data was collected on specific measures implemented to reduce PU development.

Data was gathered on three levels: baseline patient survey, second daily patient data collection, and RNs adherence to the PU prevention bundle. Baseline patient survey and second daily patient data collection were collected for both intervention and control ICUs; however, RNs intervention fidelity to the PU prevention bundle was collected for the intervention unit only. As per Phase One, Part A, the data collection processes were piloted with validated instruments where available, including SOFA (Vincent et al., 1998), PU staging scales (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009b), and Braden scale (Smith et al., 1995).

**Instruments**

The baseline patient data, second daily patient data collection, SOFA, PU staging tools, and Braden Scale score instrument were previously outlined in Phase One, Part A.

RNs adherence to the PU prevention bundle (intervention unit only).
The intervention fidelity (process of care) of RNs to the PU prevention bundle was measured through two levels: researcher audit and RN self-reporting. The researcher audit included a series of ordinal questions (see Appendix A). The ordinal questions covered key aspects of the PU prevention bundle: risk assessment, skin assessment, skin care, nutrition, repositioning, support surface, and education and training. This audit was collected every two weeks. The RN self-report included RNs' demographic details, RNs’ reflection toward adherence to the bundle, and one open-ended question (see Appendix A). The purpose of the open-ended question was to provide an opportunity for RNs to note any facilitators and barriers that may have affected their ability to adhere to the PU prevention bundle and that could be addressed in ‘real time’.

5.5.9 Procedure

Initial procedures for this phase were as per Phase One Part A. The researcher attended each ICU second daily (alternating ICUs) to liaise with the NUMs and recruit patients, and obtain informed consent from the patient or the patient's next of kin. Furthermore, for all patients recruited, the researcher collected the patient's demographic data and completed second daily patient data collection, as per the data collection tool.

For the control group, the researcher collected data using the Phase One Part A data collection forms. The control group proceeded with standard care as per Table 5.1. For the intervention group, the ICU RNs who delivered the intervention were trained in implementation of the PU prevention bundle. Results from Phase One Part B were used to develop appropriate and targeted educational resources for the ICU
RNs in the intervention group, such as positive attitude towards PU prevention, and awareness of workload. All ICU RNs were informed about the PU prevention bundle through in-service, meetings, and one-to-one bedside education, all provided by the researcher. The training and education program consisted of: 1) brochures that explained the elements of the PU prevention bundle and presented the evidence that supported the bundle; 2) a PowerPoint presentation with a handout used during in-service; 3) consultation and clarification on an individual basis with the researcher throughout the study; and 4) feedback to staff in the intervention unit of the weekly PU incidence rates.

Measuring the RNs’ fidelity (processes of care) to compliance with the PU prevention bundle is important to assist in understanding the strengths and weakness of the intervention, determine the association between intervention and research outcomes, and to enhance both internal and external validity of the research (Horner, Rew, & Torres, 2006). The RNs' compliance to the intervention was measured on two levels: audit and RN self-report (see Appendix A). The audit was conducted every two weeks by the researcher and was a de-identified audit. The finding of this audit were presented as a percentage and compared with new PU events per patient that occurred that week. This feedback was provided to all RNs working in the intervention unit. The RN self-report was collected from a convenience sample of RNs working in the intervention hospital. The researcher distributed the survey manually every four weeks during the implementation of the PU prevention bundle. Participation in this survey was voluntary. Completion of the survey indicated consent. Completed surveys were deposited in a marked and sealed mailbox located in the ICU nurses’ station for a week. The survey was anonymous. The findings were compared with PU incidence. A
detailed description of the implementation and adoption of the bundle is presented in the publication in Chapter 8.

5.5.10 Data Management

As previously outlined for Phase One, Part A.

5.5.11 Data Analysis

Data was first checked for normality of distribution. Descriptive statistics were used to describe each group: experimental and control. PU cumulative incidence rates were measured for both groups. Log-rank and Cox proportional-hazards analyses were used to compare time to new PU events between the two groups, and to determine a hazard ratio. A generalised liner model (Poisson regression) was used to measure incidence rates over a certain period of time to test the effectiveness of the intervention over time (i.e., by checking the slope of the incidence rate between the two groups over time) (Dobson & Barnett, 2008; Hardin & Hilbe, 2007). The assumption of this analysis is that the outcome (incidence rate) has a positive distribution (i.e., is positively skewed). This test is appropriate when the mean is equal to the variance (Dobson & Barnett, 2008; Hardin & Hilbe, 2007). PU stage differences between groups were analysed using Chi-square test of independence.

To determine the proportion of RNs who adhered to the key aspects of the PU prevention bundle, cross-tabulation was utilised. Following this, the Spearman rank correlation coefficient test was used to explore the association between two variables that were either both continuous variables or did not met the assumption of linearity, normality, and homogeneity (Cronk, 2006; Kirkwood & Sterne, 2003; Tabachnick &
Further details regarding the data analysis of this section are presented in the publication in Chapter 8.

### 5.5.12 Ethical Considerations

Ethical approval to conduct this study was obtained from the Unit of Ethics of King Abdul-Aziz Hospital and King Fasil Hospital, Ministry of Health, Makkah, Saudi Arabia and the Queensland University of Technology (QUT) Human Research Ethics Committees (1300000341), Australia (see appendix C, F). In this phase, informed written consent was sought from all eligible participants. The study was explained verbally to all participants and their family members. Moreover, information letters were posted on each patient’s bed. These notices informed participants and their next of kin about the nature, purpose, and risk/benefits of this study.

### 5.6 CHAPTER SUMMARY

This chapter outlined the methods used to measure the effectiveness of the care bundle protocol in reducing the incidence of PU development in the KSA critically ill patient population, together with the identification of the facilitators and barriers that hindered or assisted with the implementation the PU prevention bundle. The study design, setting, and population, and the research questions were presented, along with a description of the data collection process and proposed analyses for both phases.

The findings for this study are presented as articles in the next three chapters. This is followed by Chapter 9, which presents an integration of all findings in this study, guided by the study’s conceptual framework.
Chapter 6: (Article 3) Saudi Arabian Adult Intensive Care Unit Pressure Ulcer Incidence and Risk Factors: a Prospective Cohort Study

This chapter includes the following article:


This article presents the findings of Phase One Part A of this study, which was the assessment of the practice environment as recommended by the research implementation model, the Ottawa Model of Research Use (OMRU). The aim was to describe the characteristics of ICU patients in the Kingdom of Saudi Arabia (KSA), identify the incidence of PUs in the ICU in the KSA, and determine risk factors associated with PU development in the KSA population.

This article answers research questions 4-6:

**Research Question 4**: What are the characteristics of the ICU patients in the KSA?

**Research Question 5**: What is the incidence of PU development in critically ill patients in the intensive care unit of two tertiary referral hospitals in the KSA?

**Research Question 6**: What are the factors associated with PU development in KSA ICUs?
This paper adds to the existing literature by providing, for the first time, a report of PU incidence in the KSA. The study also reveals different risk factors that may accelerate PU development in the KSA critically ill patient population in the ICU. These results indicate the importance of implementing a comprehensive PU prevention program.

Findings from this phase were published in the International Wound Journal, as the results from this study would be of interest to all healthcare practitioners involved in the care of patients with PUs. The International Wound Journal has an impact factor of 2.15. This article has been cited twice in Google scholar, and three times on the Scopus database.


6.1 Abstract

The purpose of this study was to identify pressure ulcer (PU) incidence and risk factors that are associated with PU development in patients in two adult intensive care units (ICU) in Saudi Arabia. A prospective cohort study design was used. A total of 84 participants were screened second daily basis until discharge or death, over a consecutive 30-day period, out of which 33 participants with new PUs were identified giving a cumulative hospital-acquired PU incidence of 39.3% (33/84 participants). The incidence of medical devices-related PUs was 8.3% (7/84). Age, length of stay in the ICU, history of cardiovascular disease and kidney disease, infrequent repositioning, time of operation, emergency admission, mechanical ventilation and lower Braden Scale scores independently predicted the development of a PU. According to binary logistic regression analyses, age, longer stay in ICU and infrequent repositioning were significant predictors of all stages of PUs, while the length of stay in the ICU and infrequent repositioning were associated with the development of stages II–IV PUs. In conclusion, PU incidence rate was higher than that reported in other international studies. This indicates that urgent attention is required for PU prevention strategies in this setting.

**Key words:** Incidence; intensive care; medical devices-related pressure ulcer; pressure ulcer; risk factors
6.2 INTRODUCTION

Pressure ulcers (PUs) are one of the most common problems faced globally in healthcare settings (Feuchtinger, Halfens, & Dassen, 2007; Nijs et al., 2009; Shahin, Dassen, & Halfens, 2008). PUs have an impact on rising health care costs and on patient’s health through the increase of both morbidity and mortality (Vollman, 2010). Studies that examine PU development have become of increasing interest in the drive to improve patient outcomes. PUs are a predictable and preventable phenomena; thus, making this complication one of the key indicators to measure quality of nursing care and patient safety in the healthcare setting (Aydin et al., 2004; Tayyib, Coyer, & Lewis, 2013).

The National Pressure Ulcer Advisory Panel (NPUAP) and the European Pressure Ulcer Advisory Panel (EPUAP) (National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009) defined a PU as a lesion or trauma to the skin and underlying tissue resulting from unrelieved pressure, shear, friction, moisture, or a combination of all these, usually over a bony prominence. PU staging refers to a recognised and established system to classify the level of tissue damage or depth of injury observed (National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009). Use of the NPUAP/EPUAP PU-staging system enables objectivity of assessment of the depth of tissue injury by the health care workers.

PU prevalence data varies widely across both settings and country. Prevalence rates have been reported at: 3% - 26% in North America (Berlowitz, 2014; Woodbury & Houghton, 2004), 8.1% - 49% across Europe (Shahin et al., 2008; Vanderwee et al., 2007), 3% - 50% in Australia (Elliott, McKinley, & Fox, 2008; Prentice, Stacey, & Lewin, 2003), 7% - 44.4% in Middle East (Saleh, 2007; Tubaishat, Anthony, & Saleh,
Further, PU incidence data also varies by clinical setting: in long-term care from 2.3% - 23.9%; in acute care from 0.4% - 38.6%; in home care from 0% -17%; and in rehabilitative care from 0% -6% (Dorner, Posthauer, Thomas, & National Pressure Ulcer Advisory, 2009; Saleh, 2007). However, data highlight that intensive care units (ICUs) have the highest PU incidence in health care settings – these incidence rates have been reported as high as 50% (Keller, Wille, van Ramshorst, & van der Werken, 2002). The high rates in the ICUs can be attributed to the high acuity of patients, the nature of their critical illness and the highly invasive nature of the interventions and therapies that critically ill patients receive (Johnson & Meyenburg, 2009; Vollman, 2010).

Identifying patients at risk for PUs development is essential for effective implementation of PU prevention programs and usage of resources. Tayyib and colleagues (Tayyib et al., 2013) ascertained 28 factors associated with accelerated PU development in critically ill patients; however the most frequently reported risk factors were older age, longer ICU stay, history of cardiovascular and diabetes disease and infrequent repositioning.

There is a paucity of research examining the extent of hospital-acquired pressure ulcers (HAPUs) in Middle East countries with only two studies identified. One Saudi Arabian (SA) study (Saleh, 2007) reported acute care PU prevalence of 44.4% and incidence of 38.6%. A second Jordanian study reported overall PU prevalence of 12% in the health care setting, and 29% PU prevalence in the intensive care setting (Tubaishat et al., 2011). However, prevalence data does not adequately reflect the magnitude of the problem; it provides a snapshot of the problem for quality assurance purposes. Incidence data, on other hand, provides an accurate figure and a picture of
the extent of the problem in the health care setting over a period of time (Baharestani et al., 2009).

In SA, no reported baseline data exists on PU incidence in ICU. This is the first study conducted in the Middle East, specifically Saudi Arabia, to identify PU incidence in the intensive care setting. Therefore, this study aimed to: (i) describe characteristic of the ICU patients in Saudi Arabia, (ii) identify the incidence of PUs in the ICU in Saudi Arabia, and (iii) determine risk factors associated with PU development in this population. This study also provided a benchmark for PU incidence in the ICU and risk factors studies in Saudi Arabia and a comparison with other international studies.

6.3 MATERIALS AND METHOD

6.3.1 Study Design

This multicentre prospective observational cohort study was completed over a 4 weeks consecutive period between July and August 2013 in the ICUs of two major metropolitan hospitals in Saudi Arabia.

6.3.2 Participants and Setting

All patients admitted to the ICU during the data collection period, who were aged 18 years or more, were included in the study.

The research setting was two hospitals operated by the Ministry of Health, Saudi Arabia. Both facilities are major tertiary care hospitals, each with over 400 beds and ambulatory services. These two facilities each provide services to patients of the western region of Saudi Arabia and from neighboring regions and each site has 24
intensive care beds. Patient admission diagnoses in both ICUs include: cardiovascular illness, respiratory disease, cancer, renal dysfunction, sepsis and multi-trauma injury such as head injury. A diverse number of complex treatments and advanced technological equipment are provided for intensive care patients to support their body system functions during critical illness. According to the portfolios of both ICUs the average length of patient stay in 2011 was 8 - 9 days (King Abdul-Aziz Hospital, 2011; King Fasiel Hospital, 2011).

6.3.3 Data Collection

A data extraction form was specifically designed for this study. Data were collected on three levels: baseline ICU survey; baseline patient survey; and second daily patient’s skin inspection and data collection. Data collection processes were piloted with validated instruments where available including the Sequential Organ Failure Assessment score (SOFA) (Vincent et al., 1998); Braden Scale score (Smith et al., 1995); and PU-staging scales (National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009).

Baseline ICU data

Current system-level data present at the time of commencement of data collection at each ICU were collected, which included total bed capacity, ratio of ventilator/non-ventilator beds, annual number of patient admissions, average length of patient stay, number of patient mechanical ventilation days, nurse/patient ratios, existence of specific practices regarding skin care, and the types of strategies used to prevent PU development.
Baseline patient data

Patient demographic data was collected on admission for all patients that included age, sex, nationality, body mass index (BMI) and clinical demographic data including diagnosis on admission, comorbidities, emergency or elective admission, length of time in operating theatre or emergency department prior to ICU admission in hours if applicable, Braden Scale Score (Smith et al., 1995), presence or absence of PU on admission (yes/no), mechanical ventilation (yes/no) duration in days if applicable, ICU length of stay in days, and ICU outcome (discharge to ward or death).

Second daily patient data collection

Every second day patients’ skin was assessed using standard physical examination techniques (Talley & O'Connor, 2014). The data collected included the presence or absence of a PU. If a PU present, it’s grading and site, patients’ ventilation status, frequency of patient repositioning and SOFA score were also recorded.
Established data collection tools

Braden Scale Score.

The Braden Scale score (Smith et al., 1995) is a well-recognised, widely used and validated score for predicting risk of PU development (Pancorbo-Hidalgo, Garcia-Fernandez, Lopez-Medina, & Alvarez-Nieto, 2006). Accordingly, it consists of six elements: sensory perception; moisture; activity; mobility; nutrition; and friction and shear. The total score ranges from 6 to 23, with a higher score indicating a lower risk of developing a PU and vice-versa. Using this scale all patients are divided into four subcategories: at mild risk (score 15-18), moderate risk (score 13-14), high risk (score 10-12), and very high risk (score ≤ 9).

PU staging.

PUs were identified as either community-acquired PUs (CAPU) or hospital-acquired PUs (HAPU), and if they related to equipment, as medical device-related PUs (MDRPU). CAPUs were defined as PU diagnosed on admission, or within the first 24 hours of the patient’s admission to ICU. Further, PUs were classified according to NPUAP and EPUAP (National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009) definitions in relation to stage, type or site of injury (e.g. skin or mucosal ulcers). Additionally the PU site was identified on the data collection form by drawing a circle over the relevant area in the body figure.

SOFA.
SOFA was designed to determine the extent of a person's organ function or rate of failure in the ICU (Ferreira, Bota, Bross, Mélot, & Vincent, 2001). The score is based on the description of six-organ dysfunction/failure: the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems. Each organ is graded from 0 (normal) to 4 (the most abnormal), providing a daily score of 0 to 24 points. The purpose of the SOFA score is to create a reliable, simple and continuous score that can be easily applied in all institutions. Furthermore, the SOFA score provides an indication of patient acuity on a daily basis (i.e. when measured).

6.3.4 Procedure

Permission to access the ICUs was received from the medical and nursing directors. All ICU nurses and doctors were informed in writing and in person about the study. All the patients who met the study inclusion criteria were included in the study. The researcher, who was trained in data collection tools, collected all data to ensure reliability.

While a comprehensive skin examination and assessment was performed second daily on each participant, owing to the variation in admission times, data were collected daily over a consecutive 30 day period in the ICU. Data was collected on participants on a second daily basis until patient discharge from ICU or death. The baseline ICU data was collected at the time of commencement of the study and patient baseline data collection was completed on admission.

6.3.5 Ethical Considerations

Ethical approval to conduct this study was obtained from the Unit of Ethics of the relevant hospitals, Saudi Arabia and the Queensland University of Technology.
(QUT) Human Research Ethics Committees, Australia. This study received approval with waiver of informed consent, in accordance with National Health and Medical Research Council (NHMRC) guidelines. Measuring PU incidence in the ICU does not involve an intervention or a change to standard care. Furthermore, informed consent can be impractical to obtain when patients are critically ill, mechanically ventilated and sedated (National Health and Medical Research Council (NHMRC), 2007). As this study aimed to identify the incidence of PU development in two ICUs, complete patient numbers were crucial to accurately calculate the incidence.

6.3.6 Statistics

Descriptive statistical methods were performed using SPSS (version 21; SPSS, Chicago, IL). Level of statistical significance was set at a p-value less than or equal to 0.05 ($p \leq 0.05$) (Sterne & Kirkwood, 2010). All demographic and clinical characteristics were analyzed using descriptive statistics (frequencies and means where appropriate). Incidence was calculated as cumulative incidence, defined as the proportion of the participants that develop new PUs within a specific time (Baharestani et al., 2009). Bivariate analyses using chi square, in-dependent t test, and MannWhitney U were performed to identify the variables associated with PU development. A binary logistic regression model was used to develop the best model for predicting PU occurrence in the ICU. It also explored the direction of the relationship between the predictive variables and PU occurrence.
6.4 RESULTS

6.4.1 Baseline Intensive Care Unit Characteristics

Table 6.1 shows the main characteristics of both ICUs. For both ICUs, the staffing ratio was one nurse to two, or at times three, mechanically ventilated patients and one charge nurse per shift for each of the three eight-hour shifts per day. In both hospitals the registered nurse in-charge of the ICU was not always supernumerary and was sometimes allocated to provide care for two patients. Registered nurses (RNs) delivered complete patient care. Furthermore, there were no dedicated clinical instructors or nurse educators in the units and no dedicated respiratory therapists or physiotherapists.

Both study facilities had practices related to the prevention of PU development (see Table 6.1). These practices included physical examination of the patient’s skin each shift (however, no risk assessment tool was used), use of support surfaces to manage patient load and pressure, and a two-hourly repositioning policy. Additionally, routine skin hygiene practice for ICU patients in both units was a bed-bath at 6:00 am using an antiseptic soap containing 2% of hydrogen peroxide without application of a skin moisturiser.
Table 6.1 Baseline Intensive Care Unit (ICU) Characteristic

<table>
<thead>
<tr>
<th>Variable</th>
<th>ICU 1</th>
<th>ICU 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total bed capacity</td>
<td>24 beds</td>
<td>24 beds</td>
</tr>
<tr>
<td>Ratio of ventilator/non-ventilator beds</td>
<td>6:1</td>
<td></td>
</tr>
<tr>
<td>Annual number of patient admissions,</td>
<td>2000-2500 Patients/annually</td>
<td>2000-2300 Patients/annually</td>
</tr>
<tr>
<td>Average length of patient stay</td>
<td>9 days</td>
<td>10 days</td>
</tr>
<tr>
<td>Nurse/patient ratio</td>
<td>1:2 to 1:3</td>
<td>1:2 to 1:3</td>
</tr>
<tr>
<td>ICU patient skin care:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Risk assessment</td>
<td>No PU risk assessment scale used</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Skin assessment</td>
<td>Comprehensive physical assessment of the patient’s skin is undertaken and documented within 24 hours of admission and every eight hours.</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Skin care:</td>
<td>Bed-bath once a day at 06:00hours using antiseptic soap containing 2% hydrogen peroxide.</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Nutrition</td>
<td>Nutrition plan for each patient will be provided by clinical nutritionist</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Repositioning</td>
<td>Patients’ position alternated form right side, back and then left side or vice versa.</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Support surface</td>
<td>All patients managed on reactive support surface (i.e. air mattress)</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Education and training</td>
<td>During the orientation for new ICU staff</td>
<td>Same as per ICU 1</td>
</tr>
<tr>
<td>• Documentation of pressure ulcers</td>
<td>Pressure ulcer documentation tool especially designed for the hospital.</td>
<td>Same as per ICU 1</td>
</tr>
</tbody>
</table>
6.4.2 Characteristics of the Study Population

Of a total of 90 patients admitted to the ICUs during 30-day study period, 84 participants were included to this study. Six participants were excluded as they had CAPUs on admission. Participant mean age was 52.8 years, with a range of 18 to 99 years. Almost two-thirds of the participants were men (56, 66.6%). Majority of the individual in the study sample were non-Saudi nationals (46, 54.8%). Table 6.2 provides an overview of participants’ demographic characteristics and clinical features. About 85.7% of the participants were at high risk for PU development with a mean Braden scale score of 10 (SD 2.12).

Table 6.2 Demographic and Clinical Characteristics of Study’s Participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total participants (n=84)</th>
<th>Participants with PU (n=33)</th>
<th>Test</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (number, %)</td>
<td>56 (66.7)</td>
<td>18 (54.5)</td>
<td>3.59 *</td>
<td>0.58</td>
</tr>
<tr>
<td>Nationality (number, %)</td>
<td></td>
<td></td>
<td>1.9 *</td>
<td>.168</td>
</tr>
<tr>
<td>Saudi</td>
<td>38 (45.2)</td>
<td>18 (54.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pakistani</td>
<td>6 (7.1)</td>
<td>3 (9.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td>4 (4.8)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burmese</td>
<td>5 (6)</td>
<td>2 (6.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bangladeshi</td>
<td>4 (4.8)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yemeni</td>
<td>3 (3.6)</td>
<td>2 (6.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indonesian</td>
<td>2 (2.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thai</td>
<td>2 (2.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaysian</td>
<td>1 (1.2)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>1 (1.2)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Egyptian</td>
<td>3 (3.6)</td>
<td>2 (6.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algerian</td>
<td>1 (1.2)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sudanese</td>
<td>2 (2.4)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somali</td>
<td>2 (2.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigerian</td>
<td>3 (3.6)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethiopian</td>
<td>2 (2.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mauritanian</td>
<td>4 (4.8)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burkinabe</td>
<td>1 (1.2)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years) (mean, SD, range)</td>
<td>(52, 20.1, 18-99)</td>
<td>(65.45, 20.21, 27-99)</td>
<td>5.33 †</td>
<td>&lt;0.001§</td>
</tr>
<tr>
<td>BMI (mean, SD)</td>
<td>(26.18, 3.86)</td>
<td>(26.67, 3.89)</td>
<td>0.926 †</td>
<td>0.357</td>
</tr>
<tr>
<td>Braden scale (mean, SD)</td>
<td>(10, 2.1)</td>
<td>(9.33, 1.63)</td>
<td>537.5 ‡</td>
<td>0.004 §</td>
</tr>
<tr>
<td>Admission via emergency department (Yes)</td>
<td>64 (76.2)</td>
<td>29 (87.9)</td>
<td>4.093 *</td>
<td>0.043 §</td>
</tr>
</tbody>
</table>

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### Table 6.2: Demographic and Clinical Characteristics of Participants with PUs

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total participants (n=84)</th>
<th>Participants with PU (n=33)</th>
<th>Test</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of time in emergency department (min) (mean, SD)</td>
<td>(81.40, 54.89)</td>
<td>(81.55, 50.62)</td>
<td>653.0 ‡</td>
<td>0.081</td>
</tr>
<tr>
<td>Admission post operation (Yes)</td>
<td>11 (13.1)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of time in operating theatre (min) (mean, SD)</td>
<td>(50.9, 24.16)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comorbidities (number, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>46 (54.8)</td>
<td>20 (60.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin dependent diabetes</td>
<td>43 (51.2)</td>
<td>18 (54.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>11 (13.1)</td>
<td>6 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney disease</td>
<td>9 (10.7)</td>
<td>6 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory disease</td>
<td>19 (22.6)</td>
<td>7 (21.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart disease</td>
<td>20 (23.8)</td>
<td>12 (36.4)</td>
<td>4.722 *</td>
<td>0.03§</td>
</tr>
<tr>
<td>Nil</td>
<td>7 (8.3)</td>
<td>3 (9.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis (number, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>17 (20.2)</td>
<td>6 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical related illness</td>
<td>50 (59.5)</td>
<td>16 (48.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Surgery</td>
<td>10 (11.9)</td>
<td>6 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sepsis/Infectious disease</td>
<td>7 (8.3)</td>
<td>5 (15.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU Length of stay (days) (mean, SD)</td>
<td>(9.1, 6.66)</td>
<td>(13.3, 8.36)</td>
<td>397.0 ‡</td>
<td>&lt;0.001§</td>
</tr>
<tr>
<td>SOFA Score (mean, SD)</td>
<td>(7.8, 3.01)</td>
<td>(8.75, 3.16)</td>
<td>1.9 †</td>
<td>0.06</td>
</tr>
<tr>
<td>Mechanical ventilation (yes)</td>
<td>64 (76.2)</td>
<td>31 (93.9)</td>
<td>5.86 *</td>
<td>0.015§</td>
</tr>
<tr>
<td>Average hours of patient repositioned hours (mean, SD)</td>
<td>(3.8, 1.3)</td>
<td>(4.96, 1.28)</td>
<td>7.304 †</td>
<td>&lt;0.001§</td>
</tr>
<tr>
<td>Average days before PU development (SD, median, range)</td>
<td>N/A</td>
<td>10.09 (4.62, 9.5-23)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ICU, intensive care unit; PU, pressure ulcer; SOFA, Sequential Organ Failure Assessment.
* Pearson Chi-Square test
† t-test
‡ Mann-Whitney U test
§ Significance at P < 0.05

6.4.3 Incidence Rate of PUs in ICUs

Of the 84 patients, 33 patients with new PUs were identified giving a HAPU incidence of 39.3% (33/84 patients). Table 6.2 shows the demographic and clinical characteristics of participants with PUs. A total of 41 HAPUs were recorded in 33 patients. The common areas of PU development were sacrum (24.3%) and heel (29.2%), with a greater tendency for PUs to develop in the heels. Grade I (23/41) and II (15/41) PUs were the most often recorded. Only three PUs were stage III, and no grade IV PU was recorded (see Table 6.3). The overall incidence of MDRPU was 8.3%
(7/84). Of the 41 HAPUs, 8 (20%) were related to medical devices, and the most common site was the ear (37.5%).

Table 6.3 PU Incidence of Surveyed Participants (n=84)

<table>
<thead>
<tr>
<th>Variable</th>
<th>HAPU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants with Pus</td>
<td>33</td>
</tr>
<tr>
<td>Number of PUs per participants</td>
<td></td>
</tr>
<tr>
<td>One (number, %)</td>
<td>19</td>
</tr>
<tr>
<td>Two (number, %)</td>
<td>4</td>
</tr>
<tr>
<td>Three (number, %)</td>
<td>2</td>
</tr>
<tr>
<td>Four (number, %)</td>
<td>0</td>
</tr>
<tr>
<td>Description of PUs:</td>
<td></td>
</tr>
<tr>
<td>Patients with skin ulcers</td>
<td></td>
</tr>
<tr>
<td>Suspected deep injury</td>
<td>0</td>
</tr>
<tr>
<td>PU Stage I (number, %)</td>
<td>23</td>
</tr>
<tr>
<td>PU Stage II (number, %)</td>
<td>15</td>
</tr>
<tr>
<td>PU Stage III &amp; IV (number, %)</td>
<td>3</td>
</tr>
<tr>
<td>Unstagable (number, %)</td>
<td>0</td>
</tr>
<tr>
<td>MDRPUs * (number, %)</td>
<td>8 (19.5)</td>
</tr>
<tr>
<td>Total number of PUs</td>
<td>41</td>
</tr>
<tr>
<td>Skin ulcer location (number, %)</td>
<td></td>
</tr>
<tr>
<td>Occiput</td>
<td>1</td>
</tr>
<tr>
<td>Ear</td>
<td>2</td>
</tr>
<tr>
<td>Elbow</td>
<td>1</td>
</tr>
<tr>
<td>Shoulder</td>
<td>2</td>
</tr>
<tr>
<td>Ischium</td>
<td>1</td>
</tr>
<tr>
<td>Sacrum</td>
<td>10 (24.3)</td>
</tr>
<tr>
<td>Buttock</td>
<td>4</td>
</tr>
<tr>
<td>Heel</td>
<td>12 (29.2)</td>
</tr>
<tr>
<td>MDRPU Location (number, %)</td>
<td></td>
</tr>
<tr>
<td>Nare</td>
<td>1</td>
</tr>
<tr>
<td>Lip</td>
<td>1</td>
</tr>
<tr>
<td>Neck</td>
<td>2</td>
</tr>
<tr>
<td>Ear</td>
<td>3</td>
</tr>
<tr>
<td>Leg</td>
<td>1</td>
</tr>
</tbody>
</table>

6.4.4 Risk Factors

Table 6.2 shows that age (t(82) = 5.33, p< 0.001), length of stay in the ICU (U= 397.0, z= 1723.0, p <0.001), history of cardiovascular disease (X2 =4.722, p= 0.03), infrequent reposition (t(48.7) = 7.308, p< 0.001), emergency admission (X2 =4.093, p= 0.043), mechanically ventilation status (X2 =5.86, p= 0.015), and a lower Braden
Scale score (U= 537.5, z= 1098.5, p= 0.004) were significantly associated with all stages of PU development. Mechanical ventilated patients (X2 =5.707, p= 0.017), length of stay in ICU (U= 397.0, z= 1723.0, p <0.001) and infrequent repositioning (t (82) = -4.562, p < 0.001) were positively associated with the development of stage II-IV PUs.

