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## Implementing a Hospital-Acquired Pressure Ulcer Prevention Program

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Dr. Melanie Hardin-Pierce, Advisor

Final DNP Project Report

Implementing a Hospital-Acquired Pressure Ulcer Prevention Program

Maryann L. Lancaster, BSN, RN

University of Kentucky

College of Nursing

Spring 2015

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## Dedication

This capstone project is dedicated to my husband Eli, without whose never failing support and encouragement I would not have achieved my dreams. Your endless help and belief in me kept me motivated to be the success I wanted to be. To my family, thank you for your help, encouragement, and constant love that helped me reach my goals.

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Introduction to Final DNP Practice Inquiry Report

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Pressure ulcers are injury to skin and underlying tissues caused by constant pressure (Reilly et al., 2007). The breakdown of skin occurs from an insufficient blood supply to these cells, typically at bony prominences (Smeltzer et al., 2008, Brindle & Wegelin 2012). Any prolonged and unrelieved pressure causes an occlusion of blood flow, ischemia, and ultimately cell death (Salcido et al., 2007). Iatrogenic pressure ulcers that occur during hospitalization are called Hospital-Acquired Pressure Ulcers, or HAPU.

HAPUs are a significant problem in patient care and have deleterious implications for the patient and the healthcare system. The development of pressure ulcers increases the length of hospital stay on average by 4 days (Calianno, 2007b). Between 1999 and 2003 a 63% increase in length of stay occurred in which pressure ulcers were a listed diagnosis in patient medical records (Calianno, 2007b). Among patients with pressure ulcers, self-reports described an increase in pain and suffering (Pieper et al., 2009). Pressure ulcers complicated the healing process and increased the mortality likelihood for hospitalized patients, which were reported as the cause of death for 115,000 individuals between 1990 and 2001 (AHRQ, 2013; Brem et al., 2010). Estimates for prevalence range from 0.4% to 38% in acute care hospitals (AHRQ, 2013). The estimated cost of pressure ulcers in the United States ranges from \$2.2 to \$3.6 billion a year (Calianno 2007a, 2007b), with a mean cost of \$43,180 per hospitalization (Department of Health and Human Services (DHHS) 2008). Effective October 1, 2008, The Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for treating Stage III or IV HAPUs (Calianno 2007a, 2007b; Berquist-Beringer et al., 2009). Stage III and IV HAPU reported in 2008 to the Department of Health and Human Services totaled 257, 412 events (DHHS, 2008). With the devastating effects to patients and healthcare institutions, nursing is challenged with identifying innovative ways to prevent HAPU. The debilitated hospitalized patient with acute

and chronic multisystem failure is at greatest risk for skin breakdown, and our role as bedside clinicians is to identify risk factors and reverse pressure-related skin changes through prevention (Calianno 2007a).

The overall purpose of this practice inquiry is to implement a HAPU prevention program at TriHealth, a healthcare organization in Cincinnati, Ohio, and evaluate an emerging preventive strategy utilizing a high-risk assessment tool and intervening with a soft silicone foam-bordered dressing (Mepilex® Border Sacrum, Mölnlycke Health Care) to reduce HAPU development. The first manuscript is a review of the studies published between 2010 and 2014 that have utilized Mepilex® dressings in adult inpatient hospitals as an effective intervention for the prevention of HAPUs in acutely ill populations. The findings from this review provided evidence to support nursing interventions to identify high-risk critically ill patients and initiate additional prophylaxis above and beyond the nursing standards of care to prevent HAPU formation. Subsequently, these evidence-based recommendations helped direct a research study assessing the high-risk characteristics associated with skin breakdown and HAPU formation among critically ill adult patients at Bethesda North Hospital (Intensive Care Unit) using a preventive Mepilex® dressing. The focus of the second manuscript was to determine if any hospital- specific and/or patient-specific variables were associated with skin breakdown and HAPU formation. Additionally, the second manuscript suggests that prophylactic application of Mepilex® dressings may be effective in HAPU reduction. The impetus of a potentially new assessment tool for assessing acutely ill patients for high-risk variables for skin breakdown supported changing clinical practice guidelines for the prevention of HAPU. The evidence from manuscript two, demonstrating early identification of high-risk criteria among acutely ill patients and the adjunctive use of Mepilex® dressings to prevent skin breakdown and HAPU formation,

was adopted into TriHealth's Pressure Ulcers: Guidelines for Prevention and Treatment policy. The purpose of the final manuscript is to evaluate the implementation of these new guidelines via analysis of the change in nursing knowledge before and after an education didactic on the changes implemented, and the change in nursing clinical behaviors, i.e. are the nurses adhering to the new guidelines, through a retrospective medical record review of nursing documentation throughout the TriHealth organization.

A Literature Review of Mepilex® Dressings to Prevent Hospital Acquired Pressure Ulcers

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## **Abstract**

Hospital-Acquired Pressure Ulcers (HAPUs) are a significant healthcare problem in the United States. HAPU increase the length of hospital stays, patient pain and suffering, complications in the healing process, and mortality and morbidity, as well as healthcare costs, which are estimated to be 2.2 to 3.6 billion dollars annually. Insurance provider reimbursement has greatly become dependent on patient outcomes, with HAPUs considered to be a result of poor quality nursing care. As of 2008, Stage III and IV pressure ulcers are no longer reimbursable, resulting in healthcare organizations' implementation of pressure ulcer prevention guidelines and interventions to prevent HAPU formation. New evidence, reporting varied degrees of success, has emerged utilizing soft silicone foam bordered dressings (Mepilex®) as an adjunctive prevention therapy for pressure ulcer formation. The purpose of this paper is to review the studies published between 2010 and 2014 that describe the use of Mepilex® dressings for HAPU prevention. Six studies met inclusion criteria. Findings suggest that Mepilex® dressings produce clinically relevant reduction in HAPU incidence and prevalence, and further recommend healthcare organizations benefiting from implementing protocols to include Mepilex® dressing application to patients at risk for skin breakdown.

*Keywords:* Pressure Ulcer, Hospital Acquired Pressure Ulcer (HAPU), Mepilex®, soft silicone foam border dressing, prevention

## **Introduction**

### **Problem Focus**

Pressure ulcers are wounds caused by constant pressure to underlying skin tissue (Reilly, Karakousis, Schrag, & Stawicki, 2007). The breakdown of skin occurs from an insufficient blood supply, typically at bony prominences, most commonly the sacrum (Smeltzer, Bare, Hinkle, & Cheever, 2008; Brindle & Wegelin, 2012). The prolonged and unrelieved pressure on skin causes an occlusion of blood flow, ischemia, and ultimately cell death (Salcido, Popescu, & Ahn, 2007). Pressure ulcers occurring during a stay within a medical facility are deemed to be hospital-acquired pressure ulcers (HAPU). HAPU increase the length of hospital stays, patient pain and suffering, complications in the healing process, potential death, as well as health care costs (Armstrong et al., 2008). The estimated cost of HAPU in the United States ranges from \$2.2 to \$3.6 billion a year (Calianno, 2007a; Calianno, 2007b) with the mean cost of \$43,180 per hospital stay (Department of Health and Human Services, 2008).

### **Population of Interest**

Identification of patients at risk for HAPU development is important for prevention initiatives. In a literature review, McGough (1999) reported over 40 different pressure ulcer prevention assessment tools. It was concluded that none of these tools were consistently reliable for all clinical situations (i.e. different patient groups have different clinical needs and pressure ulcer prevention tools should be used in the appropriate clinical setting). In the acutely ill population, early identification of patient characteristics, comorbid risk factors, and inpatient care interventions and therapies are needed to isolate those at high-risk, and implement evidence-



based preventive strategies to reduce incidence of pressure ulcer formation, therefore the adult acutely ill individual will be the target population for this literature review (Reilly et al., 2007; Cox 2011).

### **Purpose of the Review**

With the devastating effects to patients and healthcare institutions, nursing is challenged with early identification of high-risk patients, and implementing innovative ways to prevent HAPU above traditional standards of care to improve patient outcomes. With high prevalence rates at our healthcare organization, a quality improvement project was initiated to identify strategies to reduce HAPU rates in the medical-surgical intensive care unit (MSICU). At this time, an important preventive strategy using a soft silicone foam-bordered dressing (Mepilex® Border Sacrum, Mölnlycke Health Care) was a novel preventive approach to this clinical problem. The Skin Care Committee responsible for HAPU prevention and treatment at our organization, along with the author of this article, questioned the reliability and validity of prophylactic dressing using among acutely ill populations. Thus, we formulated the PICOT question for this inquiry; ‘among adult acutely ill hospitalized patients, does the use of sacral prophylactic silicone foam dressings compared to individuals receiving standard of care preventative measures, reduce the prevalence of hospital acquired pressure ulcers?’

The purpose of this review paper is to compile and evaluate the research evidence supporting the use of Mepilex® dressings as an effective intervention for the prevention of HAPUs in the acutely ill population. The literature will be analyzed including a critique of the methodological design and articulation of the strengths and gaps within the current literature. From this review, we will formulate an estimate of usefulness to the proposed clinical problem

with recommendations to nursing practice. Recommendations from supporting evidence suggest nursing interventions to include early identification of high-risk acutely ill patients and initiate additional prophylaxis above and beyond the nursing standards of care to prevent pressure ulcer formation. Subsequently, the evidence-based review may translate into changes in hospital policy that dictate the use of Mepilex® dressings as a standard of care not only for critically ill patients but for all patients admitted to the hospital.

## **Literature Review**

### **Systematic Approach**

The U.S. National Library of Medicine National Institutes of Health (PubMed) and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases were searched for the reported use of a Mepilex® Border dressing as a prophylactic measure to prevent HAPU development. The search was limited from 2000 to 2014, English-language, and adult human Intensive Care Unit (ICU) subjects. Articles were selected if the Mepilex® dressing was used on critically ill or ICU patients with no pre-existing pressure ulcer upon admission to the hospital, and excluded if the Mepilex® dressing was used as a treatment intervention for patients with pressure ulcers or medical conditions of the sacralcoccygeal area. Programs that evaluated other preventive interventions such as specialty bed mattresses or other skin care products such as creams or medications were eliminated from this review. To refine the search, studies were excluded if they weren't available in English language.

Six articles met criteria and were used for this literature review. The breakdown of articles include a randomized control trial (RCT) (n=1), retrospective descriptive studies (n=2), and non-randomized prospective control trials (n=3). Literature synthesis of these articles will

evaluate the research process and the synthesis of research findings for 1) acutely ill patient characteristics and risk factors for pressure ulcer development, 2) current recommendations for pressure ulcer prevention and 3) interventions to reduce HAPU incidence, specifically studies whose intervention utilize Mepilex® Border Sacrum dressings as a prophylactic device.

## **Summary of Evidence**

### **Comprehensive Summary of Relevant Literature**

The Centers for Medicare and Medicaid Services ‘never-event’ payment provisions for HAPU reimbursement require healthcare providers to develop pressure ulcer prevention strategies and interventions for professional advancement, quality patient care, and financial survival. The suggested preventive strategies include patient education, clinician training, developing communication and terminology materials, implementing toolkits and protocols, and healthcare and patient provider adherence to policies and standards of care. The literature identified integrating the components of simplification and standardization of pressure ulcer interventions and documentation as ways to improve process of care (Armstrong et al., 2008; Sullivan & Schoelle, 2013). In addition to providing preventive strategies, clinicians must be able to identify patients deemed at risk of skin breakdown. Numerous patient characteristics and ICU-based variables were associated with skin breakdown; however, the key implication derived from these specific studies suggested that understanding these high-risk factors is important for early detection. Current risk assessment tools may not accurately incorporate these ICU specific variables, thus development of an ICU specific risk assessment tool could be warranted (Bours, De Laat, Halfens, & Lubbers, 2001; Nijs et al., 2008; Cox, 2011).

The six studies recognized a novel approach in preventing ulcers by using an absorbent soft, silicone, self-adherent, foam border dressing in the sacral area before pressure ulcers develop (Brindle, 2010; Butcher & Thompson, 2010; Brindle & Wegelin, 2012; Chaiken, 2012; Walsh, et al., 2012; Cubit, McNally, & Lopez, 2013; Santamaria et al., 2013). Brindle (2010) performed a research study utilizing absorbent soft silicone self-adherent dressings in a surgical-trauma ICU. Of the 41 identified high-risk patients that received the preventive sacral dressing, there was a zero percent pressure ulcer incidence in the treatment group. A subsequent study comparing a preventive Mepilex® group (n=50) to a standard care group (n=35) resulted in a reduced pressure ulcer incidence in the treatment group (Brindle & Wegelin, 2012). Chaiken (2012) and Walsh et al. (2012) reported reduced pressure ulcer incidence when the Mepilex® dressing was applied to patients during quality improvement initiatives. Similarly a study of early preventive intervention to utilize the sacral Mepilex® among individuals admitted through the emergency department (ED) supports the findings of reduced HAPU incidence (Cubit, et al., 2012). More recently, a RCT in Australia demonstrated statistically and clinically relevant reduction of heel and sacral pressure incidence by 10% between the Mepilex® intervention (n=219) and control groups (n=221) (Santamaria et al., 2012).

## **Sampling**

The samples included in this literature review include adult patients admitted to the ICU. Sampling was based on a convenience sample from the respective ICU setting or known admission to the ICU. Three of the studies used eligibility inclusion identifiers based on a criterion checklist developed by Brindle (Brindle, 2010; Brindle & Wegelin, 2012; Walsh et al., 2012). One study initiated the intervention in the Emergency Department (ED) on patients knowingly admitted to the ICU (Santamaria et al., 2013). The studies lack an analysis of power

to determine effect size of the sample, apart from the RCT with a determined power of 220 individuals per group (Santamaria et al., 2013). The smallest intervention group produced a sampling size of 41 participants with the largest group having 440 participants.

One potential drawback to the studies' sampling plans was the size of the samples. Small sample sizes can reduce the representation of the population of interest and produce a sampling bias from over or under-representation. The studies within this review may over-represent the risk of HAPU formation alone just from the acuity of illness associated with ICU settings, i.e. the more sick the patient the increased risk of HAPU. Demographic variables were limitedly reported to demonstrate homogeneity of the populations studied. ICU-specific covariates that were statistically supportive of pressure ulcer development included history of vascular disease, vasopressor use such as Dopamine, Dobutamine, Norepinephrine, dialysis, infection, length of stay, age, total Braden score, level of mobility and friction/shear (Bours et al., 2001; Nijs, 2008; Cox, 2012).

## **Research Design**

Chaiken (2012) and Walsh et al. (2012) studied the effect of silicone foam dressing on HAPU incidence using a non-experimental observational design. A standard for comparison between HAPU formation between the intervention and control group involved the use of incidence or prevalence data. Both studies obtained historical data on HAPU incidence or prevalence for their unit, and then prospectively applied the silicone dressing to all patients admitted to their intensive care unit (ICU). Incidence rates were tracked during the prospective data collection timeframe, and then compared to the retrospective historical data. The research

design lacks any regard to any confounding characteristics between the pre-intervention group to the post-intervention group for similarity, acuity, or healthcare therapies received.

Three studies were quasi-experimental controlled trials without randomization (Brindle, 2010; Brindle & Wegelin, 2012; Cubit et al., 2012). The quasi-experimental design was intended to compare the intervention outcomes with the independent variable to establish causality. While the quasi-experimental studies included an intervention and used a comparison group as a control, these studies lacked randomization and blindness. In the more recent publication Brindle and Wegelin (2012) offered a pseudo-randomization of the participants and investigators by blinding room assignments post-operatively as intervention rooms versus standard care rooms. Brindle (2010) and Brindle and Wegelin (2012) suggested that a large randomized control trial is needed to truly determine if the reduction in HAPU incidence is related to this dressing or to an extraneous variable. Santamaria et al., (2013) did such a study with randomization of individuals in the ED by designating the control and intervention group through a pre-prepared series of envelopes randomized by a computer-generated set of numbers to allocate to each patient.

### **Methods to Data Collection**

Several of the studies relied on the assessment skills, knowledge, and expertise of staff nurses to accurately implement the intervention, assess findings, and alert the research team of any skin alterations, while some of the study designs were executed by the research team entirely. The influence of staff nurse involvement poses concern about whether such involvement could influence data quality or study outcomes. All studies acknowledge that prior to initiation ICU staff nurses were educated on the application of the dressing, HAPU education and training, and review of the standards of care for preventive skin interventions such as

turning, repositioning, risk assessment tool documentation, etc. Chaiken (2012) suggest that the influence of the research team's education and encouragement could have increased the compliance towards the standards of care for skin prevention, thus a potential extraneous variable influencing the data towards reduced HAPU incidence.

Brindle and Wegelin (2012) and Cubit et al's (2012) experimental studies required a specialized data collection form to be created to capture all the covariates of interest and the skin assessment identifying pressure ulcers. These tools allowed staff nurses to indicate nominal inclusion criteria applicable to the participant, interventions that were completed, and demographic information at the time of data collection. Strengths of these tools include the ease of use to staff nurses and capturing the information needed to achieve the goals of the study. However there was no indication or report of pre-testing for validity, reliability, sensitivity, specificity, or fidelity. The remaining studies collected relevant data through retrospective and prospective audits of the patients' charts and electronic medical records.

## **Findings**

The findings of the studies all demonstrate lower HAPU incidence in the intervention group utilizing the silicone dressing compared to the control group only receiving standard skin care prevention practices. Table 1 summarizes the HAPU incidence rates resulted in the studies with the greatest of incidence difference of 11.5% (Brindle, 2010).

Brindle and Wegelin (2012) deliver the most in depth analysis of their data. Twenty-one covariates derived from eligibility criteria and patient characteristics demonstrated no statistically significant differences between the intervention group and the control group with all p-values greater than 0.058, which is supportive of the notion that the samples in each group

were similar in acuity of illness and characteristics. A representative sample suggests that the reduced HAPU incidence is related to the silicone dressing. Hazard ratios were calculated to compare the two groups with regard to risk of pressure ulcer formation, and after adjustment were made to equilibrate severity between groups, the standard care individuals were 3.6 times more at risk over time to develop a pressure ulcer than those with a preventative Mepilex® applied to their sacrum. However, the hazard ration of 3.6 was not statistically significant with achieving a p-value of 0.296. Similarly, Santamaria et al. (2013) assessed patient variables and demographics, but no analyses were computed to determine an association between the covariates and pressure ulcer formation, however, a calculated hazard ratio of 0.19 between groups was determined, which was statistically significant achieving a p-value of 0.002. To further support the association of the Mepilex® innovation Cubit et al., (2012) identified his control group at 5.4 times increased risk for pressure ulcer injury than those receiving the prophylactic dressing.