All of the factors mentioned above were entered into a binary logistic regression model as exploratory variables for all stages of PU development (Table 6.4). Age (OR: 1.254; 95% CI: 1.054–1.492; p = 0.011), longer stay in the ICU (OR: 1.831; 95% CI: 1.014–3.309; p = 0.045), and infrequent repositioning (OR: 250.04; 95% CI: 5.230-11954.16; p = 0.005) were significant predictors of all stages of PUs. Length of stay in ICU (OR: 1.23; 95% CI: 1.087–1.392; p = 0.001), and infrequent repositioning (OR: 2.96; 95% CI: 1.23–7.153; p = 0.015) were associated with the development of stage II-IV PUs.
Table 6.4 Risk Factors of Pressure Ulcer (PU) Development Using Binary Logistic Regression

A) For all PU stages

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>95% C.I. for EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>AGE</td>
<td>.226</td>
<td>.089</td>
<td>6.521</td>
<td>.011</td>
<td>1.254</td>
<td>1.054</td>
</tr>
<tr>
<td>Infrequent repositioning</td>
<td>5.522</td>
<td>1.973</td>
<td>7.831</td>
<td>.005</td>
<td>250.043</td>
<td>5.230</td>
</tr>
<tr>
<td>ICU_LOS</td>
<td>.605</td>
<td>.302</td>
<td>4.019</td>
<td>.045</td>
<td>1.831</td>
<td>1.014</td>
</tr>
<tr>
<td>Constant</td>
<td>-32.969</td>
<td>12.746</td>
<td>6.691</td>
<td>.010</td>
<td>.000</td>
<td></td>
</tr>
</tbody>
</table>

Nagelkerke R Square = 0.914
Hosmer and Lemeshow Test $\chi^2 = 2.395$, df = 8, $p = .966$

B) For participants with stages II- IV

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>95% C.I. for EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infrequent repositioning</td>
<td>1.087</td>
<td>.449</td>
<td>5.861</td>
<td>.015</td>
<td>2.966</td>
<td>1.230</td>
</tr>
<tr>
<td>ICU_LOS</td>
<td>.207</td>
<td>.063</td>
<td>10.762</td>
<td>.001</td>
<td>1.230</td>
<td>1.087</td>
</tr>
<tr>
<td>Constant</td>
<td>16.511</td>
<td>7157.897</td>
<td>.000</td>
<td>.998</td>
<td>14810627.253</td>
<td></td>
</tr>
</tbody>
</table>

Nagelkerke R Square = 0.683
Hosmer and Lemeshow Test $\chi^2 = 1.781$, df = 8, $p = .987$
6.5 DISCUSSION

6.5.1 Characteristics of the Study Population

Results of this study showed an increased percentage of participants from outside Saudi Arabia. This is typical of the patient population in this research setting as Makah is a city of significant spiritual significance with many Muslims travelling to Makah for religious pilgrimage. Almost 72% (33/46) of non-Saudi participants were older than 40 years, which is expected, as many Muslims delay the pilgrimage journey until they become older (Centers for Disease Control and Prevention (CDC), 2013). The reasons behind this could be financial, social, or spiritual beliefs.

6.5.2 Incidence of PUs

In this study the cumulative incidence of HAPUs in the adult ICUs was 39.3%. This HAPU rate was higher than other international studies’ finding of 1.8% (Stotts, Brown, Donaldson, Aydin, & Fridman, 2013), 7.5-14.3% (Gunningberg, Donaldson, Aydin, & Idvall, 2012), and 12% (Tschannen, Bates, Talsma, & Guo, 2012). A possible explanation of the higher PU incidence rate in ICUs in this study is the length of stay in the ICU (mean 9.3 days), which is longer than other times periods reported in international studies (Cox, 2010; Kaitani, Tokunaga, Matsui, & Sanada, 2010; Nijs et al., 2009; Sanada et al., 2007). In the SA context the longer length of stay may be related to patients’ prognosis, patients’ treatment, and the fact that in Saudi Arabia, withholding or withdrawal of treatment is not practiced because of religious and cultural beliefs. Furthermore, the incidence rate may be high because of low nurse/patient ratios (i.e 1:2 or 1:3), and consequent high nursing workload leading to infrequent repositioning of these high risk patients, thus accelerating PU development.
We found the mean time to reposition patients in this study was 4.96 hours, although it is acknowledged that this data was collected retrospectively from the patient’s chart and may therefore not present an accurate picture of clinical care. Although low nurse/patient ratios exist in other countries, the ICU patient care delivery is organized differently. For example, in the United States, patient care in intensive care is provided by a dedicated team including RNs (care co-ordinator), nursing assistants (who provide hygiene care), respiratory therapists, nutritional consultants, and ICU physicians (Amaravadi, Dimick, Pronovost, & Lipsett, 2000; Haupt et al., 2003). Conversely, in Australia and the United Kingdom, the nurse/patient ratio for mechanically ventilated patients is 1:1 however, RNs provide and coordinate all patient care (Armstrong, 2009). A number of studies have reported that the high nurse/patient ratio was significantly associated with high quality, safety, and positive patient outcome (McGahan, Kucharski, Coyer, & Winner, 2012; Stone et al., 2007; Whitman, Kim, Davidson, Wolf, & Wang, 2002).

Interestingly, our findings show a low incidence rate of MDRPUs, but these accounted for one fifth of HAPUs in this study. MDRPUs in the ICU remain an under-reported phenomenon however our findings are similar to other reported MDRPUs rates (Apold & Rydrych, 2012; Black et al., 2010; Coyer, Stotts, & Blackman, 2013). The majority of MDRPUs were related to poor positioning or fixation of respiratory equipment. Occurrence of these ulcers could be prevented with implementation preventive strategies such as regular assessment of the area underneath and around medical devices and regular repositioning or securement of devices (Fletcher, 2012). Using protective dressings to secure and stabilize devices also could reduce risk for MDRPU development.
Of the PUs identified in this study, 56% were found to be stage I while 36.5% were stage II. Consistent with findings from previous research (Sanada et al., 2007; Sayar et al., 2009) the most common anatomical areas for PU development in this study were the sacrum and heels. The majority of the patients in this study were positioned in a semi-fowler’s position with no heel elevation or off-loading of pressure, leading to increased pressure points on the heels and sacrum. This was compounded by reduced frequency of patient repositioning. Santamaria and colleagues (2013) found the prophylactic use of a soft silicone multi-layered foam dressing effective in the prevention of sacral and heel PUs in trauma and critically ill patients.

6.5.3 Risk Factors

The present study indicates that age, length of stay in ICU, history of cardiovascular disease and kidney disease, infrequent repositioning, time of operation, emergency admission, mechanically ventilated patients, and lower Braden scale scores were significant factors contributing to PU development. This finding corroborates that of other reported international findings (Cox, 2010; Eachempati, Hydo, & Barie, 2001; Tayyib et al., 2013). However, there are conflicting findings in the literature regarding age as a PU risk factor. Many studies report ICU patients over 60 show significant association with PU development; similar to our findings (Cox, 2010; Eachempati et al., 2001; Frankel, Sperry, & Kaplan, 2007). Hoshowsky and Schramm (1994) state that patients who are aged over 40 were at high risk for PUs development. This is in contrast to studies which demonstrate that age is not predisposing factor for PUs development (Nixon, Brown, McElvenny, Mason, & Bond, 2000; Sayar et al., 2009; Theaker, Kuper, & Soni, 2005). However, comparison between studies is limited
by small sample sizes, shorter stays in the ICU (Theaker et al., 2005), differing nurse/patient ratios (Sayar et al., 2009), and purposive sample age (Nixon et al., 2000). Thus, further research is needed to examine different age groups as predictors of PUs development and include them in the risk assessment scale.

In contrast, the present study did not find an association between PU development and other factors previously identified such as: low BMI (Fife et al., 2001); and time spent in the emergency department (Eachempati et al., 2001). A possible explanation for this is related to; those studies had some limitations such as: small sample size, retrospective design, and excluding grade I PU. Therefore, further prospective longitudinal studies are required to confirm the association between those factors and PUs occurrence in ICUs.

6.6 LIMITATIONS

Our study is limited by the time frame of data collection. A longer data collection period may have provided different data. Beside the frequency of repositioning, we did not collect data on processes of care measures and, therefore cannot confirm the preventative PU measures were carried out according to hospital/unit policy. Furthermore, data on patient repositioning time frames was recorded retrospectively from patient notes.

6.7 CONCLUSION

This study has reported the PU incidence in two ICUs in SA hospitals. It is argued that measuring PU incidence rates is essential for obtaining an accurate picture
of the scope of the problem and for evaluating quality of care and monitoring patient outcomes. The data presented in this study provides baseline information of PU incidence rates in the ICU in Saudi Arabia, thus significantly adding new information in this area. The PU incidence rate in SA ICUs is high (39.5%), which indicates that more attention is required for PU prevention. Furthermore, urgent implementation of evidence-based PU prevention protocols is needed to alleviate this pressing problem. This study also reports that MDRPUs are a continuing problem in the ICU. A set of prevention strategies to prevent potential MDRPUs for highly dependent patients is recommended to directly address this problem. Furthermore, identification of risk factors that accelerate PU development in ICU in Saudi Arabia is essential to determine appropriate prevention strategies and appropriate usage of available resources.

Findings from this study indicate strongly that implementation of a comprehensive PU prevention program could prevent the majority of PU development in the ICU in Saudi Arabia. Randomized control trials are needed to develop and determine optimal PU prevention and management strategies. Moreover, continued measurement and evaluation of PU incidence, including MDRPUs, and evaluation of the risk factors for PU development are recommended in SA hospitals to monitor and promote best practice in skin care for highly dependent patients.
6.8 REFERENCES


http://qut.summon.serialssolutions.com/link/0/eLvHCXMwA20DBnZ7LE1TgZ0JszQjg0Sj1GSLpDQzw8Rk8xSLZEvjVJTBNqTS3E2UQc7NNcTZQxdWKsan5OTEG4FnioEVi6GhGANvImjhd14JeINYCT-36QcvTZb0996298j2e8n6WwGN5SUH


Elliott, R., McKinley, S., & Fox, V. (2008). Quality improvement program to reduce the prevalence of pressure ulcers in an intensive care unit. American Journal
**Chapter 6:**

**Article 3**

Saudi Arabian Adult Intensive Care Unit Pressure Ulcer Incidence and Risk Factors: a Prospective Cohort Study


Haupt, M. T., Bekes, C. E., Brilli, R. J., Carl, L. C., Gray, A. W., Jastremski, M. S., ... & Horst, M. (2003). Guidelines on critical care services and personnel: Recommendations based on a system of categorization of three levels of care*. 

174 Chapter 6: (Article 3) Saudi Arabian Adult Intensive Care Unit Pressure Ulcer Incidence and Risk Factors: a Prospective Cohort Study


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Outcomes. *Medical Care*, 45(6), 571-578.
doi:10.1097/MLR.0b013e3180383667


dysfunction/failure in intensive care units: Results of a multicenter, prospective study. *Critical Care Medicine, 26*(11), 1793-1800.


Chapter 7: (Article 4) Pressure Ulcer Prevention in the Saudi Arabian Intensive Care Unit: Registered Nurse Attitudes Toward Prevention Strategies and Perceived Facilitators and Barriers to Evidence Implementation

This chapter presents the following article:


This article provides the findings of Phase One Part B of this study, which was the assessment of the potential adoptors according to the Ottawa Model of Research Use (OMRU). The aim of this phase was to examine attitudes towards PU prevention strategies in a group of critical care nurses practicing in the KSA. Further, this study aimed to identify KSA RNs perceptions of any barriers and facilitators that could influence the adoption and implementation of high quality evidence to reduce PU occurrences in the ICU.

This article answers research questions 7-9:

**Research Question 7:** What is the RNs attitude towards PUs prevention in a Saudi Arabian tertiary referral hospital ICU?
Research Question 8: What are the facilitators and barriers for RNs in the adoption of PU prevention strategies in a Saudi Arabian tertiary referral hospital ICU?

Research Question 9: Is there any association between participants’ characteristics and RNs’ attitude, or perceived barriers and facilitators to implement the PU prevention strategies?

Findings revealed that overall, RNs had positive attitudes towards PU prevention, and their perceived barriers for implementation of PU prevention strategies were time demands and limitations in their knowledge. However, they also perceived some factors that increased their ability to implement the PU prevention strategies, such as availability of support surfaces and skin care products. These factors were addressed during the planning and design of the strategies of implementation in Phase Two of this study for effective translation and adoption of the PU prevention bundle.

This paper address the gap in the literature by providing, for the first time, the perceived barriers and facilitators that influence the implementation of PU prevention strategies in the ICU in the KSA. The study also evaluated the ICU RNs attitudes, which impact directly in the implementation of effective evidence of PU prevention.

Findings from this phase were published in the Journal of Wound Ostomy Continence Nursing, as the results from this study would be of interest to all healthcare practitioners aiming to improve the quality of care provided, related to wound. The Journal of Wound Ostomy Continence Nursing has an impact factor of 1.177. Further, the findings of this phase of the study were presented with the title “Identifying Registered Nurses’ Attitudes and Perceived Facilitators and Barriers Towards Pressure Ulcer Prevention Strategies in the Intensive Care Unit” at the following conference: European Wound Management Association Conference. London, May 2015.
Pressure ulcer prevention in the Saudi Arabian intensive care unit: registered nurse attitudes toward prevention strategies and perceived facilitators and barriers to evidence implementation


7.1 ABSTRACT

**Purpose:** The purpose of this study was to examine registered nurses' (RNs) attitudes toward PU prevention strategies. Barriers and facilitators perceived by RNs to potentially impact on the adoption and implementation of PU prevention interventions in the intensive care unit (ICU) were examined.

**Design:** Descriptive cross-sectional survey.

**Subjects and Setting:** The target population was RNs practicing in an ICU of a major tertiary hospital, King Abdul-Aziz, Makkah in Saudi Arabia. Fifty-six of the available 60 ICU RNs participated in this study.

**Methods:** Data were collected via survey using the Attitude towards Pressure ulcer Prevention instrument, which included 13 items rated with four point Likert scale, and the modified Pressure Ulcer Prevention in the PICU "Barriers and Facilitators" instrument included 27 items incorporated into three parts: demographic information, potential barriers to optimal skin care, and potential facilitators to skin care. The survey took 10 to 15 minutes to complete. Data were analysed with descriptive-correlation statistics and multiple regression analysis. Thematic analysis was undertaken for qualitative data.
Results: Participants demonstrated positive attitudes toward PU prevention (μ=38.19/52, 73.44%). No significant differences were found between demographic characteristics of the participants with the RNs attitude subscale, and perceived barriers and facilitators associated with implementing PU prevention in the critical care setting. Several barriers influenced the ability of RNs to implement PU prevention strategies including: time demands (β=0.388, p=0.011), limitation of RNs knowledge (β=-0.632, p=0.022), and current document format (β=0.344, p=0.046). Statistically significant facilitating factors which increased respondent’s ability to undertake PU prevention were: ease of obtaining pressure reduction surfaces (β=-0.388, p=0.007), collaboration with interdisciplinary teams (β=0.37, p=0.02), and availability of appropriate skin care products (β=0.44, p=0.015). Thematic analysis of open ended questions highlighted workload as a barrier that impedes implementation of care specific to PU prevention.

Conclusion: Findings from this study highlighted that ICU RNs showed a positive attitude towards PU prevention. Further, factors that facilitated PU prevention in the ICU were identified as availability of pressure relieving support surfaces, appropriate skin products and collaboration between the healthcare professional team. However, perceived barriers which significantly impeded PU prevention practices were found to be a low level of PU prevention knowledge and workload demand. Identifying context specific factors that may facilitate or impede implementation of PU prevention interventions will promote the translation evidence in the ICU.

Keywords: Pressure ulcer, barriers, facilitators, registered nurses’ attitude, intensive care.
7.2 INTRODUCTION

Pressure ulcers (PU) adversely affect morbidity, increase levels of pain, length of stay, and the potential for secondary infection (Graves, Birrell, & Whitby, 2005; Vollman, 2010). Despite multiple articles and guidelines specific to PU prevention strategies (Dealey et al., 2013; European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009; Lyder, 2003; Meesterberends, Halfens, Lohrmann, & De Wit, 2010; Peterson, 2009), PU prevalence and incidence remains clinically relevant, particularly in the intensive care unit (ICU) (Berlowitz, 2014; Tayyib, Coyer, & Lewis, 2015). We believe this disparity reflects a gap between dissemination and implementation of evidence-based PU prevention approaches in clinical practice.

Multiple studies have focused on identification of factors that impact implementation of best available evidence in daily clinical practice (Dalheim, Harthug, Nilsen, & Nortvedt, 2012; Kunic & Jackson, 2013; Leasure, Stirlen, & Thompson, 2008; Moore & Price, 2004; Mwebaza, Katende, Groves, & Nankumbi, 2014). Several studies have found that poor adherence to evidence implementation may be a consequence of healthcare professional practices, such as questionable decision making (Flanagan, 2005; McCaughan, Thompson, Cullum, Sheldon, & Thompson, 2002); a lack of knowledge or education (Dalheim et al., 2012; Leasure et al., 2008; Weng et al., 2013), the complexity of the intervention (Leasure et al., 2008), and the time required to deliver the intervention (Dalheim et al., 2012). In addition, certain organizational and environmental factors are likely to influence implementation of evidence-based prevention strategies such as patient/family cooperation (Grol & Wensing, 2004), documentation requirements (Grol & Grimshaw, 2003), consideration of the ratio of risk versus benefit in current practice (Boström, Kajermo,
Nordström, & Wallin, 2009; Griffiths et al., 2001), characteristics of the healthcare setting (Boström, Kajermo, Nordström, & Wallin, 2009; Griffiths et al., 2001), and lack of organizational support (Fink, Thompson, & Bonnes, 2005; Grol & Grimshaw, 2003).

Some authors have observed that RNs may demonstrate poor adherence to PU prevention strategies, possibly owing to perceptions that these interventions are less important than management of the patient’s critical illness (Buss, Halfens, Abu-Saad, & Kok, 2004; Meesterberends et al., 2010; Panagiotopoulou & Kerr, 2002; Qaddumi & Khawaldeh, 2014). Strand and Lindgren (2010) identified that lack of time, severity of patient illness, limited access to pressure redistribution devices, and inadequate knowledge act as barriers to implementation of PU prevention in the ICU. Uncooperative patients (Grol & Wensing, 2004), shortage of staff (Al Kharabsheh, & Saleh, 2014; Mwebaza et al., 2014), lack of training (Jankowski & Nadzam, 2011), busy wards (Thompson et al., 2008), nurses’ attitudes (Beeckman, Defloor, Demarré, Van Hecke, & Vanderwee, 2010), lack of access to literature (Jankowski & Nadzam, 2011; Panagiotopoulou & Kerr, 2002), resources (Mwebaza et al., 2014), equipment and guidelines (Al Kharabsheh, & Saleh, 2014; Jankowski & Nadzam, 2011) have also been identified as barriers to PU prevention.

In Saudi Arabia (SA), PUs in the ICU are a significant problem; a recent study found a 39.3% incidence (Tayyib et al., 2015) which is comparatively higher than other international studies (1.8%-14.3%) (Gunningberg, Donaldson, Aydin, & Idvall, 2012; Stotts, Brown, Donaldson, Aydin, & Fridman, 2013). We believe that implementation of new PU prevention strategies are essential in order to reduce PU occurrences in ICUs in SA. The implementation of PU prevention evidence requires staff education and positive attitudes concerning the urgent need to reduce PU occurrences (Strand &
Lindgren, 2010). Therefore, understanding and recognition of barriers to adoption of PU prevention strategies is crucial. The purpose of this study was to examine attitudes to PU prevention strategies in a group of critical care nurses practicing in SA. Further, this study aimed to identify SA RNs’ perceptions of any barriers and facilitators which may impact on the adoption and implementation of high quality evidence to reduce PU occurrence in the intensive care setting.

7.3 METHODS

We used a descriptive, cross-sectional design to guide data collection and analysis. Data were collected from July 10th to August 16th, 2013 in the ICU of a major metropolitan government-funded public hospital, the King Abdul-Aziz, located in Makkah, SA. Common diagnoses of patients admitted to the ICU are cardiovascular illness; respiratory diseases; cancer; renal dysfunction; burns; sepsis; and multi-trauma injuries. The ICU has 24 beds staffed by approximately 60 RNs; the ICU staffing ratio is 1 nurse to every 2 to 3 mechanically ventilated patients. Registered nurses deliver all direct patient care. Additionally, there is one charge nurse per shift for each of the three 8 hour shifts per day; this person typically cares for 2 patients.

Ethical approval to conduct this study was obtained from the Human Ethics Committees of the King Abdul-Aziz hospital and Queensland University of Technology, Australia. The survey was anonymous with no identifying information collected, therefore consent to participate was deemed by completion of the survey and posting the survey in the mail box at the nurse’s station.

7.3.1 Instruments

Data was collected using a survey comprising 42 items. The survey was divided into 4 sections: demographic information; potential barriers to optimal skin
care; potential facilitators to skin care; and RNs’ attitudes towards PU care and prevention in ICU. Thirty eight items were borrowed (with permission) from the Attitude towards Pressure ulcer Prevention instrument (APuP) (Beeckman et al., 2010) instrument and the Barriers and the Barriers and Facilitators tool used in the pediatric ICU at the Children's Hospital of Wisconsin in Milwaukee (Schindler, 2009). An additional 4 items were constructed based on current literature and local context.

The Barriers and Facilitators instrument has not been formally evaluated for validity and reliability (Schindler, 2009). However, the instrument was modified in this study for use in critical care setting for adults. The original instrument consisted of 3 dimensions: RN demographic information; and barriers and facilitators for implementing the PU prevention bundle in a pediatric ICU. The survey comprised 25 items; 19 were answered via a 10 point Likert scale where 0 indicated the barrier or facilitator influence PU prevention practices to no extent to 10 indicated the facilitator or barrier influenced practice to a great extent. The instrument also contained 2 open-ended questions and 4 demographic items.

The fourth section of the survey was the Attitude towards Pressure ulcer Prevention (APuP) instrument to measure RNs’ attitudes towards PU prevention (Beeckman et al., 2010). The APuP includes 13 items that query 5 dimensions: personal competency to prevent PU, priority of PU prevention, PU impact on the patient and society, personal responsibility for PU prevention, and confidence in the effectiveness of prevention strategies. All items were rated on a 4 point Likert scale where 1 indicates strongly disagree and 4 indicates strongly agree. The cumulative score for this section of the survey was 52; higher scores indicate a more positive attitude to PU prevention. The mean cut point of the attitude score was >70% (>36.4/50), indicating a positive attitude toward PU prevention. The original
instrument validation reported internal consistency with a Cronbach’s alpha of 0.79, (Kaiser-Meyer-Oklin [KMO]=0.72), and construct validity was statistically significant with Bartlett’s test of sphericity ($\chi^2$ (78) = 1062.6, P<=0.001) (Beeckman et al., 2010).

**Evaluation of validity and reliability**

We evaluated validity and reliability of items in sections 1 to 3 of the survey. We evaluated content validity using a panel of 5 expert nurses with >7 years of clinical experience. The panel included 2 nurse educators (one from King Abdul-Aziz and one from King Faisal hospital) and 2 critical care nursing leaders (one from King Abdul-Aziz and one from King Faisal hospital), and one adult care RN.

The process of inferring content validity included providing the participants an overview of the research and providing them with a copy of the survey. Panel members were asked to evaluate the relevance of the items to intensive care nursing practice and management of adult critically ill patients. The relevance of the survey items was measured by five point Likert scale for each item (1=irrelevant to 4=highly relevant). A content validity index of 0.97 and Cronbach’s alpha coefficient of 0.85 were achieved.

Construct validity was assessed for the 13 items that queried potential barriers to optimal skin care, and the 7 items that queried facilitators to optimal skin care using KMO and Bartlett’s test of Sphericity. For barriers to optimal skin care KMO = 0.874 and Bartlett’s Test of Sphericity was significant ($\chi^2$ (78) = 573.18, p=<0.001). Also, for potential facilitators to optimal skin care KMO =0.78, and Bartlett’s Test of Sphericity was significant ($\chi^2$ (21) = 316.48, p=<0.001). All of the above results show
the structure of the questionnaire measures the intended outcome and measures this consistently, thus indicating sufficient validity and reliability of the survey.

7.3.2 Study Procedures

The researcher collaborated with the ICU nurse unit manager (NUM) of the study site who provided a list of all RNs who worked in the ICU. The researcher then made personal contact with each RN, providing a copy of the study information sheet detailing the overview and purpose of the study. Participation in this survey was voluntary.

7.3.3 Data Analysis

Descriptive statistical and correlation statistical methods were performed using SPSS (version 21; SPSS, Chicago, IL). Differences between both groups were analyzed using an independent t-test, Analysis of Variance (ANOVA), Mann-Whitney U test or χ² test depending on the measurement level of the appropriate outcome variable; p-values ≤0.05 were deemed statistically significant. Multiple regression analysis was used to predict any barriers or facilitators that influence RNs’ ability in PU preventive care.

The survey included 2 open-ended questions to provide opportunities for additional comment. Narrative responses were analyzed and reviewed using thematic analysis. This approach comprised of 6 steps: familiarization with the data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report (Braun & Clarke, 2006).
Scores from negative statements in the APuP were inverted to obtain a cumulative score recommended for measurement of registered nurse’s attitude toward PU prevention (Beeckman et al., 2010). In addition, multinominal regression and correlation analyses were used to detect any association between the demographic variable and RNs attitude subscale.

### 7.4 RESULTS

Of the 60 ICU nurses, 56 nurses participated in this study. The majority were female (80.4%) and 50% held a bachelor’s degree in nursing. Table 7.1 summarizes their demographic characteristics.

<table>
<thead>
<tr>
<th>Table 7.1 Demographic Characteristics of Study’s Participants (N = 56)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n (%)</strong></td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>Diploma</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
</tr>
<tr>
<td>Master’s degree</td>
</tr>
<tr>
<td>Years practicing as an RN</td>
</tr>
<tr>
<td>Years practicing in a Critical Care Unit</td>
</tr>
<tr>
<td>Years employed in hospital</td>
</tr>
<tr>
<td>* = Standard Deviation</td>
</tr>
</tbody>
</table>

The majority of participants had a positive attitude toward PU prevention strategies as shown by the mean score of 38.19 out of 52 possible points (73.44%, Table 7.2). The impact subscale of the APuP, which reflects how RNs’ perceive the consequences of PUs on patients and society and the expectation of the quality of PU prevention care provided, had the lowest score in comparison to other subscales (μ=8.19/12, 68%). Similarly, mean priority subscale were also low (μ=8.28/12,
69%), meaning RNs considered PU prevention care as a secondary priority in their daily routine work. No significant differences were found between demographic characteristics of the participants and the APuP attitude subscale.
Table 7.2 RNs Attitudes toward PU Prevention in the ICU

<table>
<thead>
<tr>
<th>Variable</th>
<th>SD^a n (%)</th>
<th>D^b n (%)</th>
<th>A^c n (%)</th>
<th>SA^d n (%)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1: Personal competency to prevent pressure ulcers (3 items) (maximum score=12)</td>
<td>9.30 (1.69)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F1.1 (+)^f I feel confident in my ability to prevent PU</td>
<td>2 (3.6)</td>
<td>6 (10.7)</td>
<td>26 (46.4)</td>
<td>22 (39.3)</td>
<td>3.21</td>
</tr>
<tr>
<td>F1.2. (+)^f I am well trained to prevent PU</td>
<td>1 (1.8)</td>
<td>14 (25)</td>
<td>16 (28.6)</td>
<td>25 (44.6)</td>
<td>3.16</td>
</tr>
<tr>
<td>F1.3. (-)^f PU is too difficult. Other are better than I am</td>
<td>12 (21.4)</td>
<td>31 (55.4)</td>
<td>10 (17.9)</td>
<td>3 (5.4)</td>
<td>2.93</td>
</tr>
<tr>
<td>F2: Priority of PU prevention (three items) (maximum score=12)</td>
<td>8.28 (1.55)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F2.1. (-)^b Too much attention goes to the prevention of PU</td>
<td>1 (1.8)</td>
<td>8 (14.3)</td>
<td>35 (62.5)</td>
<td>12 (21.4)</td>
<td>1.96</td>
</tr>
<tr>
<td>F2.2. (-)^f PU prevention is not that important</td>
<td>29 (51.8)</td>
<td>16 (28.6)</td>
<td>6 (10.7)</td>
<td>5 (8.9)</td>
<td>3.23</td>
</tr>
<tr>
<td>F2.3. (+)^f PU prevention should be a priority</td>
<td>6 (10.7)</td>
<td>9 (16.1)</td>
<td>15 (26.8)</td>
<td>26 (46.4)</td>
<td>3.09</td>
</tr>
<tr>
<td>F3: Impact of PU (three items) (maximum score=12)</td>
<td>8.19 (1.49)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F3.1. (-)^f A PU almost never cause discomfort for a patient.</td>
<td>26 (46.4)</td>
<td>15 (26.8)</td>
<td>11 (19.6)</td>
<td>4 (7.1)</td>
<td>3.12</td>
</tr>
<tr>
<td>F3.2. (-)^f The impact of PU on a patient should not be exaggerated</td>
<td>16 (28.6)</td>
<td>12 (21.4)</td>
<td>24 (42.9)</td>
<td>4 (7.1)</td>
<td>2.71</td>
</tr>
<tr>
<td>F3.3. (+)^e The financial impact of PU on society should not be exaggerated</td>
<td>13 (23.2)</td>
<td>16 (28.6)</td>
<td>21 (37.5)</td>
<td>6 (10.7)</td>
<td>2.36</td>
</tr>
<tr>
<td>F4: Responsibility in PU prevention (two items) (maximum score=8)</td>
<td>6.34 (1.47)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F4.1. (-)^f I personally feel not responsible if a PU develops in my patient</td>
<td>23 (41.1)</td>
<td>18 (32.1)</td>
<td>10 (17.9)</td>
<td>5 (8.9)</td>
<td>3.05</td>
</tr>
<tr>
<td>F4.2. (+)^e I personally have an important task in PU prevention</td>
<td>3 (5.4)</td>
<td>3 (5.4)</td>
<td>25 (44.5)</td>
<td>25 (44.5)</td>
<td>3.28</td>
</tr>
<tr>
<td>F5: confidence in the effectiveness of prevention (two items) (maximum score=8)</td>
<td>6.07 (1.50)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F5.1. (+)^e PUs are preventable in high risk patients</td>
<td>7 (12.5)</td>
<td>13 (23.2)</td>
<td>17 (30.4)</td>
<td>19 (33.9)</td>
<td>2.86</td>
</tr>
<tr>
<td>F5.2. (-)^f PUs are never preventable</td>
<td>28 (50)</td>
<td>16 (28.6)</td>
<td>8 (14.3)</td>
<td>4 (7.1)</td>
<td>3.21</td>
</tr>
<tr>
<td>Total attitude score (maximum score=52)</td>
<td>38.19 (5.67)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: PU = pressure ulcer.

^a= Strongly Disagree, ^b= Disagree, ^c= Agree, ^d=Strongly Agree, ^e=Positive statement, ^f=Negative statement
Results also indicated that RNs reported a moderate level of ability to overcome barriers related to the implementation of evidence for optimal skin care ($\mu = 5.02 \pm 2.60$). Table 7.3 presents an overview of the barriers perceived by the participants for optimal skin care delivery. Participants rated time demands as the highest barrier ($\mu=6.16 \pm 2.078$). Further, insufficient resources and expertise, patient’s severity of illness, insufficient equipment, lack of authority to implement change, low priority by medical staff, and lack of patient/family cooperation were moderate barriers to optimal skin care. These items all had mean scores of between 4 out of 10 and 4.86 out of 10.

Table 7.3 Overview of the Barriers for PU Prevention Implementation (N = 56)

<table>
<thead>
<tr>
<th>Variable</th>
<th>$M (SD)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to overcome barriers</td>
<td>5.02 (2.60)</td>
</tr>
<tr>
<td>Insufficient resources/expertise</td>
<td>4.86 (2.57)</td>
</tr>
<tr>
<td>Demand of time</td>
<td>6.16 (2.08)</td>
</tr>
<tr>
<td>Patient's severity of illness</td>
<td>4.59 (2.65)</td>
</tr>
<tr>
<td>Insufficient equipment</td>
<td>4.55 (2.90)</td>
</tr>
<tr>
<td>Lack of authority to change</td>
<td>4.46 (2.35)</td>
</tr>
<tr>
<td>Low priority by medical staff</td>
<td>4.25 (3.05)</td>
</tr>
<tr>
<td>Patient/Family lack of cooperation</td>
<td>4.11 (2.46)</td>
</tr>
<tr>
<td>Low priority by nursing staff</td>
<td>4 (2.43)</td>
</tr>
<tr>
<td>Limitation of RN ability</td>
<td>3.89 (2.73)</td>
</tr>
<tr>
<td>Limitation of RN knowledge</td>
<td>4.84 (3.26)</td>
</tr>
<tr>
<td>Current documentation format</td>
<td>3.79 (2.36)</td>
</tr>
<tr>
<td>Low priority by RN</td>
<td>3.48 (2.49)</td>
</tr>
</tbody>
</table>

Multiple regression analysis was conducted to examine if these barriers predicted RNs ability to overcome barriers in the ICU (Table 7.4). The model was statistically significant ($F(12, 43) = 3.57$, $p=0.001$, $R^2=0.51$). Analysis revealed that items related to time demands ($\beta =0.388$, $p=0.011$), limitation of RNs knowledge ($\beta$
=-0.632, p=0.022), and current documentation format (β =0.344, p=0.046) were statistically significantly associated with RNs ability to provide optimal skin care, as measured by self-report.

Table 7.4 Multiple Regression Analysis for Variables Predicting the Ability of RNs to Overcome Barriers

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demand on time</td>
<td>0.486</td>
<td>0.183</td>
<td>0.388</td>
<td>0.011</td>
</tr>
<tr>
<td>Limitation of RN ability</td>
<td>0.200</td>
<td>0.260</td>
<td>0.210</td>
<td>0.445</td>
</tr>
<tr>
<td>Limitation of RN knowledge</td>
<td>-0.505</td>
<td>0.212</td>
<td>-0.632</td>
<td>0.022</td>
</tr>
<tr>
<td>Low priority by medical staff</td>
<td>-0.188</td>
<td>0.201</td>
<td>-0.219</td>
<td>0.357</td>
</tr>
<tr>
<td>Low priority by nursing staff</td>
<td>0.218</td>
<td>0.292</td>
<td>0.204</td>
<td>0.458</td>
</tr>
<tr>
<td>Low priority by RN</td>
<td>0.176</td>
<td>0.239</td>
<td>0.168</td>
<td>0.466</td>
</tr>
<tr>
<td>Current documentation format</td>
<td>0.379</td>
<td>0.184</td>
<td>0.344</td>
<td>0.046</td>
</tr>
<tr>
<td>Insufficient resources/expertise</td>
<td>0.269</td>
<td>0.243</td>
<td>0.266</td>
<td>0.273</td>
</tr>
<tr>
<td>Insufficient equipment</td>
<td>-0.078</td>
<td>0.158</td>
<td>-0.087</td>
<td>0.623</td>
</tr>
<tr>
<td>Patient's severity of illness</td>
<td>-0.277</td>
<td>0.168</td>
<td>-0.282</td>
<td>0.107</td>
</tr>
<tr>
<td>Patient/Family lack of cooperation</td>
<td>0.001</td>
<td>0.197</td>
<td>0.001</td>
<td>0.994</td>
</tr>
<tr>
<td>Lack of authority to change</td>
<td>0.182</td>
<td>0.190</td>
<td>0.164</td>
<td>0.343</td>
</tr>
</tbody>
</table>

7.4.1 Thematic Analysis

Thematic analysis of open-ended questions related to the barriers towards PU prevention in ICU revealed a broad and over-arching theme we have labelled, impact of workload. Participants in this study identified increased workload as directly influencing their ability to implement PU prevention care. One participant stated, “We are so busy, and don’t have enough staff to provide optimal care.”

Participants further noted that education played an important part in providing optimal care, particularly in informing staff about current PU prevention approaches. Responses indicated that increased awareness and training could help RNs provide
high quality care for PU prevention in ICU. As one respondent noted, “As we are busy, I don’t have time to know and learn new things about PU.”

7.4.2 Facilitators Assisting in Evidence Implementation

Participants indicated that education about pressure ulcer grading and ease of obtaining pressure redistribution surfaces were the 2 most helpful facilitators to delivering PU preventive care. The mean scores of 6.45 and 6.29 out of 10 indicate these factors act as moderately helpful facilitators (See Table 7.5).

Table 7.5 Overview of the Facilitators for PU Prevention Implementation (N = 56)

<table>
<thead>
<tr>
<th>Variable</th>
<th>M (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education about PU grading</td>
<td>6.45 (2.49)</td>
</tr>
<tr>
<td>Ease of obtaining pressure reduction surfaces</td>
<td>6.29 (2.34)</td>
</tr>
<tr>
<td>Current documentation format</td>
<td>5.80 (2.47)</td>
</tr>
<tr>
<td>Education about Braden risk assessment scale</td>
<td>5.68 (2.81)</td>
</tr>
<tr>
<td>Interdisciplinary team collaboration</td>
<td>5.54 (3.34)</td>
</tr>
<tr>
<td>Availability of appropriate skin care products</td>
<td>5.16 (3.58)</td>
</tr>
<tr>
<td>Efforts are being made to facilitate your ability to prevent PU</td>
<td>5.46 (2.79)</td>
</tr>
</tbody>
</table>

Multiple regression analysis was also calculated to evaluate whether these facilitators could predict RNs’ perceived ability to prevent PU development in ICU. The model was statistically significant (F(6,49)=32.552, p=<0.001, R^2 = 0.799). Statistically significant facilitators that increased RNs ability to undertake PU preventive interventions in the ICU were ease of obtaining pressure reduction surfaces (β=-0.388, p=0.007), collaboration with interdisciplinary teams
(nursing/medicine/pharmacy/dietary) (β=0.37, p=0.02), and availability of appropriate
skin care products (β=0.44, p=0.015, Table 7.6).

Table 7.6 Multiple Regression Analysis for Variables Facilitating the Ability of RNs toward PU Prevention

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education about PU grading</td>
<td>-0.03</td>
<td>0.13</td>
<td>-0.03</td>
<td>0.80</td>
</tr>
<tr>
<td>Current documentation format</td>
<td>0.07</td>
<td>0.09</td>
<td>0.06</td>
<td>0.45</td>
</tr>
<tr>
<td>Ease of obtaining pressure reduction surfaces</td>
<td>-0.40</td>
<td>0.14</td>
<td>-0.34</td>
<td>0.007</td>
</tr>
<tr>
<td>Team Collaboration</td>
<td>0.31</td>
<td>0.13</td>
<td>0.37</td>
<td>0.02</td>
</tr>
<tr>
<td>Availability of appropriate skin care products</td>
<td>0.34</td>
<td>0.13</td>
<td>0.44</td>
<td>0.015</td>
</tr>
</tbody>
</table>

7.5 DISCUSSION

Participants had a positive attitude toward PU prevention. Multiple studies
have been conducted that found that a positive attitude toward a particular area was
positively associated with provision of high quality nursing care (Fishbein & Ajzen,
argued that RNs’ negative attitudes toward an issue (i.e., PU prevention) may
contribute to increased non-compliance, which may lead to a higher ICU acquired PU
prevalence rate.

Nevertheless, we also found that participants identified PU prevention care as
a lower priority in their daily routine care, thus creating a potential where evidence
based PU prevention strategies may be neglected in favor of other interventions
deemed more important to immediate care needs. This finding is supported by other
studies where registered nurses ranked PU prevention lower in importance than other
nursing care tasks (Buss et al., 2004; Moore & Price, 2004; Strand et al., 2010). While
the care in intensive care predominantly focuses on the disorders that necessitated admission to a critical care unit, skin assessment must be incorporated in the initial overall patient assessment and in their ongoing care (Australian Wound Management Association, 2012; European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009).

In addition to a lower prioritization for PU preventive interventions, we found that RNs’ attitude was that PUs have a low impact on patients and society. Beeckman et al. (2010) suggest a positive association between the APuP subscales of patient and societal impact and quality of care provided towards PU prevention.

Respondents’ indicated that time was the most significant barrier to implementation of evidence based PU preventive interventions. This finding is consistent with others who reported that lack of staff time impedes the implementation of PU preventive interventions (Jankowski & Nadzam, 2011; Mwebaza et al., 2014; Strand et al., 2010). Nevertheless, quantifying the time needed for PU prevention within the context of a clinical workload is difficult. Time in the clinical practice setting is typically quantified as minutes or hours. Thompson et al. (2008) suggested being “time poor” also incorporates mental time; the energy required for RNs to implement evidence and the culture of busyness. As a result, environmental factors more profoundly influence our concept of time as much as a quantifiable unit of time such as minutes or hours (McCaughan et al., 2002; Thompson et al., 2008). Nurses who indicate a lack of time as a barrier to implementing PU prevention interventions actually may be basing their perceptions on factors that are not directly related to a unit of time such as lack of experience, low confidence, or difficulty problem solving (Thompson et al., 2008). Our study findings suggest that environmental and personal factors should be addressed to enhance adherence to PU preventive interventions.
We found that participants’ self-identified lack of knowledge about PU preventive interventions also influenced implementation of these actions in daily practice. Lack of knowledge among critical care nurses has been barrier to effective PU prevention in previous studies (Buss et al., 2004; Chang, Russell, & Jones, 2010; Mwebaza et al., 2014; Qaddumi & Khawaldeh, 2014). Numerous factors have been identified that may contribute to lower levels of RNs’ knowledge such as staffing shortages, limited availability of clinical instructor/or nurse educators in the clinical area, and high staff turn-over rates (Grol & Grimshaw, 2003; Hulsenboom, Bours, & Halfens, 2007; Moore & Price, 2004; Qaddumi & Khawaldeh, 2014). Several studies suggest that increased awareness, and regular training, and availability of current clinical practice guidelines may positively influence adoption of PU preventive interventions in the critical care setting (Hulsenboom et al., 2007; Qaddumi & Khawaldeh, 2014). Therefore, the availability of clinical instructors and the addressing of all the factors above may enhance the implementation of up-to-date evidence in PU prevention in the SA ICU.

Analysis found that the ICU documentation format was not perceived as a barrier to implementation of PU prevention care. This contrasts to previous work suggesting documentation is a barriers for implementation of PU preventive interventions (Al Kharabsheh, & Saleh, 2014). However, these data must be interpreted with caution because the research site hospital PU documentation tool was limited to site and grade (stage) of PU, wound size, and weekly follow-up assessment for PU. International PU prevention guidelines recommended documentation should be more comprehensive and include comprehensive skin assessment on admission, daily skin assessment, risk assessment scores, and positioning regimes to promote RNs
communication and continuity of patient care (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009).

Collaboration with an interdisciplinary team was seen as a facilitator to implementation of evidence based PU preventive interventions. This result is consistent with previous studies (Dalheim et al., 2012; Jankowski & Nadzam, 2011). Ease of obtaining pressure relieving devices and availability of appropriate skin care products are facilitating factors were also identified as facilitating PU preventive care (Mwebaza et al., 2014; Qaddumi & Khawaldeh, 2014). However, availability of resources without an informed knowledge base is not adequate for maintaining effective PU prevention and management (Jankowski & Nadzam, 2011).

7.6 LIMITATIONS

We acknowledge limitations in the external validity of results owing to design elements. The sample size was drawn from a single location. Additional limitations include reliance on self-report for some study findings as compared to direct observation of RN practice.

7.7 CONCLUSIONS

Recognizing and identifying factors which impact on evidence implementation in pressure ulcer prevention strategies is the first step in moving toward translation, adoption, and dissemination of PU prevention evidence. Key findings from this study highlight that RNs in our ICU have a positive attitude towards PU prevention. Moreover, PU prevention was facilitated by the availability of pressure relieving
support surfaces and appropriate skin care products, and collaboration between the healthcare professional team. However, barriers impeding the implementation of PU prevention strategies were identified as RNs lack of knowledge on this topic and demands of a high workload.

7.8 ACKNOWLEDGMENT

Thanks are extended to all ICU staff of the hospital for their participation. Doctoral scholarship provided to the first author by the Ministry of Higher Education, Umm Al-Qura University, SA is also gratefully acknowledged.

7.9 KEY POINTS

- Understanding and addressing factors that could impede or facilitate pressure ulcer (PU) prevention strategies is important for successful translation of research findings.
- Positive attitude of registered nurses towards PU prevention is a motivational factor for facilitating implementation PU prevention strategies.
- The most frequently cited perceived barriers to PU prevention evidence implementation were related to workload, insufficient knowledge, and time demands.
- The most important facilitators assisting implementation of PU prevention evidence were ease of obtaining pressure reduction surfaces, collaboration with interdisciplinary teams, and availability of appropriate skin care products.
7.10 REFERENCES


http://qut.summon.serialssolutions.com/link/0/eLvHCXmwQ4wAwMqDxPR0IooDYL0KumUDPK-

OG1pDKuvdRBnk3FxDnD10YWWmEpOTjywh2JqZgms5QwN-a6wePzVPOQ4flpxSKb-vZrzAEzpKlM


Chapter 8: (Article 5) A Two-Arm Cluster Randomised Control Trial to Determine the Effectiveness of a Pressure Ulcer Prevention Bundle for Critically Ill Patients

This chapter includes the following article:


This article presents the findings of Phase Two of this study. This chapter represents Phases 4-6 of the OMRU model, which belong to the monitoring and evaluation category. In the previous chapters, incidence and barriers and facilitator studies, workload, and equipment were identified as barriers to PU prevention. It was beyond the scope of this study to address nursing workload or the departments equipment. Therefore, the intervention, the PU prevention bundle, targeted skin and risk assessment, skin care, repositioning, and medical devices related ulcers, and education and training.

The aim of this paper was to test the effectiveness of a PU prevention bundle in reducing incidence of PUs in critically ill patients in a KSA ICU. The research hypotheses were: (a) KSA ICU patients who received the PU prevention bundle would have a decreased PU incidence of 25% or greater when compared to patients who received standard care; and (b) KSA ICU patients who received the PU prevention bundle would have fewer numbers of PUs/patient, and full thickness PUs (Stage II to
IV) compared to those patients who received standard care. Moreover, the study aimed to evaluate the process of care with implementation of the PU prevention bundle.

This article answers research questions 10-15:

**Research Question 10**: Does a PU prevention bundle reduce the cumulative incidence of PU development in critically ill patients in the intensive care unit of a KSA tertiary referral hospital?

\[ H_0: \text{There is no difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care.} \]

**Research Question 11**: Does a PU prevention bundle decrease the cumulative PU incidence by 25% or greater when compared to standard hospital care?

\[ H_0: \text{The difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care was less than 25%}. \]

**Research Question 12**: Will patients who receive a PU prevention bundle develop PU later in their intensive care unit stay?

\[ H_0: \text{There is no significant difference in a delayed time to PU development with implement the PU prevention bundle.} \]

**Research Question 13**: Will patients who receive the PU prevention bundle have fewer numbers of PUs per patient during their ICU stay?

\[ H_0: \text{There is no significant difference in number of PU per patients with implement the PU prevention bundle during the ICU stay.} \]

**Research Question 14**: Will patients who receive the PU prevention bundle have fewer full thicknesses PUs (Stage III and IV)?
\(H_0\): There are no significant differences in full thicknesses PUs (Stage III and IV) with implement the PU prevention bundle.

**Research Question 15:** Does the PU prevention bundle increase the adherence to the process of care compared to the hospital standard skin care?

The publication adds to the existing body of literature by providing evidence that a bundle of best available evidence to prevent PU development in the ICU context is effective. Moreover, findings showed that standardisation, through the bundle approach, improved implementation and adoption of new practices in the clinical setting.

Findings from this phase were published in the *Journal of Nursing Scholarship*, as the results from this study were able to contribute to the quality of nursing practice and patient safety. The *Journal of Nursing Scholarship* has an impact factor of 1.636. The chapter is presented according to the style guidelines of the journal; using the American Psychological Association (APA), (6th ed) referencing style and American English spelling. Tables and figures are presented at the end of the publication according to the respective journal submission guidelines. The article has been cited three times in Google scholar.

The findings of this phase of the study were also presented at the following conferences:

**Symposium of Advance Wound Care. Las Vegas, Nevada, USA, October 2014.**

“A pressure ulcer prevention care bundle and its impact on pressure ulcer incidence in critical care: randomized control trial”
The 11th Emirates Critical Care Conference in conjunction with the 7th Asia Africa Conference of the World Federation of Societies of Intensive and Critical Care Medicine, the 11 International Pan Arab Critical Care Medicine Society Conference, and the 2nd Middle East Surviving Sepsis Campaign Meeting. Dubai, UAE, April 2015.

“Testing the efficacy of a pressure ulcer prevention bundle to improve the skin integrity of ICU patients”
A Two-Arm Cluster Randomized Control Trial to Determine the Effectiveness of a Pressure Ulcer Prevention Bundle for Critically Ill Patients


8.1 ABSTRACT

**Purpose:** This study tested the effectiveness of a pressure ulcer (PU) prevention bundle in reducing the incidence of PUs in critically ill patients in two Saudi intensive care units (ICUs).

**Design:** A two-arm cluster randomized experimental control trial.

**Methods:** Participants in the intervention group received the PU prevention bundle, while the control group received standard skin care as per the local ICU policies. Data collected included demographic variables (age, diagnosis, comorbidities, admission trajectory, length of stay) and clinical variables (Braden Scale score, severity of organ function score, mechanical ventilation, PU presence, and staging). All patients were followed every two days from admission through to discharge, death, or up to a maximum of 28 days. Data were analysed with descriptive correlation statistics, Kaplan-Meier survival analysis, and Poisson regression.

**Findings:** The total number of participants recruited was 140: 70 control participants (with a total of 728 days of observation) and 70 intervention participants (784 days of observation). PU cumulative incidence was significantly lower in the intervention group (7.14%) compared to the control group (32.86%). Poisson regression revealed the likelihood of PU development was 70% lower in the
intergroup. The intervention group had significantly less Stage I ($p = .002$) and Stage II PU development ($p = .026$).

**Conclusions:** Significant improvements were observed in PU-related outcomes with the implementation of the PU prevention bundle in the ICU; PU incidence, severity, and total number of PUs per patient were reduced.

**Clinical Relevance:** Utilizing a bundle approach and standardized nursing language through skin assessment and translation of the knowledge to practice has the potential to impact positively on the quality of care and patient outcome.

**Keywords:** Bundle care, incidence, intensive care, pressure ulcer.
8.2 INTRODUCTION

Critically ill patients who are managed in an intensive care unit (ICU) may experience multiple physiological changes that relate directly to their illness and possibly even care (Vollman, 2010). Many ICU patients are mechanically ventilated and sedated and therefore unable to move or change position themselves. Further, the patients’ critical illness may involve hemodynamic instability, which potentially may complicate and accelerate the effects of prolonged immobility. As mobility is a natural defense to alleviate prolonged pressure on the skin (Shahin, Dassen, & Halfens, 2008), extensive exposure to pressure, from lying or sitting, on a specific part of the body renders patients at greater risk for skin breakdown. Therefore, ICU patients are at high risk for impaired skin integrity, particularly pressure ulcer (PU) development.

PUs have been identified as a worldwide problem that contribute significantly to increasing healthcare costs, the compromising of an individual’s health, morbidity, and, in some cases, mortality (Vollman, 2010). The prevalence worldwide of PUs in the ICU remains high and is documented between 3% and 50% (Berlowitz, 2014; Elliott, McKinley, & Fox, 2008). A recent Saudi Arabian study indicates PU incidence rate to be 39.3% (Tayyib, Coyer, & Lewis, 2015), which when compared with other international incidences is high (Gunningberg, Donaldson, Aydin, & Idvall, 2012; Stotts, Brown, Donaldson, Aydin, & Fridman, 2013). It is clear there is a need for examination of current ICU skin care practices in this complex practice environment.

For the most part, PUs are predictable and preventable and are thus a priority patient safety and risk management issue. Evidence suggests that PUs could be prevented with the implementation of PU guidelines or a care bundle (Gray-Siracusa & Schrier, 2011). Robb et al. (2010) suggest that the care bundle approach is more effective than clinical guidelines. This may be because of the mandatory and audited
nature of care bundles, whilst clinical guidelines are regarded as advisory. The term care bundle refers to the implementation of a set of three to six mandatory interventions that are targeted toward a specific procedure, symptom, or treatment (Horner & Bellamy, 2012). A care bundle approach has been frequently used in clinical practice, as it provides improvement in the delivery of evidence-based care and results in patient outcomes (Horner & Bellamy, 2012).

While a number of studies reveal a positive link between the care bundle and patient outcomes in the ICU (Baldelli & Paciella, 2008; Gillespie, 2007), PU prevention guidelines/bundles for intensive care patients are not well defined. The intensive care context poses special challenges to preventing PU development due to the high acuity of patients and the highly invasive nature of interventions and therapies that critically ill patients receive. The development of any comprehensive and effective PU prevention guideline or bundle should be based on up-to-date, high-quality evidence related to the core components of those guidelines as well as the usage of advanced technological, contextually compatible measures for reducing the incidence of PUs.

Some individual PU prevention strategies have a positive impact in the reduction of PU development. Successful individual strategies include: a comprehensive examination and assessment of the patient’s skin (Revello & Fields, 2012); assessment of risk using a validated risk assessment scale and implementation of intervention strategies based on risk (Guy, 2012); implementation of strategies such as pressure-relieving devices (Manzano et al., 2013); regular repositioning as per patient need (Vanderwee, Grypdonck, De Bacquer, & Defloor, 2007); assessment of and regular repositioning and resecurement of medical devices (Coyer, Stotts, &
Blackman, 2014); and particular strategies to address high-risk sites for PU development (i.e., sacrum and heels) (Reilly, Karakousis, Schrag, & Stawicki, 2007). These strategies can be grouped together in a bundle to reduce the incidence of PU development for critically ill patients in the ICU.

Given the high PU incidence in Saudi Arabia, and the evidence that suggests the benefits of a PU prevention bundle, use of a PU prevention bundle in the Saudi ICU context is likely to improve patient outcomes and reduce the morbidity and mortality rates of ICU patients. This study will evaluate the effectiveness of a PU prevention bundle in a Saudi ICU.

### 8.3 AIM

The aim of this study was to test the effectiveness of a PU prevention bundle in reducing incidence of PUs in critically ill patients in a Saudi ICU. The research hypotheses are: (a) Saudi ICU patients who receive the PU prevention bundle will have a decreased PU incidence of 25% or greater when compared to patients who receive standard care, and (b) Saudi ICU patients who receive the PU prevention bundle will have fewer full thickness PUs (Stage II to IV) compared to those patients who receive standard care.

### 8.4 METHODS

#### 8.4.1 Study Design

The design for this study is a two-arm cluster randomized experimental control trial. A two-arm trial can be used to evaluate a single intervention against control;
however, this design only provides limited information about the effectiveness of the intervention within a single setting (Grimshaw, Campbell, Eccles, & Steen, 2000).

8.4.2 Setting and Participants

Data were collected during October 2013 to February 2014 across two Saudi Arabian tertiary referral hospital ICUs. ICUs are specialist areas that deliver complex multisystem support for adults needing comprehensive intensive care and monitoring by specialist care staff. Patients admitted to both hospital ICUs have similar high acuity and medical diagnoses, including cardiovascular illness, respiratory diseases, cancer, renal dysfunction, burns, sepsis, and multi-trauma injuries such as head injury. Each ICU was staffed with approximately 60 registered nurses (RNs). All RNs who provide care for ICU patients have tertiary qualifications, the minimum being a bachelor of nursing degree with many also having a diploma in nursing. For both hospitals the ICU staffing ratio is one nurse to two or three mechanically ventilated patients and one charge nurse per shift for each of the three 8-hr shifts per day. In both hospitals the RN in charge of the ICU was not always supernumerary and sometimes provided care for two patients.

All participants who were admitted during the study collection period were included in the study if they were 18 years of age or older and were expected to stay in the ICU for more than 24 hr. Those excluded were patients admitted to the ICU with an existing PU, those with a medical condition that contraindicated the bundle intervention, and those diagnosed with any stage PU in the first 24 hr of admission to the ICU.
8.4.3 Sample Size

Sample size was calculated based on the PU incidence of 39.3% in both centers from a previous prospective study (Tayyib et al., 2015). Therefore, the effective sample size to detect a difference in PU incidence by 25% or greater with 80% power, significance criterion of \( p =<.05 \), and assuming two-tailed statistical analyses was 48 persons per group (Eng, 2003).