### **Limitations, Strengths, & Gaps**

Evidence related to pressure ulcers is abundantly available for etiologies, prevention, and treatment. Traditionally, Mepilex® dressing use has been known as an evidence-based treatment intervention for individuals with pressure ulcers. A limitation to the research includes very little knowledge on prophylactic Mepilex® dressings used to prevent HAPU from occurring. The articles presented in this review are the only published findings regarding this concept. Future studies are needed, with larger sample size and randomization, to provide sound statistical support that a silicone dressing does reduce HAPU incidence. Specific to the articles analyzed in this review, the general limitations include small sampling sizes, minimal statistical analysis, and the potential of numerous extraneous variables (covariates) that need analysis into their influence



of HAPU formation. Since the inception of this idea, no other study exists using an alternate type of dressing. Only the Mepilex® Border dressing has been used and the question exists if a different dressing could produce similar results or even better. The authors in this literature review report a limitation to their study regarding the influence of the education and training of the staff nurse regarding HAPUs and may have increased compliance and diffusion of the standards of care, thus an additional source towards HAPU prevention, and should be considered in future studies. Another limitation introduced in these studies is the influence of self-reporting from staff nurses. Several of the studies relied on the documentation of the nurses, thus self-reporting, of their assessment and interventions. This introduces bias, possible under/over estimation of the problem, and potential for nursing to simply be mistaken or misremembered the assessment and interventions provided for the patient. Self-reporting reduces the validity of the results.

The strength of these studies is the reproducibility to demonstrate a reduction of pressure ulcer incidence, as seen in all of the studies included in this review. Replication trials continue to show differences in HAPU incidence between the control and intervention groups, and are suggestive that the Mepilex® dressing may be influencing these findings. Being able to prevent a pressure ulcer for our patients equates to less patient pain and suffering, shorter hospitalization times, and decreased healthcare costs. This begs to answer the practical question for nurses to perform clinically simple and relatively cost neutral intervention to reduce HAPU formation when the evidence does not statistically support it. A fiduciary benefit might be implied by Chaiken (2012), who reported a total cost of the silicone dressing during the 6-month period of \$6,653.00 (n=273). While this is only one figure of the financial burden of using the silicone dressing preventatively, as reported, the average cost to treat a HAPU is \$43,180 (Department of

Health and Human Services, 2008). A cost-benefit analysis of monies saved as a result of using the Mepilex® dressing rather than money spent for pressure ulcer treatment may be warranted and support the acceptance of this practice. The potential financial incentive to healthcare institutions, insurance reimbursement, and patient costs can be considered as strengths to this innovation.

### **Recommendations for Practice**

As healthcare requirements become more stringent and reimbursement reliant upon quality patient outcomes, the use of the Mepilex® dressing may be an easy solution to a large problem. The articles from this review are suggestive that the use of prophylactic silicone dressings may be effective at HAPU prevention as seen through reduction of incidence scores. Similar findings replicated in these studies provide further support that the Mepilex® dressing may reduce HAPU incidence, unfortunately very limited descriptive and inferential statistics exist from only one RCT to defend the causality. Despite the limited statistical support, the clinical practicality to use Mepilex® to reduce new cases of iatrogenic pressure ulcers exists, and based on what evidence is available a change in nursing practice is recommended to 1) utilize an assessment tool to better identify patients at risk and 2) prophylactically use a silicone foam dressing on acutely ill patients admitted to hospitals.

The authors of this literature review support the use of a silicone dressing as an additional measure for pressure ulcer prevention and have adopted the practice into their preventative standards of care. It should be noted that these studies consistently recommend the routine use of a Mepilex® dressing should not be the only intervention used to reduce HAPU in the ICU, however, it should be considered as an adjunctive therapy when traditional preventative

interventions alone prove ineffective or only partly effective (Chaiken, 2012). Brindle (2010) comments that nurses must rely on their bedside skills and not on the application of the Mepilex® dressing, in that it does not replace quality nursing care. The Mepilex® can serve as an adjunct to reduce pressure ulcer formation and enhance patient outcomes. Santamaria et al., (2013) study produced substantial support with their RCT that resulted in policy and procedural mandates within their institution, and evidence from Cubit et al., (2012) envisages identification and application of Mepilex® dressings at early stages of the patient's hospitalization, for instance in the ED. Standardization of prophylactic Mepilex® dressings on acutely ill patients is recommended based on the current evidence available, and hospital organizations should implement policies to include these recommendations as additional preventive measures.

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Table 1:

*Literature Review HAPU Incidence (%) Reported*

Incidence	Brindle (2010)	Chaiken (2012)	Walsh et al. (2012)	Brindle & Wegelin (2012)	Cubit et al. (2012)	Santamaria et al. (2013)
Comparison	11.5%	12.3%*	12.5%	11%	10.3%	13.1%
Intervention	0%	1.8%	7%	2%	1.96%	3.1%

\*Prevalence



Factors associated with risk of skin breakdown and pressure ulcer formation among individuals in the intensive care unit with a sacral Mepilex® dressing during a HAPU quality improvement project.

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## Abstract

**Aim & Objectives:** To examine factors associated with skin breakdown and pressure ulcer development among critically ill patients to whom Mepilex®, a prophylactic silicone dressing, for the prevention of sacral pressure ulcers, had been applied.

**Background:** Recent studies have begun to understand factors associated with the risk for skin breakdown among hospitalized critically ill patients. Several studies have shown favorable reduction in pressure ulcers when prophylactic silicone dressings were applied to high-risk individuals; however there is much to be learned regarding the factors associated with pressure ulcers among critically ill patients. Understanding such factors is important for the development of evidence-based risk assessment tools specific for intensive care unit patients.

**Design:** Prospective longitudinal study

**Methods:** Data collection occurred March 1-May 31, 2012 among patients admitted to the Intensive Care Unit (ICU). Variables including patient demographics, the criteria for applying a Mepilex®, Braden Scale score, primary diagnoses and comorbidities, body mass index, and length of hospitalization and days in the ICU were collected. Univariate logistic regression analyses were performed to determine the association between study variables and skin breakdown.

**Results:** 47 patients enrolled in the study. Two developed sacral pressure ulcers and 20 had skin breakdown in other locations. Characteristics contributing to skin breakdown included associated respiratory or cardiac diagnosis, being on a ventilator > 12 hours, using sedation/paralytics, using restraints, being on continuous renal replacement therapy, and having a Braden score  $\leq 12$ .

**Conclusions:** The identified variables may be important in understanding risk factors for skin breakdown leading to pressure ulcers, and may be considered additional criteria in a pressure ulcer risk assessment tool among ICU patients.

**Relevance to Clinical Practice:** Individuals with the identified variables may be at greater risk for pressure ulcers and may benefit from prophylactic silicone dressings.

**Keywords:** Pressure ulcer risk factors, Mepilex®, hospital acquired pressure ulcer, HAPU, prevention, silicone dressing, skin breakdown

Factors associated with risk of skin breakdown and pressure ulcer formation among individuals in the intensive care unit with a sacral Mepilex® dressing during a HAPU quality improvement project

## **Introduction**

Hospital acquired pressure ulcers (HAPU) are a significant problem in patient care. The development of pressure ulcers can increase the length of hospital stays, patient pain and suffering, complications in the healing process, potential death, as well as increase health care costs (Armstrong et al. 2008). The estimated cost of pressure ulcers in the United States is a staggering expense ranging from \$2.2 to \$3.6 billion a year (Calianno 2007a; Calianno, 2007b) with the mean cost of \$43,180 per hospital stay (Department of Health and Human Services, 2008). Effective October 1, 2008, The Centers for Medicare and Medicaid Services (CMS) no longer reimburse hospitals for treating Stage III or IV HAPU (Calianno 2007a; Calianno, 2007b; Berquist-Beringer et al. 2009). With the devastating effects to patients and healthcare institutions, nursing is challenged with identifying innovative ways to prevent pressure ulcers from occurring. In the critically ill population, early identification of patient characteristics and comorbid risk factors are needed to isolate those at high-risk, with implementation of evidence-based preventive strategies to reduce incidence of pressure ulcer formation. An important recent preventive strategy includes the use of soft silicone-foam bordered dressings (Mepilex® Border Sacrum, Mölnlycke Health Care) with varied degrees of success (Brindle, 2010; Butcher & Thompson, 2010; Brindle & Wegelin, 2012; Chaiken, 2012; Walsh et al., 2012; Cubit et al., 2013, Santamaria et al., 2013). The purpose of this study is to describe patient characteristics and variables associated with skin breakdown and HAPU development among a critically ill patient population to whom Mepilex® has been applied for the prevention of sacral pressure ulcer development. We hypothesized that the application of the Mepilex® dressing to the sacrum

would reduce the incidence of HAPU formation in our ICU patient sample throughout the length of hospitalization.

## **Background**

Pressure ulcers are wounds caused by constant pressure to underlying skin tissue (Reilly, Karakousis, Schrag, & Stawicki, 2007). The breakdown of skin occurs from an insufficient blood supply, typically at bony prominences commonly the sacrum, elbows, knees, occiput, ischium, heels, and coccyx (Smeltzer, Bare, Hinkle, & Cheever, 2008; Brindle & Wegelin, 2012). The prolonged and unrelieved pressure on skin causes an occlusion of blood flow, ischemia, and ultimately cell death (Salcido, Popescu, & Ahn, 2007). The skin is the largest organ of the body and its integrity is dependent upon the function of all other organ systems for nutrition, circulation, and immune function. Even with multifocal preventive interventions, the burden of disease in the acutely hospitalized patient can overwhelm the skin and lead to HAPU formation (Armstrong et al., 2008). The severely debilitated patient with multisystem failure is at greatest risk, and part of our role as bedside clinicians is identifying the problem early and intervening to reverse pressure related skin changes (Calianno, 2007a).

Critically ill patients are at high risk for developing HAPU due to intrinsic and extrinsic factors. Intrinsic factors include impaired mobility and motor dysfunction, muscular atrophy, impaired sensory perception or cognition, decreased tissue perfusion, poor nutritional status, and altered mental status or consciousness. Extrinsic factors include the exposure of body surfaces to pressure, friction, shear, and moisture (Brindle & Wegelin, 2012). In addition to these factors, critically ill patients may have further comorbid chronic and acute medical diagnoses that put them at the highest risk of pressure ulcer development (Reilly et al., 2007; Cox 2011).

Identification of patients at risk for pressure ulcer development is important for prevention initiatives. Several validated assessment tools designed to identify patients at risk for pressure ulcers, (e.g., the Braden Scale, Norton Scale, Waterlow Scale) have been developed and tested (Norton, 1962; Waterlow, 1987; Braden & Bergstrom, 1989). In a literature review, McGough, (1999) reported over 40 different pressure ulcer prevention tools. It was concluded that none of these tools were consistently reliable for all clinical situations, as different patient groups have different clinical needs and pressure ulcer prevention tools should be used in the appropriate clinical setting. One of the most widely accepted pressure ulcer risk assessment tools, which has shown to have the best reliability and validity indicators in various healthcare settings, is the Braden Scale, which produces a pressure ulcer risk score based on known risk factors of mobility, altered mental status/consciousness, moisture, and nutrition (Braden & Bergstrom, 1989; Braden Scale, n.d.). The Braden Scale addresses six categories for predicting a pressure score risk including: sensory perception, moisture, activity, mobility, nutrition, and friction and shear (Bergstrom et al., 1987; Braden & Bergstrom, 1989). A Braden score of 12 or less indicates the greatest risk, a score of 13-18 is low to moderate risk, and greater than 18 indicates the lowest risk. Patient characteristics and severity of illness in the ICU population puts a majority of patients in Braden's high-risk, if fact Brindle (2010) stated nearly 100% of ICU patients have a Braden Score of 18 or less, indicating HAPU risk. Several studies have suggested that the six Braden categories are not significantly predictive for pressure ulcer development in the critically ill population, indicating a possible limitation of the Braden Scale when applied to ICU patients. These studies have shown that the categories of mobility and friction/shear (Cox, 2011), moisture and mobility (Bours et al., 2001), sensory perception (Carlson et al., 1999), and friction and shear (Tescher et al., 2012) are significant predictors

within ICU populations. Although the Braden Scale can predict increased risk for skin breakdown in the ICU patient, the sole reliance on this tool may limit the use of additional preventive interventions for the high-risk individuals among ICU nurses (Brindle, 2010).

In addition to the Braden Score, numerous scoring systems have been developed to determine acuity or severity of illness scores for patients admitted to the hospital and ICU. Two examples are the Acute Physiology and Chronic Health Evaluation (APACHE) score or the Sequential Organ Failure Assessment (SOFA) score. These tools can be used on acutely ill patients to determine acuity or severity of illness, and predict mortality and morbidity. Another benefit of using these scoring tools in research trials is the advantage of assessing patients in trials with restrictive eligibility criteria, which eliminates patients with comorbid disease. In other words, restrictive criteria increase the certainty that any observed difference is attributable to the disease or treatment, and not confounded by comorbid disease (Charlson et al., 1986). Eliminating patients with comorbid conditions from trials increases the efficiency of the trial, but does so at a cost of limited generalizability beyond the population studied and possible poor participant recruitment and participant attrition (Charlson et al., 1986). An alternative approach for research trials is to classify patients with comorbid diseases and their risk for mortality during participation in the study. The Charlson Comorbidity Index (CCI) uses a weighted index of comorbidity comprised on various medical conditions and assigns a weighted risk (score 1, 2, 3 or 6) for these diseases. Charlson et al., (1986) found that the number and seriousness of comorbid diseases was a significant predictor of 1-year survival ( $p < 0.0001$ ) and at each increased level of weighted risk, there was a stepwise increase in the cumulative mortality attributable to the comorbidity index ( $p < 0.0001$ ) (Charlson et al., 1986). CCI was determined to a valid, reliable method for estimating risk of death from comorbid disease for use in

longitudinal studies (Charlson et al., 1986). The relevance with comorbidity exists with pressure ulcers, because it is known that comorbid disease is a major risk factor for developing pressure ulcers and affects the healing process for individuals suffering from pressure ulcers (Cox, 2011; NPUAP, 2013).

A review of the literature identified a number of studies using a novel approach in preventing ulcers by using an absorbent soft, silicone self-adherent foam border dressing in the sacral area before pressure ulcers develop (Brindle, 2010; Butcher & Thompson 2010; Brindle & Wegelin 2012; Chaiken, 2012; Walsh et al., 2012; Cubit et al., 2013; Santamaria et al., 2013). Brindle (2010) performed a research study utilizing absorbent soft silicone self-adherent dressings in a surgical-trauma ICU. Of the 41 identified high-risk patients that received the preventive sacral dressing, there was a zero percent pressure ulcer incidence in the treatment group. A subsequent study comparing a preventative Mepilex® group (n=50) to a standard care group (n=35), resulted in a reduced pressure ulcer incidence in the treatment group (Brindle & Wegelin, 2012). Chaiken (2012) and Walsh et al. (2012) reported reduced pressure ulcer incidence when the Mepilex® dressing was applied to patients during quality improvement initiatives. Similarly a study of early preventive intervention to utilize the sacral Mepilex® amongst individuals in the emergency department supports the findings of reduced HAPU incidence (Cubit, 2012). More recently, a randomized control trial in Australia demonstrated statistically and clinically relevant reduction of heel and sacral pressure incidence by 10% between the Mepilex® intervention and control groups (Santamaria et al., 2012).

Bethesda North Hospital, part of the TriHealth organization, is a Level III care facility. Specifically, the Medical Surgical Intensive Care Unit (MSICU) provided the setting for this study. This mixed population ICU consists of 22 beds with an additional 10 beds for the



Cardiovascular ICU. The cardiovascular ICU population was excluded from this study. At Bethesda North Hospital, pressure ulcer prevention standards of care are based on an interdisciplinary approach including identification of pressure ulcer risk through Braden Scoring (Bergstrom et al., 1987), nursing interventions such as turning patients every two hours, use of skin care products, as well as specialty pressure redistribution devices and beds. A collaborative effort utilized evidence-based practices as a quality improvement process to implement the use of the Mepilex® dressing as an additional preventive intervention to reduce HAPU incidence and improve patient outcomes. This study examines the outcomes of the use of the Mepilex® dressing on HAPU formation and skin breakdown as well as patient characteristics and other variables associated with skin breakdown among ICU patients.

## **Methods**

### **Design, Sample, & Setting**

This study is part of longitudinal cohort study investigating the effect of a prophylactic Mepilex® dressing on pressure ulcer incidence. TriHealth's Institutional Review Board approved the study. Informed consent was obtained from each participant by the Primary Investigator and one enrollment nurse upon patient admission to the MSICU. Patients are admitted to the MSICU from various settings, including direct admission from external facilities or transfer from other departments within the hospital. The reason for admission to the MSICU was based upon the patient's clinical severity or acuity of illness requiring intensive monitoring or specialized therapy. All patients admitted into the MSICU at Bethesda North Hospital from March 1, 2011 through May 31, 2011 were evaluated for inclusion and exclusion criteria. A checklist protocol enumerated criteria that would determine if the participant should have a Mepilex® dressing

applied. The checklist was derived from Brindle's patient selection tool (Brindle, 2010; Brindle & Wegelin, 2012) which included criteria for automatic application of the Mepilex® dressing. These included surgical procedures lasting greater than 4 hours, cumulative surgeries lasting 8 hours or more per current admission, cardiac arrest, rapid response, vasopressor use, body mass index (BMI) >40 or <18, mechanical ventilation, quadriplegia or spinal cord injury, drive line use such as ventricular assist devices or Intra Aortic Balloon Pump (IABP), Rotoprone, Continuous Renal Replacement Therapy (CRRT), continuous and bi-level positive airway pressure (CPAP/BIPAP), Braden score <13, and past history of pressure ulcers. In addition to the automatic criteria, a list of secondary factors included weeping edema/anasarca, traction, age >65 years old, a preexisting diabetes mellitus diagnosis, bed rest, liver failure, malnutrition defined as prealbumin < 20 mg/dL, albumin <2.5 g/dL, nothing by mouth for 3 or more days, sedation/paralytic use, restraint use, or fecal/urinary incontinence not controlled by a indwelling catheter or fecal management device.