8.4.4 Intervention: PU Prevention Bundle

The PU prevention bundle was designed to reduce PU incidence or severity, to be suitable for RNs to deliver, and to fit within the care delivery structure of the ICUs. The intervention (a PU prevention bundle) was a bundle of best available evidence based on the latest international guidelines for PU prevention (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel [EPUAP & NPUAP], 2009) allied with PU prevention strategies related to medical devices. These guidelines were modified and interpreted for the ICU context. The key aspects of the PU prevention bundle were risk assessment, skin assessment, skin care, nutrition, repositioning, support surface, education and training, and care of medical devices (Table 8.1).
Table 8.1 The Pressure Ulcer (PU) Prevention Bundle for Critically Ill Patients

<table>
<thead>
<tr>
<th>Intervention</th>
<th>The PU prevention bundle</th>
<th>Standard care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk assessment</td>
<td>Completion and documentation of Braden risk assessment scale within 24 hours of ICU admission and daily thereafter.</td>
<td>No PU risk assessment scale used</td>
</tr>
<tr>
<td>Skin assessment</td>
<td>Physical assessment of the patient’s skin is undertaken and documented within 4 hours of admission and every 8 hours thereafter. Loss of skin integrity assessed (and documented) using the PU staging tool, noting site, size, depth, and if any exudates are present.</td>
<td>Physical assessment of the patient’s skin completed and documented within 24 hours of admission and once daily thereafter. No requirement for documentation. Loss of skin integrity assessed (and documented) using local hospital PU documentation tool. No documentation required for Stage I PUs.</td>
</tr>
<tr>
<td>Skin care:</td>
<td>Patients bed-bathed once per day using a pH balanced cleansing agent (pre-package washcloth). Skin treated with a topical moisturiser.</td>
<td>Once a day bed-bath using antiseptic soap containing 2% hydrogen peroxide. Moisturiser applied at discretion of RN.</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Nutritional status assessment is undertaken by the clinical nutritionist on admission</td>
<td>Nutritional status assessment is undertaken by the clinical nutritionist on admission</td>
</tr>
<tr>
<td>Repositioning</td>
<td>Patients repositioned using a three hourly turning schedule using a ‘turn clock’. Foot of the bed elevated by 20 degrees if clinically permitted. Patient's heels are elevated and supported. Drawsheets used to transfer and lift patients Where clinically possibly patients are mobilised daily to sit out of bed on chair. Position documented including the time of repositioning and position adopted.</td>
<td>Patients repositioning two hourly as per ICU policy Foot of the bed elevated by 20 degrees if clinically permitted. There was no policy for heel elevation. There is no policy for use drawsheet or any lifting devices. There is no policy to mobilize patient out of bed.</td>
</tr>
<tr>
<td>Support surface</td>
<td>All ICU patients were managed on air mattresses</td>
<td>All ICU patients were managed on air mattresses</td>
</tr>
<tr>
<td>Intervention</td>
<td>The PU prevention bundle</td>
<td>Standard care</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Education and training</td>
<td>RNs educated in the conduct of accurate and reliable Braden Scale Score risk assessment.</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>All ICU health practitioners, especially RNs, educated on targeted bundle elements of PU prevention (e.g. risk assessment, the role of repositioning in PU prevention, correct methods for patient repositioning and use of equipment in reducing pressure, friction and shear forces).</td>
<td>Educated RNs during the orientation period of new ICU staff regarding PU prevention strategies (e.g. positioning policy every 2 hours, PU stages, and PU documentation).</td>
</tr>
<tr>
<td>MDRPU</td>
<td>Assessment of skin around/underneath medical devices every 12 hours. Securement and repositioning of Nasogastric tubes (NGT) and endotracheal tubes (ETT) as per techniques outlined in the study bundle.</td>
<td>Resecurement of NGT and ETT daily during patient bed bath. There is no policy for skin assessment around/underneath medical devices, repositioning and resecurement of NGT or ETT.</td>
</tr>
</tbody>
</table>
8.4.5 Measurements

Data were gathered using a baseline patient survey including demographic and clinical data, and second daily patient data collection, including Braden risk assessment scale score, Sequential Organ Failure Assessment (SOFA) score, a skin assessment tool, and PU staging. Further, processes of care (i.e., bundle delivery) were measured. Data collection tools were revised by a panel of six expert nurses.

Baseline patient survey

Participant demographic information collected was age, sex, nationality, body mass index (BMI), clinical data included diagnosis on admission, comorbidities, length of time in operating theatre or emergency department prior to ICU admission if applicable, mechanical ventilation (yes or no), ICU length of stay in days, and ICU outcome (discharge to ward or death).

Second daily patient data collection

Skin Assessment Tool

A tool to record a standardized approach to skin examination and assessment was designed by the researchers using a standard physical assessment technique and common areas for PU development (Talley & O’Connor, 2014).

PU staging

PUs were defined and staged according to EPUAP and NPUAP (2009) criteria. PUs were identified as skin or mucosal and, if applicable, by cause (i.e., medical-
device related ulcer [MDRU]). Further, PU site was identified on the data collection form by drawing a circle over the relevant area in the body figure.

**Braden Risk Assessment Scale**

The Braden Scale score for predicting PUs reflects the conceptualization of the physiological sequelae of PU development and formation. Accordingly, it is consists of six elements: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. While the first five elements are rated from 1 (*most impaired*) to 4 (*least impaired*), the last item, “friction and shear,” is rated from 1 (*problem*) to 3 (*no problem*). The total possible score is 23 (Smith et al., 1995). Scores were divided into five subcategories: no risk (19–23), at mild risk (15–18), moderate risk (13–14), high risk (10–12), and very high risk (9 or below; Smith et al., 1995).

**SOFA score**

SOFA is a scoring system to determine the extent of the patient’s organ function or rate of failure in the ICU. The score is based on six organ dysfunction or failure scores: respiratory, cardiovascular, hepatic, coagulation, renal, and neurological systems. Each organ is graded from 0 (*normal*) to 4 (*the most abnormal*), providing a daily score of 0 to 24 points. The SOFA score is a more sensitive approach to organ dysfunction development 24 hr after admission to the ICU (Qiao, Lu, Li, Shen, & Xu, 2012).
**Process of care**

RNPs’ process of care performance based on the PU prevention bundle and standard skin care (see Table 9.1) were measured using a checklist for compliance (yes or no).

### 8.4.6 Randomization

Randomization at the patient level was not practical as changes to practice to deliver the bundle required a whole-unit approach (hospital level). To avoid selection and accidental biases, the research sites (hospitals) were randomized to either the intervention or control arm of the study by computer-generated randomization, where one hospital ICU was the intervention arm and the other the control arm. Recruitment and enrollment of the participants is described in a Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 9.1).

### 8.4.7 Blinding

The bundle was implemented at hospital level. Owing to the nature of the bundle, blinding of participants and healthcare providers was not feasible. The researcher with a trained bedside nurse assessed each participant’s skin regularly every 48 hr, to avoid any detection bias and ensure reliability of the PU assessment.

### 8.4.8 Endpoints

The primary endpoint of the study was ICU patient stay up to a maximum of 28 days. A 28-day endpoint was chosen based on the findings of a previous study...
showing mean time to develop a PU was 10.09 days in this patient population (median 9 days, $SD$ 4.6195 days, range 5–23 days; Tayyib et al., 2015). Secondary endpoints were death or discharge from the ICU prior to 28 days.

### 8.4.9 Procedure

Following ethical approval, the researcher attended each ICU every second day (alternating ICUs) to screen, recruit, and collect data using the data collection tools previously discussed. All patients were followed until discharge, death, or up to a maximum of 28 ICU days (study endpoints), whichever occurred first. The intervention required a whole-ICU adoption. Therefore, in the intervention group, the ICU RNs were informed about the study’s PU prevention bundle through in-service, meetings and one-to-one bedside education provided by the researcher. The training and education program consisted of (a) brochures that explain the elements of the PU prevention bundle, present the evidence that supports the bundle, and provide the outcome of the implementation of the bundle in reducing PU incidence in the ICU; (b) a PowerPoint presentation with handout used during in-service; (c) consultation and clarification with the researcher, which continued throughout the study. RNs’ compliance to the intervention was audited monthly and feedback was provided. The control group received usual standard skin care and PU prevention practices guided by the policies and procedures of the ICU (see Table 8.1).

### 8.4.10 Ethical Considerations

Ethical approval to conduct this study was obtained from the Unit of Ethics of the relevant Saudi hospitals, as well as the Queensland University of Technology
Human Research Ethics Committees (1300000341), Australia. Informed written consent was sought from all eligible participants or their family members.

8.4.11 Statistical Methods

Descriptive statistical and correlation statistical methods were performed using SPSS (version 21; SPSS, Chicago, IL, USA). PU cumulative incidence rate was measured using the proportion of participants who developed a new PU within a specific time divided by the total number of participants who were at risk for PU development (Baharestani et al., 2009). Log-rank and Cox proportional hazards analyses were used to compare time to new PU events between the two groups and to determine a hazard ratio. The Poisson regression model was used to compare the incidence rate ratio differences between groups with 95% confidence intervals (CIs). A generalized linear model robust variance estimator was used to account for repeated measures. PU stage differences between groups were analyzed using the chi-square test of independence.

8.5 RESULTS

8.5.1 Characteristics of the Study Populations

Of the 140 patients who met study inclusion criteria when admitted to the study ICUs during the enrolment period, 70 participants were allocated to the control group and had a total of 728 days of observation and 70 participants were allocated to the intervention group and had a total of 784 days of observation (see Figure 8.1). There were no significant differences between either group in all demographic characteristics and all clinical characteristics, with the exception of time in the operation room (Table
8.2). Braden Scale scores showed that the majority of participants in both groups were at high risk for PU development.

Figure 8.1 Consolidate Standards of Reporting Trials [CONSORT] Diagram Presenting the Study Enrolment in both Groups: Control and Intervention
<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=70)</th>
<th>Intervention (n=70)</th>
<th>Test</th>
<th>Sig. (p)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of observation</td>
<td>728</td>
<td>784</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (number, %)</td>
<td>48 (68.6)</td>
<td>50 (71.4)</td>
<td>0.136a</td>
<td>0.712</td>
</tr>
<tr>
<td>Age in years (mean, SD)</td>
<td>52 (19.5)</td>
<td>47.5 (22.5)</td>
<td>-1.383b</td>
<td>0.169</td>
</tr>
<tr>
<td>BMI (mean, SD)</td>
<td>32.1 (31.1)</td>
<td>28 (20.7)</td>
<td>-1.807b</td>
<td>0.073</td>
</tr>
<tr>
<td>Braden scale score (mean, SD)</td>
<td>10.01</td>
<td>10.17 (2.23)</td>
<td>2380.5c</td>
<td>.763</td>
</tr>
<tr>
<td>Length of time in operating theatre in minutes (mean, SD)</td>
<td>43.33</td>
<td>78.12 (45.97)</td>
<td>17.50c</td>
<td>0.018*</td>
</tr>
<tr>
<td>Length of time in emergency department in minutes (mean, SD)</td>
<td>(27.24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comorbidities (number, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>38 (54.2)</td>
<td>27 (38.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin dependent diabetes</td>
<td>29 (41.4)</td>
<td>22 (31.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>15 (21.4)</td>
<td>5 (7.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>37 (52.8)</td>
<td>24 (34.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>19 (27.1)</td>
<td>23 (32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis (number, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>9 (12.9)</td>
<td>17 (24.3)</td>
<td>4.04</td>
<td>0.256</td>
</tr>
<tr>
<td>Medical related illness</td>
<td>42 (60)</td>
<td>40 (57.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-surgery</td>
<td>11 (15.7)</td>
<td>6 (8.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sepsis/Infectious disease</td>
<td>8 (11.4)</td>
<td>7 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU Length of stay in days (mean, SD)</td>
<td>10.4 (7.69)</td>
<td>11.2 (8.8)</td>
<td>2428.5c</td>
<td>0.928</td>
</tr>
<tr>
<td>SOFA Score (mean, SD)</td>
<td>3.7 (1.95)</td>
<td>3.8 (1.76)</td>
<td>2306c</td>
<td>0.548</td>
</tr>
<tr>
<td>Outcome (number, %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU-Discharged</td>
<td>39 (55.7)</td>
<td>41 (58.6)</td>
<td>1.796a</td>
<td>0.407</td>
</tr>
<tr>
<td>ICU up-to 28days</td>
<td>7 (10)</td>
<td>11 (15.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>24 (34.3)</td>
<td>18 (25.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical ventilation (yes)</td>
<td>72.9%</td>
<td>70%</td>
<td>.140a</td>
<td>0.708</td>
</tr>
<tr>
<td>Frequent of repositioning in hours (mean, SD)</td>
<td>3.01 (1.30)</td>
<td>4.67 (2.10)</td>
<td>-8.33b</td>
<td>0.001*</td>
</tr>
</tbody>
</table>

*Note: BMI = Body Mass Index; ICU = Intensive care unit; SOFA = Sequential Organ Failure Assessment. a Pearson Chi-Square test, b t-test, c Mann-Whitney U test, * Significance at p < 0.05
Table 8.3 outlines the demographic features and clinical characteristics of participants who developed a PU whilst in the ICU. Twelve PUs developed in five participants in the intervention group, while 37 PUs developed in 23 participants in the control group. There were no significant differences between groups, with the exception of age, where the mean age of participants in the intervention group (63 years) was significantly higher than that of the control group (56 years; \( t = 0.683, p = .02 \)).
Table 8.3 Demographic and Clinical Characteristics of Patients with Pressure Ulcers (PUs)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=23)</th>
<th>Intervention (n=5)</th>
<th>Test</th>
<th>Sig.(p)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of observation</td>
<td>373</td>
<td>95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (number, %)</td>
<td>16 (69.6)</td>
<td>3 (60)</td>
<td>0.172a</td>
<td>0.678</td>
</tr>
<tr>
<td>Age in years (mean, SD)</td>
<td>55.9 (17.7)</td>
<td>63 (33.9)</td>
<td>0.683b</td>
<td>0.021*</td>
</tr>
<tr>
<td>BMI (mean, SD)</td>
<td>27.56 (5.4)</td>
<td>25.53 (3.55)</td>
<td>-.796b</td>
<td>.488</td>
</tr>
<tr>
<td>Braden scale score</td>
<td>9.5 (.89)</td>
<td>9.2 (.44)</td>
<td>-.772b</td>
<td>.103</td>
</tr>
<tr>
<td>ICU length of stay in days (mean, SD)</td>
<td>16.21 (7.89)</td>
<td>19 (12.3)</td>
<td>51.50c</td>
<td>.71</td>
</tr>
<tr>
<td>SOFA Score (mean, SD)</td>
<td>3.78 (1.2)</td>
<td>3.75 (1.7)</td>
<td>-.057a</td>
<td>.396</td>
</tr>
<tr>
<td>Total number of PUs</td>
<td>37</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of PUs per patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One (number)</td>
<td>12</td>
<td>2</td>
<td>7.937a</td>
<td>.005*</td>
</tr>
<tr>
<td>Two (number)</td>
<td>7</td>
<td>1</td>
<td>4.773a</td>
<td>.029*</td>
</tr>
<tr>
<td>Three (number)</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four (number)</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stages of skin PUs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspected deep injury</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PU Stage I (number)</td>
<td>19</td>
<td>6</td>
<td>1976c</td>
<td>.002*</td>
</tr>
<tr>
<td>PU Stage II (number)</td>
<td>13</td>
<td>5</td>
<td>2172c</td>
<td>.026*</td>
</tr>
<tr>
<td>PU Stage III &amp; IV (number)</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstagable (number)</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDRUs</td>
<td>7</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin ulcer location (number)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elbow</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum</td>
<td>14</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buttock</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel</td>
<td>10</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. BMI = Body Mass Index; ICU = Intensive care unit; MDRU = Medical devices related Ulcer; SOFA = Sequential Organ Failure Assessment. a Pearson Chi-Square test, b t-test, c Mann-Whitney U test, * Significance at p < 0.05
8.5.2 Cumulative PU Incidence

PU cumulative incidence was significantly different between the intervention group (7.14%, 5/70 patients) and the control group (32.86%, 23/70 patients; $X^2 = 14.46, df = 1, p < .001$).

8.5.3 PU Prevention Bundle versus Standard Care

Implementation of the PU prevention bundle was associated with a delayed time to adverse event (PU) occurring when comparing the control to the intervention (for those who developed a PU, it developed earlier in the control group; Figure 2). There were 12 PU events (17.1%) in the intervention group, as compared with 37 PU events (52.8%) in the control group (Breslow’s generalized Wilcoxon = 11.130, $df = 1, p < .001$), assuming events were independent. Multivariate survival Cox regression confirmed that the relative PU rates were 0.14 times lower amongst the intervention group compared to the control group (95% CI 0.05–0.38). This was a statistically significant difference of relative PU rate between both groups ($p < .001$; see Figure 8.2).

![Figure 8.2 Kaplan-Meier Survival Curves - PU Development Between Intervention and Control Group](image-url)
8.5.4 PU Rate over the Study Period

There was a statistically significant difference in total number of PUs that developed between the intervention (12/70) and control (37/70) groups (exp $\beta = 0.30$, 95% CI, 0.158–0.588, $p < .001$), indicating the likelihood of PU development to be 70% lower in the intervention group.

8.5.5 PU Severity

The most common area for PU development was the sacrum, then heels, for both groups (see Table 9.3). The intervention group had significantly less Stage I and II PU development ($U = 1,976$, $p = .002$, and $U = 2,172$, $p = .026$, respectively). MDRUs were more frequently found in the control group (7/23) than in the intervention group (2/5). The most common areas for MDRUs were nare and neck.

8.5.6 Processes of Care

Processes of care performance was highest (100%) for admission skin assessments and documentation within required time frames in both groups (control group within 24 hrs; intervention group within 4 hrs), and daily ongoing assessment (control group during bed bath, intervention group every 8 hr). There was no difference between groups in frequency of bed baths, as patients in both groups were bathed once per day. In the intervention group, 85% of participants were repositioned every 3 hr, while in the control group 20% of participants were repositioned more frequently every 2 hr as per that particular ICU policy. In the control group the mean frequency of repositioning was every 4.67 hr. The practice of supporting participants’ heels using heel protectors was significantly different between groups (97% in the intervention
group; 0% in control group; $X^2 = 132.22, p < .001$). Patient mobilization out of bed did not differ between the groups.

### 8.6 DISCUSSION

#### 8.6.1 PU Incidence

The results of this study support the effectiveness of the PU prevention bundle in an adult Saudi ICU, showing that a substantial reduction in the cumulative incidence of hospital-acquired PUs (HAPUs), total number of PUs per patient, and time to first PU development in the intervention group can be achieved. The assumption of the effectiveness of the PU prevention bundle in the reduction of PU development for critically ill patients is indirectly supported by the shape of the survival curves for time to first PU development, which showed a growing gap during the follow-up period (see Figure 9.2). The PU prevention bundle, based on the most recent available evidence of PU prevention strategies, combined several measures that targeted risk factors. Therefore, we could not estimate the effect of individual prevention measures (Horner & Bellamy, 2012). The bundle approach (i.e., mandatory implementation of all strategies) may be considered successful because a marked reduction in PU incidence from 32.86% to 7.14% was recorded.

Despite a significant reduction in PU development, one wonders why the incidence was not lower. Possible explanations include nursing care deviations in the PU prevention bundle, patients staying longer in the ICU, or the presence of disease burdens with secondary skin failure, making total eradication of PUs extremely difficult. It also may be a combination of any or all of the above proposed explanations. Another confounder may relate to nurses’ workload as the nurse/patient ratio was one
to two or one to three, and nurses delivered all patient care. However, the incidence rate of HAPUs now is similar to that reported in other international studies (Gunningberg et al., 2012; Stotts et al., 2013)

8.6.2 PU Severity

Our analyses revealed that the implementation of the PU prevention bundle has significantly reduced the severity of PUs. Further, the prevention bundle has been shown to be effective in other international studies, which reported that regular assessment of the patient’s skin and mucous membranes around and underneath devices, with regular repositioning of devices, is essential to reduce MDRU incidence (Coyer et al., in press). These findings confirmed that the PU prevention bundle results in improvement in patient outcomes in a Saudi setting, as well as other international settings.

8.6.3 Process of Care

The bundle approach is more efficient than a single intervention in changing practice (Horner & Bellamy, 2012). However, lack of compliance by RNs can hinder the success of any bundle or any process for that matter. Soban, Hempel, Munjas, Miles, and Rubenstein (2011) suggest that successful reporting of the intervention (PU prevention bundle) should include the intervention’s effect on patient’s outcome (PU incidence) and process of care, to understand the extent of conducting each intervention and its effect. This study showed increased compliance of most processes of care with implementation of the PU prevention bundle; patients were repositioned more frequently, had an improvement in ongoing care regarding medical devices (i.e.,
assessment, repositioning, and resecurement), and the patients’ heels were elevated and supported with greater frequency.

Interestingly, this study found that control group delivery of the PU prevention processes of care were dependent on RNs’ clinical decision and provided no uniformity of care. Several studies argue that standardization, high reliability, and compliance of bundle implementation will improve PU prevention in the ICU (Chaboyer et al., 2013; Revello & Fields, 2012). Evidence suggests it is no longer sufficient to rely on RNs’ clinical judgment in this area—the risk of variance in practice and key elements being omitted (due to a multiplicity of reasons) is too high. This study showed a high RN compliance to delivery of the PU prevention bundle (processes of care); thus, enabling the PU prevention bundle to be successfully translated in the clinical practice (ICU). Further, this study suggests that using a bundle approach, with extensive education and training, regular feedback of the performance, and increased RN awareness about the extent of the problem, will improve RN compliance and the reduction of HAPUs in the ICU.

8.7 LIMITATIONS, FUTURE RESEARCH, AND APPLICATION OF FINDINGS

This study was conducted in two Saudi Arabian ICUs; therefore, the generalizability of results is limited to this single setting. Testing a PU prevention bundle in a different organizational context may be required for additional resources and training. Further research should build on proven PU prevention success strategies and evaluate risk factors that could accelerate the PU development in those patients to understand any potential trade-off between risk factors and PU development.
Measuring prevalence and incidence of PUs regularly, increasing staff awareness about the problem, using PU prevention strategies, and implementing evidence-based practice toward PU prevention will positively impact the quality of care and patient outcomes.

### 8.8 IMPLICATIONS FOR PRACTICE

This bundle had a positive impact on reducing PU development-related outcomes, especially incidence and severity of PUs and MDRPUs. Utilizing a bundle approach and standardized nursing language through skin assessment and translation of the knowledge to practice is essential for PU-related outcomes. Correctly identifying risk factors for PU development and high-risk patients and linking with relevant nursing interventions will achieve the desired outcome of PU reduction in the ICU, consequently improving quality of care and patient safety.

### 8.9 CONCLUSIONS

The results of this study showed significant improvements in reducing PUs and PU-related events through the implementation of the PU prevention bundle in Saudi ICUs. It would appear that the use of the PU bundle can reduce PU incidence, severity, and total number of PUs per patient. Since this comprehensive bundle was based on international guidelines with evidence based on PU prevention strategies for skin or mucosal PUs, it should also be recognized that it is highly likely an increased staff awareness about PU prevention, and staff training and education, may also contribute to successful results in improving patient care.
8.10 ACKNOWLEDGMENTS

Thanks are extended to all ICU staff, patients, and families of the two hospitals for their assistance during data collection for this study. Doctoral scholarship to the first author by the Ministry of Higher Education, Umm Al-Qura University, Saudi Arabia is also gratefully acknowledged.

8.11 CLINICAL RESOURCES:

- International Guideline Prevention of Pressure Ulcers: Quick Reference Guide:

- Prevention and Treatment of Pressure Ulcers: Quick Reference Guide:
8.12 REFERENCES


Chapter 9: (Article 6) Translating Pressure Ulcer Prevention into Intensive Care Nursing Practice: Overlying a Care Bundle Approach with a Model for Research Implementation

This chapter includes the following article:


This article presents how all of the findings from the previous chapters informed the overall goal, which was the implementation of the PU prevention bundle to improve skin integrity in the ICU context, guided by the study’s conceptual framework. This article explores whether using a knowledge translation framework can assist the advanced practice nurse to implement new evidence (the PU prevention bundle) appropriately and successfully into practice. The use of new evidence should enable patients to receive the most up to date, evidence based care, improve the quality of care the patient receives, and enhance patient safety. The aims of this article were to examine how the Ottawa Model of Research Use (OMRU) model was used to guide the implementation of a PU prevention bundle integrated into the daily practice context of an ICU. Further, this paper provides an in-depth account of this approach as a comprehensive vehicle for using high quality evidence to improve skin integrity of critically ill patients.

This article answers research question 16:
Research Question 16: Does the OMRU model, as a framework, facilitate the implementation of the PU prevention bundle in the ICU context?

This publication adds to the existing body of literature by providing evidence that use of the OMRU, a translation model, enhanced the integration of evidence-based practice into daily clinical practice in a consistent and effective manner. Furthermore, confidence in the research outcome, presented in previous chapters, is enhanced through addressing the process of care, and the barriers and facilitators that impact upon the implementation of an intervention, and using effective strategies for implementation.

Findings from this phase were published in the Journal of Nursing Care Quality, as the results from this study were able to contribute to the international audience of advanced nursing practice and patient safety. The Journal of Nursing Care Quality has an impact factor of 1.389.
Translating Pressure Ulcer Prevention into Intensive Care Nursing Practice: Overlaying a Care Bundle Approach with a Model for Research Implementation


9.1 ABSTRACT

This article reports on the development and implementation process used to integrate a care bundle approach (a pressure ulcer [PU] prevention bundle to improve patients’ skin integrity in intensive care) and the Ottawa Model of Research Use (OMRU). The PU prevention care bundle demonstrated significant reduction in PU incidence, with the OMRU model providing a successful consolidated framework for implementation of bundled evidence in an effective, efficient, and consistent manner into daily clinical nursing practice.

Keywords: care bundle, implementation, Ottawa of Model Research Use, pressure ulcer prevention bundle
9.2 BACKGROUND

Hospital acquired pressure ulcers (HAPUs) are one of the most serious problems in healthcare settings. High prevalence and incidence of pressure ulcer (PUs) acquired during hospitalization globally (Berlowitz, 2014; Nijs et al., 2009) supports a lack of comprehensive processes to guide the implementation of effective PU prevention strategies in the clinical setting, particularly in intensive care units (ICU). Such a lack of process may lead to PU development, which in turn, increases cost and length of stay, as well as morbidity and mortality (Bennett, Dealey, & Posnett, 2004; Brown, 2003; Graves, Birrell, & Whitby, 2005).

Skin breakdown impacts negatively on the patient’s quality of life. All critically ill patients managed in ICUs are more susceptible for PU development due to their high acuity, physiological responses to critical illness, and subsequent length of stay in ICU (Cooper, 2013). Consequently, urgent attention to implement PU prevention strategies is required. Evidence suggests that implementing different PU prevention strategies as guidelines, or care bundles could reduce HAPU development (Kiernan & Downie, 2011).

The terms “evidence-based guideline” and “care bundle approach” refer to a set of interventions that are targeted towards a specific procedure, symptom or treatment. Robb (2010) argues that the care bundle approach is more effective than simply following clinical guidelines (Robb et al., 2010) This may be because of the inherent importance of all elements of a care bundle, whilst clinical guidelines are recommendations only intended to optimize patient care.

The bundle approach has been shown to be effective in many areas such as: prevention of PUs, and ventilator-associated pneumonia, as well as increased
compliance for hand hygiene. (Gray-Siracusa & Schrier, 2011; Hawe, Ellis, Cairns, & Longmate, 2009; Pincock, Bernstein, Warthman, & Holst, 2012) However, this approach does not acknowledge the effect of the practice environment (ICU), which is never static, on clinical practice performance and outcomes. In addition, the process of adoption of the care bundle must be considered (Camporota & Brett, 2011). Therefore, introduction of a care bundle approach itself may be insufficient to change practice in a complex area. A systematic and dynamic model is required to guide the translation of the PU prevention bundle in ICU. One such effective model to promote research uptake by health care practitioners is the Ottawa Model for Research Use (OMRU) (Rycroft-Malone & Bucknall, 2011).

This model was chosen as it is dynamic, not a linear process, and it is focuses upon the implementation of existing research evidence into practice, taking into account the overall context, personal practice, and those responsible for the implementation. Whilst OMRU has been used in the implementation of a number of clinical interventions, including skin integrity program, there is a limited literature integrating the care bundle approach and OMRU principles.

This article presents how the OMRU model guided a two-arm cluster randomized control trial (cRCT) which tested the effectiveness of a PU prevention bundle (Tayyib, Coyer, & Lewis, 2015b). The cRCT study was conducted in two Saudi Arabian tertiary referral hospital intensive care units from June 2013 to February 2014, where one hospital ICU was the intervention arm and the second was the control. All patients who admitted during a study period were recruited and followed until discharge, death, or up to a maximum of 28 ICU days (study endpoints), whichever occurred first, and the 6-PU stages system was used as the outcomes measure. Further, this paper provides insight into this approach and argues the OMRU and care bundle approach is a
comprehensive vehicle for integrating high quality evidence (PU prevention bundle) into the daily practice to improve skin integrity within an ICU practice setting.

9.3 THE OTTAWA MODEL OF RESEARCH USE (OMRU)

The OMRU, designed by Logan and Graham, is an interactive model for using knowledge in clinical practice. The OMRU is not a sequential stage model of change practice (Rycroft-Malone & Bucknall, 2011). The OMRU model has three implicit assumptions: patients play a key role in every aspect of model elements; the process can be repeated at any stage of the implementation; and the environment that may affect all aspects of the translation process (Logan & Graham, 1998). Many studies have applied the OMRU model when translating evidence into the clinical practice context (Hogan & Logan, 2004; Logan, Harrison, Graham, Dunn, & Bissonnette, 1999; Stacey, Pomey, O'Connor, & Graham, 2006).