After enrollment into the study, entire body skin assessments for any noted changes in skin integrity occurred every three days throughout the entire length of hospitalization. Concurrently during this assessment, the Mepilex® was removed and the sacral coccygeal skin was assessed, and the research team replaced the Mepilex® dressing. The research team utilized data collection forms to record assessment findings, indicated the inclusion criteria applicable to the patient on each assessment day, and calculated the Braden Scale pressure ulcer risk assessment score.

Prior to the start of the study, all units within Bethesda North Hospital were notified of this study and education on the daily care procedures for the application, monitoring, and documentation of the Mepilex® dressing was provided. In-service education was delivered on

Braden Scale calculation and TriHealth's standards for preventive care measures for skin breakdown. During the course of the study, the Primary Investigator was available to provide support to the unit nurse as well as address participant needs.

## **Measures**

### **Independent variables.**

Several independent variables were measured, including the maximum number of criteria for applying the Mepilex® dressing during the patient's length of hospitalization, Braden Scale score, primary diagnoses, BMI, demographic variables, length of hospitalization in days, and the number of days spent in the MSICU. To measure the burden of comorbid disease, Charlson's Comorbidity Index (Charlson et al., 1987) calculated a weighted score based on the number of comorbid diseases. Charlson's Comorbidity Index was used to determine the level of comorbidity that existed among participants. With statistical manipulation, comorbidity can be "leveled" so the influence of comorbidity can be equal among all participants, thus suggesting results are more of an influence of the intervention being studied. Additionally, higher CCI levels are indicative of a greater comorbidity and illness among participants, suggesting a greater exposure to patient specific characteristics and hospital-based interventions to manage a higher level of illness, thus a potentially higher risk of skin breakdown.

Independent variables also included the criteria used to assess whether patients require Mepilex® dressing application. These criteria are surgical procedures lasting greater than 4 hours, cumulative surgeries lasting 8 hours or more per current admission, cardiac arrest, rapid response, vasopressor use, body mass index (BMI) >40 or <18, mechanical ventilation, quadriplegia or spinal cord injury, drive line use such as ventricular assist devices or Intra Aortic

Balloon Pump (IABP), Rotoprone, Continuous Renal Replacement Therapy (CRRT), continuous and bi-level positive airway pressure (CPAP/BIPAP), Braden score <13, and past history of pressure ulcers. In addition to the automatic criteria, a list of secondary factors include weeping edema/anasarca, traction, age >65 years old, a preexisting diabetes mellitus diagnosis, bed rest, liver failure, malnutrition defined as prealbumin < 20 mg/dL, albumin <2.5 g/dL, nothing by mouth for 3 days or more, sedation/paralytic use, restraint use, or fecal/urinary incontinence not controlled by an indwelling catheter or fecal management device.

### **Dependent variables.**

The primary dependent variable was measured by the presence of skin changes noted on the sacral area during hospitalization, along with a secondary dependent variable of any skin breakdown noted on all areas of skin. The research team completed skin assessments and documented any changes in skin integrity, and staged the breakdown according to the National Pressure Ulcer Advisory Panel guidelines (NPUAP, 2007) guidelines. A skin assessment tool was designed specifically for this study, based on one from a similar study measuring covariates of pressure ulcer risk among patients with Mepilex® dressings (Brindle, 2010; Brindle & Wegelin, 2012). All research personnel were simultaneously trained on how to complete the assessment form by the Primary Investigator, and were able to demonstrate correct documentation on the assessment tool. It should be noted that no studies have tested the reliability or validity of this assessment tool. Noted skin changes that did not meet criteria of the NPUAP guidelines but may have been suggestive of early skin impairment, such as pink, reddened, or blanchable skin, were documented by description. For analysis, the primary and secondary dependent variables were dichotomized into having skin breakdown, coded as “1” and not having skin breakdown coded as “0.”

## **Data Analysis**

Of the 50 participants enrolled in the study, two withdrew and data from one patient was lost during the study, thus the analysis was based on data from 47 individuals. Descriptive analysis was completed for the sample characteristics using means with standard deviation for continuous variables and frequencies for categorical variables. Descriptive statistics included frequency of skin breakdown on any body part, including the sacrum. In addition to the frequency of skin integrity changes, a description of what type of breakdown was included, based on NPUAP guidelines. Independent sample t-tests [with Levene's test for equality of variance] were used to examine the mean differences in skin break down and continuous study variables including age, length of stay for entire hospitalization, the number of days in the ICU, Charlson's comorbidity index, and the maximum number of application criteria. Fisher's exact tests were further used to examine differences in skin break down with categorical variables. Univariate logistic regression analyses examined the association between all study variables and skin breakdown. Since no participant with skin breakdown had a Braden Score greater than 12, the Braden Score was used as a continuous variable for the logistic regression analysis. For all analyses an alpha level  $p < 0.05$ , and all analyses will be performed using IBM statistics version 20 (IBM Corp., Armonk, NY, USA).

## **Results**

### **Sample Description**

Table 1 provides a description of the sample. The majority of the sample was female (57.4%), with mean age of 71.1 ( $\pm$  11.9) years, Caucasian (91.5%), and had private health insurance (53.2%). The majority of the sample (40%) was obese (i.e., BMI > 30). The maximum

number of enrollment criteria during the individual's length of hospitalization showed a mean of 5.9 ( $\pm$  2.6) criteria. The mean length of hospitalization for the sample was 10.7 ( $\pm$  7.8) days with 5.0 ( $\pm$  3.2) days spent in the MSICU. The mean Braden Score on admission was 11.7 ( $\pm$  2.0), with 87.2% of the sample having a Braden Score  $\leq$  12. The mean Charlson comorbidity index score was 3.5 ( $\pm$  2.4) suggestive that the overall sample had existing comorbid disease burden, which is suggestive that higher comorbidity may increase risk for pressure ulcers (Cox, 2011; NPUAP, 2013). In comparison to individuals without skin breakdown, individuals with any skin breakdown had longer lengths of stay, more days spent in the MSICU, lower Braden Scores, higher Charlson comorbidity index, and increased number of qualifying enrollment criteria. Individuals with respiratory and cardiac admitting diagnoses were more likely to have skin breakdown as compared to those with surgical or other admitting diagnoses ( $p = .013$ ). Furthermore, individuals with a lower Braden Scale score on admission had higher rates of skin breakdown ( $p = .031$ ).

### **HAPU Occurrence and Skin Breakdown**

Of the 47 participants, two (4.3%) developed sacral HAPU. The first participant developed a Stage II pressure ulcer on day seven of the hospital stay, which resolved by time of discharge. The second participant developed a Stage II pressure ulcer on day 17 that was present at the day of discharge. Twenty individuals developed skin breakdown, which was defined as a staged pressure ulcer defined by NPUAP or signs of early skin breakdown as red, pink, blanchable skin. Among the 20 individuals, there were 5 (25%) Stage-I wounds, 4 (20%) deep tissue injury (DTI), 3 (15%) Stage II, and 12 (60%) indicative of early skin breakdown. These wounds were noted on elbows, ears, hip, buttocks or gluteal fold, lip, toes, and ankles.

## **Association Between Application Criteria for Mepilex® and Sacral Skin Breakdown or any Skin Breakdown**

Figure 1 illustrates the association between sacral skin breakdown or any skin breakdown along with salient criteria used at enrollment for the application of the Mepilex® dressing. Sacral skin breakdown was associated with the use of restraints ( $p = .052$ ). Any skin breakdown was significantly associated with restraint use ( $p = .000$ ), sedation/paralytic administration ( $p = .001$ ), CRRT ( $p = .038$ ), and mechanical ventilation greater than 12 hours ( $p = .021$ ).

### **Other Study Variables Associated with Any Skin Breakdown**

Eleven potential predictors of any skin breakdown were examined (Table 2). As compared to ‘other’ diagnoses, a respiratory (OR- 19.5,  $p = .003$ ) or cardiac (OR-6.50,  $p = .058$ ) primary diagnoses were strong predictors for skin breakdown. Moreover as compared to those with 2-4 application criteria, those with 5-7 (OR= 7.11,  $p = .018$ ) and those with 8-12 (OR= 9.60,  $p = .007$ ) were more likely to have skin breakdown. While many of the variables did not demonstrate statistical significance (possibly due to low power), those that may indicate clinical relevance include individuals who were male, 66 years of age or older, and with a BMI greater than 25, with a greater likelihood to develop skin breakdown compared to their referents.

## **Discussion**

The purpose of this study was to examine factors associated with HAPU and skin breakdown among ICU patients with a preventative sacral Mepilex® dressing. Our findings suggest that several characteristics contribute to skin breakdown among patients in an intensive care unit including primary admitting diagnoses related to respiratory or cardiac medical conditions, ventilator use greater than 12 hours, use of sedation/paralytics and restraints, CRRT,

and Braden scores  $\leq 12$ . These risk factors may be important in understanding the risk factors among ICU patients for skin breakdown leading to HAPU's

First, our study indicated an association between mechanical ventilator use greater than 12 hours with sacral or any skin breakdown ( $p = .021$ ), and individuals with a respiratory diagnosis on admission being predictive of HAPU formation (OR- 19.5,  $p= .003$ ). Studies have found that pressure ulcer development is related to respiratory illnesses, respiratory failure, and mechanical ventilation within the ICU and other settings (Reilly et al., 2007; Nijs et al., 2008; Senturan et al., 2009). Individuals who receive ventilation are typically sedated, immobilized from restraints, demonstrate high-risk Braden Scores (Carlson, 1999), have direct pressure exerted on the sacrococcygeal region from elevation of the head of bed, and have frequent friction and shearing forces from sliding increasing risk of damage to the skin (Santamaria et al., 2013). This finding from our study suggest the need for a nursing protocol or interventions that increase the monitoring and assessment of skin for breakdown among individuals with a respiratory illness diagnosis and/or who are on mechanical ventilation while in the ICU setting.

Second our findings support a cardiac primary diagnosis on admission (OR-6.50,  $p= .058$ ) was a strong predictor for skin breakdown. Our findings corroborate the findings of other studies, which have found that cardiovascular disease, hemodynamic instability, and vasopressor administration are significant factors associated with pressure ulcer formation (Carlson, 1999; Nijs et al., 2008; Cox, 2011; Tschannen et al., 2012). This hemodynamic instability can compromise tissue perfusion and may subsequently predispose the skin to ischemia that increases risk of skin breakdown. Hence, critically ill individuals with cardiac disease or hemodynamic instability and on vasopressors should also be monitored and assessed more frequently to reduce subsequent HAPU within the ICU setting.



Third, we found that CRRT therapy was associated with increased risk for skin breakdown ( $p = .038$ ). Limited studies have analyzed CRRT with pressure ulcer formation. It is suggested that the association between CRRT and skin breakdown may be a result of the immobility caused by the dialysis intervention itself (Nijs et al., 2008). Future studies may examine the underlying mechanisms that determine the association between CRRT and pressure ulcer formation to develop adequate prevention strategies.

Finally, in our study 87.2% had a Braden Score  $\leq 12$  with a mean Braden Score of 11.7. The calculated Braden scores at admission were significantly associated with skin breakdown ( $p = .031$ ). Studies have shown varied outcomes to total Braden Score and the reliability and validity of the individual six subscales as being predictive or only partially predictive of pressure ulcer risk (Bours et al., 2001; Carlson et al., 1999; Cox, 2011; Iranmanesh et al., 2012; Tescher et al., 2012). Although our study indicates a relationship between the total Braden score and skin breakdown, further analyses would be needed to delineate if the six Braden subscales independently had a significant association for changes in skin integrity. However, such analyses are beyond the scope of the present study. Future studies with adequate sample sizes should examine the relationship between Braden Scale subscales and skin integrity.

### **Limitations**

A small sample size ( $n=47$ ) produced a homogenous sample with minimal generalizability outside of the ICU populations. Moreover there are other factors that may have affected pressure ulcer development that were not measured among patients such as smoking (Suriadi et al., 2007). In addition, the type of bed or mattress on which patients occupied was not considered as a variable in the study, due to the transition of patient care through the hospital and the variance of type of bed and mattress the patient occupied. Changes in the type of bed or

mattresses to which participants were assigned may have influenced pressure ulcer development. We also recognize the influence of staff education on the Mepilex® dressing prior to the start of this study, which may have influenced the results. Moreover, patient participation in this study and additional skin assessments and visits by the investigation team may have influenced nurses to engage in preventative skin measures more frequently than required. We also recognize the limitation of our assessment tool, which was designed for this study without testing of validity or inter-rater reliability. Future research would benefit from a larger sample size with power analysis and participant, as well as use of an assessment tool with demonstrated validity.

### **Conclusions**

As healthcare requirements become more stringent and reimbursement reliant upon quality patient outcomes, understanding additional factors that predispose patients to HAPU can allow for earlier identification in order to initiate preventive interventions. ICU patients, many of whom are deemed high risk for HAPU, identification of individuals based on medical interventions and therapy such as ventilator use, sedation/paralytics administration, restraint application, CRRT, respiratory or cardiac medical diagnoses, and Braden Scale scores, may be considered for additional criteria for a pressure ulcer risk assessment tool. The results of our study suggest that healthcare providers assess for patient characteristics and hospital-based interventions and therapies as additional variables for pressure ulcer risk. Early and improved identification of such risk factors can lead to prevention strategies, such as use of prophylactic Mepilex® dressing use. While this study did not compare incidence or prevalence rates found in this study to a comparison, we believe that among our population a notable difference in HAPU incidence was found between participants with “any skin breakdown” (n=20) and “sacral skin breakdown” (n=2). We suggest that along with an ICU specific assessment tool, there is clinical

relevance for the use of prophylactic silicone foam dressings. Mepilex® dressing may be an easy solution to a significant problem with clinical practicality to potentially reduce new cases of iatrogenic pressure ulcers. While few studies statistically show the benefits of Mepilex® and reduce HAPU incidence, the clinical practicality exists to use Mepilex® as an adjunctive therapy to nursing standards of care. Hence it is recommended to incorporate a patient- and intervention-specific assessment tool, and utilize evidence based prevention strategies (such as the use of the Mepilex® dressing) as part of routine practice to lower HAPU incidence and enhance patient outcomes within the ICU setting.

### **Relevance to Clinical Practice**

Assessment of the identified risk factors for skin breakdown can be applied to traditional pressure ulcer risk assessment scores to improve early identification of critically ill individuals at risk for pressure ulcer formation. Individuals with these identified variables may benefit from prophylactic silicone dressings as a pressure ulcer prevention strategy to reduce HAPU incidence. With insurance reimbursement more reliant upon patient outcomes, hospitals must implement new screening tools and nursing interventions to reduce hospital-acquired conditions. Hospitals that modify existing standards of care to include additional risk assessments (such as the tool used in this study) and incorporate Mepilex® dressings as an adjunctive therapy may benefit from reduce HAPU incidence.

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Table 1: *Sample Characteristics*

		Total (N = 47)		No Skin breakdown (n = 27)		Any skin breakdown <sup>a</sup> (n = 20)		Difference
		n	%	n	%	n	%	p
<b>Gender</b>								<b>.551</b>
	Male	20	42.6	10	37.0	10	50.0	
	Female	27	57.4	17	63.0	10	50.0	
<b>Age</b>								
	<65	12	25.5	9	33.3	3	15.0	<b>.191</b>
	66>	35	74.5	18	66.7	17	85.0	
<b>Ethno/Cultural</b>								<b>.836</b>
	Caucasian	43	91.5	25	92.6	18	90.0	
	African American	2	4.3	1	50.0	1	5.0	
	Hispanic/Latin American	1	2.1	0	0	1	5.0	
	Asian/Pacific Islander	1	2.1	1	3.7	0	0	
<b>Insurance Provider</b>								<b>.328</b>
	Medicare	20	42.6	12	44.4	8	40.0	
	Private	25	53.2	15	55.6	10	50.0	
	No insurance/ Self-pay	2	4.3	0	0	2	10.0	
<b>Primary Diagnoses on admission<sup>b</sup></b>								<b>.013</b>
	Respiratory	12	25.5	3	11.1	9	45.0	
	Cardiac	10	21.3	5	18.5	5	25.0	
	Surgical	10	21.3	6	22.2	4	20.0	
	Other	15	31.9	13	48.1	2	10.0	
<b>Braden score categories<sup>c</sup></b>								<b>.031</b>
	6-12	41	87.2	21	77.8	20	100	
	13-18	6	12.8	6	22.2	0	0	
<b>Body Mass Index</b>								<b>.546</b>
	<18.5 (Underweight)	3	6.4	3	11.1	0	0	
	18.6-24.9 (Normal)	12	25.5	7	25.9	5	25.0	
	25-29.9 (Overweight)	13	27.7	7	25.9	6	30.0	
	> 30.0 (Obese)	19	40.4	10	37.0	9	45.0	
		Mean	SD	Mean	SD	Mean	SD	p
<b>Length of Hospital Stay</b>		10.7	7.8	10.1	8.3	11.5	7.1	<b>.551</b>
<b>Number of days in the MSICU</b>		5.0	3.2	4.3	2.9	5.9	3.3	<b>.104</b>
<b>Braden Score</b>		11.7	2.0	12.0	2.4	11.4	1.4	<b>.321</b>
<b>Charlson co-morbidity index scores</b>		3.5	2.4	3.2	2.3	3.8	2.6	<b>.421</b>
<b>Maximum number of Mepilex® application criteria</b>		5.9	2.6	5.0	2.3	7.2	2.4	<b>.801</b>

a. Any skin breakdown includes pressure related changes based on the NPUAP staging guidelines, deep tissue injury (DTI), unstageable wounds, incontinence associated skin changes, and signs of early pressure related changes of red/pink blanchable skin on all areas of the body.

b. The primary diagnosis on admission were categorized into respiratory (including individuals with chronic obstructive pulmonary disease, pneumonia, respiratory failure, pleural effusion), cardiac (including individuals with myocardial infarction, arrhythmias, hyper/hypotension, vascular disorders, and stroke), surgery (including individuals with neurosurgery, exploratory laparotomy, nephrectomy, orthopedic surgery), and other (metabolic disorders, GI bleed, neurologic disorders, and sepsis/septic shock)

c. Braden scores range from 6-23, with lower scores indicating greater risk for pressure ulcer development

Table 2. *Univariate logistic regression analyses to determine factors associated with any skin breakdown<sup>a</sup>*

		Any Skin Breakdown (Univariate)	
		B [s.e]	OR [95% CI]
<b>Gender</b>			
	Male (referent)	1.00	-
	Female	-.53 [0.60]	0.59 [0.18-1.90]
<b>Age</b>			
	<65 (referent)	1.00	-
	66>	1.04 (0.75)	2.83 [0.66-12.26]
<b>Ethno/Cultural</b>			
	Caucasian	-.33 [1.05]	0.72 [0.09-5.60]
	Other (referent)	1.00	-
<b>Insurance Provider</b>			
	Medicare <sup>b</sup>	-.18 [0.60]	0.83 [0.26-2.69]
	Private (referent)	1.00	-
<b>Primary diagnoses on admission<sup>c</sup></b>			
	Respiratory	2.97 [1.01]	19.50 [2.69-141.35]
	Cardiac	1.87 [0.99]	6.50 [0.94-45.11]
	Surgical	1.47 [1.00]	4.33 [0.61-30.57]
	Other (referent)	1.00	-
<b>Braden score</b>			
<b>Body Mass Index<sup>d</sup></b>			
	<18.5-24.9 (Underweight/Normal) (referent)	1.00	-
	25-29.9 (Overweight)	.54 [0.78]	1.71 [0.37-7.92]
	> 30.0 (Obese)	.59 [0.72]	1.80 [0.44-1.31]
<b>Maximum number of Mepilex® criteria during length of stay</b>			
	2-4 (referent)	1.00	-
	5-7	1.96 [0.83]	7.11 [1.40-36.12]
	8-12	2.26 [0.84]	9.60 [1.85-49.88]
<b>Length of hospital stay (Days)</b>		.02 [.04]	1.02 [.95-1.10]
<b>Number of days in the MSICU</b>		.16 [.10]	1.17 [.96-1.43]
<b>Charlson comorbidity index scores</b>		.10 [.13]	1.11 [.87-1.42]

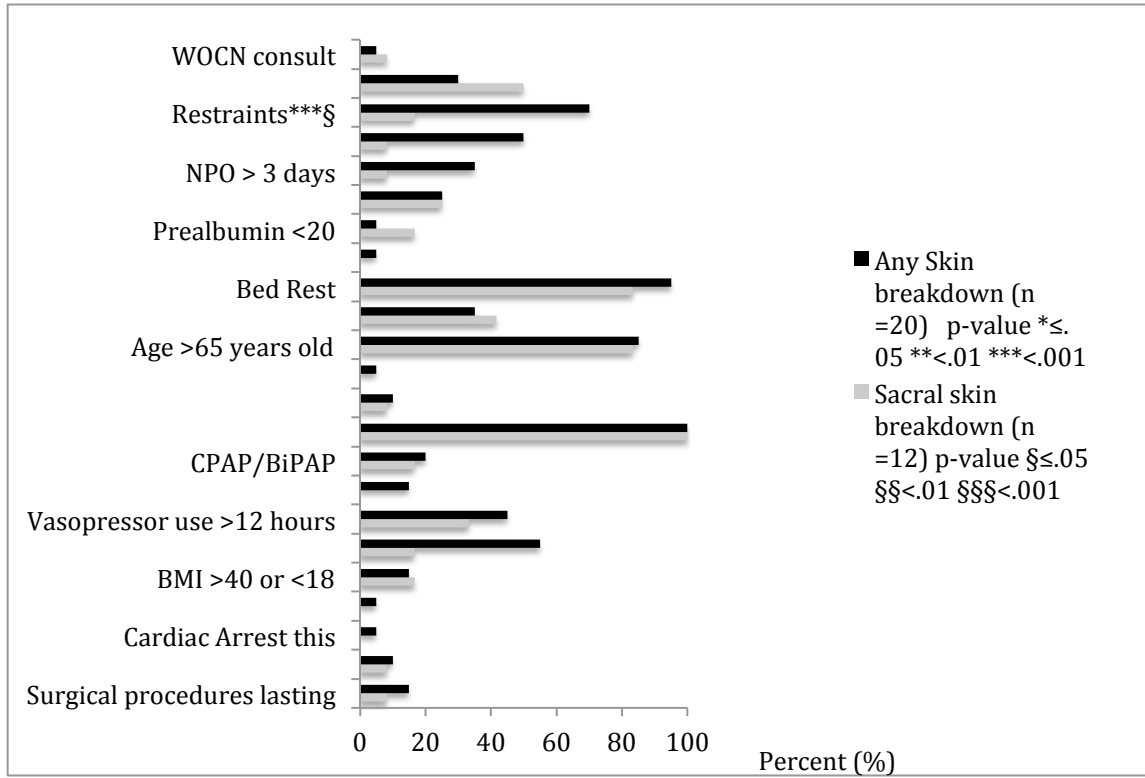
a. Any skin breakdown includes pressure related changes based on the NPUAP staging guidelines, deep tissue injury (DTI), unstageable wounds, incontinence associated skin changes, and signs of early pressure related changes of red/pink blanchable skin on all areas of the body.

b. The Medicare category includes two individuals who had no insurance or self-pay.

c. The primary diagnosis on admission were categorized into respiratory (including individuals with chronic obstructive pulmonary disease, pneumonia, respiratory failure, pleural effusion), cardiac (including individuals with myocardial infarction, arrhythmias, hyper/hypotension, vascular disorders, and stroke), surgery (including individuals with neurosurgery, exploratory laparotomy, nephrectomy, orthopedic surgery), and other (metabolic disorders, GI bleed, neurologic disorders, sepsis/septic shock)

d. Body Mass Index includes three individuals who were underweight and were combined with the normal weight category for analysis

Figure 1: Association between criteria for Mepilex® application and observed sacral or any skin breakdown



WOCN= Wound Ostomy and Continence Nursing, NPO= Nothing by mouth, CPAP/BiPAP= Continuous Positive Airway Pressure/Bi-level Positive Airway pressure, CRRT= Continuous Renal Replacement Therapy, BMI= Body Mass Index

Implementing a Hospital-Acquired Pressure Ulcer Prevention Protocol with a Sacral Mepilex®  
Dressing and Evaluation of Nursing Protocol Adherence

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## Abstract

**Objective:** To implement a Hospital-Acquired Pressure Ulcers (HAPU) prevention program utilizing an assessment tool to identify patients at risk, and intervene with a sacral Mepilex® dressing. Our aims are to determine if a change in nursing knowledge and change in nursing behavior after implementing our program.

**Background:** HAPUs are a significant problem in patient care and healthcare organizations must implement prevention protocols to reduce HAPU prevalence. Guidelines for implementing HAPU prevention programs suggest use of a validate risk assessment tool and initiating preventive interventions. One intervention found in the literature is the adjunctive use of prophylactic Mepilex® dressings to sacral skin.

**Design:** Descriptive study with a prospective one-group pre and post-test design, followed by a retrospective medical record review.

**Methods:** A HAPU education was disseminated to TriHealth nurses who voluntarily participated in a 15-question test before and after the HAPU educational didactic. A paired t-test was performed to determine a difference in mean pre/post-test scores. After completion of the educational didactic, units with 65% completion were included in a medical record review to determine adherence to nursing clinical behaviors relating to the new policy.

**Results:** 1,182 nurses completed the pre-test and 1,514 completed the post-test. Paired t-test analysis determined a difference in mean scores before and after our educational intervention, indicating change in nursing knowledge. 65 medical records were reviewed from 5 units at TriHealth. The mean percent completion of required documentation was 62.2%, and an analysis of variance determined a difference in mean percent completion scores between hospitals, but

not unit location. Nurses correctly identified at-risk patients in 50.8% of medical records and used a prophylactic Mepilex® dressing; however 16.9% of at-risk patients were missed. The most identified Mepilex® application criteria included age >65 years, mechanical ventilator use, surgical procedures lasting  $\geq 4$  hours, and Braden Scale scores <13.

**Conclusion:** A change in nursing knowledge was evident after our educational didactic, however, our medical record review indicates a failure to consistently follow the HAPU protocol to identify, intervene, and maintain pressure ulcer prevention practices for patients at-risk.

**Relevance to Clinical Practice:** This HAPU prevention protocol may be successful at changing nursing knowledge, but had variable impact on changing nursing behaviors. Additional program evaluation is needed to identify areas to support our nurses for long-term sustainability.

**Keywords:** HAPU, pressure ulcer, implementation, adherence, Mepilex®, silicone dressing

# Implementing a Hospital-Acquired Pressure Ulcer Prevention Protocol with a Sacral Mepilex® Dressing and Evaluation of Nursing Protocol Adherence

## **Introduction**

Pressure ulcers are wounds caused by constant pressure to underlying skin tissue (Cuddigan, Berlowitz, & Ayello, 2001). The breakdown of skin occurs from an insufficient blood supply at bony prominences commonly the sacrum, coccyx, ischium, occiput, knees, and ankles (Smeltzer, Bare, Hinkle, & Cheever 2008; Brindle & Wegelin, 2012). The prolonged and unrelieved pressure on skin causes an occlusion of blood flow, ischemia, and ultimately cell death (Salcido, Popescu, & Ahn, 2007). Acutely ill patients are at greatest risk for pressure ulcers from intrinsic and extrinsic factors. Intrinsic factors include impaired mobility and motor dysfunction, muscular atrophy, impaired sensory perception or cognition, decreased tissue perfusion, poor nutrition, and altered mental status or consciousness. Extrinsic factors include the exposure of body surfaces to pressure, friction, shear, and moisture (Allman, Gosnell, Bergstrom, & Cuddigan, 1993). In addition to these factors, acutely ill hospitalized patients have co-morbid chronic and acute medical diagnoses that put them at the highest risk for pressure ulcer development (Reilly et al., 2007; Cox, 2011). Even with preventive interventions, the burden of disease and comorbidity can overwhelm the skin allowing for the formation of pressure ulcers (Armstrong, Ayello, et al., 2008). Iatrogenic pressure ulcer development that occurs as a result of healthcare involvement is termed Hospital-Acquired Pressure Ulcer or HAPU.

HAPUs are a significant problem in patient care and have deleterious implications for the patient and the healthcare system. The development of pressure ulcers increased the length of hospital stay on average by 4 days (Calianno, 2007b). Between 1999 and 2003 a 63% increase

in length of stay occurred in which pressure ulcers were a listed diagnosis in patient medical record (Calianno, 2007b). Among patients with pressure ulcers, self-reports described an increase in pain and suffering (Pieper et al., 2009). HAPU complicates the healing process and increased the mortality likelihood for hospitalized patients, which were reported as the cause of death for 115,000 individuals between 1990 and 2001 (AHRQ, 2013; Brem et al., 2010). Estimates for prevalence range from 0.4% to 38% in acute care hospitals (AHRQ, 2013). The estimated cost of pressure ulcers in the United States ranges from \$2.2 to \$3.6 billion a year (Calianno 2007a, 2007b), with a mean cost of \$43,180 per hospitalization (Department of Health and Human Services (DHHS), 2008).

### **Background**

The Centers for Medicare and Medicaid Services (CMS) with support from the National Quality Forum (NQF) determined a list of serious and costly iatrogenic healthcare errors called “Never Events” (Calianno, 2007; CMS, 2006). “Never Events” are errors that cause serious injury or death to the patient resulting in increased costs to treat (Calianno, 2007). Twenty-seven “Never Events” are listed with CMS and NQF with Goal No. 14: Pressure Ulcer Prevention. Goal No. 14: Pressure Ulcer Prevention, recommends for the use of a validated risk assessment tool to identify patients at risk for development of pressure ulcers, and an approach to prevent injury in high-risk patient populations (Calianno, 2007; NPUAP, 1992). In addition to the new standards to reduce the incidence of HAPU, CMS no longer reimburses hospitals for treating acquired Stage III or IV HAPU (Berquist-Beringer et al, 2009; Calianno, 2007; CMS, 2006).

The CMS “Never Event” payment provisions for HAPU reimbursement has resulted in healthcare providers to develop pressure ulcer prevention strategies and interventions for



professional advancement, quality patient care, and financial survival. The suggested preventive strategies include: patient education, clinician training, developing communication and terminology materials, implementing protocols, and ensuring healthcare and patient provider adherence to standards of care and policies. Healthcare literature identifies integrating the components of simplification and standardization of pressure ulcer interventions and documentation as ways to improve process of care (Armstrong et al, 2008; Sullivan & Schoelle, 2013). In addition to providing preventive strategies, clinicians must be able to identify patients deemed at risk of skin breakdown. Numerous patient characteristics and hospital-based variables were associated with skin breakdown, however, the key implication derived from evidence-based literature suggest that understanding and identifying these high-risk factors is important for early detection (Bours et al., 2001; Nijs et al., 2008; Cox, 2011).

Identification of patients at risk for HAPU development is an important prevention initiative. Several validated assessment tools designed to identify patients at risk for pressure ulcers (e.g., the Braden Scale, Norton Scale, Waterlow Scale) have been developed and tested (Norton, 1962; Waterlow, 1987; Braden & Bergstrom, 1989). In a literature review, McGough, (1999) reported over 40 different pressure ulcer prevention assessment tools. It was concluded that none of these tools were consistently reliable for all clinical situations, as different patient groups have different clinical needs, and pressure ulcer prevention tools should be used in the appropriate clinical setting. One of the most widely accepted pressure ulcer risk assessment tool, which has shown to have the best reliability and validity indicators in various healthcare settings, is the Braden Scale, which produces a pressure ulcer risk score based on known risk factors (Braden & Bergstrom, 1989; Braden Scale, n.d.). The Braden Scale addresses six risk factor categories for predicting HAPU risk including: sensory perception, moisture, activity, mobility,

nutrition, and friction and shear (Bergstrom et al., 1987; Braden & Bergstrom, 1989). A Braden score of 12 or less indicates high risk, a score of 13-18 is low to moderate risk, and greater than 18 indicates the lowest risk. Several studies have suggested that individually the six Braden categories were not significantly predictive for pressure ulcer development in the acutely ill population, indicating a possible limitation of the Braden Scale when applied to this population. These studies have shown that the categories of mobility and friction/shear (Cox, 2011), moisture and mobility (Bours et al., 2001), sensory perception (Carlson et al., 1999), and friction and shear (Tescher et al., 2012) are significant predictors within acutely ill populations. Although the Braden Scale can predict increased risk for skin breakdown in the acutely ill patient, the sole reliance on this tool may limit the use of additional assessment and preventive interventions for the high-risk individuals (Brindle, 2010). Another limitation of pressure ulcer risk assessment tools is the variability of knowledge and competence from nursing providers in the use of these tools. Surveys of nursing competence on pressure ulcers demonstrate lack of confidence on knowledge of pressure ulcer identification, staging, and prevention (Berquist-Beringer, et al., 2009).

As important as it is for early identification of patients at risk for HAPU, nursing standards of care and policy must direct care providers to initiate preventive strategies. Well known and understood evidence-based practices suggest interventions such as turning patients frequently, use of positioning devices, application of products for moisture control, optimizing nutrition, and promoting mobility and activity, for example (NPAUP, 2013). An adjunctive HAPU prevention strategy has emerged in the literature using prophylactic soft silicone foam-bordered dressings (Mepilex® Border Sacrum, Mölnlycke Health Care) among high-risk individuals to reduce HAPU development (Brindle, 2010; Butcher & Thompson, 2010; Brindle

& Wegelin, 2012; Chaiken, 2012; Walsh et al., 2012; Cubit et al., 2013; Santamaria et al., 2013). The Mepilex® dressing reduces friction and shearing, wicks moisture away from the skin, provides a foam protective core for pressure redistribution, and the patented silicone technology (Safetac®) permits atraumatic removal of the Mepilex® for skin assessment and dressing change (Mölnlycke Health Care, 2015).

In a review of six studies, specifically evaluating the prophylactic use of Mepilex® dressings and its efficacy, HAPU rates were decreased among individuals to whom a preventive Mepilex® was applied. Brindle (2010) used the silicone self-adherent dressings in a surgical-trauma ICU; of the 41 high-risk patients who received the preventive sacral dressing, there were no HAPUs in the treatment group compared with a prevalence of 11.5% in the control group. A subsequent study comparing a standard care group (n=35) to a preventive Mepilex® group (n=50) resulted in a reduced pressure ulcer incidence from 11% to 2%, respectively (Brindle & Wegelin, 2012). Clinically relevant studies from Walsh et al. (2012) reported a 5.5% difference in pressure ulcer rates in a quality improvement initiative using sacral Mepilex® dressings, and Chaiken (2012) reported a prevalence rate of 13.3% prior to the use of Mepilex® dressings, which was reduced to 1.3% after Mepilex® dressing use was implemented in their ICU. Similarly in a retrospective medical record review evaluating early preventive intervention utilizing the sacral Mepilex® among individuals admitted from the emergency department, findings demonstrated reduced HAPU incidence with a difference of 8.3% between the Mepilex® intervention group and the control group (Cubit et al., 2013). More recently, a randomized controlled trial in Australia showed statistically and clinically relevant reduction of heel and sacral pressure incidence by 10% ( $p = 0.001$ ) between the Mepilex® intervention and control groups (Santamaria et al., 2013). Thus, prophylactic sacral Mepilex® application has

promising data to support HAPU reduction, and are suggestive to healthcare organizations to integrate protocols for the application of a prophylactic Mepilex® dressing as adjunctive therapy to current nursing standards of care for individuals at risk for skin breakdown.