The OMRU consists of six phases framed by assessment, monitoring and evaluation: 1) research-based innovation, 2) the practice environment, 3) potential adopters, 4) implementation of the intervention, 5) adoption, and 6) outcomes (see Figure 9.1).
Chapter 9: (Article 6) Translating Pressure Ulcer Prevention into Intensive Care Nursing Practice: Overlying a Care Bundle Approach with a Model for Research Implementation

Figure 9.1 The Ottawa Model of Research Use for Implementing a PU Prevention Bundle in ICU
(Adapted from Graham & Logan, 2004)

Assess
barriers and support

Monitor
intervention and degree of use

Evaluation
outcomes

Research-based innovation
(PU prevention bundle)
Development process
Innovation attributes

Potential adopters (ICU RNs)
Awareness
Attitudes
Knowledge/skill
Concerns
Current practices

Practice environment (ICU)
Patients
Culture/social
Structural
Economic
Uncontrolled events

Implementation intervention strategies
(Education and training, and process of care)
Barrier management
Transfer
Follow up

Adoption (implement effectively)
Intention
Use

Outcomes
(PU incidence in ICU)
Patient
Practitioner
System

Note: Italic, and underline = Study specific information
The model is classified as a planned action model as it provides direction as to the issues that should be addressed and the activities that change agents should undertake (Rycroft-Malone & Bucknall, 2011). When knowledge transfer is being planned, the model relies on a process of assessing, monitoring, and evaluating each element before, during, and after the decision is made, to promote uptake of the innovation (Rycroft-Malone & Bucknall, 2011). The OMRU directs change agents through assessment of the barriers and facilitators to research use related to the practice environment (in this instance the ICU), adopter characteristics (specialist intensive care nurses), and the clinical innovation (PU prevention bundle). An implementation plan is then tailored to overcome the identified barriers. The strategies to deliver the intervention are based on the situational assessment and the transfer of the strategies with ongoing evaluation. How the evidence-based research is transferred to clinical practice is then monitored. Finally, the intervention is evaluated by assessing the effect on patients, practitioners and system to determine the effectiveness of the intervention in valid and reliable ways. The following discussion illustrates how the OMRU can be used to direct the implementation of a PU prevention bundle innovations in ICU.

9.3.1 Phase 1: Research-Based Innovation (PU Prevention Bundle)

Innovations in the hospital setting can be defined as changing standard practices based on current knowledge and research data. Innovation has been presented in different forms, including procedures, policy, practice guidelines, and care bundles (Rycroft-Malone & Bucknall, 2011). Whenever an innovative care bundle is planned, the following steps should be considered: a review of the relevant literature, a synthesis of the best evidence along with the contextual demands and formation of an integrated bundle of care. A panel of international experts, constituting the National Pressure...
Ulcer Advisory Panel (NPUAP) and European Pressure ulcer Advisory Panel (EPUAP), as an international consensus committee reviewed evidence on PU prevention strategies and found consensus in the following guidelines for the general context. These guidelines were contextualized to the Saudi Arabia (SA) ICU context and presented as a care bundle (presented in Table 9.1) (Tayyib, Coyer, & Lewis, 2015a).

The PU prevention bundle was reviewed by a panel of five local expert nurses who had a range of seven to 14 years of clinical experience. The panel included two nurse educators (one from each hospital) and two critical care nursing supervisors (one from each hospital), and one adult care registered nurse (RN). In addition, the bundle was also tailored to the individual practice environment (ICU) and the potential adopters (RNs). For example, despite international guideline recommendations for the use of any high specification mattress for all at risk patients (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP & NPUAP), 2009), our PU prevention bundle suggested use of an air mattress because this is the only mattress available in ICUs in Saudi Arabia.
Table 9.1 NPUAP & EPUAP Guideline, Standard, & the PU Prevention Bundle

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk assessment:</td>
<td>- No PU risk assessment scale used</td>
<td>- Completion and documentation of Braden risk assessment scale within 24 hours of ICU admission and daily thereafter.</td>
</tr>
<tr>
<td>- Using a structured risk assessment that addresses mobility, activity, friction and shear, sensory reception, and body temperature.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin assessment/skin care:</td>
<td>- Physical assessment of the patient’s skin completed and documented within 24 hours of admission and once daily thereafter. No requirement for documentation</td>
<td>- Physical assessment of the patient’s skin is undertaken and documented within 4 hours of admission and every 8 hours thereafter.</td>
</tr>
<tr>
<td>- Physical assessment and documentation for any sign of skin changes</td>
<td>- Loss of skin integrity assessed (and documented) using local hospital PU documentation tool. No documentation required for Stage I PUs.</td>
<td>- Loss of skin integrity assessed (and documented) using the PU staging tool, noting site, size, depth, and if any exudates are present.</td>
</tr>
<tr>
<td>- Pain assessment related to pressure</td>
<td>- Once a day bed-bath using antiseptic soap containing 2% hydrogen peroxide. Moisturiser applied at discretion of RN.</td>
<td>- Patients bed-bathed once per day using a pH balanced cleansing agent (pre-package washcloth). Skin treated with a topical moisturiser.</td>
</tr>
<tr>
<td>- Keep the skin clean, moist, and dry.</td>
<td>- No skin massages or rubs.</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Nutrition:</td>
<td>Nutritional status assessment is undertaken by the clinical nutritionist on admission</td>
<td>Nutritional status assessment is undertaken by the clinical nutritionist on admission</td>
</tr>
<tr>
<td>- Assess nutritional status regularly.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repositioning:</td>
<td>Patients repositioning two hourly as per ICU policy</td>
<td>Patients repositioned using a three hourly turning schedule using a ‘turn clock’.</td>
</tr>
<tr>
<td>- Frequent patient repositioning is recommended according to patient’s need, and support surfaces.</td>
<td>Foot of the bed elevated by 20 degrees if clinically permitted. There was no policy for heel elevation</td>
<td>Foot of the bed elevated by 20 degrees if clinically permitted. Patient's heels are elevated and supported.</td>
</tr>
<tr>
<td>- Using a 30-degree tilted side-lying position</td>
<td>There is no policy for use drawsheet or any lifting devices.</td>
<td>Drawsheets used to transfer and lift patients</td>
</tr>
<tr>
<td>- Seating patients out of the bed (if possible) to maintain a full range of motion.</td>
<td>There is no policy to mobilize patient out of bed.</td>
<td>Where clinically possibly patients are mobilised daily to sit out of bed on chair.</td>
</tr>
<tr>
<td>- Patient’s heels should be supported and elevated</td>
<td>No documentation required for patient positioning</td>
<td>- Position documented including the time of repositioning and position adopted</td>
</tr>
<tr>
<td>- Documentation of repositioning regimen and position adopted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NPUAP &amp; EPUAP prevention guideline (2009)</strong></td>
<td><strong>Standard PU prevention care</strong></td>
<td><strong>The PU prevention bundle (our intervention)</strong></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Support surface:</td>
<td>- All ICU patients were managed on air mattresses</td>
<td>- All ICU patients were managed on air mattresses</td>
</tr>
<tr>
<td>- Use higher-specification foam mattresses for all at-risk</td>
<td></td>
<td>- RNs educated in the conduct of accurate and reliable Braden Scale Score risk assessment.</td>
</tr>
<tr>
<td>Education and training include:</td>
<td></td>
<td>- All ICU health practitioners, especially RNs, educated on targeted bundle elements of PU prevention (e.g. risk assessment, the role of repositioning in PU prevention, correct methods for patient repositioning and use of equipment in reducing pressure, friction and shear forces).</td>
</tr>
<tr>
<td>- Conducting of risk assessment scale in reliable and accurate ways.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Conducting a comprehensive skin assessment for any signs of skin changes.</td>
<td>- Educated RNs during the orientation period of new ICU staff regarding PU prevention strategies (e.g. positioning policy every 2 hours, PU stages, and PU documentation).</td>
<td></td>
</tr>
<tr>
<td>- Considering role and method of repositioning and use of equipment for repositioning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical devices:</td>
<td>- Resecurement of NGT and ETT daily during patient bed bath. There is no policy for skin assessment around/underneath medical devices, repositioning and resecurement of NGT or ETT.</td>
<td>- Assessment of skin around/underneath medical devices every 12 hours. Securement and repositioning of Nasogastric tubes (NGT) and endotracheal tubes (ETT) as per techniques outlined in the study bundle.</td>
</tr>
<tr>
<td>- Assessment of the area underneath medical devices.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9.3.2 Phase 2: Practice Environment (ICU)

The second assessment element is the practice environment. The impact of the practice environment on the translation of research into practice has been identified in a considerable volume of research (Bradley et al., 2005; Mitchell, Fisher, Hastings, Silverman, & Wallen, 2010). The ICU is a complex and dynamic environment, thus it has both promoting and constraining influences on the process of translating evidence into practice. Our study was conducted in the two ICUs of major metropolitan government-funded public hospitals in Saudi Arabia. Both ICUs each have 20 to 24 beds, each with single rooms, staffed by approximately 60 RNs. The ICU staffing ratio is one RN to every two to three mechanically ventilated patients. At the time of the study there were no dedicated clinical instructors or nurse educators in the units. The ICU patient case mix comprised of cardiovascular and respiratory diseases; cancer; renal dysfunction; burns; sepsis; and multi-trauma injuries. Both ICUs are specialist areas that deliver complex multi-system support for life-threatening patient or after major surgery.

Ethical approval to conduct this study was granted by the Unit of Ethic of the relevant Saudi hospitals as well as the Queensland University of Technology Human Research Ethics Committee (130000034), Australia. Our study was unanimously approved and supported by the medical and nursing directors of the ICUs, as the research aims were congruent with each organisation’s mission and vision for PU prevention. Prevention of PUs was considered a routine component of day to day nursing care in the study sites, and it was provided based on individual RN clinical judgement.

Prior to our study, ICU PU incidence using the 4 staging classifications (I-IV) (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel
(EPUAP & NPUAP, 2009) was measured monthly. The head nurse was responsible for calculating and reporting incidence rates, including PU related to medical devices, to the hospital administration department. However, this data was not fed back to RNs in the ICU. Further, the incidence report relied on retrospective data from RN reports, which may not be reliable. This data were used locally to determine if appropriate prevention strategies were used.

No evidence addressing the magnitude of the PU problem in the SA ICU settings has previously been reported. Our study undertook prospective observational incidence data collection to determine accurate PU data in the ICU. We previously found that HAPU incidence was high (39.3%), of which stage I and II were the most often noted (Tayyib, Coyer, & Lewis, 2015b), compared to other international intensive care settings (1.8%-14.3%) (Gunningberg, Donaldson, Aydin, & Idvall, 2012; Stotts, Brown, Donaldson, Aydin, & Fridman, 2013). The clinical process at this site was that individual RNs are responsible for clinical decision-making and implementing the appropriate prevention strategies. If PUs occur, the physician will be notified and involved in the treatment plan. Cultural beliefs at the study site highlight that RNs play an important decision-making role in preventing and treating PUs. However, the RNs, who are caring for the ICU patients, are from different cultural and language backgrounds. Such cultural diversity could affect the consistency of provided care towards preventing PU development, especially when the provided care is based on individual decision-making and there is an absence of opinion leader at the study site.

The environmental barriers and facilitators relating to PU development were assessed through a cross-sectional survey of intensive care RNs to determine the characteristics of the setting related to HAPU prevention as a performance
improvement initiative (Tayyib, Coyer, & Lewis, 2016a). The modified Pressure Ulcer Prevention in the PICU "Barriers and Facilitators" survey included items about the potential barriers/ facilitators to optimal skin care. The following findings from this survey directly impacted the research translation: workload was identified as a significant barrier to providing optimum skin care; three facilitating factors that enhanced the ability of RNs to provide optimum skin care were the availability of pressure reduction surfaces (p=.007), convenience of appropriate skin care products (p=.015), and collaboration with interdisciplinary teams (nursing/medicine/pharmacy/dietary) (p=.02) (Tayyib et al., 2016a).

9.3.3 Phase 3: Potential Adopters (Specialist RNs)

The third assessment element of the OMRU model is potential adopter groups. Potential adopter refers to practitioners, intensive care RNs, who implemented the PU prevention bundle. Assessment of RNs for their attitudes towards, and willingness to, implement a HAPU prevention bundle comprises three concepts: awareness of the problem and the HAPU prevention bundle innovation, the intention of RNs to change current practice and concern about PU as a problem (Rycroft-Malone & Bucknall, 2011).

In the study site, the RNs demonstrated a lack of awareness regarding HAPU incidence, as the reporting of internal incidence data were at an administrative level only. Additionally, RNs’ attitudes, and perceived barriers and facilitators to PU prevention were assessed to understand both potential obstacles and expediters (Tayyib et al., 2016a). This was measured via two surveys using the Attitude towards Pressure Ulcer Prevention instrument (APuP) (Beeckman, Defloor, Demarré, Van Hecke, &
Vanderwee, 2010), and the modified Pressure Ulcer Prevention in the PICU "Barriers and Facilitators" instruments.

The majority of potential adopters were female (80.4%), and 50% held a bachelor’s degree in nursing. The original survey was analysed using a 4-point Likert scale (1=strongly disagree, 4= strongly agree) and with a mean cut-off point of a positive attitude score of >70% (Beeckman et al., 2010). Findings reveal that the majority of participants had a positive attitude toward PU prevention strategies (73.44%) (Tayyib et al., 2016a). However, the potential adopters had low scores below the positive attitude that regards the consequences of PUs on patients and society, and priority of PU prevention sub-scales (68%, 69% respectively). A 10-point Likert scale (1=lower, 10=highest) was employed to rate perceived personal barriers to implementing the PU prevention bundle. Time demands (p=.011), and limitation of RNs knowledge (p=.022) were noteworthy adopter-specific limitations to implementing the PU prevention bundle.

Our assessment demonstrated factors that impeded and facilitated the implementation of new practices towards PU prevention. These issues were addressed during development of the PU prevention bundle, and used to design the strategies that enhance, disseminate, diffuse, implement, and sustain the PU prevention bundle. Strategies that were used will be discussed in the next phase.

9.3.4 Phase 4: Intervention Implementation (Education and Training of PU Prevention Bundle)

The implementation phase includes addressing barriers and facilitators, translating knowledge into practice, and the follow-up activities. Logan and Graham
advise that successful knowledge uptake rests with adapting knowledge implementation strategies to salient barriers of the individual and their organisation, and identifying evidence-based innovations that are applicable to their clinical setting.

During our study, intervention implementation strategies were tailored and sequenced based on the clinical innovation, practice environment, and adopter profiles. Literature suggests that utilising multiple research transfer strategies to ensure awareness, understanding, training and skill of each potential adopter facilitates change in a routine practice (Bingham & Main, 2010; Doherty, 2006). Roger (2003) suggests that five stages of the innovation decision process include knowledge and awareness of the potential adopters about the innovation before implementation; the persuasion stage, involving the development of positive attitudes towards the innovation; the decision stage about the potential adopters’ decisions regarding the use of innovation; the implementation and translation stage; and the final stage, which includes the continuity of integrating the innovation into routine care (Rogers, 2003).

An interactive educational in-service was conducted by one of the authors as opinion leader and expert PU nurse, to familiarize intensive care RNs members about the bundle. The content of the 1-hour workshop included a didactic component detailing the magnitude of the PU problem, its implications for the patients, and organisational level concerns, prevention strategies, and the core elements of prevention guidelines. In addition, availability of the printed brochures, study booklets, and the presence of an opinion leader (researcher) on the site every second day for eight hours that provided an opportunity to remind RNs of the importance of the bundle elements and for further consultation. It has been argued that the presence of opinion leaders has a positive educational influence in changing daily practice through increased research uptake (van Riet Paap et al., 2015; Yap, Kennerly,
Bergstrom, Hudak, & Horn, 2016). Interactive workshops that combine research results with value for the nurses’ experiential knowledge have been shown to be effective facilitators of change (Young & Paterson, 2007). Adopters’ feedback from the in-service was overwhelmingly positive and upheld the importance of change. Moreover, the presence of the opinion leader, the researcher, in the research setting facilitated research uptake and use (Borgert, Goossens, & Dongelmans, 2015).

Biweekly reminders of the study were generated through placing a colorful page in the communication notebook and reminders at ICU staff meetings, which promoted their practice change towards PU prevention (Tayyib et al., 2015a; Tayyib, Coyer, & Lewis, 2016b). Ongoing motivation of the RNs, through repeating the aim of implementing the bundle and patient safety, is considered to be a successful fundamental translation strategy (Hogan & Logan, 2004). Audit and feedback have been proven effective in improving performance (Borgert et al., 2015). Bundle audits and monthly personal self-reports were conducted to determine and address perceived barriers and facilitators of the bundle implementation.

9.3.5 Phase 5: Adoption

The next step in monitoring the cycle is the adoption of the innovation, which includes intention to use and continued use of the PU prevention bundle (Rycroft-Malone & Bucknall, 2011). Monitoring a care bundle implementation is essential to determine the degree of diffusing the bundle throughout intensive care RNs, and the barriers and facilitators that affected the process of care. This phase would determine the impact of the PU prevention bundle on the desired change of reduced PU incidence.
Adoption of the PU prevention bundle was monitored through a PU prevention bundle compliance checklist completed by the researcher through direct observation, patients’ records, and a RNs self-evaluation checklist every two weeks during the implementation and evaluation period, which included a four time points (Tayyib et al., 2016b). Sharing the results following each data collection point was effective in increasing uptake of the bundle and reaching the high implementation (Tayyib et al., 2016b). High implementation compliance required a score of 75% or greater (Wilson et al., 2010).

In our study, the compliance checklist, which included 30 yes/no questions, revealed that intensive care RNs had a high level of compliance overall toward the implementation of the bundle, as shown by the mean score of 22.43/30 (78.1%). However, the compliance across the four time points revealed that the intensive care RNs needed more time to be familiar with the bundle (Tayyib et al., 2016b). Furthermore, this study showed that the adoption and sustaining of the bundle was not affected by the cultural diversity and characteristics of the intensive care RNs. This reflects that the bundle was reliable, easy to implement, compatible with the context, and was clear and non-controversial.

The RN self-evaluation survey suggests that, in general, intensive care RNs perceived that both the innovation and knowledge acquired during the bundle implementation increased their awareness of the effective PU prevention strategies, satisfaction and confidence to implement effective PU prevention in ICU. In term of barriers to implementation of the bundle, a RNs self-evaluation survey also found that severity of illness or high acuity was identified as the main barriers to embedding the bundle elements (Tayyib et al., 2016b).
9.3.6 Phase 6: Outcome

The last step of the model includes evaluation of the outcomes of this practice change (the implementation of the PU prevention bundle). The outcome should be evaluated on patients, practitioners, and healthcare system levels (Rycroft-Malone & Bucknall, 2011). The aims of this phase were to determine whether the promotion of adoption is of value or not in terms of reduction of incidence or prevalence of PU in critically ill patients in ICU. However, this phase will be interpreted according to the compliance result of the potential adopters (RNs).

One of the OMRU’s key assumptions of research adoption is improved patient outcome. In our study this was a reduction in the incidence of PUs in ICU. The PU incidence rate was measured prospectively using the proportion of participants who develop a new PU within a specific time divided by the total number of participants who were at risk of PU development (Baharestani et al., 2009). The bundle was implemented in the intervention group for all ICU patients until discharge, death, or up to a maximum of 28 ICU days (study end points), whichever occurred first. The PU incidence outcome was compared between the intervention that received the PU prevention bundle and control group, which received the PU prevention standard care. Evaluation of the innovation, the PU prevention bundle, also should consider the intensive care RNs compliance to the bundle (Horner, Rew, & Torres, 2006). Since the intensive care RNs had higher compliance to the bundle in their practice, this confirms that the PU prevention bundle could be the main reason for the differences of the PU incidence between both groups. The implementation of the PU prevention bundle resulted in significantly decreased PU incidence from 32.86% (23/70 patients) to 7.14% (5/70 patients) in the intervention group ($\chi^2=14.46$, $df=1$, $p < .001$) (Tayyib et al., 2015a). Moreover, the intervention group had a significant reduction of stage I
\( (U = 1,976, p = .002), \) stage II \( (U = 2,172, p = .026) \) and less medical device-related PUs compared to the control group (Tayyib et al., 2015a). This reduction could contribute to lower healthcare costs and increased safety and quality of care. In addition, this research has a significant practical impact on the ICU by changing the repositioning policy to 3 hours and using a pH balanced cleansing agent (pre-package washcloth) for patients during their bed baths.

### 9.4 DISCUSSION

Implementation of best evidence-based PU prevention strategies is an organizational and nursing goal for improving quality of care. However, the processes of evidence translation in real clinical practice are complex. Using an effective framework, such as the OMNU model, has been important as it provided a complete insight of translation processes in the real setting. Mapping out the translation of an evidence-based initiative is a deliberate process that aims to counterbalance barriers and facilitators to make practice changes. The PU prevention bundle research project illustrates an example of a successful performance improvement initiative which addressed a specific problem (PU).

During the implementation period, the OMNU model was found to be highly suitable for modifying practice, embedding a new practice in the routine care and managing the factors that affect the translation process of the PU prevention bundle. Implementation research projects to improve nursing practice require initial and ongoing support at the organization level for a clinical change to practice (Graham & Logan, 2004; Yap et al., 2016). While potential adopters demonstrated positive attitudes towards PU prevention, they perceived a limitation of personal PU prevention
knowledge and workload as barriers to providing effective care. This could indicate that the RNs recognised the values of additional educational programs that were related to up to date effective evidence in PU prevention and implementation. Learning theories recommend using a variety of educational strategies, including recurring, tailored in-service educational sessions, face-to-face interviews, and printed copies of the study (Prior, Guerin, & Grimmer-Somers, 2008). Engaging a researcher as opinion leader during the implementation created a credible effect on increased uptake of the bundle. Nursing workload as a barrier to practice change is a significant hurdle to overcome. For this study the frequency of patient repositioning was modified from two hourly to every three hours, with the latter supported by evidence (Yap et al., 2016), to assist intensive care RNs to adopt a practice change of regular patient repositioning.

Ongoing trending of the findings of PU incidence in the study site would serve to inform the development of additional value of the PU prevention bundle. Evaluating patient outcomes and, PU incidence, are equally vital to ongoing quality improvement initiatives that attempt to translate research into practice. Audit and feedback strategies were used in a safe and comfortable environment, in the presence of an opinion leader, which enhanced the sustainability of the successful implementation of the PU prevention bundle (Yap et al., 2016). These strategies have been confirmed with other implementation studies in order to promote a high level of sustained performance of clinical practice that is directed to improving healthcare outcomes and patient safety (Borgert et al., 2015).

Dissemination and implementation of evidence-based research are essential to the delivery of high-quality care that optimizes patients’ outcomes. Addressing the
process of care, and the barriers and facilitators that impact upon the implementation of an intervention, and using effective strategies for implementation, will promote compliance and sustain the intervention in clinical practice. Using the OMRU, a translation model, will enhance the integration of evidence-based into daily clinical practice in a consistent and effective manner. The confidence of the research outcome will increase and similar results will be achieved with replicating the study.

9.5 CONCLUSION

Using a knowledge translation framework can facilitate the uptake of research into practice, which can improve health care outcomes for patients. In this article, use of the OMRU model facilitated the successful dissemination of a new PU prevention care bundle in the ICU. The transfer of knowledge into practice is a complex process and more research is needed regarding the effectiveness of different teaching and learning strategies in different practice settings. Moreover, this article demonstrated that use of a care bundle approach overlaid with a research translation model, the OMRU, promoted change effectively through structured sequences of bundle design, adaptation, and implementation. This contributed to evidence-based practice that resulted in improvement in patient safety (PU incidence reduction) and enhancement the quality of care received by patients and their families.
9.6 REFERENCES


Chapter 10: Conclusion

10.1 INTRODUCTION

This research evaluated the effectiveness of the implementation of the pressure ulcer (PU) prevention bundle for critically ill patients to improve skin integrity care. This chapter constitutes the conclusion of the study, and addresses a summary of the research and key findings, followed by a consideration of the strengths and limitations of the research undertaken. The chapter concludes with a discussion of the broader implications of, and recommendations that arise from, the study findings as they relate to nursing practice, education, policy, and future research.

10.2 SUMMARY OF THE RESEARCH FINDINGS

The overall goal of this research was to reduce PU incidence in critically ill patients in the intensive care (ICU) setting. This was accomplished by applying both preventive and corrective action strategies utilising a care bundle approach allied with an evidence translation framework into the real practice setting. To ensure that this aim was achieved, the research questions are now reviewed.

At the commencement of the study, 16 research questions were posed (Section 1.2), all of which were answered, as shown below.
Research Question 1: What are the factors that accelerate PU development in adult ICUs?

Research Question 2: What are the common risk assessments that are used and the most effective scales for identifying at risk patients for PU development in the ICU?

A literature review (see Chapter 2) was conducted to examine research published between 2000 and 2012 identifying potential risk factors for the acceleration of PU development, and the common risk assessment scales (RASs) utilised in adult ICUs. Nineteen articles were included in this review: eight studies addressing PU risk factors, eight studies addressing risk assessment scales, and three studies that overlapped both areas. The review found that PU development is enhanced by the presence of multiple, rather than single, risk factors in the one critically ill individual.

A list of accelerating factors was identified and conceptualised under two labels: intrinsic (inherent factors of critical illness) and extrinsic (related to external forces) factors. A total of 28 factors were identified as the main risk factors for PU development in ICU settings in two or more studies. The intrinsic factors identified in two or more studies were older age, increased length of stay in the ICU, and history of cardiovascular disease. The extrinsic factors identified in two or more studies were the administration of norepinephrine and patient repositioning (turning). However, there have been inconsistencies in how these factors are measured. Thus, a risk factor prediction model for critically ill patients has yet to be developed.
The review identified RASs that have been examined in many studies in terms of predictive performance. No evidence has demonstrated whether some scales are more effective than others to determine which patients are more susceptible to PU development in the ICU. Possible explanations are: 1) that there is no clear evidence regarding which core components, either intrinsic or extrinsic risk factors, accelerated the development of PU in the ICU, and, 2) nurses’ competencies in conducting a scale may be inconsistent. However, a RAS is considered a fundamental component for any prevention and management plan. This review found that the Braden Scale is the most appropriate to use in ICUs, which was confirmed by the latest systematic review conducted in 2013 (Garcia-Fernández, 2013).

The findings from this review (Chapter 2) formed the basis for identifying the potential risk factors that should be addressed during the design and planning of the PU prevention intervention. Moreover, it facilitated the selection of a RAS instrument, the Braden Scale, for use in this research.

**Research Question 3: What are the effects of prevention strategies on the incidence/prevalence of pressure ulcers in adult ICUs?**

A systematic review (see Chapter 3) was undertaken to specifically examine prevention strategies aimed at ameliorating known risk factors associated with PU development in critically ill patients. Twenty-five studies were included, with moderate to strong evidence. The review demonstrated that different prevention strategies had a significant impact in reducing the hospital-acquired PUs (HAPUs) in ICU. The review showed that a silicon foam dressing had a significant reduction in HAPU incidence on the scarum area. However, this result should be considered with
caution due to substantial heterogeneity across the included studies. The review concluded there was no certainty regarding which prevention strategies were more effective than others in the ICU context. The findings from this review formed the basis for the selection of the care bundle approach and addressed the translation research model, the OMRU (Chapter 4).

Following the review’s findings, the PU prevention bundle (intervention) was designed based on the latest international guideline at the time of the study (2009) and interpreted to the KSA ICU setting, taking into consideration that it was time-consuming; the clinical practitioner workload; and resource allocation including personnel, supplies, and equipment. Further, the PU prevention bundle was accepted for implementation by the local expert clinical professionals. Consequently, the first phase of the OMRU model, developing the clinical innovation, was addressed.

**Research Question 4: What are the characteristics of the ICU patients in the KSA?**

The results of this study (see Chapter 6) reported that the majority of ICU patients were male (66.6%), and that their mean age was 53 years. More of the individuals in the study sample were non-Saudi nationals (54.8%). This was attributed to the study site, Mekkah, being of religious significance and attracting global pilgrimage. Patients were admitted to the ICU with different diagnoses, such as cardiovascular illness, respiratory disease, cancer, renal dysfunction, burns, sepsis, and multi-trauma injuries. Approximately 85.7% of the participants were at predominantly high risk for PU development, with a mean Braden Scale score of 10 (SD 2.12). The average SOFA score was 7.8 (SD 3.01), and the length of stay in the ICU was nine days.
Research Question 5: What is the incidence of PU development in critically ill patients in the intensive care units of two tertiary referral hospitals in the KSA?

The study found that the PU incidence rate in the KAAH ICU hospital was 40.9% and the KFH ICU was 37.5%. The total PU incidence rate in both ICUs was high (39.3%), and ulcers related to medical devices were a significant problem, (24%) of the total HAPUs (see Chapter 6).

Research Question 6: What are the factors associated with PU development in the ICU in the KSA?

The study suggests (see Chapter 6) that the predictor factors that accelerated the development of PUs in the KSA ICU context included: age (OR: 1.254; 95% CI: 1.054–1.492; p = 0.011), longer stay in the ICU (OR: 1.831; 95% CI: 1.014–3.309; p = 0.045), and infrequent repositioning (OR: 250.04; 95% CI: 5.230-11954.16; p = 0.005). Length of stay in ICU (OR: 1.23; 95% CI: 1.087–1.392; p = 0.001), and infrequent repositioning (OR: 2.96; 95% CI: 1.23–7.153; p = 0.015) were associated with the development of stage II-IV PUs. The frequency of repositioning was addressed during design of the PU prevention bundle.