It is known that implementing preventive strategies will reduce HAPU from occurring, and the immediacy of implementing HAPU protocols is crucial to attaining quality improvement (Calianno, 2007b; Barker et al., 2013; Sullivan & Schoelles, 2013). Guidelines for implementing pressure ulcer prevention within hospital organizations suggest 1) use of a validated pressure ulcer risk assessment and 2) use of pressure ulcer prevention interventions (Barker et al., 2013, Calianno, 2007b). With the focus of implementing new HAPU prevention guidelines within our healthcare organization, our recommendations are twofold. First, in the hospitalized population early identification of patient characteristics, comorbid risk factors, and hospital-based therapies are needed to isolate those at high-risk. We are recommending, in addition to Braden Scale assessment, a nursing delivered patient-specific and therapy-specific assessment tool for all patients admitted to the hospital (Reilly, 2007; Cox 2011). Second, with the evidence-based knowledge on HAPU prevention and supportive evidence from Mepilex® dressings as an adjunctive therapy, we are recommending patients deemed high-risk from our assessment tool have a prophylactic Mepilex® dressing applied and maintained during hospitalization (Brindle 2010, Butcher & Thompson 2010, Brindle & Wegelin 2012, Chaiken 2012, Walsh et al., 2012, Cubit et al., 2013, Santamaria et al., 2013). With these recommendations implementation of our evidence-based protocol for screening high-risk variables associated with skin breakdown may empower nurses to accurately identify patients for HAPU risk, intervene with nursing interventions, and be proactive in preventing HAPU development.

## Methods

### Purpose

Utilizing evidence-based recommendations, in conjunction with TriHealth's Skin Care Committee, the Primary Investigator proposed changes to TriHealth's Pressure Ulcers: Guidelines for Prevention and Treatment (see Appendix A). The proposed changes include a protocol for the assessment of high-risk criteria among adult patients admitted to the hospital, and use of prophylactic Mepilex® sacral dressing for HAPU prevention. This new protocol will require registered nurses to perform a skin assessment on all patients admitted to TriHealth for specific high-risk criteria, apply a Mepilex® dressing if applicable, and complete required maintenance and documentation of the dressing until the patient is discharged from the hospital. These changes are in addition to the current standards of care, and do not replace existing guidelines. Guideline changes were reviewed and approved by TriHealth's Skin Care Committee and Department of Wound Ostomy and Continence (WOCN), to ensure accuracy, expertise knowledge, and face validity on the proposed changes. Additionally, all changes to this policy were reviewed and approved administratively by TriHealth's Nursing Practice Council and Policy and Procedures Council prior to implementing this study.

Our goal to implement new pressure ulcer prevention guidelines within TriHealth to standardize the identification of high-risk variables, requires education and training to the nurses responsible for the assessment and maintenance of these policy changes. Effective use of the new protocol requires an increase in nursing knowledge about HAPU prevention and use of treatment strategies and clinical practice behaviors. These include correct application of the Mepilex® dressing and consistent electronic medical record (EMR) documentation about skin assessments and strategies used for prevention and management. Therefore, the purpose of this

study is to evaluate the knowledge difference before and after an education didactic pertaining to the policy changes and HAPU prevention with Mepilex® dressings and to evaluate the adherence to the change. Our study had two specific aims, in Phase I, our purpose is to determine a change in nursing knowledge and in Phase II, our purpose is to determine a change in nursing clinical behavior through fidelity monitoring of nursing documentation adherence.

### **Study Design and Setting**

This descriptive study had a prospective design in Phase I with a didactic education provided to all registered nurses providing inpatient nursing care with a one-group pretest-posttest design to determine whether mean scores on a HAPU knowledge assessment were significantly different. Phase II was a retrospective medical record review to determine adherence to the new nursing standards of care and Mepilex® protocol via nursing documentation in the electronic medical record. TriHealth's Nursing Education Council and Research Council approved both Phase I and II of this study. Subsequently, the study underwent expedited review, including the waivers for informed consent, authorization, and documentation of informed consent, and was approved through the Institutional Review Board (IRB) (see Appendix B).

The study occurred at Bethesda North Hospital, Good Samaritan Hospital, and Bethesda Butler Hospital in Cincinnati, Ohio. These three hospitals collectively are part of the TriHealth organization, and provide a total of 1,028 inpatient beds. TriHealth employs approximately 3,000 nurses with roughly 2,000 nurses providing inpatient care to hospitalized patients. Our population of interest for this study is the convenience sample of registered nurses at TriHealth that are considered to provide care on adult inpatient units and departments.

## **Procedure**

*Phase I:* TriHealth uses an education platform called LEARN (Learning Effectiveness And Resource Network), a subsidiary of the Catholic Health Initiative HealthStream Learning Center, to disseminate education modules to TriHealth employees for voluntary continuing and mandatory education. This platform was used to obtain the convenience sample (n=2,051) of nurses for our program, and to deliver the education and training for this study. The Primary Investigator developed the education content to be delivered in the LEARN didactic education and created the 15 multiple-choice pretest/posttest questions (see Appendix C). The expert knowledge and opinion from TriHealth's Department of Wound Ostomy and Continence Nursing and Skin Care Committee was used to ensure face validity of the pressure ulcer content delivered in the LEARN education. The content for the didactic education was submitted to TriHealth's Corporate Education Department to be developed into the LEARN education module. During the development phase of the LEARN module, the Primary Investigator maintained active participation to ensure accuracy of the content, reviewed, and approved the completed version prior to dissemination.

On February 15, 2015 the LEARN didactic module was disseminated to 2,051 nurses at Bethesda North, Good Samaritan, and Bethesda Butler Hospitals. Nurses were provided with a 6-week due date to complete the education. Each participant was notified via letter from the Primary Investigator (included in the module) of the nature of this study and their voluntary completion of the 15-question pre/post-test analysis. Due to the changes in TriHealth's standards of care and policy change, the educational content alone was considered mandatory for all inpatient nurses to complete. The HAPU assessment test consisted of 15 multiple-choice questions. The categorical breakdown includes seven questions pertaining to the Mepilex®

protocol and interventions, five questions pertaining to policy changes and standards of nursing care, two questions related to pressure ulcer staging, and one question in regards to Braden scoring. Each TriHealth nurse has a unique and confidential username and password to access LEARN, and the freedom to complete the module at any preferred location. There was no time limit to complete the pre/post-test evaluation or the education module once started, and nurses had the ability to stop the module and to return at a later time.

*Phase II:* After four weeks completion of the LEARN education didactic, inpatient units from Bethesda North, Good Samaritan, and Bethesda Butler Hospitals were assessed for percent completion of the HAPU prevention module. Once units achieved 65% or greater completion of the LEARN didactic they were included for the medical record review in Phase II. The LEARN database has the data reporting capability to indicate which units have achieved 65% or greater completion. From this list, the Primary Investigator evenly divided 65 medical records for review. The Primary Investigator utilized TriHealth's EMR "TriHealth Connect" to obtain a master list of 65 randomly selected medical records paired with a unique identifier from the participating units. All data extracted from the 65 medical records included de-identified medical data related to nursing documentation of the Mepilex® protocol. The de-identified data for this portion of the study was collected and recorded on Sacral Silicone Foam Dressing Algorithm Fidelity Scale: Inpatient Chart Review Form (see Appendix D). Later it was imported into an electronic spreadsheet that was used for data analysis.

Rogers' Theory of Diffusion and Innovation helps provide explanations why a new idea or technology is spread through organizational cultures (Rogers, 2003). Rogers proposes different individuals will accept change at different rates and categorizes participants (percent of adopters) as early adopters (2.5%), innovators (13.5%), early majority (34%), late majority



(34%), and laggards (16%) (Rogers, 2003). Rogers' theory has been applied to many implementation studies as a systematic framework to how to acculturate new practices. Critical mass effect, imbedded in Rogers' Theory of Diffusion of Innovation, suggests that a specific number of adopters of a new innovation are required to produce a self-sustaining change or effect to achieve an end-result. The concept of critical mass was used in this study as a proposed (necessary) percentage of 65% completion of the intervention in delivered in Phase 1, to produce the desired outcome of change in nursing clinical behaviors in Phase II. Required critical mass percentages to achieve outcomes vary in the literature, with rates as low as 12% of adopters to achieve critical mass up to rates exceeding 30%, however, Rogers suggests about 10-20% adoption of the new innovation is needed to achieve critical mass (Rogers, 2003; Gladwell, 2002; Institute for Health Improvement, 2015). In our study we selected a 65% rate of completion of the LEARN didactic, to capture a large enough sample whom completed the education. With a higher completion rate, we hoped to reduce the possibility to selecting medical records for review being completed by a nurse who had not had the opportunity to complete the education. Within the 65% of nurses who completed the education, our desire was to capture nursing documentation in medical records completed by our early adopters (2.5%), innovators (13.5%), early majority (34%), and some of the late majority (34%). Rogers' Theory of Diffusion and Innovation, specifically critical mass, was applied to our medical record review in effort to reduce bias in our results.

## **Data Analysis**

The LEARN educational didactic was disseminated to 2,051 inpatient nurses. 1,182 nurses voluntarily participated in the pre-test, 1,514 participated post-test analysis, and 1,100 submitted demographic data. Descriptive analyses were completed for the sample characteristics

using frequencies for the nominal and ordinal categorical variables. For the pre/post-test analysis we used descriptive statistics, which included frequencies of correct and incorrect responses to each of the 15- pre/post-test questions, and means with standard deviations for any continuous variables. A paired-sample t-Test was used to determine if there was a significant change in participants' mean score following the completion of the LEARN education module designed to increase participants' knowledge of our HAPU prevention guidelines.

In Phase II, as mentioned previously, inpatient units from Bethesda North, Good Samaritan, and Bethesda Butler, were assessed after 4 weeks of Phase I for 65% or greater completion of the LEARN didactic. The units that achieved 65% or greater were included in the medical record review. Sixty-five medical records were equally divided between the 5 participating units, thus 13 medical records were reviewed on each participating unit. The measured variables on the Sacral Silicone Foam Dressing Algorithm Fidelity Scale (Appendix D) included 1) completion of an admission skin assessment, 2) the nursing selected Mepilex® application criteria, 3) pressure ulcer prevention interventions, 4) maintenance of Mepilex® dressing, 5) dressing interventions during shift, 6) documentation of skin site assessment, and 7) initiation of plan of care. Each of the measured items were coded as 0=Incomplete, 1= Complete, and 2= Not Applicable. A percentage, from the seven items documented, was calculated to produce a total percent score for adherence. The total score was converted into a 1 to 5 Likert scale with a rating of 5 indication excellent adherence and a rating of 1 representing complete or almost complete lack of adherence. A Likert score of 5 indicated adherence for 90% or more of the expected documentation in the medical record, 4 indicated 70% to 89% of expected documentation, 3 indicated 50%-69% of expected documentation, 2 indicated 11% to 49% of expected documentation, and 1 indicated 10% or less of expected documentation.

On the Sacral Silicone Foam Dressing Algorithm Fidelity Scale (Appendix D), adherence item number two, the “nursing selected Mepilex® application criteria”, addresses the nurses’ documentation of patient-specific and hospital-specific variables admissible for Mepilex® application. Twenty-one variables were measured as 1) surgical procedure or cumulative surgeries lasting greater than 4 hours per current admission, 2) cardiopulmonary arrest or rapid response this admission, 3) vasopressor administration, 4) body mass index greater than 40 or less than 18, 5) mechanical ventilation, 6) quadriplegia or spinal cord injury, 7) drive lines including ventricular assist devices (VAD), intra-aortic balloon pump (IABP), or extracorporeal membrane oxygenation (ECMO), 8) Rotoprone, 9) Continuous Renal Replacement Therapy (CRRT), 10) continuous or bi-level positive airway pressure (CPAP/BiPAP), 11) Braden score 13 or less, 12) past history of pressure ulcers, 13) sedation or paralytic administration greater than 12 hours, 14) restraints, 15) weeping edema/Anasarca, 16) traction, 17) patient age greater than 65 years old, 18) diabetes mellitus, 19) bed rest, 20) malnutrition defined as prealbumin <20mg/dl, Albumin <2.5mg/dl, nothing by mouth (NPO) greater than 3 days), and 21) fecal/urinary incontinence controlled by indwelling catheter/fecal management device.

In Phase II, descriptive statistics included frequency of the categorical variables measured in the adherence of nursing documentation, and means with standard deviation for all continuous variables. A one-way between group analysis of variance (ANOVA) was conducted to explore the impact of hospital and unit location on the percent of medical record documentation completed. Statistical analyses were performed with an alpha level  $p < 0.05$ , and were considered statistically significant. All analyses were performed using SPSS IBM statistics version 22.0 (IBM Corp., Armonk, NY, USA).

## Results

### Sample Description

Table 1 provides a description of our sample that completed the pre/post-test questionnaire. A total of 1,100 nurses from Bethesda North, Good Samaritan, and Bethesda Butler voluntarily completed the demographic assessment. The majority of our sample was female (92.2%), falling into the age range of 46-55 years (27.2%), and Caucasian (92%). When evaluating work tenure, nursing specialty, and highest level of education, majority of our participants selected 0-5 years work tenure (26.3%), with most of our nurses working within surgical or peri-operative services (26.7%) followed by medical-surgical nursing (23.8%). As expected our participants mostly obtained a Bachelors of Science (BSN) nursing education at 49.4% followed by Associate Degree Nurses (ADN) at 45.1%.

### Impact of Pre and Post-Test Assessment on Nursing Knowledge

A total of 1,182 nurses completed the voluntary pre-test questionnaire and 1,514 participated in the post-test questionnaire. A paired-sample t-Test was conducted to evaluate the impact of the LEARN pressure ulcer education didactic on participants' mean scores on our 15-question pre and post-test analysis. Table 2 shows the impact of the LEARN education of the pressure ulcer prevention pre and post-test scores. There was a statistically significant improvement in the mean scores from the pre-test (Mean= 56.0, SD= 30.3) to the post-test (Mean= 85.4, S.D.= 9.6),  $t(14)= 4.86$ ,  $p < .000$ . The mean increase in scores was 29.5 between the two tests. Each of the 15-questions was evaluated for comparison of the pre-test score to the post-test score correct response. Using only the frequency of correct responses for each question, Figure 1 depicts the difference from the pre-test to the post-test. With only one data point, we are unable to determine statistical significance, however, an improvement in post-test

score was appreciable for all 15 questions. Six of the 15 questions demonstrated a 30% or greater change between the pre-test score and the post-test score (Table 3).

### **Documentation Adherence Monitoring**

Sixty-five medical records (n=65) were reviewed between Bethesda North Hospital (BN), Good Samaritan Hospital (GSH), and Bethesda Butler Hospital (BB). Five inpatient units met criteria for review including the Cardiovascular ICU (BN), Medical-Surgical ICU (BN), Neurology ICU (GSH), Surgery/Peri-Surgical Services (GSH), and In-Patient unit (BB). Table 4 provides the description of medical records reviewed per hospital and unit location. Twenty-six medical records were reviewed from Bethesda North (40%) and Good Samaritan (40%) Hospitals, and 13 medical records were reviewed from Bethesda Butler Hospital (20%). From the 65 medical records, the percent of completed documentation ranged from 0 to 100%, with an average percent completed of 62.2% (S.D.= 29.9). A one-way between group analysis of variance was conducted to explore the impact of hospital and unit location on the percent of medical record documentation completed. There was a statistically significant variance in mean percent of documentation completed for the three hospitals,  $F(2, 62) = 5.6, p = .006$  (Table 5). Despite the significant difference the actual difference in mean percent completion scores was relatively small. Post-hoc comparisons using Tukey HSD test indicated the difference between mean scores by location for Bethesda North (M=75.81, S.D. 18.4), being significantly different than the mean score from Good Samaritan Hospital (M=50.0, S.D. 32.1,  $p = .004$ ), but were not significantly different than Bethesda Butler Hospital (M=59.3, S.D.=34.3,  $p = .201$ ) (Table 5). Similarly, when looking at each individual units included in this study, the one-way analysis of variance determine the mean percent completion scores per unit was different,  $F(4, 60) = 2.8, p =$

.017. However, when addressing the mean percent difference between units none were statistically different from each other.

We developed a 5-point Likert scale to categorize the percent documentation that was complete per medical record (Figure 2). Our results showed 72% of the medical records achieved 50% or greater completion of the required documentation, with most medical records (n=28) achieving a Likert rating of 4 indicating 70%-89% completion. Looking more specifically at the Mepilex® protocol interventions, our study found that 30.8% (n=20) of the medical record documentation indicated the patient did not meet application criteria for the Mepilex® dressing (Table 6). Just over half the charts at 50.8% (n=33) met criteria and a prophylactic Mepilex® was indicated, whereas, 16.9% of patients met criteria for the Mepilex® dressing, however the nurse missed the criteria and no Mepilex® was used. Only 1.5% (n=1) of our patients did not meet the Mepilex® application criteria, but erroneously a Mepilex® was applied anyway (Table 6). To explore the relationship between the Mepilex® application criteria and the hospital location and unit a Chi-square test for independence was attempted, however, violation of the minimum cell frequency assumption prohibited accurate results and was not concluded.

The measured variables on the Sacral Silicone Foam Dressing Algorithm Fidelity Scale included items 1) completion of an admission skin assessment, 2) the nursing selected Mepilex® application criteria, 3) pressure ulcer prevention interventions, 4) maintenance of Mepilex® dressing, 5) dressing interventions during shift, 6) documentation of skin site assessment, and 7) initiation of plan of care. Each of these variables were measured as 0= Incomplete, 1= Complete, or 2= Not Applicable, and are described in Table 7. Figure 5 depicts the adherence of nursing documentation with the frequency for completion of each variable measure. Item 1 had

53.8% incompleteness of its measure. Item 1: Completion of an admission skin assessment contained two subscales on the Sacral Silicone Foam Dressing Algorithm Fidelity Scale including A) a skin assessment was completed on admission and B) if the timely assessment was completed within “4 eyes in 4 hours.” When looking at the subscale items, only 1 medical record did not complete a skin assessment on admission (subscale A), while 58.5% of the time documentation of “4 eyes in 4 hours” was incomplete (subscale B), accounting for the high level of item 1 incompleteness. Item 2: Nursing selected Mepilex® application criteria was complete 72.3% of the time and was our highest completed category. Item 3: pressure ulcer prevention intervention documentation was completed in 47.7% of the medical records. Item 4 included the maintenance of the Mepilex® dressing and measured if the dressing was dated and changed every 72 hours or when soiled, and item 5 indicated dressing interventions including peeling back the dressing to evaluate sacral skin per shift, changing the dressing, or removal. Item 4 and 5 documentation was incomplete in 43.1% of the medical records reviewed, compared to 27.7% completion. Item 6 monitored the sacral skin assessment as “within the defined limits” or if a HAPU formed. Per nursing documentation there were zero HAPUs identified in the 65 medical records reviewed, and only 1 individual identified with a pressure ulcer present on admission to the hospital. With that, Item 6 had 52.3% completion of documentation indicating sacral skin was assessed and was “within the defined limits.” Lastly, item 7 measured if the nurse initiated the patient’s Plan of Care to include “potential for compromised skin integrity.” Nursing documentation reported item 7 being completed 47.7% of the time.