Research Question 7: What are the RNs attitudes towards PUs prevention in a Saudi Arabian tertiary referral hospital ICU?
The study’s results (see Chapter 7) revealed intensive care RNs showed a positive attitude towards PU prevention, with a mean score of 38.19 out of a possible 52 points (73.44%). However, the impact and priority subscale of the APuP instrument had the lowest score in comparison to other subscales (68%, 69% respectively). This suggests that intensive care RNs did not consider the powerful effect of PU development nor consider it urgent issues.

**Research Question 8: What are the facilitators and barriers for RNs in the adoption of PU prevention strategies in a Saudi Arabian tertiary referral hospital ICU?**

The study’s findings demonstrated three perceived factors that facilitated PU prevention: the availability of pressure relieving support surfaces ($\beta = -0.388$, $p = 0.007$), appropriate skin care products ($\beta = 0.44$, $p = 0.015$), and collaboration between the healthcare professional teams ($\beta = 0.37$, $p = 0.02$). On the other hand, RNs lack of up-to-date knowledge about PU prevention ($\beta = -0.632$, $p = 0.022$) and the demands of a high workload ($\beta = 0.388$, $p = 0.011$) were identified as barriers to implementing effective strategies to prevent PU development (see Chapter 7).

**Research Question 9: Is there any association between participants’ characteristics and RNs’ attitude, or perceived barriers and facilitators to implement the PU prevention strategies?**

The study’s findings showed no significant differences between the demographic characteristics of the intensive care RNs and the APuP attitude subscale,
or perceived barriers and facilitators for implementation of the PU prevention bundle (see Chapter 7).

According to the OMRU model, the assessment of barriers and facilitators related to the practice environment (ICU) and the potential adopters (RNs) is essential to facilitate the research intake. In this study, the results of the assessment phase, which included the incidence and facilitators and barriers study, informed Phase Two through the calculation of the effective sample size for Phase Two (cRCT). Moreover, the design of the intervention and selection of effective strategies for the implementation and adoption of the research were informed by the assessment of the barriers and facilitators in the second study.

**Research Question 10:** Does a PU prevention bundle reduce the cumulative incidence of PU development in critically ill patients in the intensive care unit of a Saudi Arabian tertiary referral hospital?

**H₀:** There is no difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care.

Key findings from this phase showed a significant reduction in PU cumulative incidence in the intervention group (7.14%) compared to the control group (32.86%) (X² = 14.46, df = 1, p < .001) (see Chapter 8). The null hypothesis was rejected.
Research Question 11: Does a PU prevention bundle decrease the cumulative PU incidence by 25% or greater when compared to standard hospital care?

*H₀:* The difference in PU incidence between ICU who implements the PU prevention bundle with ICU continuing to implement standard care was less than 25%.

The result of this study shows that the likelihood of PU development was 70% lower in the intervention group (see Chapter 8). The null hypothesis was rejected.

Research Question 12: Will patients who receive a PU prevention bundle develop a PU later in their intensive care unit stay?

*H₀:* There is no significant difference in a delayed time to PU development with implement the PU prevention bundle.

A survival curve revealed that the implementation of the PU prevention bundle was associated with a significantly delayed time to PU development (p < .001) (see Chapter 8). The null hypothesis was rejected.

Research Question 13: Will patients who receive the PU prevention bundle have fewer numbers of PUs per patient during their ICU stay?

*H₀:* There is no significant difference in number of PU per patients with implement the PU prevention bundle during the ICU stay.

The implementation of the PU prevention bundle showed a significant reduction in the total number of PUs that developed between the intervention (12/70)
and control (37/70) groups (exp β = 0.30, 95% CI, 0.158–0.588, p < .001) (see Chapter 8). The null hypothesis was rejected.

**Research Question 14: Will patients who receive the PU prevention bundle have fewer full thicknesses PUs (Stage III and IV)?**

\( H_0: \) There are no significant differences in full thicknesses PUs (Stage III and IV) with implement the PU prevention bundle.

The results demonstrated that the intervention group had a significant reduction in Stage I (\(U=1976, p=0.002\)), Stage II PU development (\(U=2172, p = .026\)), and no full thicknesses PUs were developed (see Chapter 8). The null hypothesis was rejected.

**Research Question 15: Does the PU prevention bundle increase the adherence to the process of care compared to standard hospital skin care?**

The RNs had a high level of compliance toward the implementation of each key element of the PU prevention bundles compared to the control group. For example, in the intervention group, the adoption of the repositioning regimen element was high (85%), while in the control group, 20% of participants were repositioned as per that particular ICU’s policy. This study also showed that the characteristics of the intensive care RNs did not affect the implementation and adoption of the bundle (see Chapter 8). This reflects that the bundle was accepted and applicable for implementation. Moreover, the effectiveness of the implementation strategies that were proposed, such as active learning classes, one-to one education, reminders, presence of opinion leaders, and audit and feedback,
enhanced the research uptake and integrated the implementation of the new bundle into daily practice.

**Research Question 16: Does the OMRU model, as a framework, facilitate the implementation of the PU prevention bundle in the ICU context?**

This study also supports the emphasis on using translation knowledge frameworks allied with a care bundle approach to confirm adequate delivery of key components and to assist with the interpretation of outcome results (see Chapter 9). This study concludes that continued monitoring of PU incidence rate and sustaining of PU prevention bundles enables in-depth analysis and timely responses to changes in PU rates going forward.

### 10.3 STRENGTHS AND LIMITATIONS

This research has had a significant impact on the PU prevention field, particularly in the context of KSA PU research. This study has made a significant contribution to PU prevention in the KSA, as it the first study to determine the incidence of PU events in KSA ICUs and the first to test the effectiveness of a PU prevention bundle, comprised of the best available evidence, to improve skin integrity. The research has also demonstrated a comprehensive conceptual framework that can be used to guide future evaluations of interventions within health care research. This study validated the OMRU model as able to demonstrate comparable outcomes and promote adoption and sustainability of the changing health care reform. According to the conceptual framework, this research systematically identified the barriers and
facilitators, either among healthcare providers or at organisational levels, that affected the adoption and implementation of PU prevention bundles in ICU, and then addressed them. This research can be seen as an example of effective translation of evidence in complex environments such as the ICU. Furthermore, the use of a two-arm cluster randomised control trial design was a strength of this study. Finally, this study also contributed to adding up-to-date knowledge regarding PU prevention and management that will enable nurses to provide high quality evidence-based nursing care.

However, this study does have limitations. Firstly, the study’s findings were limited to the study settings due to practical constraints (time, access, and finance). Secondly, the PU prevention bundle (the intervention) was not based on a high level of evidence; such as meta-analysis, or RCTs; as there is a lack of strong evidence regarding the effectiveness of some elements in PU prevention in the ICU (e.g., risk assessment scale and frequency of repositioning). Therefore, the intervention may not reflect the true nature of the care bundle approach, where, if one intervention element is removed the outcome is diminished. Thirdly, the self-evaluation and retrospective method may have led to bias in reporting and overestimation of the compliance results (Van de Mortel, 2008). Finally, health economic analysis of the intervention implementation was not conducted.

10.4 IMPLICATIONS AND RECOMMENDATIONS

The findings of this study not only contribute to a theoretical understanding of the study phenomenon in the KSA, but could also be translated into practice for the benefit of patient safety and quality of care received. Finally, implications and recommendations for practice, education, and future research are drawn from the study.
10.4.1 Implications and Recommendations for Practice

Implementation of the PU prevention bundle decreased the overall incidence in a clinically meaningful way. It is unclear which individual intervention may have been the most influential. Rather, it is likely that the synergistic effect of the bundle of interventions led to a more significant decrease in incidence than any one of the interventions might have had on its own. The PU prevention bundle was applied to all patients in the ICU, with significant improvement of skin care, which reflects that the PU prevention bundle was sensitive to the skin of patients who are most at risk. However, standard PU prevention practices in KSA need to reflect contemporary guidelines for example it is recommended that the practice of using draw sheet to reposition patient be discontinued in favour of slide sheets and the use of hydrogen peroxide as a cleansing agent is discontinued in favour of a pH balanced, gentle no rinse cleansing agent.

Standardised nursing language through risk assessment and translation of knowledge to practice is essential for PU-related outcomes. Increased compliance to the PU prevention bundle by the intensive care clinician reflects the extent to which the bundle was accepted. Moreover, there was a positive relationship between increased practitioners’ familiarity with, and increased compliance to, the care bundle in the ICU context. Monitoring the process of care, the link between intervention implementation and research outcomes was systematically explored and evaluated, ultimately leading to a greater understanding of the strengths and weakness of the intervention, enhancing both the internal and external validity of the research, and increasing opportunities for replicating the study in other settings with the same result. Since this bundle was introduced, several other initiatives have been introduced for the
nursing staff, including educational opportunities. For example, the study demonstrated that despite having access to the right skin care products, nurses needed more education and training about how and when to use them.

The presence of the opinion leader (researcher) played an important role in educating the staff, ensuring that skin assessments were being completed, and that the staff understood and maintained fidelity (process of care) to the pressure ulcer prevention bundle. Following the conclusion of the study, there is now a pressure ulcer champion in these two KSA ICUs and an additional clinical instructor whose role, in part, is to provide education about PU prevention strategies. Regular monitoring of the PU rate will provide valuable information about the pressure ulcer itself, and also which risk factors appear to contribute to pressure ulcer development.

### 10.4.2 Implications and Recommendations for Education

The KSA intensive care RNs had a positive attitude towards PU prevention, implying that RNs were eager for knowledge related to PU prevention, wound care, and the products available to them. Thus, staff education should be undertaken prior to any policy changes to inform staff of new standards for assessing, monitoring, preventing, and treating skin breakdown. Ideally, the education for all new policy changes and expectations would be given by the opinion leader. Education efforts should focus on specific, measurable interventions to be performed consistently across the unit in order to enhance the effect of prevention efforts.

This study suggests that traditional nursing education may not be sufficient to create or sustain changes in nursing practice. A need exists for new and innovative strategies to bring education to clinical nurses, including interactive technology, “hands on” learning opportunities, training at the bedside, and audit and feedback. This
study revealed the importance of the connection between change in practice and improved outcomes to sustain any change in practice.

10.4.3 Implications and Recommendations for Policy Consideration

Policy changes should be based on the need to change factors that precede the development of a PU. Accurate measurement of the incidence of PUs, both before and after the implementation of the guidelines, is important in determining the effectiveness of the interventions detailed in the previous chapter. To measure the incidence of skin breakdown, the literature suggests the use of a skin care team to perform audits and help staff members with comprehensive skin assessments (Bernabe, 2012; Pasek et al., 2008). In order to accurately determine the incidence of PUs in hospitalised patients, a detailed assessment must be performed on every patient upon admission to the ICU, preferably within four to eight hours of arrival (Coyer et al., 2015; NPUAP, EPUAP, & PPPIA, 2014). Subsequent skin care assessments should take place frequently, and should include the use of a standardised assessment tool in order to monitor the development of any skin breakdown over time (Bernabe, 2012; Lyder et al., 2012).

Policies should also include the formation of a skin care team to be responsible for compiling and monitoring the data across the unit. To determine if the interventions suggested in Chapter 4 are effective, baseline data would be compared to subsequent information as it is gathered. Moreover, comprehensive documentation should be incorporated into any PU prevention care to increase the understanding of the level of effectiveness of the intervention. Documentation should be contextualised to the ICU and provide options for consistent and feasible documentation of skin assessments, pressure ulcer staging, interventions completed for skin care, and appropriate risk
assessment scales. Staff education about the importance of consistent documentation will need to be completed prior to the implementation of guidelines.

10.4.4 Implications and Recommendations for Future Research

The findings of this study provide guidance for future investigation. First, this study should be replicated on a larger scale to validate that this bundle of care, using a slide sheet instead of a draw sheet, is actually associated with improved patient outcomes in different ICUs. Little is known about the factors associated with nurses’ adequate implementation of the PU prevention bundle in mechanically ventilated patients. Further identification of these factors will promote a broader understanding, thereby facilitating the development of interventions aimed at improving nurses’ adherence to evidence-based practices.

Secondly, future research is needed to develop and test quality improvement measures that specifically address other barriers and facilitators to nurses’ adherence to the PU prevention bundle. These measures should be based on strategies that have been empirically shown to have effectively changed nursing practice. In doing so, attention must be given to strategies that might facilitate nurses’ process of implementing evidence-based practice. One of the first issues to deal with may be how to address nurses’ overconfidence in their implementation of standardised protocols and decision making.

Thirdly, in extending research in this patient population, additional studies are needed to evaluate the level of nursing compliance required to demonstrate a significant decrease in the development of PUs. In this study, an overall high level of compliance to the PU prevention bundle was found, despite the high workload and a shortage of bedside RNs in the ICU, which would imply this bundle is compatible and suitable to use in a complex setting (ICU). Moreover, the PU incidence was not
influenced by the compliance level. Further research is needed to confirm that a minimal level of compliance to this bundle may be beneficial in the PU incidence reduction.

Fourthly, increased length of stay has been associated with an increased risk of PU development in the literature and in this study (Tayyib, et al., 2013; Tayyib, et al., 2015a). This pattern raises questions about whether patients can be identified early as potentially having a long ICU stay, as well as whether early targeted interventions could help decrease pressure ulcer development in patients who have extended ICU stays. Finally, more research is required to determine the efficacy of PU prevention interventions based on standardised criteria for reporting interventions.

10.5 IMPACT OF THIS RESEARCH ON PRACTICE TO DATE

This study on PU prevention bundle effectiveness has had a significant and practical impact at the unit and national level. Following the conclusion of this study, the PU prevention bundle used in this research was adopted at both the control and intervention sites. Furthermore, this adoption has been sustained over time and is ongoing at the time of submission of this thesis. Both ICU research sites now have a PU champion (RN) position to increase staff awareness and to facilitate the currency of clinical knowledge in PU prevention strategies. The intervention site still uses an internal benchmarking strategy with feedback of monthly PU incidence rates to all staff within the intensive care unit. Moreover, the quality and patient safety department from the intervention hospital has requested a copy of the two-arm cRCT paper published in the *Journal of Nursing Scholarship*, to submit to the KSA Ministry of Health (MOH). Consequently, if accepted by the KSA MOH, it will then be distributed
to all MOH hospitals, with a recommendation from the MOH that the PU prevention care bundle be adopted in all MOH hospitals ICUs. The latter particularly shows the long lasting significant impact of this research on national clinical practice in the KSA.

Following a conference presentation in Dubai, UAE, a copy of the two-arm cRCT published paper was also requested by one major metropolitan UAE hospital, as they wished to use this as evidence to guide a comprehensive local PU prevention project.


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Appendices

Appendix A

RESEARCH INSTRUMENTS

1) **Baseline Patient Data**

![Baseline Patient Data](image)
2) Second Daily Patient Data Collection Form

<table>
<thead>
<tr>
<th>Items</th>
<th>Study Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Date</td>
<td></td>
<td>/ / 13</td>
<td>/ / 13</td>
<td>/ / 13</td>
<td>/ / 13</td>
<td>/ / 13</td>
<td>/ / 13</td>
<td>/ / 13</td>
</tr>
<tr>
<td>2 SOFA Score</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>3 Mechanical ventilation</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Skin assessment data</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>4 Comprehensive skin assessment documented on patient’s record?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>5 Is the loss of skin integrity present?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>6 Is the loss a Stage II?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>7 If yes to 6, what is the Stage II stage? (see staging tool)</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>8 If yes, attach body chart form and tick box. (See attached form)</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>9 Is the loss related to Surgical wound?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>10 Invasive lines?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>11 Other: E.g. trauma, burns.</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>12 Loss to skin integrity documented on patient’s record?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Skin hygiene data</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>13 Has the patient been bathed in the previous 24 hours?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>14 If greater than once, how many times?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>15 Was a moisturizer applied to dry flaky skin?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Turning schedule</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>16 In the previous 24 hours was the patient repositioned every 2 hours?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>17 If no, average length of time to reposition in the last 24 hours?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Elimination of shear and friction</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>18 Is exposed skin protected using padding?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>19 Are heel protectors applied?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Promotion of mobility</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>20 Is the patient mobile?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>21 If no, have they sat out of bed in the last 24 hours?</td>
<td></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>

Comments:
3) **Sequential Organ Failure Assessment Score (SOFA) Instrument**

### The Sequential Organ Failure Assessment score “SOFA score”

<table>
<thead>
<tr>
<th>Organ System</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Organ scores</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiration</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\text{PaO}_2$ / $\text{FiO}_2$ (in mmHg)</td>
<td>$&gt;400$</td>
<td>301 - 400</td>
<td>201 - 300</td>
<td>101 - 200</td>
<td>$\leq 100$</td>
<td>(with respiratory support)</td>
</tr>
<tr>
<td><strong>Coagulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets ($\times 10^7$ / mm$^3$)</td>
<td>$&gt;150$</td>
<td>101 - 150</td>
<td>51 - 100</td>
<td>21 - 50</td>
<td>$\leq 20$</td>
<td></td>
</tr>
<tr>
<td><strong>Liver</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilirubin (mg / dl)</td>
<td>$&lt;1.2$</td>
<td>1.2 - 1.9</td>
<td>2.0 - 5.9</td>
<td>6.0 - 11.9</td>
<td>$&gt;12.0$</td>
<td></td>
</tr>
<tr>
<td>(μmol / L)</td>
<td>$&lt;20$</td>
<td>20 - 82</td>
<td>33 - 101</td>
<td>102 - 204</td>
<td>$&gt;204$</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>No hypotension</td>
<td>MAP $&lt; 70$ mmHg</td>
<td><strong>dopamine $\leq 5.0$ (doses are given in $\mu g$ / kg / minute) or any dose dobutamine</strong></td>
<td><strong>dopamine $&gt;5.0$ (doses are given in $\mu g$ / kg / minute) or epinephrine $\leq 0.1$ or norepinephrine $\leq 0.1$ or any dose vasopressin or any dose metaraminol or any dose phenylephrine</strong></td>
<td><strong>dopamine $&gt;15.0$ (doses are given in $\mu g$ / kg / minute) or epinephrine $&gt;0.1$ or norepinephrine $&gt;0.1$</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Renal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine (mg / dl)</td>
<td>$&lt;1.2$</td>
<td>1.2 - 1.9</td>
<td>2.0 - 3.4</td>
<td>3.5 - 4.9</td>
<td>$&gt;5.0$</td>
<td></td>
</tr>
<tr>
<td>mmol/l</td>
<td>$&lt;0.110$</td>
<td>0.110 - 0.170</td>
<td>0.171 - 0.299</td>
<td>0.200 - 0.440</td>
<td>$&gt;0.440$</td>
<td></td>
</tr>
<tr>
<td><strong>OR Urine output (ml / d)</strong></td>
<td>or $&lt; 500$ ml / day</td>
<td>or $&lt; 200$ ml / day</td>
<td>or $&lt; 200$ ml / day</td>
<td>or $&lt; 200$ ml / day</td>
<td>or $&lt; 200$ ml / day</td>
<td></td>
</tr>
<tr>
<td><strong>CNS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasgow Coma Scale</td>
<td>15</td>
<td>13-14</td>
<td>10-12</td>
<td>6-9</td>
<td>$&lt;6$</td>
<td></td>
</tr>
</tbody>
</table>

**Total SOFA score**
4) **PU Staging Tool**

**PU STAGING TOOL**

Patient Initials: [___] [___] [___]  
Patient Study Number: [___] [___] [___] [___]

1) **Pressure injury Staging**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected deep tissue injury</td>
<td>Is characterised by the discoloration of intact skin by purple- or maroon-coloured or blood-filled blisters as a consequence of prolonged pressure, shear or friction to underlying tissue.</td>
</tr>
<tr>
<td>Stage I</td>
<td>Is marked by non-blanchable redness of intact skin that is not dissolved by relief of pressure. It is localised over a bony prominence. It can be painful, firm, warmer or cooler as compared to another area.</td>
</tr>
<tr>
<td>Stage II</td>
<td>Is defined as partial thickness loss including the epidermis and dermis. It appears as a shallow pink ulcer or superficial blister or abrasion.</td>
</tr>
<tr>
<td>Stage III</td>
<td>Is involves full-thickness tissue loss. This damage may include subcutaneous tissue but not the underlying fascia. As a result of the anatomical difference of each part of the body, assessing the depth of stage III PrI varies.</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Is involves full-thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. In stage IV PrI, undermining and tunnelling of the wound can be observed.</td>
</tr>
<tr>
<td>Unstageable</td>
<td>Is full-thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, grey, green or brown) and/or eschar (tan, brown or black) in the wound bed. This may confound the identification of the depth of the tissue.</td>
</tr>
</tbody>
</table>

All Nasal and Lip Pressure Ulcer (PU) need to be coded as Muscoal PU (MPU) and not staged (ie no number)

2) Pressure Ulcer Prevalence Body Chart Form

Date: _________________  Time: _______________

- Circle the location of Pressure Ulcer and indicate the stage
- If more than one Pressure Ulcer found please indicate a number to correspond with the additional Pressure Ulcer documentation audit sheet.

INSTRUCTION:
- Inform RN at bedside  YES  NO
## 5) Braden Risk Assessment Scale

<table>
<thead>
<tr>
<th>Items</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensory Perception</strong>&lt;br&gt;- Ability to respond meaningfully to pressure related discomfort</td>
<td>1. Completely Limited Unresponsive (does not moan, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation. OR limited ability to feel pain over most of body surface.</td>
<td>2. Very Limited Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness. OR has a sensory impairment that limits the ability to feel pain or discomfort over ½ of body.</td>
<td>3. Slightly Limited Responds to verbal commands, but cannot always communicate discomfort or need to be turned. OR has some sensory impairment that limits ability to feel pain or discomfort in 1 or 2 extremities.</td>
<td>4. No Impairment Responds to verbal commands. Has no sensory deficit that would limit ability to feel or voice pain or discomfort</td>
<td></td>
</tr>
<tr>
<td><strong>Moisture</strong>&lt;br&gt;- Degree to which skin is exposed to moisture</td>
<td>1. Constantly Moist Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient/client is moved or turned.</td>
<td>2. Very Moist Skin is often, but not always, moist. Linen must be changed at least once a shift.</td>
<td>3. Occasionally Moist Skin is occasionally moist, requiring an extra linen change approximately once a day.</td>
<td>4. Rarely Moist Skin is usually dry. Linen only requires changing at routine intervals.</td>
<td></td>
</tr>
<tr>
<td><strong>Activity</strong>&lt;br&gt;- Degree of physical activity</td>
<td>1. Bedfast Confined to bed</td>
<td>2. Chairfast Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.</td>
<td>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.</td>
<td>4. Walks Frequently Walks outside the room at least twice a day and inside the room every 2 hours during waking hours.</td>
<td></td>
</tr>
<tr>
<td><strong>Mobility</strong>&lt;br&gt;- Ability to change and control body position</td>
<td>1. Completely Immobile Does not make even slight changes in body or extremity position without assistance.</td>
<td>2. Very Limited Makes occasional slight changes in body or extremity position but unable to make</td>
<td>3. Slightly Limited Makes frequent though slight changes in body or extremity position independently.</td>
<td>4. No Limitations Makes major and frequent changes in position without assistance.</td>
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<tr>
<td>Nutrition - Usual food intake pattern</td>
<td>Never eats a complete meal. Rarely eats more than 1/3 of any food offered.</td>
<td>Rarely eats a complete meal and generally eats only about 1/3 of any food</td>
<td>Eats over half of most meals. Eats a total of 4 servings of protein (meat,</td>
<td>Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or</td>
<td></td>
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<tr>
<td></td>
<td>Eats 2 servings or less of protein (meat or dairy products) per day. Takes</td>
<td>offered. Protein intake includes only 3 servings of meat or dairy products per</td>
<td>dairy products) each day. Occasionally will refuse a meal, but will usually</td>
<td>more servings of meat and dairy products. Occasionally eats between meals.</td>
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<tr>
<td></td>
<td>fluids poorly. Does not take a liquid dietary supplement. OR is NPO and/or</td>
<td>day. Occasionally will take a dietary supplement. OR receives less than</td>
<td>take a supplement if offered. OR is on a tube feeding or TPN regimen which</td>
<td>Does not require supplementation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>maintained on clear liquids or IV’s for more than 5 days.</td>
<td>optimum amount of liquid diet or tube feeding.</td>
<td>probably meets most of nutritional needs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friction and Shear</td>
<td>Requires moderate to maximum assistance in moving.</td>
<td>Moves feebly or requires minimum assistance. During a move, skin probably</td>
<td>Moves in bed and in chair independently and has sufficient muscle strength</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>slides to some extent against sheets, chair restraints, or other devices.</td>
<td>to lift up completely during move. Maintains good position in bed or chair at</td>
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<tr>
<td></td>
<td></td>
<td>Maintains relatively good position in chair or bed most of the time, but</td>
<td>all times.</td>
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<tr>
<td></td>
<td></td>
<td>occasionally slides down.</td>
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</table>

**Total Braden Score**
6) Barriers and Facilitators Survey

Pressure Ulcer Prevention Bundle in ICU
Barriers and Facilitators

Pressure Ulcers continue to be a significant problem in ICU. We are interested in hearing from you about what (if anything) gets in the way of you being able to provide optimal skin care for your patients, as well as what (if anything) helps you to provide optimal skin care for your patients. This is part of a research study being conducted in the ICU. Your participation is voluntary and implies informed consent. We anticipate that the survey will take 10 to 15 minutes to complete. Some questions may seem the same, but we would appreciate your response to all questions.

Part 1 Demographic information

1. Sex: Male □ Female □
2. Education: Diploma □ Bachelor degree □ Master degree □ Post registration ICU qualification certificate □
3. Number of years as a RN? ____ Years
4. Number of years working in the ICU? ____ Years
5. Number of years employed in this hospital? ____ Years

Part 2 Potential barriers to optimal skin care
Below are some potential barriers to optimal skin care. The scale ranges from 0 (Not a barrier) to 10 (A major barrier). Please select the number that best rates these barriers to your personal ability to provide optimal skin care for your patients.

1. Competing demands on my time
   
   0 1 2 3 4 5 6 7 8 9 10

   Not a barrier A major barrier

2. Limitations in my ability to assess risk of pressure injury development
   
   0 1 2 3 4 5 6 7 8 9 10

   Not a barrier A major barrier

3. Limitations in my knowledge about pressure injury prevention
   
   0 1 2 3 4 5 6 7 8 9 10

   Not a barrier A major barrier

4. Low priority given to pressure injury prevention by medical staff
   
   0 1 2 3 4 5 6 7 8 9 10

   Not a barrier A major barrier
5. Low priority given to pressure ulcer prevention by nursing staff
   0 1 2 3 4 5 6 7 8 9 1
   Not a barrier           A major barrier

6. Low priority given to pressure ulcer prevention by me
   0 1 2 3 4 5 6 7 8 9 1
   Not a barrier           A major barrier

7. Current documentation format for pressure ulcer risk/ nursing interventions
   0 1 2 3 4 5 6 7 8 9 1
   Not a barrier           A major barrier

8. Insufficient resources to provide guidance/expertise in pressure ulcer prevention
   0 1 2 3 4 5 6 7 8 9 1
   Not a barrier           A major barrier

9. Insufficient supplies/equipment to provide optimal pressure ulcer prevention care
   0 1 2 3 4 5 6 7 8 9 1
   Not a barrier           A major barrier

10. Low priority given to pressure ulcer prevention due to the severity of patient’s illness
    0 1 2 3 4 5 6 7 8 9 1
      Not a barrier           A major barrier

11. Low cooperation levels from patients or/and their family
    0 1 2 3 4 5 6 7 8 9 1
      Not a barrier           A major barrier

12. Lack of authority to change patient care
    0 1 2 3 4 5 6 7 8 9 1
      Not a barrier           A major barrier
13. What other barriers to pressure ulcer prevention are not included on this tool?

14. In general, to what degree do you feel you are able to overcome barriers and ultimately provide optimal skin care for your patients?

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</table>

Not at all able  Very able

**Part 3 potential facilitators to optimal skin care**

Below are some potential facilitators to optimal skin care. The scale ranges from 0 (Not at all helpful) to 10 (very helpful). Please select the number that best rates these facilitators to your personal ability to provide optimal skin care for your patients.

1. Education about Braden risk assessment of pressure injury development

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Not at all helpful  Very helpful

2. Education about pressure ulcer grading

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<th>3</th>
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</table>

Not at all helpful  Very helpful

3. Current documentation format for pressure ulcer risk/ nursing interventions

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</table>

Not at all helpful  Very helpful

4. Ease of obtaining pressure reduction surfaces

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</table>

Not at all helpful  Very helpful

5. Collaboration with interdisciplinary team (nursing/medicine/pharmacy/dietary)
Part 4 RNs attitude towards pressure ulcer prevention
Below are some questions about assessment of RNs’ attitude towards pressure ulcer prevention. The scale ranges from 1 (disagree) to 4 (strongly agree). Please select the number that indicates how much you agree or disagree with each of the following statements.