### **Indicators for Mepilex® Application**

Twenty-one variables were included in the HAPU protocol to initiate application of Mepilex® dressings. Fourteen of these variables were considered “high-risk” with requiring

only 1 criteria present to use the dressing, and 7 were considered “moderate-risk” requiring 5 or more cumulatively for Mepilex® dressing application. In our medical record review, Figure 3 depicts the frequency at which nurses identified and documented these criteria. Of the variables to select from, bed rest, weeping edema/anasarca, CRRT, Rotoprone, Drive Lines, and quadriplegia/Spinal cord injury were variables not selected by the nurse. The variables selected most frequently include patient age being greater than 65 years (26.2%), surgical procedure or cumulative surgeries lasting greater than 4 hours per current admission (26.2%), Braden Scale Score 13 or less (16.9%), and mechanical ventilation (20%).

### **Discussion**

The purpose of our study was two-fold. Our first goal was to determine if there was a change in nursing knowledge before and after an educational didactic about HAPU and the new policy changes being implemented. Second we wanted to determine if there was a change in nursing clinical behavior as seen through the adherence of documentation of policy interventions. Previous studies have suggested implementing pressure ulcer prevention policies increase nursing knowledge and effectively changed practice behaviors (Pieper & Mattern, 1997; Sinclair et al., 2004; Armstrong et al., 2008; Chicano & Drohllshagen, 2009). Furthermore, when pressure ulcer policies are employed and nursing education is provided, pressure ulcer incidence and prevalence was reduced (Armstrong et al., 2008; Holmes & Edelstein, 2007; Gibbons, Shanks, Kleinhelter & Jones, 2006; Ayello & Lyder, 2006; Catania, 2007; Chicano & Drohllshagen, 2009). Our results indicate that a change in nursing knowledge occurred. A paired sample t-test demonstrated statistically significant differences ( $p < .000$ ) between correct responses on our pre-test and post-test questionnaire, suggesting our LEARN pressure ulcer didactic changed the nurses’ knowledge after the intervention. The mean score from our pre-test



responses was 56.0% compared to our post-test scores of 85.4% falls within the findings supported in the literature. Studies examining pre/post-test evaluation on change in nursing knowledge pertaining to HAPU prevention have demonstrated variable findings. One study indicated a statistically significant improvement ( $p < .001$ ) in nursing knowledge between a pre-test, post-test 1, and post-test 2 scores (Sinclair et al., 2004). At a 3-month follow up post-test 2 indicated a sustained improvement in nursing knowledge compared to the pre-test, but at slightly lower rate than the initial post-test 1 results (Sinclair et al., 2004). Tweed and Tweed (2008) examined knowledge scores before and after an education program in a New Zealand medical-surgical ICU, and showed no significant difference between pre and post-test scores after an educational intervention. Although we have a statistically significant difference between mean scores before and after our intervention, we cannot say that our intervention alone caused the increase between our scores. There are potential confounding influences such as years of experience in nursing, specialty of nursing, previous knowledge, skill, and experience with HAPU prevention that could have contributed to this difference. Zullkowski et al., (2007) reported knowledge scores with significant differences between nurses certified in wound care to those who were not ( $p < .000$ ). Similarly to certification, Mockridge and Anthony (1999) demonstrated that nurses ( $N=145$ ) in the United Kingdom scored better on pressure ulcer knowledge assessment tests if they had higher levels of education. Tweed and Tweed (2008) reported differently, and found no association between their test scores and demographic data including the number of years as a nurse, tenure of experience in the ICU, education on pressure ulcers, or qualifications such as specialty certifications.

Studies have revealed that staff nurses often perform poorly on tests measuring knowledge of pressure ulcer identification, staging, and prevention (Berquist-Beringer, et al.,

2009). A recent survey of 692 nurses found that 70% considered their basic education on pressure ulcers to be insufficient. This study found knowledge and confidence with identifying and staging pressure ulcers increased with age and experience, with only 62% of hospital nurses feeling confident in their abilities to identify and stage pressure ulcers and with new nurses having less than 50% confidence (Ayello, Baranoski, & Salati, 2005; Zullkowsky, 2007). Berquist-Beringer et al., (2009) assert that pressure ulcer education does improve knowledge, but suggests that regular educational updates are warranted for the sustainability and long-term understanding of HAPU knowledge and practice standards. Additional studies supports this notion, that improved identification of pressure ulcers and ongoing nursing education to increase knowledge and awareness of clinical standards are associated with reduce HAPU incidence rates (Young, Evans & Davis, 2003). Initial nursing education, ongoing updates, and nursing support are clearly warranted for the success of implementing new standards of care. Our pre/post-test analysis suggests that our education didactic was successful at changing nursing knowledge, however, the long-term implications and sustainability need to be evaluated and measured to determine the overall effect of implementing our HAPU prevention policy.

The second aim of this study was to determine if a change in nursing clinical behavior was seen through the adherence of documentation of policy interventions. Our study indicates a mean rate of completed documentation in our medical record review of 62.2% (S.D.= 29.9). Seventy-two percent of our medical records achieved 50% or greater completion of the required documentation. Our documentation adherence results are slightly lower to the findings found in the literature. Barker et al. (2013) found in medical record audits after implementing a pressure ulcer prevention program, showed a high compliance to documentation at a rate greater than 84%. Other studies addressing nursing documentation adherence to pain management protocols

showed similar findings of 85% adherence, but also found mixed variability in the consistency in the type of pain management documentation (Jablonski & Ersek, 2009). One study implementing pressure ulcer policies and upgrading EMR documentation requirements measured documentation adherence, and found 99% compliance due to the EMR enabling nurses to identify HAPU risk and directing nursing assessment towards specific interventions for HAPU prevention (Chicano & Drolshagen, 2009). In our study we analyzed the mean percent documentation score per hospital location and unit to identify if one location or unit had lower documentation rates than others. The mean percent completion score was statistically significant per hospital location, but the actual difference in completion scores was only significant between Bethesda North and Good Samaritan Hospitals. Similarly, the mean percent completion score in the 5 units included in the medical review were statistically significant, but the difference between them was not. This may suggest that Good Samaritan Hospital had lower mean completion rates than Bethesda North and Bethesda Butler hospital, and contributed to the overall lower completion scores compared to other studies.

Several explanations can be provided to why our results were lower than other studies. The first explanation is the LEARN education was not completed by the nurses whose documentation was being audited. This has the potential of introducing misclassification bias into the data we collected, as the nurse might have been unaware of how to correctly document or the clinical behaviors needed for the HAPU policy. Second, there is the potential that the LEARN education was not successful at changing knowledge or behaviors. As mentioned in Rogers' Theory of Diffusion of Innovation, participant characteristics and willingness to change lie on a continuum of early adopters to laggards (Rogers, 2008). We do not know the nurses' beliefs or perceptions pertaining to the changes we introduced, or their willingness to complete

the required interventions and documentation. The culture of change may have influenced our results. Last, nursing documentation may not reflect actual practice. It is possible the nurse completed the HAPU protocol assessment, interventions, and maintenance, but the documentation was not accurate to the care provided. Reversely, documentation could have indicated the HAPU interventions were followed, but indeed were not delivered to the patient. The level of adherence to evidence-based guidelines for pressure ulcer prevention may be misleading when just evaluating documentation alone.

From the medical records reviewed (n=65), 50.8% met criteria for the Mepilex® dressing, 30% did not meet criteria thus no Mepilex® was used, 16.9% of patients met criteria but the dressing application was missed, and 1.5% did not meet criteria but a Mepilex® was used anyway. In attempts to determine if correct identification of Mepilex® application criteria was associated with hospital location or unit, we attempted a chi-square test for independence, but violated minimum expected cell frequency assumptions, thus results were inconclusive. In the studies evaluating Mepilex® efficacy, participant selection came from an ICU population suggesting higher-acuity of illness, co-morbidity, and the likelihood of more intense hospital-based interventions such as mechanical ventilation, longer surgical procedures, vasopressor administration, etc. (Brindle 2010, Cox, 2011; Brindle & Wegelin 2012; Chaiken, 2012; Walsh et al., 2012; Cubit et al., 2013; Santamaria et al., 2013). In the present study, the cardiovascular ICU, medical-surgical ICU, and neurology ICU had the highest percentage of medical records indicating the patient met criteria for Mepilex® application. Whereas, the inpatient unit at Bethesda Butler and surgical-services at Good Samaritan Hospital, both had high rates for not meeting Mepilex® application criteria. This may suggest that the application criteria are more specific to the critically ill patient population. Additionally, when evaluating the nurse selected

criteria for Mepilex® application, the top selected variables were age being greater than 65 years (26.2%), surgical procedure or cumulative surgeries lasting greater than 4 hours per current admission (26.2%), Braden Scale Score 13 or less (16.9%), and mechanical ventilation (20%). Studies evaluating critically ill patients for predictors of pressure ulcers have similarly found that age, vasopressor administration, mechanical ventilation, and length of surgical procedure were major contributors to pressure ulcers (Cox, 2011; Aronovitch, 1999; Senturan et al., 2009).

### **Limitations**

This study had several important limitations. First, timing of the LEARN education and the EMR documentation changes occurred simultaneously, which potentially introduced bias to the nursing responses on the pre/post-test analysis. The potential of having seen the EMR documentation changes prior to receiving the LEARN education could have skewed the responses from participants, and lead to more favorable responses on the pre/post-test questions pertaining to the new Mepilex® protocol and policy changes. Although there were no specific questions related to EMR documentation requirements, the changes to the EMR directed the Mepilex® protocol and maintenance, as well as the changes made to TriHealth's Pressure Ulcers: Guidelines for Prevention and Treatment policy. This might have provided knowledge prior to taking the pre-test or post-test.

Second, the LEARN didactic was provided to a convenience sample of nurses. Because this was a change to hospital policy all nurses were mandated to complete the LEARN didactic, and only the pre/post-test analysis were considered voluntary. Participants self-selected to complete the pre/post-test analysis and these scores were not compared to a control group. This introduces potential confounding variables such as pre-existing knowledge, level of experience, interest in HAPU prevention, etc., to why nurses participated or didn't. The LEARN database

provides only total percentages of the responses provided, therefore, in this study it was not possible to determine associations between participant demographics to the scores achieved, that is, was tenure, years of nursing experience, unit location, etc., an influencing factor of the scores achieved? To strengthen this limitation of this study, we recommend using a time-series approach with a non-equivalent control group that would complete the pre/post-test only without the didactic intervention to introduce research control. Additionally, having a study design with the capability of associating demographic information to mean scores would help us better understand the influence of confounding variables as mentioned above.

Third, the medical record review was completed retrospectively to determine if the nurse completed the appropriate documentation. This threatened the validity of the data, as the Primary Investigator could only collect data for the variables of interest that were previously documented. Documentation in medical records may not reflect actual practice, so level of adherence to evidence-based guidelines for pressure ulcer prevention may be misleading. Furthermore, data points were subject to the accuracy and completeness of the documenting nurse, and as previously mentioned misclassification bias could have contributed to incorrect documentation. Only the primary investigator completed the medical record review, which precluded the potential for inter-rater reliability difference and additional misclassification bias to the findings. Another limitation to the medical record review is the small sample size (n=65) of records reviewed, which limits the generalizability to other populations.

Finally, this study described a sample of nurses who completed a educational didactic and then observed if the change in nursing knowledge translated into changes in nursing behavior through documentation. The impact of these changes on patient outcomes, particularly HAPU incidence and prevalence was not measured. The impact of screening patients with our high-risk

assessment tool were not measured in this study, nor can these findings provide causal effectiveness of our assessment tool in identifying patients at-risk for HAPU reduction. Our findings may not be generalizable to other facilities or populations outside of acute care inpatient settings.

### **Implications to Clinical Practice**

It is abundantly evident and supported that pressure ulcer prevention strategies are imperative for HAPU reduction, improved quality outcomes, and financial survival in healthcare organizations. Findings from the reviewed studies suggest that pressure ulcer education does improve knowledge, but regular educational updates are needed for the sustainability and long-term understanding of HAPU knowledge and practice standards. Additionally, studies suggest early identification of HAPU risk and ongoing nursing education to increase knowledge of clinical standards were associated with reduce HAPU prevalence. This HAPU prevention program may provide nurses with the education necessary to proactively identify acutely ill patients at-risk for HAPU and intervene with prevention strategies. The long-term success of this program will need to provide future support and education to the bedside nurse. This will drive and sustain the changes in practice.

Medical record audits to measure documentation adherence are not new to healthcare. Audits help us determine areas for improvement in the care we provide to ultimately produce better patient outcomes. The American Nurses Association (ANA) stated that nursing documentation needs to be accurate, consistent, timely, and sequential (ANA, 2005). Data from this study suggests a need for nursing support to perform the new clinical behaviors and on the documentation of these practices. Our analysis determined a difference in mean completion rates between the three hospital locations. With this difference, it is recommended efforts be directed

towards all facilities, but in particular to Good Samaritan Hospital and Bethesda Butler, as they produced lower adherence rates compared to Bethesda North. Our HAPU prevention documentation alluded to several areas of incompleteness, particularly to the maintenance and intervention of the Mepilex® dressing once it was applied to a patient. Investigating why these areas of documentation have low completion rates should be evaluated and possibly adapted to meet the needs and ease of use for the nurse.

### **Implications to Future Research**

Future research should include studies evaluating the effectiveness of implementing HAPU prevention programs including nursing adherence to the policy, nursing satisfaction, and the sustainability of implemented changes. Having replication studies that evaluate protocol implementation, such as our protocol implemented at TriHealth, could demonstrate the generalizability of this protocol to other healthcare organizations and populations. It would be imperative to demonstrate the sensitivity and specificity of our high-risk assessment tool to prove reliability and validity for identifying at-risk patient populations. We recommend a future study that determines these variables to provide statistical support for the use of this tool.

Another important area to address with future research is the organizational impact on HAPU reduction. Understanding the implications of Mepilex® dressings and our prevention protocol on HAPU prevalence and incidence trends, before and after implementing such a prevention program, will help demonstrate the success or failure of the goals of this program. Additionally, studies could evaluate the cost-benefit implications of reduced HAPU as a result of the prevention program using Mepilex® dressings. While our study focused on the nursing participant, the impact on patient outcomes to prevent HAPU formation should further be studied



to investigate the perceived improvement in the quality care that is delivered and patient satisfaction as a result of our prevention strategies.

### **Conclusion**

The goals of our study were to change nursing knowledge and nursing behaviors. Results of this study indicate our LEARN educational didactic of HAPU prevention was successful at changing nursing knowledge. Variable results from our medical record review suggest areas of needed improvement in changing nursing behaviors. Our medical record review revealed nursing failure to consistently follow our HAPU prevention guidelines and intervene with preventive interventions with the Mepilex® dressing. While nursing documentation may not reflect actual practice behaviors, we feel our medical record review did demonstrate we are in the beginning stages of change, and that our efforts for this program should not stop here. We need to continue to provide support to the bedside nurse to sustain these policy changes and find ways to improve the adherence to documentation and increase use of the HAPU prevention protocol. This is essential for the long-term success of this program, and hopes for improved patient outcomes. Future research including testing of our assessment tool for validity, reliability, and generalizability would help provide added support for the use of our assessment tool and this program. A follow-up longitudinal study could compare nursing knowledge and adherence at a later time to evaluate the sustainability and long-term outcomes of this program, and furthermore analysis of HAPU prevalence rates before and after implementing this program to determine the impact of HAPU reduction.