1. I feel confident in my ability to prevent pressure ulcers.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

2. I am well trained to prevent pressure ulcers.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

3. Pressure ulcers are too difficult. Others are better than I am.
   1  2  3  4
Appendices

4. Too much attention goes to the prevention of pressure ulcers.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

5. Pressure ulcer prevention is not that important.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

6. Pressure ulcer prevention should be a priority.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

7. A pressure ulcer almost never causes discomfort for a patient.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

8. The impact of pressure ulcers on a patient should not be exaggerated.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

9. The financial impact of pressure ulcers on society should not be exaggerated.
   1  2  3  4
   Strongly disagree  Disagree  Agree  Strongly agree

10. I personally do not feel responsible if a pressure ulcer develops in my patient.
    1  2  3  4
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

11. I personally have an important task in pressure ulcer prevention.

<table>
<thead>
<tr>
<th>1</th>
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</table>

12. Pressure ulcers are preventable in high risk patients.

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<th>2</th>
<th>3</th>
<th>4</th>
</tr>
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</table>

13. Pressure ulcers are never preventable.

<table>
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<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

Thanks for your willingness to participate.
7) PU Prevention Bundle Adherence Self-Report

"Pressure Ulcer Prevention Bundle Adherence Self-Report"

Complete one bundle adherence checklist for the last shift. By completing this survey you are giving consent to participate in this research project related to adherence to PU prevention.

**Part 1 Demographic information**

1. Sex: Male [ ] Female [ ]
2. Education: Diploma [ ] Bachelor degree [ ] Master degree [ ] Post registration ICU qualification certificate [ ]
3. Number of years as a RN? _____ Years
4. Number of years working in the ICU? _____ Years
5. Number of years employed in this hospital? _____ Years

**Part 2 RNs reflection**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Strongly disagree</th>
<th>disagree</th>
<th>agree</th>
<th>strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Do you feel you have received enough education to conduct the Braden Scale score risk assessment?</td>
<td></td>
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</tr>
<tr>
<td>2  Do you feel you have received enough education to undertake comprehensive skin physical assessment?</td>
<td></td>
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<tr>
<td>3  Do you feel you have received sufficient training in documenting skin integrity assessment?</td>
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<tr>
<td>4  Do you feel you have received enough education and training regarding the role of repositioning in PrI prevention, correct methods for repositioning and use of equipment in reducing pressure, friction and shear forces?</td>
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<tr>
<td>5  The PrI prevention was easy to implement.</td>
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</table>

**Part 2 Pressure ulcer prevention bundle Adherence**

We would like to get your best guess about how much you can rate yourself for the PrI prevention bundle adherence. Please make a mark on the following scale:

<table>
<thead>
<tr>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
</table>

**Part 3 Potential barriers and facilitators could affect the RNs adherence**

1. Please identify any barriers and facilitators in following the PU prevention bundle?

*Thanks for your willingness to participate.*
## 8) Researcher Audit of the PU Prevention Bundle

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Completed Braden risk assessment scale for the patients within the first 24 hours after admission.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2  Completed Braden risk assessment scale with any changes in patient’s physical condition noted, and daily risk assessment thereafter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3  Documented the risk assessment scale score?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4  Completed comprehensive physical examination of the patient’s skin within 4 hours of ICU admission.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5  Documented skin assessment within 4 hours of patient’s admission.</td>
<td></td>
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</tr>
<tr>
<td>6  Performed physical examination of the patient’s skin within last 8 hours.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7  Documented physical examination of the patient’s skin for last 8 hours.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8  Performed physical examination of the patient’s skin on each turning/repositioning manoeuvre.</td>
<td></td>
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<tr>
<td>9  Documented any loss of skin integrity.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Reported skin integrity loss to RN in charge.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Patients bed-bathed once per day.</td>
<td></td>
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</tr>
<tr>
<td>12 Pre-packaged wash clothes used for bed-bath.</td>
<td></td>
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<tr>
<td>13 Prudent amount of moisturiser applied to dry, flaky or scaling skin.</td>
<td></td>
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<tr>
<td>14 Avoided patient massage.</td>
<td></td>
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<tr>
<td>15 Avoided patient skin contact with plastic surfaces (e.g., plastic-lined disposable underpads or plastic surface of pillow.</td>
<td></td>
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<tr>
<td>16 Nutritional status assessment was undertaken by the specialist as per ICU current practice</td>
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<tr>
<td>17 On my shift, patient was turned every 3 hours.</td>
<td></td>
<td></td>
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<tr>
<td>18 Patients positioned in a full lateral turn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Support surfaces (such as a pillow) were used for patient support during repositioning/ turning.</td>
<td></td>
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</tr>
<tr>
<td>20 Patient’s position change was done according to turn clock.</td>
<td></td>
<td></td>
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<tr>
<td>21 Exposed skin was protected using padding, protective dressing.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 If clinically possible, foot of bed is elevated at 20°.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 If clinically possible, head of bed is positioned at 30-45°? Or if not possible, head of bed was positioned as required.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Patient’s heels elevated by pillow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 Heel protectors utilized</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26 Patient sat out of bed today</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 (If applicable) Appropriate technique and devices used to assist carers with transferring and lifting patients to reduce friction and shear?</td>
<td></td>
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<tr>
<td>28 Other health care teams such as physiotherapist, helped you to mobilise patients.</td>
<td></td>
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<tr>
<td>29 Positioning regimes were documented including the time of repositioning and position adopted?</td>
<td></td>
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</tr>
<tr>
<td>30 Securement and repositioning of nasogastric tubes (NGT) and endotracheal tubes (ETT) every 12 hours</td>
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Appendix B

LETTER AND APPROVAL TO USE THE INSTRUMENTS

1) Permission letter for “Pressure Ulcer Prevention in PICU (Barriers and Facilitators)

Dear Maia,

Sorry for my delayed response. You are more than welcome to use the survey. Please see attached for an electronic version. Sounds like a wonderful study!! Best of luck to you on this important work.

Kind regards,

Chris

Christina Sotaklar, PhD, CNP
Pediatric Critical Care Nurse Practitioner
Medical College of Wisconsin/Children’s Hospital of Wisconsin
800 N. Osceola Ave, MEB111
Milwaukee, WI 53226

From: nania@nania.edu
Sent: Thursday, November 08, 2012 2:14 AM
To: Sotaklar, Christina

Subject: Seeking permission for your developed instrument.

Dear Dr Sotaklar,

I am a doctoral student at Queensland University of Technology, School of Nursing, Australia. I am seeking your permission to use your Pressure Ulcer Prevention in the PICU Barriers and Facilitators Instrument in my research. My research involves implementation of an intervention bundle to reduce the incidence of pressure ulcers in a small pediatric adult intensive care unit. My study will comprise of two phases. The first phase will establish incidence of pressure ulcers in the ICU and explore potential facilitators and barriers for registered nurses in the adoption of a pressure ulcer prevention care bundle protocol. The second phase is an randomized control trial to test the intervention. I would like to use the instrument you developed in phase one.

I look forward to your positive response.

Kind regards,

Nania

Nania Tanyi's PA NI

NOMO consultant
School of Nursing
Queensland University of Technology, Victoria Park Rd, Kelvin Grove, Queensland, Australia 4059

Tel: +61 732623940. Office Inquiries & Clerk
Email: nania.tanyi@moodle. qut.edu.au
2) The Original Instrument “Pressure Ulcer Prevention in PICU (Barriers and facilitators)”

Pressure Ulcer Prevention in the PICU
Barriers and Facilitators

Children’s Hospital of Wisconsin has been looking at ways to eradicate pressure ulcers in the PICU. We are interested in hearing from you about what (if anything) gets in the way of you being able to provide optimal skin care for your patients as well as what (if anything) helps you to provide optimal skin care for your patients. You are asked to complete this survey because of the important work that you do in the PICU. This is part of a research study being conducted in the PICU. Your participation is voluntary and implies informed consent. The results of the survey will be used to drive improvement activities. No information identifying any one nurse will be collected or shared. We anticipate that the survey will take approximately 10 minutes to complete. Thank you in advance for your willingness to participate.

Demographic Information:

Male/ Female

Number of years as a RN?

Number of years employed by CHW?

Number of years working in the PICU?

Part time or Full time employment?

Below are some potential barriers to optimal skin care. On a scale of 0 to 10, with 0 being “Not a barrier” and 10 being “A major barrier” please select the number that best rates these barriers to your personal ability to provide optimal skin care for your patients over the past year.

1. Competing demands on my time

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<tr>
<td>Not a barrier</td>
<td>A major barrier</td>
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2. Limitations in my ability to assess risk of pressure ulcer development

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3. Limitations in my knowledge about pressure ulcer prevention

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4. Low priority given to pressure ulcer prevention by **medical staff**

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

5. Low priority given to pressure ulcer prevention by **nursing staff**

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

6. Low priority given to pressure ulcer prevention by **me**

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

7. Current documentation format for pressure ulcer risk/nursing interventions

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

8. Insufficient resources to provide guidance/expertise in pressure ulcer prevention

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

9. Insufficient supplies/equipment to provide optimal pressure ulcer prevention care

   0 1 2 3 4 5 6 7 8 9 10
   Not a barrier A major barrier

10. What other barriers to pressure ulcer prevention at CHW are not included on this tool?

11. In general, to what degree do you feel you are able to overcome barriers and ultimately provide optimal skin care for your patients?

   0 1 2 3 4 5 6 7 8 9 10
   Not at all able Very able

Below are some potential facilitators to optimal skin care. On a scale of 0 to 10, with 0 being “Not at all helpful” and 10 being “Very helpful” please select the number that best rates these facilitators to your personal ability to provide optimal skin care for your patients over the past year.
1. Education about Braden Q risk assessment of pressure ulcer development

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

2. Education about pressure ulcer grading

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

3. Current documentation format for pressure ulcer risk/ nursing interventions

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

4. Unit based skin care champions

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

5. Sunrise pressure ulcer prevention nursing order set

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

6. Ease of obtaining pressure reduction surfaces

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

7. Collaboration with interdisciplinary team (nursing/medicine/pharmacy/dietary)

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

8. Appropriate skin care products readily available

0 1 2 3 4 5 6 7 8 9 10
Not at all helpful Very helpful

9. What other facilitators to pressure ulcer prevention at CHW are not included on this tool?

10. In general, to what degree do you feel you that efforts are being made to facilitate your ability to prevent pressure ulcer development in the PICU?

0 1 2 3 4 5 6 7 8 9 10
Not at all A great deal
3) Permission Letter for the Attitude Towards Pressure Ulcer Prevention Instrument (APuP).

Dear Dr. [Name],

Thank you for your email. I am pleased to provide permission to use the tool for the purposes you described. The full version of the APuP is included in the [journal name] publication you mentioned in your email. Great luck with your research!

Best regards,

[Your Name]

[University Name]

[Email]

[Phone]

[Address]

[Website]

Please consider the instrument before selecting the email.

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Appendix C

ETHICAL APPROVAL

1) Ethical Approval from King Faisal Hospital, Makkah, Kingdom of Saudi Arabia
2) Ethical Approval Kind Abdul-Aziz Hospital, Makkah, Kingdom of Saudi Arabia

Research Ethic Approval Form

To: Queensland University of Technology
Subject: Ethical Approval of Research Proposal
Date: 15-05-2013

This is to certify that research proposal titled: “Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients” Submitted by: “Nahla Tayyib” was reviewed by the research and ethic committee in our hospital with respect to protecting of the rights of human subject involved in the research project. However, it is agreed that individual patient or guardian patient consent is not required for measuring incidence of pressure injury in intensive care unit.
I am pleased to inform you that the committee approves the above mentioned proposal as fulfilling the ethical requirement. Granting permission to principal investigator of the possibility of access to patient records identified for the study. Please submit your progress report to the training and education center.

Best Regard.

Head of Ethical Committee
Dr. Abdullah M. Alkhuzaiee

Head of Research Committee
Dr. Ali M. Alghamdi
2) Ethical approval from Queensland university of Technology Human Research Ethics Committees

Dear Ms Nahla Abdulgadir Hassan Tayyib,

A UHREC should clearly communicate its decisions about a research proposal to the researcher and the final decision to approve or reject a proposal should be communicated to the researcher in writing. This Approval Certificate serves as your written notice that the proposal has met the requirements of the National Statement on Research Involving Human Participation and has been approved on that basis. You are therefore authorised to commence activities as outlined in your proposal application, subject to any specific and standard conditions detailed in this document.

Within this Approval Certificate are:

- Project Details
- Participant Details
- Conditions of Approval (Specific and Standard)

Researchers should report to the UHREC, via the Research Ethics Coordinator, events that might affect continued ethical acceptability of the project, including, but not limited to:

(a) serious or unexpected adverse effects on participants; and
(b) proposed significant changes in the conduct, the participant profile or the risks of the proposed research.

Further information regarding your ongoing obligations regarding human based research can be found via the Research Ethics website [http://www.research.qut.edu.au/ethical/](http://www.research.qut.edu.au/ethical/) or by contacting the Research Ethics Coordinator on 07 3138 3201 or ethicscontact@qut.edu.au.

If any details within this Approval Certificate are incorrect please advise the Research Ethics Unit within 10 days of receipt of this certificate.

**Project Details**

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<tr>
<td>Approved Until:</td>
<td>20/08/2016</td>
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<td>Use of an interventional patient skin integrity care bundle in the intensive care unit to best manage skin integrity in critically ill patients.</td>
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<td>Experiment Summary:</td>
<td>Calculate the number of new cases of pressure injuries occurring in critically ill patients in intensive care unit during a consecutive two month period.</td>
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**Investigator Details**

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<th>Chief Investigator</th>
<th>Ms Nahla Abdulgadir Hassan Tayyib</th>
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<tr>
<td>Investigator Name</td>
<td>Type</td>
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<tr>
<td>A/Prof Fiona Coyer</td>
<td>Internal</td>
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<tr>
<td>Dr Peter Lewis</td>
<td>Internal</td>
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**Participant Details**

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RM Report No. ED01 Version 4
University Human Research Ethics Committee
HUMAN ETHICS APPROVAL CERTIFICATE
NHMRC Registered Committee Number EC00171

Date of Issue: 2018/13 (supersedes all previously issued certificates)

Location/s of the Work:
King Abdul-Aziz Hospital, Saudi Arabia

Conditions of Approval

Specific Conditions of Approval:
None apply

Standard Conditions of Approval:
The University's standard conditions of approval require the research team to:

1. Conduct the project in accordance with University policy, NHMRC / AVCC guidelines and regulations, and the provisions of any relevant State / Territory or Commonwealth regulations or legislation;

2. Respond to the requests and instructions of the University Human Research Ethics Committee (UHREC);

3. Advise the Research Ethics Coordinator immediately if any complaints are made, or expressions of concern are raised, in relation to the project;

4. Suspend or modify the project if the risks to participants are found to be disproportionate to the benefits, and immediately advise the Research Ethics Coordinator of this action;

5. Stop any involvement of any participant if continuation of the research may be harmful to that person, and immediately advise the Research Ethics Coordinator of this action;

6. Advise the Research Ethics Coordinator of any unforeseen development or events that might affect the continued ethical acceptability of the project;

7. Report on the progress of the approved project at least annually, or at intervals determined by the Committee;

8. (Where the research is publicly or privately funded) publish the results of the project in such a way to permit scrutiny and contribute to public knowledge, and

9. Ensure that the results of the research are made available to the participants.

Modifying your Ethical Clearance:
Requests for variations must be made via submission of a Request for Variation to Existing Clearance Form (http://www.research.qut.edu.au/ethics/forms/humvar/varvar.jsp) to the Research Ethics Coordinator. Minor changes will be assessed on a case by case basis.

It generally takes 7-14 days to process and notify the Chief Investigator of the outcome of a request for a variation.

Major changes, depending upon the nature of your request, may require submission of a new application.

Audits:
All active ethical clearances are subject to random audit by the UHREC, which will include the review of the signed consent forms for participants, whether any modifications / variations to the project have been approved, and the data storage arrangements.
PARTICIPANT INFORMATION SHEET FOR PHASE ONE, PART A

RESEARCH TEAM
Principal Researcher: Nahla Tayyib, PhD student, Queensland University of Technology (QUT)
Associate Researchers: Associate Professor Fiona Coyer and Dr. Peter Lewis, QUT

DESCRIPTION
This project is being undertaken by Nahla Tayyib, student, as part of a Doctor of Philosophy degree in the School of Nursing at Queensland University of Technology – Australia.

Ulcer to your skin, such as pressure ulcers, may cause you considerable harm, be painful and cause the development of serious infection which may hinder your recovery and cause you to stay longer in hospital. Although pressure ulcers are commonly preventable, worldwide the number of pressure ulcers seen in health care facilities are increasing. To date little research attention has been given to number of pressure ulcers occurring in critically ill patients in Saudi Arabian intensive care units. This study will calculate the number of new cases of pressure ulcers occurring in critically ill patients in intensive care unit during a consecutive two-month period. During the study period there will be no change to the medical and nursing practice you will receive in relation to your illness.

You are invited to participate in this research study because any patients admitted to an intensive care unit are at high risk for damage to their skin such as pressure ulcer development.

This participant information sheet contains detailed information about the study. Its purpose is to explain to you as openly and clearly as possible all procedures involved in this study. Please read this participant information sheet carefully. Feel free to ask questions about any information in the document.

PARTICIPATION
During an four (4) week period, we plan to collect initial information about you, and then on a second daily basis information about the condition of your skin. This will involve the principal researcher assessing your skin for the possibility that you may have developed a pressure ulcer. This assessment will take approximately five to ten minutes. The skin assessments will not affect or interrupt your care in the intensive care unit care.

EXPECTED BENEFITS
It is expected that this project will not directly benefit you. However, results from this study will inform a future research study, which will test strategies to prevent pressure ulcers occurring in critically ill patients in the intensive care unit.

RISKS
There are no risks beyond normal day-to-day living associated with your participation in this project. However, should you develop a pressure ulcer during this study, and this has not already been identified by the registered nurse caring for you, the researcher will inform the registered nurse caring for you. You will then receive the usual care for pressure ulcers following the hospital policy and procedures.

PRIVACY AND CONFIDENTIALITY
All information collected for this study will be treated confidentially. This information will be undertaken by the researcher only. Only the researcher will know your identity, and this will be during the data collection period only. All information will be kept in the strictest confidence in a locked filing cabinet accessible only to the researcher. It is hoped to publish a report of the findings of the research, but no information will be published that would allow any individual or organisation to be recognised.

Any data collected as part of this project will be stored securely as per protocol of the Unit of Ethics at the hospital.

Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

CONSENT TO PARTICIPATE
Measuring the number of pressure ulcers in the intensive care unit will not affect or interrupt the care you will receive. This study seeks to calculate the number of new cases of pressure ulcer in intensive care units, therefore complete patient numbers are crucial for accurate calculation. However, if you, or your family member, wish to opt out of this study by not agreeing to participate, please contact the principal researcher or let the registered nurse caring for you know. Your information will then be withdrawn from the study without comment or penalty. Your decision not to participate will not affect the care you receive in the intensive care unit.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT
If have any questions or require further information, please contact me:

Dr. Fiona Coyer – Principal supervisor
Dr. Peter Lewis – Associate supervisor
Nahla Tayyib – Student
School of Nursing
Faculty of Health
Phone (+966550106868)
Email: nahla.tayyib@student.qut.edu.au

School of Nursing
Faculty of Health
Phone (+61731383895)
Email: f.coyer@qut.edu.au

School of Nursing
Faculty of Health
Phone (+61731383834)
Email: p.lewis@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT
QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the Ethnic department of Ministry of Health on tel. +966567123507 or email makkah_research_group@hotmail.com and/or the QUT Research Ethics Unit on [+61 7] 3138 5123 or email ethicscontact@qut.edu.au. The Ethic committee of Ministry of Health and QUT Research Ethics Unit are not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep this sheet for your information.
Appendix E

PARTICIPANT INFORMATION SHEET FOR PHASE ONE PART B

RESEARCH TEAM
Principal Researcher: Nahla Tayyib, PhD student, Queensland University of Technology
Associate Researchers: Associate professor Fiona Coyer and Dr. Peter Lewis, QUT

DESCRIPTION
This project is being undertaken by Nahla Tayyib, student, as part of a Doctor of Philosophy degree in the School of Nursing at Queensland University of Technology – Australia.

Although pressure ulcers are commonly preventable, worldwide the number of pressure ulcers seen in health care facilities are increasing. This study is part of a future study testing ways to reduce pressure ulcers in the intensive care unit of this hospital. We are interested in hearing from you about what (if anything) gets in the way of you being able to provide optimal skin care for your patients, as well as what (if anything) helps you to provide optimal skin care for your patients. In order to effect change in practice, it is important to design a comprehensive, supported, and sustained approach to the prevention of pressure ulcers. Your feedback will assist us in identifying gaps in support and allow us to make changes as necessary to support your efforts in significantly reducing pressure ulcers. You are asked to complete this survey, as a registered nurse providing care for critically ill patients in the intensive care unit.

Participation
Your participation will involve completing an anonymous survey with 42 questions. This will take approximately 10 minutes of your time.

Your participation in this project is entirely voluntary. If you agree to participate, we ask that you complete the questionnaire and then post the completed questionnaire in the mail box placed at the nurses' station in the intensive care unit. Your decision to participate, or not to participate, will in no way impact upon your current or future relationship with the hospital. No consequence, comment or penalty will arise if you refuse to participate in this study. However, as the questionnaire is anonymous, once it has been submitted (posted in the mail box) it will not be possible to withdraw.

Expected benefits
This project is of benefit to you, as the information gained from your responses will assist the researchers in assessing and tailoring the training protocol for the intervention toward prevention of pressure ulcer in intensive care.

**Risks**

There are no risks beyond normal day-to-day living associated with your participation in this project. The hospital provides limited free counselling for research participants, who may experience some distress as a result of their participation in the research. Should you wish to access this service please contact (the hospital counseling service (place, tel. X.).

**PRIVACY AND Confidentiality**

All comments and responses are anonymous and will be treated confidentially. The names of individual persons are not required in any of the responses.

Any data collected as part of this project will be stored securely as per QUT’s Management of research data policy.

Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

**Consent to Participate**

The return of the completed questionnaire is accepted as an indication of your consent to participate in this project.

**Questions / further information about the project**

If you have any questions or require further information, please contact me:

- Nahla Tayyib – Student
  - School of Nursing
  - Faculty of Health
  - Phone (+966550106868)
  - Email: nahla.tayyib@student.qut.edu.au

- A/Prof. Fiona Coyer – principal supervisor
  - School of Nursing
  - Faculty of Health
  - Phone (+61731383895)
  - Email: f.coyer@qut.edu.au

- Dr. Peter Lewis – Associate supervisor
  - School of Nursing
  - Faculty of Health
  - Phone (+61731383834)
  - Email: p.lewis@qut.edu.au

**Concerns / complaints regarding the conduct of the project**

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the Ethic department of Ministry of Health tel. +966567123507 or email makkah_research_group@hotmail.com and/or the QUT Research Ethics Unit on [+61 7] 3138 5123 or email ethicscontact@qut.edu.au. The Ethic committee of Ministry of Health and QUT Research Ethics Unit are not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

*Thank you for helping with this research project. Please keep this sheet for your information.*

Appendix F
Part 1 What does my participation involve?

1 Introduction

Ulcer to a patient’s skin, such as a pressure ulcer, may be painful and cause a serious infection, which may mean a longer stay in hospital. Although pressure ulcers are preventable, worldwide the number of pressure ulcers seen in health care facilities is increasing. This study is looking at ways to reduce pressure ulcers in intensive care units.

The study will test the effectiveness of a new pressure ulcer prevention strategy, based on best available current evidence, aimed at reducing the number of pressure ulcers. The strategy consists of: risk assessment, skin assessment, skin care, nutrition, repositioning, support surfaces, and education and training for health care practitioners.

The patient, your next of kin, is invited to participate in this research study because any patients admitted to an intensive care unit are at high risk for impaired skin integrity such as pressure ulcer development. This is sometimes due to their illness and resulting management in the intensive care unit.

This project is being undertaken by Nahla Tayyib, student, as part of a Doctor of Philosophy degree at QUT.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the prevention strategies involved. Knowing what is involved will help you decide if you want the patient to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not the patient, your next of kin, might take part, feel free to talk about the study with a relative, friend or doctor.

2 What does participation in this research involve?
Sometimes we do not know which care is best for improving skin condition of intensive care unit patients. To find out, we need to compare different care to our standard practices. We will put people into groups and give each group either a different care or our standard care.

The results will be compared to see if one is better in improving skin integrity, or avoiding damage to the skin, of critically ill patients.

There are no additional costs associated with participating in this study, nor will you or the patient, your next of kin, be paid. All medical care required as part of the research project will be provided to the patient, your next of kin, free of charge.

Firstly, we will collect personal health information about your next of kin from their admission record. The information we require includes: the patient’s age, gender, nationality, body mass index (BMI) and clinical data including their reason for admission to the intensive care unit, other health conditions the patient may have, whether their admission was an emergency or elective admission, the length of time they may have spent in the operating theatre or emergency department prior to ICU admission and how long they have been in the intensive care unit.

Secondly, this study will involve approximately 300 patients from two intensive care units in Saudi Arabia. Patients in one intensive care unit will receive routine standard care and patients in the other intensive care unit will receive a different form of care for improving skin integrity. We will ask all patients admitted to the intensive care units during the study period of 4 to 6 months to take part. Registered nurses will deliver the care for improving skin integrity in each site.

Thirdly, we will conduct an assessment of your next of kin’s skin on a second daily basis while they are in the intensive care unit. This will involve the researcher assessing the patient’s skin for the possibility that they may have developed a pressure ulcer. This assessment will take approximately five to ten minutes. The skin assessments will not affect or interrupt the patient’s care in the intensive care unit.

3  Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish the patient, your next of kin, to take part, you do not have to. If you decide the patient, your next of kin, may take part and later change your mind, you are free to withdraw them from the project at any stage.

Your decision on whether the patient, next of kin, may take part or not, or to take part and then withdraw, will not affect the care the patient will receive, the patient’s or your relationship with those giving care or with the hospital.

4  What are the possible benefits of taking part?

It is expected that outcomes from this project will possibly result in decreased pressure ulcer occurrences for critically ill patients in intensive care.

5  What are the possible risks and disadvantages of taking part?

There are no risks, discomfort or inconvenience beyond usual general care associated with patient participation in this project, as no invasive interventions will be used. However, if the patient, your next of kin, experiences or has a pressure ulcer during this study, the researcher will inform the registered nurse caring for the patient. The patient will then receive the usual care for pressure ulcers following the hospital policy and procedures. If there is any adverse effect
experienced by the patient, your next of kin, related to pressure area care, the intervention will be stopped immediately and reviewed.

Part 2 How is the research project being conducted?

6 What will happen to information about me?

By signing a consent form, you consent to the researcher collecting and using personal information about the patient, your next of kin, for the research project. This information will be kept confidential by the principal researcher. The patient health information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

In accordance with privacy law requirements, the patient personal data will not be directly or indirectly identifiable. De-identified study data in a de-identified format may be published in medical or scientific journals. Medical information about the patient, your next of kin, will be held and processed on a computer. Records created in relation to this study will be kept in a safe and secure archive area for 7 years as per QUT’s Management of Research Data Policy.

7 Complaints and compensation

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the Ethics Department of Ministry of Health tel. +966 56 712 3507, or email makkah_research_group@hotmail.com and/or the QUT Research Ethics Unit on +61 7 3138 5123 or email ethicscontact@qut.edu.au. The Ethics Committee of Ministry of Health and QUT Research Ethics Unit are not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

8 Further information and who to contact

If have any questions or require further information please contact me:

Nahla Tayyib  
+966 25205906  
nahla.tayyib@student.qut.edu.au

Dr Fiona Coyer  
+61 7 3138 3895  
f.coyer@qut.edu.au

Dr Peter Lewis  
+61 7 3138 3834  
p.lewis@qut.edu.au
2) Participant Information for Patients

RESEARCH TEAM

Principal Researcher: Nahla Tayyib, PhD student
Principal and Associate Supervisors: Associate Professor Fiona Coyer and Dr Peter Lewis
School of Nursing, Faculty of Health, Queensland University of Technology (QUT), Australia

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Part 1  What does my participation involve?

1  Introduction

Ulcer to your skin, such as a pressure ulcer, may be painful and cause the development of serious infection, which may mean a longer stay in hospital. This study is looking at ways to reduce pressure ulcers in the intensive care unit of this hospital. This study will test the effectiveness of a new pressure ulcer prevention strategy based on best available current evidence and aimed at reducing the number of pressure ulcers in intensive care unit patients.

The strategy consists of: risk assessment, skin assessment, skin care, nutrition, repositioning, support surfaces, and education and training for health care practitioners.

You are invited to participate in this research study because any patients admitted to an intensive care unit are at high risk for pressure ulcer development. This is sometimes due to your illness and resulting care in the intensive care unit.

This project is being undertaken by Nahla Tayyib, student, as part of a Doctor of Philosophy degree at QUT.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what the study involves. Knowing what is involved will help you decide if you want to take part in the research. You may want a relative to read this information to you. If you are able please ask questions about anything that you don’t understand or want to know more about.

2  What does participation in this research involve?

Sometimes we do not know which care is best for improving the skin condition of intensive care unit patients. To find out we need to compare different care to our standard practices. In this study we will put patients into groups and give each group a different care or our standard care. The results will be compared to see if one is better in improving skin integrity, or avoiding damage to the skin, of critically ill patients.

There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided to you free of charge.
Firstly, we will collect personal health information about you from your admission record. The information we require includes: your age, gender, nationality, body mass index (BMI) and clinical data including your reason for admission to the intensive care unit, other health conditions you may have, whether your admission was an emergency or elective admission, the length of time you may have spent in the operating theatre or emergency department prior to ICU admission and how long you stayed in the intensive care unit.

Secondly, this study will involve approximately 300 patients from two intensive care units in Saudi Arabia. Patients in one intensive care unit will receive routine standard care and patients in the other intensive care unit will receive a different form of care for improving skin integrity. We are asking all patients admitted to the intensive care unit during the study period of 4 to 6 months to take part. Registered nurses will deliver the care for improving skin integrity in each site.

Thirdly, we will conduct an assessment of your skin on a second daily basis while you are in the intensive care unit, as is a usual part of practice in ICU. This will involve the researcher assessing your skin for the possibility that you may have developed a pressure ulcer. This assessment will take approximately five to ten minutes. The skin assessments will not interrupt your care in the intensive care unit.

3 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision on whether to take part or not, or to take part and then withdraw, will not affect the care you receive in the intensive care unit or your relationship with those providing your care or with the hospital.

4 What are the possible benefits of taking part?

It is expected that this project will possibly decrease and delay pressure ulcer occurrences for critically ill patients in intensive care by providing appropriate pressure ulcer prevention strategies.

5 What are the possible risks and disadvantages of taking part?

There are no risks, discomfort or inconvenience beyond usual general care associated with participation in this project. However, if there is any adverse effect from the study intervention, the intervention will be stopped immediately, the registered nurse caring for you will be informed and you will then receive the usual care for pressure ulcer following hospital policy and procedures.

Part 2 How is the research project being conducted?

6 What will happen to information about me?

By signing the consent form, you consent to the researcher collecting and using personal information about you for the research project. This information will be kept confidential by the principal researcher. In addition, your health information will only be used for the purpose
of this research project and it will only be disclosed with your permission, except as required by law.

In accordance with privacy law requirements, your personal data will not be directly or indirectly identifiable. De-identified study data in a de-identified format may be published in medical or scientific journals. Your medical information will be held and processed on a computer. Records created in relation to this study will be kept in a safe and secure archive area for 7 years as per QUT’s Management of Research Data Policy.

7 Complaints and compensation

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the Ethics Department of Ministry of Health tel. +966 56 712 3507 or email makkah_research_group@hotmail.com and/or the QUT Research Ethics Unit on +61 7 3138 5123 or email ethicscontact@qut.edu.au. The Ethics Committee of Ministry of Health and QUT Research Ethics Unit are not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

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3) Consent Form for Next of Kin

CONSENT FORM FOR QUT RESEARCH PROJECT
(Next of Kin)

Use of an Intervventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

RESEARCH TEAM CONTACTS

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STATEMENT OF CONSENT

By signing below, you are indicating that you:

- Have read and understood the information document regarding this project.
- Have had any questions answered to your satisfaction.
- Understand that if you or your relative has any additional questions you can contact the research team.
- Understand that you are free to withdraw from the research at any time, without comment or penalty.
- Understand that you can contact the Ethics Department of Ministry of Health on +966 56 712 3507 or email makkah_research_group@hotmail.com and/or the QUT Research Ethics Unit on +61 7 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project.
- Understand that non-identifiable data collected in this project may be used as comparative data in future projects.
- Freely agree for your relative to participate in this research project
- Understand that you will be given a signed copy of this document to keep on behalf of the participant [insert name of patient].

Name ____________________________________________
Signature ________________________________________
Date ____________________________________________

Please return this sheet to the investigator
4) Consent Form for Patient

CONSENT FORM FOR QUT RESEARCH PROJECT
(Patients)

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

RESEARCH TEAM CONTACTS

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- Understand that non-identifiable data collected in this project may be used as comparative data in future projects.
- Agree to participate in the project.

Name

________________________________________________________
Signature

________________________________________________________
Date

________________________________________________________

Please return this sheet to the investigator
5) Consent Form for Registered Nurse

CONSENT FORM FOR QUT RESEARCH PROJECT
(Registered Nurse)

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

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- Agree to participate in the project.

Name

Signature

Date

Please return this sheet to the investigator
6) Withdrawal of Consent for Next of Kin

WITHDRAWAL OF CONSENT FOR QUT RESEARCH PROJECT (Next of Kin)

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

RESEARCH TEAM CONTACTS

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nahla.tayyib@student.qut.edu.au  f.coyer@qut.edu.au  p.lewis@qut.edu.au

I hereby wish to withdraw my family member [insert name of patient] from taking part in the research project named above.

I understand that this withdrawal WILL NOT jeopardise the patient relationship with the hospital or affect the patient care will receive.

Name
Signature
Date
7) Withdrawal of Consent for Patient

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

RESEARCH TEAM CONTACTS

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I hereby wish to WITHDRAW my consent to participate in the research project named above.
I understand that this withdrawal WILL NOT jeopardise my relationship with the hospital.

Name: ________________________________
Signature: ________________________________
Date: ________________________________
8) Withdrawal of Consent for Registered Nurse

WITHDRAWAL OF CONSENT FOR QUT RESEARCH PROJECT
(Patient)

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QUT Ethics Approval Number 1300000341

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I hereby wish to WITHDRAW my consent to participate in the research project named above.
I understand that this withdrawal WILL NOT jeopardise my relationship with the hospital.

Name

Signature

Date

----------------------------------

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9) Arabic Version of Participant Information for Next of Kin

 culoventtp™-tαικεικος /tαλεβικυκεαηηε
 
 **Appendices**

 Mülllematun bi’en ñrbk (lalæqrapøə)

 استخدام حزمة من للعناية بسلامة جلد المريض ذوى الحالات الحرجة في العناية المركزية

 QUT Ethics Approval Number 1300000341

 الفريق البحث

 تهله طيب، طالبة دكتوراه

 الدكتور فيونا كوير و الدكتور بيتر لويس

 من كلية التمريض بجامعة كويزيلاند للتكنولوجيا أستراليا

 الجزء 1 على ماذا تنطوي مشاركة المريض؟

 السؤال

 إصابة جلد المريض، مثل الإصابة بالقرح السريري، قد تكون مؤلمة وتنبغي في وضع عدوى خطيرة، وهو ما قد يعني البقاء فترة أطول في المستشفى. وتحتاج هذه الدراسة إلى مساعدة اثاثيات مريضية يتم إدخالهم إلى وحدة العناية المركزية في هذا المستشفى. هذه الدراسة سوف تغطي فعالية استراتيجية الجديدة في الوقاية من الإصابات الجديدة من القرح السريري استنادًا إلى أفضل الأدلة المتاحة حاليا والتي تهدف إلى تخفيض عدد الإصابات السريرية في مرضاً ووحدة العناية المركزية. تنتمي استراتيجية من: تقييم المخاطر، تقييم الجلد، العناية بالبشرة والتجفيف، تغيير وضعية الجسم. باستمرار الاستمرار، الأسطح الدعم للنقطة الأمامية، والتعليم والتدريب للممارسات الصحية.

 المرضى، قريباً، من المرضى الذين يتم إدخالهم إلى وحدة العناية المركزية، المعرضة أكثر تعرضاً لإصابة بالقرح، وهذا نتيجة في بعض الحالات بسبب مرض أو وما يتغير من الرعاية وواجهة العناية المركزية.

 ويجري تنفيذ هذا المشروع من قبل نهلة الطيب، طالبة، كجزء من دراسة الدكتوراه في جامعة كويزيلاند للتكنولوجيا.

 هذه المنشورة تشمل معلومات يخبرك عن المشروع البحثي. وذلک يفسر وتشرح ما تنطوي عليه الدراسة.

 إذا كنت ترغب في المشاركة في هذا المشروع البحثي، يرجى طرح الأسئلة عن أي شيء كنت لا تفهم أو تريد أن تعرف المزيد عنه.

 المشاركة في هذا البحث على ماذا تنطوي؟

 في بعض الأحيان قد تحتاج إلى تعرف ما الغية هي أفضل لسلامة الجلد المريض ووحدة العناية المركزية. لعنة للكم في بعض الأحيان قد تحتاج إلى المعهاة بين استخدام استراتيجيات جديدة لسلامة الجلد وبين الرعاية المستخدمة حالياً في هذه الدراسة.

 سوف تكون خاصة بالمرضى ووحدة العناية المركزية في جميع المجموعات في جميع المحتملات، وهي متنوعة تختلف معرفة ما إذا واحد هو أفضل في تحسن سلامة الجلد، الذي يعني أن البشر تكون صحيحة، سليمة وغير التالفة، من مرضى مصابين بمرض هرمون خطرة.

 لا توجد تكاليف إضافية مربحة للمشاركة في هذا المشروع البحثي. وتم توفير كل الرعاية الطبية اللازمة جزء من مشروع البحث على كل مجاناً.

 أولاً، سوف تقوم بجميع المعلومات الشخصية المطلوبة عنمرضى، قريباً، من جمعة من المرضى الذين يتم إدخالهم إلى وحدة العناية المركزية.

 البيانات السرية مثلاً كالثالوث والوزن وما في ذلك ستكون محتويات في وحدة ما. على الرعاية، وجدوى، وعملية في وحدة المحتمل.

 إن العناية المركزية، وظروف صحية أخرى قد تكون لديك، وما كان سبب ديونه هي حالة طارئة، وكيف أن الوقت لاستغرقك في عناية المرضى، قريباً، من جمعة من المرضى الذين يتم إدخالهم إلى وحدة العناية المركزية.

 ثانياً، سوف تتطلب هذه الدراسة ما يقرب من 300 مريض من مجموعات مرضية في المملكة العربية السعودية.

 الرعاية في وحدة العناية المركزية، حيث تلقى الرعاية الروتينية، والكاملة تكشف سمات مثالية لرعاية تحتمل.

 سلامة الجلد، لن تحتمل من مجموعات المرضى الذين يتم إدخالهم إلى وحدة العناية المركزية خلال فترة الدراسة من 4 إلى 6 أشهر للمشاركة. سوف تقوم الممرضات الموجودة في العناية المركزية بتقديم الرعاية تحسين سلامة الجلد في كل موقع.
ثالثا، وسنجري تقييما لبشرة المريض، قريبك، يوم بعد يوم أثناء تواجده في وحدة العناية المركزة، كما هو جزء من الممارسة المنتظمة في وحدة العناية المركزة. وسنشمل هذا الباحث تقييما لرشح البروكسحري للاكتشف أن كنت أصابت بالجرح السريري. وهذا التقييم يستغرق ما يلب ثلث من خمسة عشر دقيقة. فإن التقييمات الجدد لا يُقطع رعايتكم في وحدة العناية المركزة.

لا بد لي للمشاركة في هذا المشروع البحثي؟

مشاركة في هذا مشروع تطوعية. إذا كنت لا ترغب في المشاركة للمريض، قريبك، فهذا من حقك. أو إذا قررت المشاركة وتغيير ذلك في وقت لاحق، فهذا من حقك. لا بد لي للمشاركة في هذا المشروع البحثي؟

ما هو الفوائد المحتملة من المشاركة؟

ومن المتوقع أن هذا المشروع سوف يقلل من القرح السريري وتأخير الإصابة بما يتعلق بها للمرضى ذوي الحالات الحرج.

ما هي المخاطر المحتملة والمشكلات المحتملة للمشاركة؟

تتوقع بعض الأشخاص أن يزيد الشعور بإصابة المريض المرتبطة بالمشاركة في هذا المشروع.

ويمكن أن يكون هناك تأثير سلبي على المريض، سيتوقف الأبحاث فيما بعد، وسيتم إبلاغ العلاج الخاص بالمرض

الجهزة 2 كيف يتم هذا المشروع البحثي؟

ماذا سيفتحك لمعلوماتك؟

من خلال توقيعك على استمارة الموافقة، موافقة ذلك للباحث بجمع واستخدام المعلومات الشخصية عن المريض، قريبك، ومشروع البحث، وسيتم إبقاء هذه المعلومات مخفية. بالإضافة إلى ذلك، لن يتم استخدام المعلومات الصحية الخاصة بالمرض إلى غرض هذا المشروع البحثي وسيتم فقط الكشف عن إذا مضى، باستثناء ما يتعلق بالقرح السريري.

وقناة للطبيبات والخصومية، لتنقل أحد من معرفة شخصية المريض بطريقة مباشرة أو غير مباشرة. تلقى بعض البيانات الطبية الخاصة بالمرض، ويبلغ على جهاز كمبيوتر، وسيتم الاحتفاظ بالبيانات الطبية الخاصة بالمرض، وملاحظاتها، في منتدى الأرشيف لمدة 7 سنوات وفقاً لإدارة جامعة كوينزلاند لحفظ البيانات البحثية.

الشكوى والتعويض

وتكرم جامعة كوينزلاند للتقنية في السلامة البحث والسلوك الأخلاقي من المشاريع البحثية. ومع ذلك، إذا كان لديك أي شكاوى أو حالات الأخلاقي، أو مخاوف حوالينا، أو مشكلات، أو إثارة في هذا المشروع، يمكنكم التواصل إلى جهاز كمبيوتر، أو إلى تلقي الحق الخاص بك بطريقة نزيهة.

وزيد من المعلومات والذين في الاتصال

إذا كان لديك أي أسئلة أو تحتاج إلى مزيد من المعلومات، يرجى الاتصال بي

الباحثة نهلة طيب

dr. فونا كوير

+966 25205906
nahla.tayyib@student.qut.edu.au

الدكتورة: بيتر لويس

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+61 7 3138 3834
p.lewis@qut.edu.au

 Appendices 375
10) Arabic Version of Participant Information for Patients

معلومات عن البحث (للمرضى)

استخدام حزمة مكونة من تدابير الوقاية من إصابة بالقرح السريرية في وحدة العناية المركزية

QUT Ethics Approval Number 1300000341

فريق البحث

نحلة طيب، طالبة دكتوراه

الباحثة:

الدكتورة فيونا كوير و الدكتور بيتر لويس

من كلية التمريض بجامعة كويز兰د لتكنولوجيا استراليا

المشرفين:

الجزء 1 على ماذا تنطوي مشاركتي؟

1

المقدمة

إصابة بقرح سريرية، مثل إصابة بالقرح السريرية، قد تكون مؤلمة وتسبب في وضع عدوى خطيرة وهو ما قد يعني البقاء لفترة أطول في المستشفى. يبحث هذا الدراسة في إصدارات القرح السريرية في وحدة العناية المركزية في هذا المستشفى. هدف الدراسة هو تقييم المدة المتاحة حاليًا، والتي تهدف إلى خفض عدد القرح السريرية في مستشفى وحدة العناية المركزية. تقام الدراسة من خلال تقييم الحالة الصحية والتشخيصية، وتقييم الأعراض الجسمية، والاستعداد للعلاج.

السياسات والتنقلية: تقييم حالات القرح السريرية، والتعليم والتوفير لممارسات العناية الصحية.

الهدف من المشاركة في هذه الدراسة البحثية: أن جميع المرضى الذين يتم إدخالهم إلى وحدة العناية المركزية المعرضين للخطر من إصابة بالقرح السريرية.

جزء من المشاركون في هذا المشروع البحثي.

إذا كنت قادرًا، برجاء طرح الأسئلة عن أي شيء كنت لا تفهم أو تريد أن تعرف المزيد عنه.

المشاركة في هذا البحث على ماذا ينتظرني؟

2

المشاركتين في هذا المشروع البحثي.

في بعض الأحيان قد نحتاج إلى معرفة أي الرعاية هي الأفضل للعناية بسلامة الجلد. لمعرفة ذلك، سنحتاج إلى مقارنة استخدام استراتيجية جديدة للعناية بسلامة الجلد مع الرعاية المستخدمة حاليا.

في هذه الدراسة، سوف نضع المرضى في مجموعتين ونمنح المجموعة الأولى حزمة العناية بسلامة الجلد، ونقد المجموعة الأخرى العناية الحالية المقدمة في العناية المركزية. سيتم مقارنة النتائج لمعرفة ما إذا كان أفضل في تحسين سلامة الجلد، مما يعني أن البشرة ستكون صحية، سليمة وغير الالتفات، من مرضى حالية للأمراض الخطيرة.

لا يوجد أي تأثير إضافي مرتبط للمشاركة في هذا المشروع البحثي. وسيتم توفير كل الرعاية الطبية اللازمة مجانًا.

أولاً، سوف تقوم بجمع المعلومات الشخصية للمرضى، مثل سجلات حالات أشخاص، واستخدام حزمة من الرعاية الشخصية.

ثانياً، سوف تقوم بجمع المعلومات الشخصية للمرضى، مثل سجلات حالات أشخاص، واستخدام حزمة من الرعاية الشخصية.

ثالثًا، سوف تقوم بجمع المعلومات الشخصية للمرضى، مثل سجلات حالات أشخاص، واستخدام حزمة من الرعاية الشخصية.

وأخيرًا، سوف تقوم بجمع المعلومات الشخصية للمرضى، مثل سجلات حالات أشخاص، واستخدام حزمة من الرعاية الشخصية.

للمزيد من المعلومات، يمكنك الاتصال بنا.

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Appendices
لا بد لي للمشاركة في هذا المشروع البحثي؟

لا بد لي للمشاركة في هذا المشروع البحثي، فهذا من حقك. إذا قررت المشاركة واتخاذ في وقت لاحق، فلكيحق الانسحاب من المشروع في أي مرحلة.

قرارك على ما إذا كنت تشك في أو المشاركة، ثم الانسحاب، لن يؤثر على الرعاية التي تتلقاها في وحدة العناية المركزية أو علاقتك مع أولئك الذين يقومون الرعاية الخاصة بك أو مع المستشفى.

ما هي الفوائد المحتملة من المشاركة؟

ومن المتوقع أن هذا المشروع سوف ربما يقلل من القرح السريرية وتأخير الإصابة للمرضى بحالات الحرج من خلال توفير استراتيجيات لحماية من الإصابة بالقرح السريرية.

ما هي المخاطر المحتملة ومساوئ المشاركة؟

ومن المتوقع عدم وجود مخاطر، وعدم الراحة أو إزعاج يتجاوز الرعاية العامة المعتادة المرتبطة بمشاركة في هذا المشروع.

الجزء 3 كيف يتم هذا المشروع البحثي؟

من خلال توقيعك على استمارة الموافقة، توافقك على استخدام المعلومات الشخصية عنك لمشروع البحث. وسيتم الإبقاء على سرية هذه المعلومات من قبل الباحث الرئيسي. وبدلاً من ذلك، لن يتم استخدام المعلومات الصحية الخاصة بك بغض النظر عن المشروع البحثي. وسيتم فقط الكشف عنك إذا رضيت وفقًا للقانون وفًا لمعايير ética. نشر بيانات الدراسة على شكل نتائج بدون الشرايين المذكورة في المجلات الطبية أو العلمية. وستستخدم المعلومات الطبية الخاصة بك معاملتها على مدار للمكلات وغيرها من المشاريع البحثية في فئة وامانة من الفئة من التوثيق. الأرشيف لمدة 7 سنوات وفقًا لإدارة جامعة كويزلايند لحفظ البيانات البحثية.

الشكاوى والتعويض

وتلتزم جامعة كويزلايند للتكنولوجيا في الأمانة البحوث والسلوك الأخلاقي من المشاريع البحثية. ومع ذلك، إذا كان لديك أي أسئلة أو تحتاج إلى مزيد من المعلومات، يرجى الاتصال بي:

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المستخدم: فيونا كوير

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f.coyer@qut.edu.au

+61 7 3138 3834

p.lewis@qut.edu.au
## Appendices

### 11) Arabic Version of Consent Form for next of Kin

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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</thead>
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<td><strong>الدكتورة فونا كوير</strong></td>
</tr>
<tr>
<td><strong>+966 25205906</strong></td>
<td><strong>+61 7 3138 3895</strong></td>
</tr>
<tr>
<td><a href="mailto:nahla.tayyib@student.qut.edu.au">nahla.tayyib@student.qut.edu.au</a></td>
<td><a href="mailto:f.cover@qut.edu.au">f.cover@qut.edu.au</a></td>
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<tr>
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<td><strong>الدكتور بيتر لويس</strong></td>
</tr>
<tr>
<td><strong>+61 7 3138 3834</strong></td>
<td><strong>+61 7 3138 3834</strong></td>
</tr>
<tr>
<td><a href="mailto:p.lewis@qut.edu.au">p.lewis@qut.edu.au</a></td>
<td></td>
</tr>
</tbody>
</table>

**بيان الموافقة**

من خلال التوقيع أدناه، أنت تشير إلى أنك:

- قرأت وفهمت وثيقة المعلومات بخصوص هذا المشروع.
- هل كان الرد على أي أسئلة للارتياح الخاص بك.
- فهمت أنه إذا كنت أو قريبك لديه أي أسئلة إضافية يمكنك الاتصال فريق البحث.
- فهمت أن أنت حر في الانسحاب من البحث في أي وقت، دون تعليق أو جزاء.
- فهمت أنه يمكنك الاتصال بقسم الأخلاقيات وزارة الصحة على +966 56 3507 712 أو البريد الإلكتروني makkah_research_group@hotmail.com
- أو وحدة أخلاقيات البحوث جامعة كوينزلاند للتحكم في +61 7 3138 3895 أو البريد الإلكتروني ethicscontact@qut.edu.au
- لدية مخاوف حول السلوك الأخلاقي للمشروع.
- فهمت أن البيانات غير قابلة للتعرف التي تم جمعها في هذا المشروع يمكن استخدام البيانات المقارنة في المشاريع المستقبلية.
- توافق بحرية لفريقك للمشاركة في هذا المشروع البحثي.
- فهمت أنك سوف تعطي نسخة موقعة من هذه الوثيقة لحفظه عن المشاركين [بدرج اسم المريض].

<table>
<thead>
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<th>التوقيع</th>
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يرجى إعادة هذه الوثيقة إلى الباحث.

---

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

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12) Arabic Version of Consent Form for Patient

موافقة على المشاركة بالبحث

Use of an Interventional Patient Skin Integrity Care Bundle in the Intensive Care Unit to Best Manage Skin Integrity in Critically Ill Patients

QUT Ethics Approval Number 1300000341

فريق البحث

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بيان الموافقة

من خلال التوقيع أدناه، أنت تشير إلى أنك قرأتم وفهمتم وثيقة المعلومات بخصوص هذا المشروع.

• فهمت أنه إذا كان لديك أي أسئلة إضافية يمكنك الاتصال فريق البحث.
• فهمت أن انت حر في الانسحاب في أي وقت، دون تعليق أو جزاء.
• فهمت أنه يمكنك الاتصال بقسم الأخلاقيات وزارة الصحة على +966 56 712 3507 أو البريد الإلكتروني makkah_research_group@hotmail.com أو وحدة أخلاقيات البحوث بجامعة كوينزلاند للتكنولوجيا في +61 7 3138 5123 أو البريد الإلكتروني ethicscontact@qut.edu.au إذا كان لديك مخاوف حول السلوك الأخلاقي للمشروع.
• فهمت أن البيانات غير قابلة للتعرف في هذا المشروع ويمكن استخدام البيانات المقارنة في المشاريع المستقبلية.
• الموافقة على المشاركة في المشروع

اسم

توقيع

تاريخ

يرجى إعادة هذه الورقة إلى الباحث

Appendices 379
Appendix G

STATEMENTS OF CONTRIBUTION OF CO-AUTHORS FOR THESIS

BY PUBLISHED PAPER


<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nahla Tayyib</td>
<td>Reviewed the literature and wrote the manuscript.</td>
</tr>
<tr>
<td>August 2012</td>
<td></td>
</tr>
<tr>
<td>Fiona Coyer</td>
<td>Reviewed the literature and valuable input from the initial draft of the manuscript</td>
</tr>
<tr>
<td>Peter Lewis</td>
<td>Reviewed and input into the manuscript</td>
</tr>
</tbody>
</table>

Principal Supervisor Confirmation

I have sighted email or other correspondence from all co-authors confirming their certifying authorship.

Fiona Coyer

QUT Verified

Signature

2/12/15

Date
2) Article 2: Effectiveness Of Pressure Ulcer Prevention Strategies for Adult Patients in Intensive Care Units: a Systematic Review

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of Chapter 3:

Publication title and date of publication or status: Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: a systematic review. (under review)

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution</th>
</tr>
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<tbody>
<tr>
<td>Nahla Toyib</td>
<td>Reviewed the literature and wrote the manuscript.</td>
</tr>
<tr>
<td>July 2015</td>
<td></td>
</tr>
<tr>
<td>Flona Coyer</td>
<td>Reviewed the literature and valuable input from the initial draft of the manuscript.</td>
</tr>
</tbody>
</table>

Principal Supervisor Confirmation:

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

__________________________
Name: Flona Coyer

__________________________
Signature: Flona Coyer

Date: 2/12/15
3) Article 3: Saudi Arabian Adult Intensive Care Unit Pressure Ulcer Incidence and Risk Factors: a Prospective Cohort Study

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of Chapter 6:


<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Najia Tayyib</td>
<td>Participated in the conception and design of the study and performed the statistical analysis and interpretation. Conducted data acquisition and drafted the manuscript.</td>
</tr>
<tr>
<td>June 2014</td>
<td></td>
</tr>
<tr>
<td>Fiona Coyer</td>
<td>Participated in the conception and design of the study and assisted in the statistical analysis and interpretation. Helped to draft the manuscript and revising it critically for important intellectual content</td>
</tr>
<tr>
<td>Peter Lewis</td>
<td>Participated in the conception and design of the study. Helped to draft the manuscript and revising it critically for important intellectual content</td>
</tr>
</tbody>
</table>

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer 2/12/15

Name Signature Date
4) Article 4: Pressure Ulcer Prevention in the Saudi Arabian Intensive Care Unit: Registered Nurse Attitudes toward Prevention Strategies and Perceived Facilitators and Barriers to Evidence Implementation

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified that:

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2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. no conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and they agree to the use of the publication in the student’s thesis and its publications on the

Australian Research Online database consistent with any limitations set by publisher requirements.

In the case of Chapter 7:

Publication title and date of publication or status: Pressure ulcer prevention in the Saudi Arabian intensive care unit: registered nurse attitudes toward prevention strategies and perceived facilitators and barriers to evidence implementation. (Accepted)

| Contributor       | Statement of contribution*
|-------------------|---------------------------------------------
| Nahid Tayyeb     | Participated in the conception and design of the study and performed the statistical analysis and interpretation. Conducted data acquisition and drafted the manuscript. |
| December 2014     |                                                                              |
| Fiona Coyer      | Participated in the conception and design of the study and assisted in the statistical analysis and interpretation. Helped to draft the manuscript and reviewing it critically for important intellectual content. |
| Peter Lewis      | Participated in the conception and design of the study. Helped to draft the manuscript and reviewing it critically for important intellectual content. |

Principal Supervisor Confirmation

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Fiona Coyer

QUT Verified

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Date
5) Article 5: A Two-Arm Cluster Randomized Control Trial to Determine the Effectiveness of a Pressure Ulcer Prevention Bundle for Critically Ill Patients.

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

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3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit,
5. they agree to the use of the publication in the student's thesis and its publication on the Austrailian Research Online database consistent with any limitations set by publisher requirements.

In the case of Chapter 5:

Publication title and date of publication or status: A two-arm cluster randomized control trial to determine the effectiveness of a pressure ulcer prevention bundle for critically ill patients (2015)

<table>
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<tr>
<th>Contributor</th>
<th>Statement of contribution*</th>
</tr>
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<tbody>
<tr>
<td>Nahid Tezyb</td>
<td>Participated in the conception and design of the study and performed the statistical analysis and interpretation. Conlected data acquisition and drafted the manuscript.</td>
</tr>
<tr>
<td>September 2014</td>
<td></td>
</tr>
<tr>
<td>Fiona Coyer</td>
<td>Participated in the conception and design of the study and assisted in the statistical analysis and interpretation. Helped to draft the manuscript and reviewing it critically for important intellectual content.</td>
</tr>
<tr>
<td>Peter Lewis</td>
<td>Reviewing and input into the manuscript for important intellectual content.</td>
</tr>
</tbody>
</table>

Principal Supervisor Confirmation

I have signed this email or other correspondence from all co-authors confirming their certifying authorship.

_ Fionna Coyer_  
Name  
QUT Verified  
Signature  
2/12/15  
Date
6) Article 6: Translating Pressure Ulcer Prevention Bundle into Intensive Care Nursing Practice: Overlying a Care Bundle Approach with a Model of Research Implementation

---

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
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3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and they agree to the use of the publication in the student’s thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of Chapter 10:

Publication title and date of publication or status: Translating pressure ulcer prevention bundle into intensive care nursing practice; overlying a care bundle approach with a model of research implementation. (under review)

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nahlia Tayyib</td>
<td>Developed study design and concept, and wrote manuscript.</td>
</tr>
<tr>
<td>November 2015</td>
<td>Input into study design and concept, input into manuscript, reviewed draft versions of the manuscript.</td>
</tr>
<tr>
<td>Fiona Coyer</td>
<td></td>
</tr>
</tbody>
</table>

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer  
Signature /  
Date  
2/12/15