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Table 1: *Phase I Sample Characteristics*

		Participants (n = 1,100)	
		n	%
<b>Gender</b>			
	Male	86	7.8
	Female	1,014	92.2
<b>Age</b>			
	18-25 years	82	7.5
	26-35 years	290	26.4
	36-45 years	217	19.7
	46-55 years	299	27.2
	56-65 years	186	16.9
	66-75 years	17	1.6
	>76 years	9	.8
<b>Ethno/Cultural</b>			
	Caucasian/White	1,012	92.0
	African American/Black	42	3.8
	Hispanic/Latin American	7	.6
	Asian	10	.9
	Other	29	2.6
<b>Work Tenure</b>			
	0-5 years	294	26.7
	6-10 years	211	19.2
	11-15 years	116	10.6
	16-20 years	90	8.2
	21-25 years	100	9.1
	26-30 years	88	8.0
	31-35 years	92	8.4
	36-40 years	78	7.1
	>41 years	31	2.8
<b>Nursing Specialty</b>			
	Medical Surgical	262	23.8
	Critical Care	209	19.0
	Emergency Department	102	9.3
	Oncology	32	2.9
	Surgical Services/Perioperative Services	294	26.7
	Long-Term/Inpatient Rehabilitation	14	1.3
	Telemetry	155	14.1
	Transitional Care	5	.5
	Psychiatric Care	27	2.5
<b>Highest Level of Education</b>			
	Associate Degree Nursing (ADN)	496	45.1
	Bachelors of Science (BSN)	543	49.4
	Master Degree of Nursing (MSN)	55	5.0
	Doctoral Degree (PhD/DNP)	6	0.6

Table 2  
*Impact of LEARN Education on Pressure Ulcer  
 Prevention Pre and Post-Test*

Variable	Pre-Test (n=15)		Post-Test (n=15)		Paired Sample Correlation		Paired t-Test
	Mean	S.D.	Mean	S.D.	R	<i>p</i>	
Participant Score	56.0	30.3	85.4	9.6	.794	.000	<.000

Table 3:  
*Difference in Mean Scores on Correct Response from Pre & Post-Tests*

	Pre-Test (%)	Post-Test (%)	Difference (%)
Question 1	66.7	90.9	24.2
Question 2	49.5	85.2	<b>35.7</b>
Question 3	77.6	90.9	13.3
Question 4	65.7	88.3	22.6
Question 5	11.9	72.2	<b>60.3</b>
Question 6	9.8	79.0	<b>69.2</b>
Question 7	86.3	91.7	5.4
Question 8	81.5	92.4	10.9
Question 9	25.2	76.4	<b>51.2</b>
Question 10	56.4	80.9	24.5
Question 11	30.8	62.9	<b>32.1</b>
Question 12	15.1	88.1	<b>73.0</b>
Question 13	96.5	97.5	1.0
Question 14	91.5	97.0	5.5
Question 15	75.0	88.3	13.3

Table 4:

*Phase II Medical Record Review Description*

Hospital	n	%
Bethesda North	26	40
CVICU	13	20
MSICU	13	20
Good Samaritan	26	40
Neuro ICU (12c)	13	20
Surgery/Peri-Surgical Services	13	20
Bethesda Butler	13	20
ICU/In-Patient Unit	13	20
TOTAL	65	100

CVICU= Cardiovascular Intensive Care Unit

MSICU= Medical Surgical Intensive Care Unit

Table 5:

*One-Way Analysis of Variance between Percent Completion and Hospital and Unit Location*

Hospital	n	%	Mean	S.D.	Mean Difference	Sig
Bethesda North	26	40	75.8	18.4	25.8	.004
CVICU	13	20	76.9	21.5		
MSICU	13	20	74.7	15.6		
Good Samaritan	26	40	50.0	32.1	9.3	.590
Neuro ICU (12c)	13	20	52.7	29.4		
Surgery/Peri-Surgical Services	13	20	47.2	35.7		
Bethesda Butler	13	20	59.3	34.4	16.5	.201
In-Patient Unit	13	20	59.3	34.4		
TOTAL	65	100	62.2	29.9		

CVICU= Cardiovascular Intensive Care Unit

MSICU= Medical Surgical Intensive Care Unit

Table 6:

*Mepilex® Criteria Frequencies per Hospital Unit Location*

Criteria*	Unit					TOTAL n (%)
	CVICU (BN)	MSICU (BN)	Neuro-ICU (GSH)	ICU/Inpatient (BB)	Surgery (GSH)	
	n (%)	n (%)	n (%)	n (%)	n (%)	
A	2 (3.1)	1 (1.5)	3 (4.6)	9 (13.8)	5 (7.7)	20 (30.8)
B	11 (16.9)	11 (16.9)	7 (10.8)	1 (1.5)	3 (3.6)	33 (50.8)
C	0 (0)	0 (0)	3 (4.6)	3 (4.6)	5 (7.7)	11 (16.9)
D	0 (0)	1 (1.5)	0 (0)	0 (0)	0 (0)	1 (1.5)

\*Criteria:

A= No Mepilex® criteria met, Mepilex® not applied

B= Mepilex® criteria met, Mepilex® applied

C= Mepilex® criteria met, RN missed application, Mepilex® not used

D= No Mepilex® criteria met, Mepilex® erroneously used

Table: 7

*Sacral Silicone Fidelity Monitoring Scale Description*

	Incomplete		Complete		Not Applicable	
	(n)	(%)	(n)	(%)	(n)	(%)
P1	35	53.8	30	46.2	0	0
P2	13	20	47	72.3	5	7.7
P3	14	21.5	31	47.7	20	30.8
P4	28	43.1	18	27.7	19	29.2
P5	28	43.1	18	27.7	19	29.2
P6	29	44.6	34	52.3	2	3.1
P7	25	38.5	31	47.7	9	13.8

Figure 1:  
*Difference in Correct Response on Pre and Post-Test Evaluation*

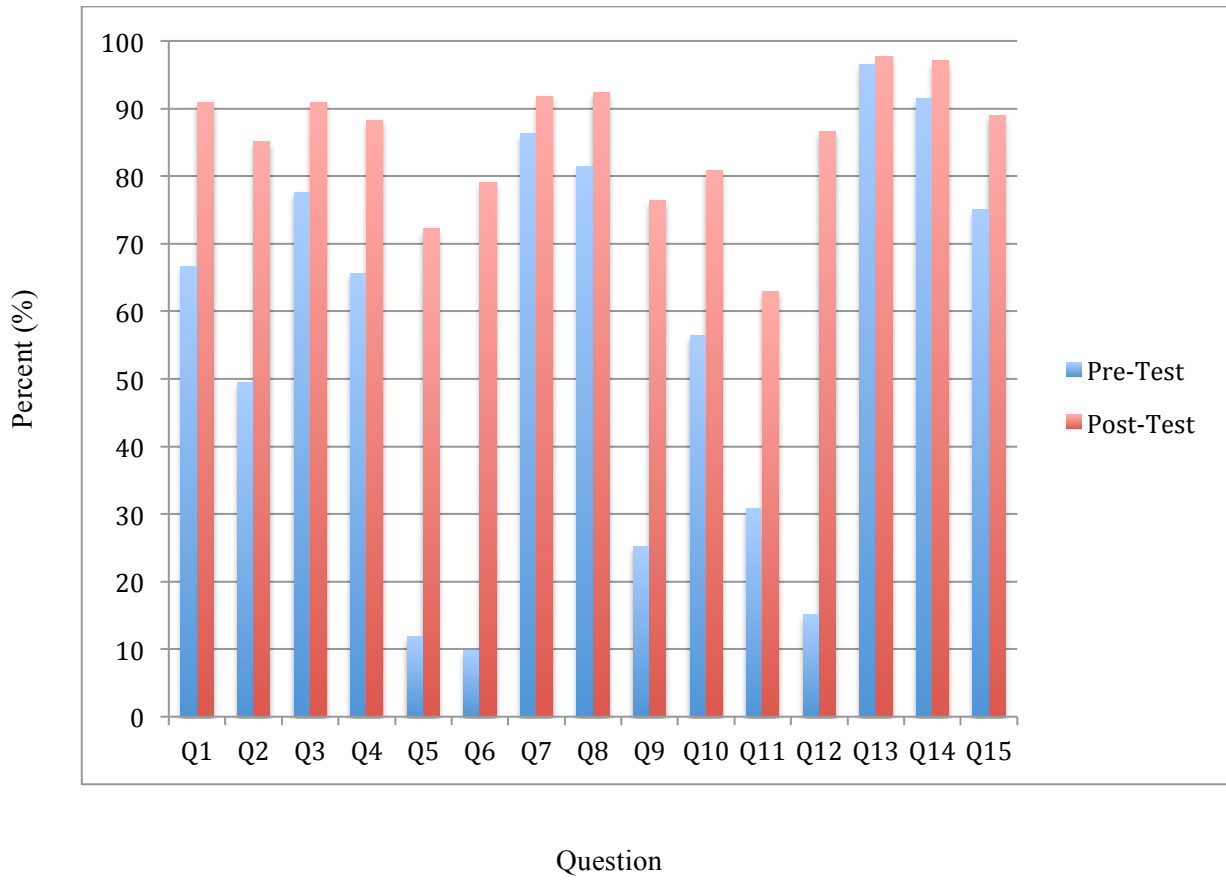


Figure 2:

*Description of Likert Scale Categorization*

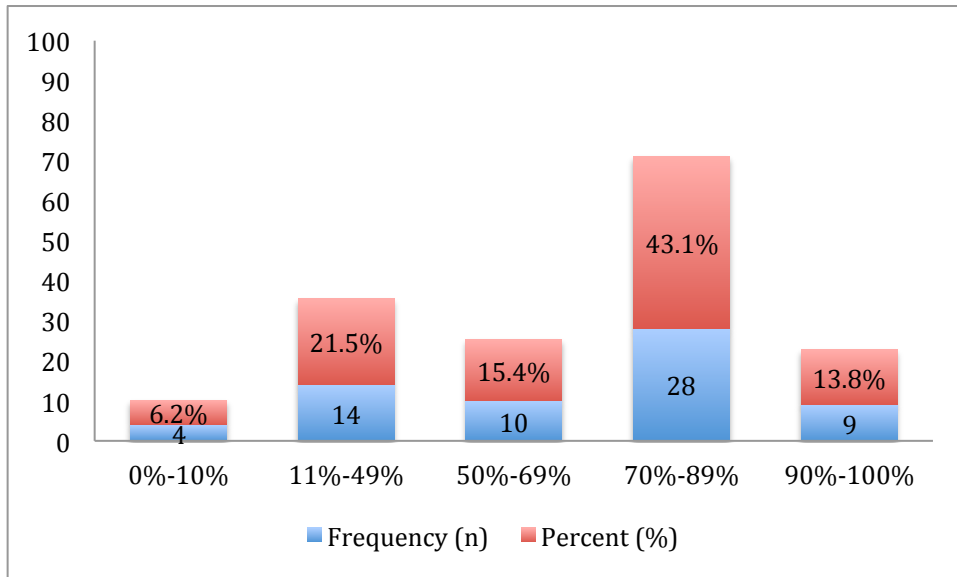
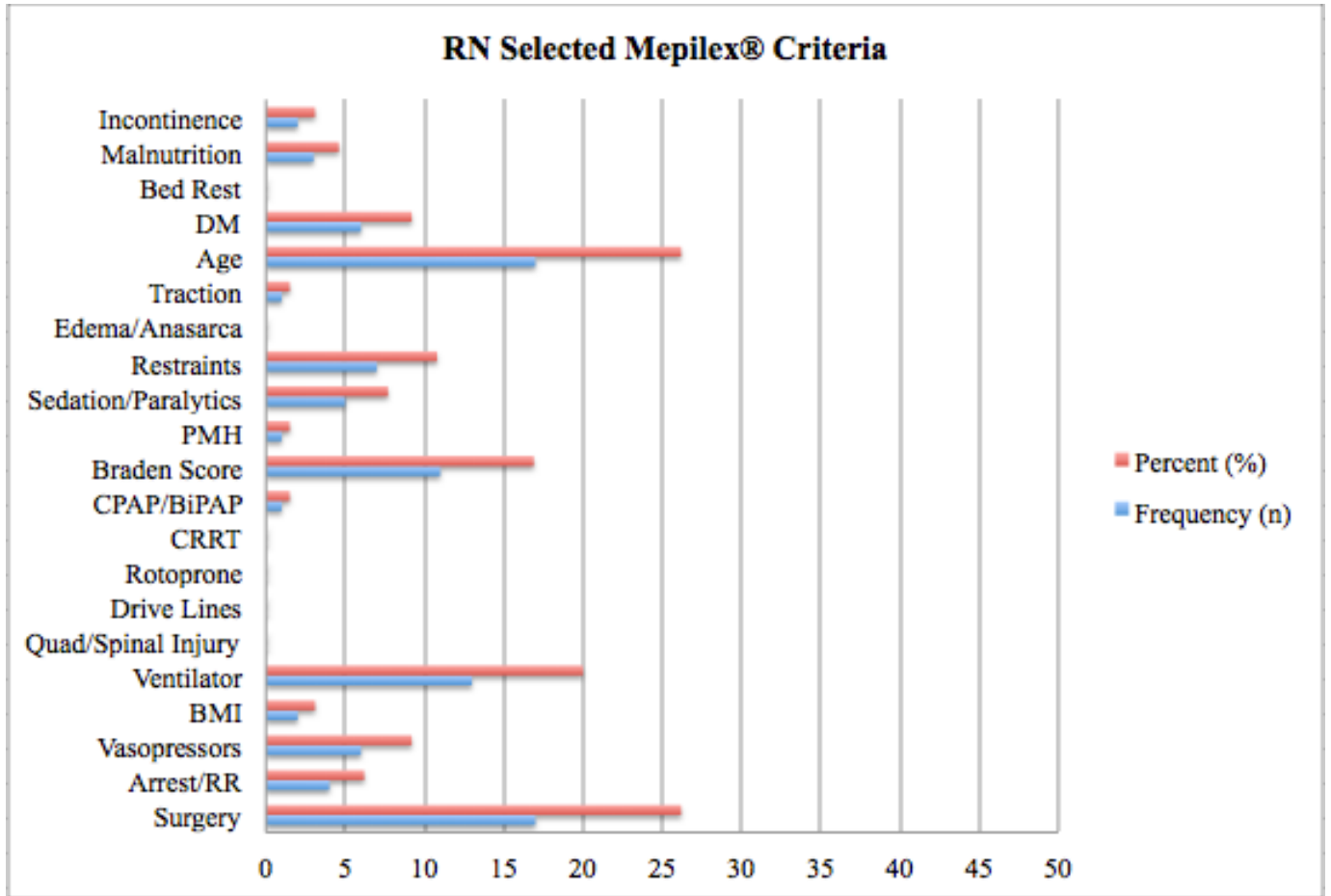


Figure 3

*Nurse Selected Mepilex Criteria*



DM= Diabetes Mellitus

PMH= Past Medical History

CPAP/BiPAP= Continuous Positive Airway Pressure/BiLevel Positive Airway Pressure

CRRT= Continuous Renal Replacement Therapy

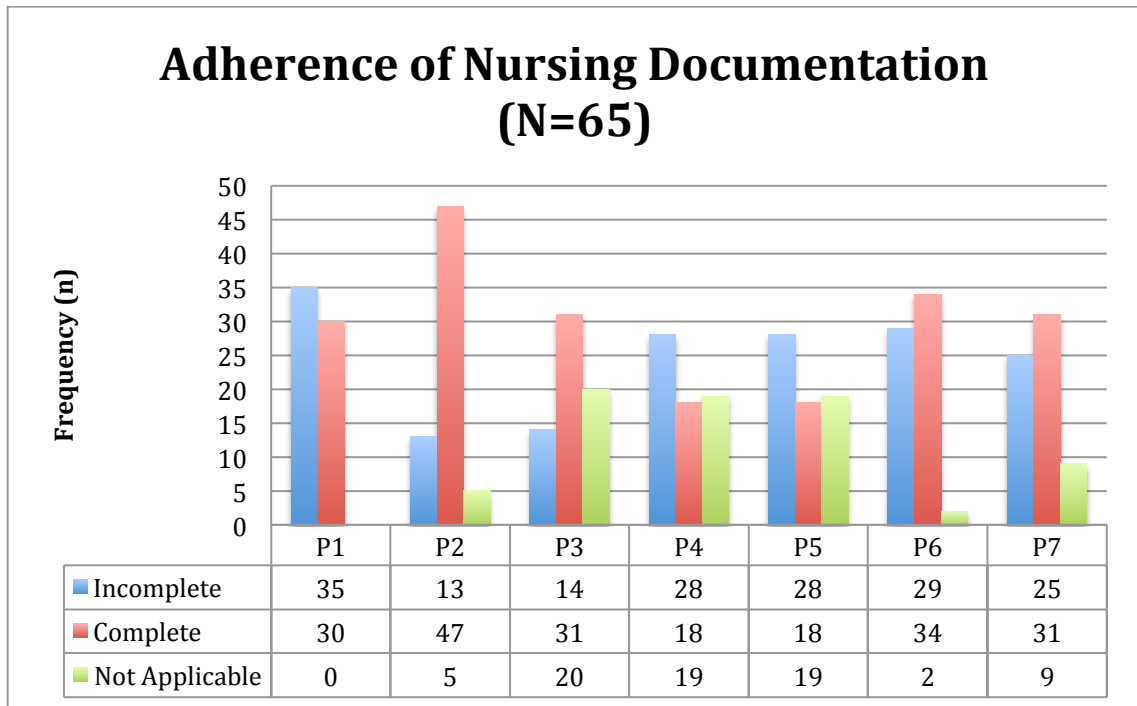
Quad/Spinal Cord= Quadriplegia/Spinal Cord Injury

BMI- Body Mass Index

Arrest/RR= Cardiopulmonary Arrest/Rapid Response

Surgery= Surgical procedure or cumulative surgeries lasting greater than 4 hours during current admission

Figure 4:  
*Adherence of Nursing Documentation*





Practice Inquiry Conclusion

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HAPUs are a preventable problem in healthcare. Since the 2008 Centers for Medicaid and Medicare Services reimbursement changes for Stage III and IV HAPU, healthcare organizations have increased awareness for HAPU prevention through provider and patient education, updating preventive skin care products and devices, and implementing prevention protocols. The improved awareness and innovative practices has brought HAPU to the forefront, and has yielded successful reduction of HAPUs in many organizations. Evidence-based recommendations suggest that healthcare organizations utilize HAPU screening tool to assess all patients for pressure ulcer risk, and to implement protocols to direct providers to prevent risk with nursing interventions. These protocols and interventions equate to improved patient-family centered care, patient outcomes, and HAPU reduction. In manuscript one, a review of the literature evaluating Mepilex® dressings as an additional preventive HAPU therapy was discussed. Although, results are varied, the Mepilex® dressing was successful at reducing HAPU prevalence or incidence in the populations to whom the dressing was applied prophylactically. It is recommended that Mepilex® dressings not replace traditional preventive standards of care, but as an adjunctive therapy for those a high-risk, or when traditional standards of care are insufficient at HAPU prevention. Evidence-based recommendations from these articles support the research designed in Manuscript two. Manuscript two examined high-risk patient-specific and hospital-specific variables that increase risk for HAPU formation in the Intensive Care Unit (ICU) population. These identified patients received the additional treatment of prophylactic Mepilex® dressings. Findings suggest that individuals with mechanical ventilations, restraint use, continuous renal replacement therapy, and sedation or paralytic administration were more likely to have HAPUs. Additionally, our findings suggest that individuals with respiratory or cardiac diagnoses on admission were more likely to have HAPUs

than their referents, and when looking at the high-risk variables, individuals with 5 or greater high-risk variables were at increased risk for HAPU. Among the 47 participants with Mepilex® dressing applied preventively, HAPU incidence varied between the sacral skin location and any other skin location; two HAPUs occurred on the sacral skin area, while 20 HAPU developed on other skin locations. From this study, we recommend for organizations to include a high-risk screening tool specific to high-risk variables, and the use of prophylactic Mepilex® dressings may be beneficial to this population. Manuscript three evaluates the implementation of a HAPU prevention program including a high-risk screening tool, preventive Mepilex® intervention, and the adherence to nursing documentation. The purpose was to determine a change in nursing knowledge and behavior as a result of the implemented HAPU prevention protocol. This descriptive study suggests that our LEARN educational didactic on TriHealth's new HAPU prevention standards of care were effective and resulted in a statistically significant change in our nurses knowledge. Our evaluation of medical records to ascertain if nurses were consistently documenting their clinical behaviors, indicating nurses are providing HAPU screening and applying and maintaining Mepilex® dressings, however, they were not consistently adhering to the protocol, specifically in the daily maintenance and evaluation of the Mepilex® dressing. Our findings overall suggest that TriHealth has begun implementing our policy change and HAPU prevention, but a great need exists to provide continued education and support to the bedside nurse on the Mepilex® dressing to help reinforce the new guidelines. Future studies are warranted to evaluate the impact of HAPU reduction before and after this program was implemented, studies to determine the reliability and validity of our high-risk assessment tool, and ongoing evaluation of nursing knowledge and adherence to this program.

## Appendix A

### TriHealth's Pressure Ulcers: Guidelines for Prevention and Treatment



#### NURSING POLICY, PROCEDURE & GUIDELINES MANUAL

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### **TITLE: PRESSURE ULCERS: GUIDELINES FOR PREVENTION AND TREATMENT**

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**Skill Level:** RN

**Policy Statement:** To provide the maintenance or improvement in skin integrity by utilizing evidence-based practice through optimal nutritional support, optimal tissue load management, and nursing care interventions. This will be achieved through the use of a risk assessment tool and treatment protocols developed to ensure these best practices

**Definitions:** CWOCN- Certified Wound Ostomy Continence Nurse  
WCC- Wound Care Certified

#### **Procedure:**

1. Risk Assessment:

- The Braden Risk Assessment Scale for the Prediction of Pressure ulcers is a tool that identifies patients' risk for pressure ulcer development. Based on the risk score specific interventions will be implemented.
- The Braden Scale will be completed with the initial assessment and daily except in the following areas: Special Care Obstetrics, Mother/Baby, Labor & Delivery. AWHONN<sup>1</sup> NeoNatal Skin Condition Score will be completed in the Neonatal Intensive Care Unit and Special Care Nursery.
- Patients will be reassessed daily, with change in condition, when a transfer occurs, or after prolonged immobility due to a procedure or surgery.

---

<sup>1</sup> AWOHNN- Association of Women's Health, Obstetric, and Neonatal Nursing

2. Prevention of Pressure Ulcer Guidelines: Refer to Patient Care Guidelines under “Pressure Ulcer Prevention” on Linknet, Clinical>Nursing>Clinical Practice> Skin, Wound, Ostomy. Braden Guidelines:
- For Braden score of 18 or less, initiate the following PRESSURE ULCER PREVENTION interventions specific to your patient’s needs, and “Potential for Compromised Skin Integrity” plan of care in Electronic Medical Records (EMR).
  - Pressure Ulcer Prevention Interventions for Braden score 18 or less (see Appendix A):  
Nursing Standards of Care
    - Inspect and document skin every shift
    - Do not massage over bony prominences or red areas
    - Show video, “Prevention of Pressure Ulcers” to patient and family (available on GetWell Network).
    - See Pressure Ulcer Prevention Guidelines on LinkNet
  - On admission to the hospital, unit, or transfer implement the sacral silicone foam dressing (Mepilex®) prevention protocol. See Sacral Silicone Foam Dressing (Mepilex®) Guidelines (see Appendix B).
3. Treatment of Pressure Ulcers:
- Two RNs will complete a head to toe skin assessment within four hours of admission and/or transfer to prospective unit (“4 eyes in 4 hours”). The RN will document completion of “4 eyes in 4 hours” and all findings in a nursing communication note or appropriate Wound LDA.
  - The RN will assess the patient’s skin every shift and will document the condition of any/all wound(s) with each dressing change.
  - Wound measurements will be documented by the RN on initial assessment, every 7 days, and with significant changes, i.e., deterioration or sharp debridement, if wound(s) deteriorates, the RN will document a wound assessment, re-measure the wound, and collaborate with the physician and notify/consult (or re-consult) the CWOCN/WCC.
  - If a surgeon is currently treating patient’s wound(s), the wound care consult must come from that surgeon.
  - The RN will collaborate with the physician to utilize the Wound Care Order Set, Wound LDA, and complete the Pressure Ulcer Documentation Form in the EMR for pressure ulcers that are present on admission (POA) and/or hospital acquired pressure ulcers (HAPU).
  - The CWOCN/WCC will be consulted based on the wound care order set, or with a physician order. The CWOCN/WCC will provide a focused assessment on the anatomical location the consult was received on.
  - The CWOCN/WCC will evaluate wounds within 72 hours of receiving the referral.
  - Reassessment by the CWOCN/WCC will be based on individualized patient needs and documented in EMR consult notation.

**Author:** TriHealth Skin Care Committee

See contact: Patti Burke, RN, CWOCN

Maryann Lancaster, RN, BSN

**Competency:** Mosby- Pressure Ulcer Prevention and Treatment

**Approval:**

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Practice Council date

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Site Chief Nursing Officer, Bethesda North Hospital date

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Site Chief Nursing Officer, Good Samaritan Hospital date

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**Evidence Table Attached: See separate form.**

**Implemented:** 8/14

**Reviewed/Revised:** 8/14

Appendix A: Pressure Ulcer Prevention Interventions

Braden Category	Intervention
Sensory Perception	<ul style="list-style-type: none"> <li>• Assess patient for ability to detect and express pain, pressure, or need for repositioning</li> <li>• Assess patient perception of biomechanical equipment (i.e. SCDs, ETT, Foley, monitoring lines, etc). Remove or reposition devices per standard of care, to prevent device related pressure.</li> </ul>
Moisture	<ul style="list-style-type: none"> <li>• Skin care products/barrier creams</li> <li>• Moisturize dry skin daily</li> <li>• Clean urine/feces with incontinence cleanser (not soap)</li> <li>• Use incontinence devices when needed to contain fecal and/or urinary drainage</li> <li>• Protect intact skin from fecal and/or urinary incontinence using a moisture barrier</li> <li>• Protect open skin from frequent fecal and/or urinary incontinence using a moisture barrier with zinc</li> <li>• Use adult diapers if needed when patient is out of bed and/or during transfers</li> <li>• Do NOT place chux for incontinence (see above)</li> </ul>
Activity & Mobility	<ul style="list-style-type: none"> <li>• Use positioning devices as needed. Refer to TriHealth Position/Pressure Redistribution Device Algorithm</li> <li>• Turn every 2 hours and as needed</li> <li>• Float heels with pillows under knees and lower legs. DO NOT put heels on pillow               <ul style="list-style-type: none"> <li>○ Boots→ refer to Heel Lift Boot Algorithm</li> </ul> </li> <li>• Use pillows only between bony prominences DO NOT use sheets, towels, or blankets</li> <li>• Limit sitting to 2 hours at a time</li> <li>• Teach patient to shift weight every 15 minutes</li> <li>• Use pressure redistribution chair cushions when sitting (Geomatt)               <ul style="list-style-type: none"> <li>○ Do NOT use donut-type device</li> </ul> </li> <li>• Keep the head of the bed less than 30 degrees unless medically contraindicated</li> <li>• See algorithm for specialty bed needs               <ul style="list-style-type: none"> <li>○ Use flat sheet on specialty bed mattresses</li> <li>○ Use maxiflo pad on low air loss mattresses</li> </ul> </li> </ul>



	<ul style="list-style-type: none"><li>• Consider PT/OT consult</li></ul>
Friction & Shear	<ul style="list-style-type: none"><li>• To prevent skin tears/friction, avoid pulling extremities when moving patient, use one pad and avoid wrinkles</li><li>• Do NOT use chux under patient (except for short term procedures as needed)</li></ul>
Nutrition	<ul style="list-style-type: none"><li>• Consider Dietary consult</li></ul>

## Appendix B: Sacral Silicone Foam Dressing (Mepilex®) Algorithm

### Nursing Standards of Care:

- Provide skin assessment in 4 hours- See Pressure Ulcers: Guidelines for Prevention and Treatment> Procedures>Item 3 on LinkNet
- Implement pressure ulcer prevention interventions per guidelines
- Evaluate patient for use of Sacral Silicone Foam Dressing (Mepilex®)
  - Apply sacral silicone foam dressing per protocol criteria (see criteria below)
    - Date/time/initial dressing & “P” for prevention
  - Peel back sacral silicone foam dressing (Mepilex®) and inspect under skin every shift assessment
    - Peel back sacral silicone foam dressing (Mepilex®) top down, to keep distal seal intact—will help prevent peeling.
  - Document sacral silicone foam dressing (Mepilex®) application on the PUP section of Daily Care/Safety
  - Document Site Assessment and Interventions
    - WDL: Within Defined Limits
    - Exceptions to WDL: See wound LDA
  - Change sacral silicone foam dressing (Mepilex®) every 72 hours or when soiled
  - DO NOT use on patients with uncontrolled incontinence
  - If sacral silicone foam dressing (Mepilex®) interferes with surgical site integrity, may postpone dressing application until completion of surgery and/or apply different shape/size dressing
  - PUP interventions are to be discussed in nursing rounds, SBAR reporting at shift change, for procedures, and transfers

### **CRITERIA FOR APPLYING SACRAL SILICONE FOAM DRESSING (Mepilex®)**

#### AUTOMATICALLY APPLY MEPILEX® IF 1 OR MORE PRESENT

- Surgical procedure or cumulative surgeries lasting greater than 4 hours per current admission
- Cardiopulmonary arrest or rapid response this admission
- Vasopressor(s) administration
- BMI: greater than 40 or less than 18
- Mechanical ventilation
- Quadriplegia or Spinal Cord Injury
- Drive Lines (LVAD, RVAD, IABP, ECMO)
- Rotoprone
- CRRT
- CPAP/BIPAP
- Braden Score: 13 or less
- Past history of pressure ulcers
- Sedation/Paralytics greater than 12 hours
- Restraints

#### APPLY MEPILEX® IF 5 OR MORE PRESENT:

- Weeping edema/Anasarca
- Traction
- Age greater than 65 y.o.
- Diabetes Mellitus
- Bed Rest
- Malnutrition (Prealbumin: <20, Albumin: <2.5, NPO greater than 3 days)
- Fecal/urinary incontinence **controlled** by indwelling catheter/fecal management device

## Appendix B

### Letter of Approval from TriHealth IRB



December 3, 2014

MaryAnn Lancaster, BSN, RN  
10500 Montgomery Road  
Cincinnati, OH 45242

**IRB Study#: 14-053**  
Study Title: Implementing a Hospital-Acquired Pressure Ulcer Prevention Protocol with a Sacral Mepilex® Dressing and Evaluation of Nursing Protocol Adherence  
Study Approved: 11/25/2014  
Study Approval Expires: 11/24/2015

Dear Mrs. Lancaster:

The new study listed above was reviewed and approved on November 25, 2014, under expedited review using Category#: 7: Individual or group behavior designation.

This is to confirm that your IRB application is now fully approved. The protocol is approved through Version# 1 dated 08/05/2014. Please note that your total subject accrual may be no more than 1,135 as noted in your original submission.

You are granted permission to conduct your study only as described in your application effective today at Bethesda North (OH 069), Good Samaritan Hospital (OH 073) and Bethesda Butler (OH ). Should your project extend beyond the expiration date of 11/24/2015, you should submit your continuing review reports 60 days before your approval will expire. IT IS YOUR RESPONSIBILITY to keep track of your project's expiration date and to submit your continuing review reports in a timely manner either to continue or to close your study. If we do not receive your reports in time to be reviewed your study must stop all activity after 11/24/2015. Please be sure to reference the Principal Investigator's name and complete IRB assigned study number in the subject line of all correspondence with the IRB.

The following items were submitted with your application and reviewed:

1. IRB Submission Form
2. Approved Administrative Review Application
3. COIs (Lancaster, Hardin-Pierce, McCord)

**Institutional Review Board**  
10498 Montgomery Road, Suite A  
Cincinnati, OH 45242

Phone: 513.865.5248  
FAX: 513.852.3825  
Email: [irb\\_hmp@trihealth.com](mailto:irb_hmp@trihealth.com)

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4. Protocol Version 1 dated 08/05/2014
5. Appendices A-L
6. SRC Approval
7. Waiver of Informed Consent
8. Waiver of Documentation of Informed Consent
9. Waiver of Authorization

The IRB reviewed the proposed research and granted the request for waiver of patient authorization to use PHI in research, based on the following findings:

1. The use/disclosure of PHI involves no more than minimal risk to the privacy of individuals
  - i. There is an adequate plan to protect the identifiers from improper use and disclosure.
  - ii. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention that is otherwise required by law.
  - iii. There is an assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
2. The research cannot practicably be conducted without the waiver or alteration.
3. The research cannot practicably be conducted without access to and use of the PHI.

The IRB reviewed the proposed research and granted the request for waiver of informed consent to participate in research, based on the following findings:

1. The research involves no more than minimal risk to the subjects.
2. The research cannot practicably be carried out without the waiver.
3. The waiver will not adversely affect the rights and welfare of the subjects.
4. When appropriate, the subjects will be provided with additional pertinent information after participation.

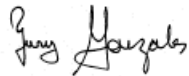
You are reminded to review the guidelines you signed in the initial application titled "Researcher Responsibilities List" and the guidelines for reporting adverse events. Failure to report or meet the requirements may result in immediate suspension of all study activities and/or entry of any further patients into this study until such time as a written explanation has been received and approved by the Institutional Review Board.

Please note that you are responsible for registering this study on ClinicalTrials.gov if this study qualifies as a clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations) and the principal investigator is designated as the responsible party (as defined in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA)(PL110-85).

December 3, 2014  
MaryAnn Lancaster  
IRB Study #: 14-053  
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Any changes to the study as approved must be promptly reported and approved before implementing except those necessary to eliminate immediate hazards. Contact the IRB office (513 865-5248) if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink that reads "Yury Gonzales". The signature is written in a cursive style with a large initial "Y" and "G".

Yury R. Gonzales, MD, FACP  
Chairman  
TriHealth Institutional Review Board  
FWA 00003114 - IRB00002744

## Appendix C

### Pre-Test/Post-Test Questionnaire

1. The head to toe skin assessment “4 eyes in 4 hours” is best defined as:
  - a. Assessment of patient’s skin by 4 unit staff on admission and 4 hours later
  - b. Assessment of patient’s skin by 2 registered nurses within 4 hours of admission to their unit
  - c. Assessment of patient’s skin by 2 unit staff personnel, including registered nurses and patient care assistants, within 4 hours of patient admission
  - d. Assessment of patient’s skin by 2 unit staff personnel, including registered nurses and patient care assistants on admission and 4 hours later
  
2. Mrs. White is a 67-year old patient that was admitted through the Emergency Department with abdominal pain with 1 week of nausea, vomiting, and diarrhea. She is dehydrated and reports not being able to eat or drink much over the past few days. She is alert and oriented, very weak and has been bed ridden for past 3 days with incontinence several times daily. What is her Braden Score Risk?
  - a. Braden Score <18- High Risk
  - b. Mrs. White does not meet criteria for Braden Score assessment
  - c. Braden Score >18- Low Risk
  - d. Braden Score >18- High Risk
  
3. Which of the following are not acceptable prevention intervention strategies for patients determine at-risk for pressure ulcers/
  - a. Use skin care products/barrier creams, Moisturize skin daily, and Protect skin from fecal and/or urinary incontinence
  - b. Use a sacral silicone foam dressing (Mepilex®), use heel lift boots, and turn patients every 2 hours
  - c. Use adult diapers to control incontinence, Massage red areas to improve circulation, Use a donut-type cushion while patient up in chair
  - d. Assess patient’s ability to detect and express pain, pressure, and need for repositioning, Float heels with pillows under knees, teach patient to shift weight every 15 minutes
  
4. Skin assessment should be completed at all the following except:
  - a. Admission to the hospital
  - b. Change in wound status
  - c. Transfer between units
  - d. Discharge to home or next care facility
  - e. After prolonged immobility such as surgery or a procedure
  
5. A patient is admitted to your unit. Which high-risk criteria would automatically indicate the need for a preventative sacral silicone foam dressing (Mepilex®) to be applied to your patient?
  - a. Body Mass Index (BMI) 38
  - b. Surgical procedure lasting 2 hours
  - c. Continuous Positive Airway Pressure (CPAP) use
  - d. Age greater than 65

6. How many low risk criteria would be required to apply a preventative sacral silicone foam dressing (Mepilex®) to your patient?
  - a. 5 or more
  - b. 3 or more
  - c. 1 or more
  - d. None, they are low risk for pressure ulcers
  
7. The correct way to apply a Mepilex® dressing to the sacral skin is:
  - a. Ensure sacral skin is clean, peel off release films from dressing, adhere to patient skin at top of gluteal cleft
  - b. Spread gluteal cleft, use skin protectant to area dressing will be applied, adhere Mepilex with distal end of dressing at top of gluteal cleft, smooth sides over buttocks
  - c. Ensure skin is clean, spread gluteal cleft and locate coccyx, peel off center release film from dressing, adhere to patient skin with distal end of dressing at patient's coccyx, remove side release and smooth over skin
  
8. What intervention with the Mepilex® dressing is correct?
  - a. Change the dressing every 72 hours or when soiled
  - b. Peel back and assess skin every 72 hours
  - c. Use dressing on patients with uncontrolled fecal or urinary incontinence to protect skin
  - d. Leave dressing in place even if patient refuses
  
9. Which of the following is NOT an acceptable exception for not applying a Mepilex® dressing?
  - a. Uncontrolled incontinence saturating Mepilex dressing
  - b. If the Mepilex® dressing interferes with surgical site integrity
  - c. Patient or family refusal
  - d. Weeping skin or edema (anasarca)
  - e. Allergy to silicone or Safetac technology adhesive
  
10. A Stage III pressure ulcer is best defined as
  - a. Full thickness tissue loss with bone, tendon, or muscle exposure
  - b. Partial thickness loss of dermis presenting as a shallow open ulcer
  - c. Full thickness skin loss without bone, tendon, or muscle exposure
  - d. Full thickness loss of tissue in which actual depth of ulcer is uncertain because wound bed is obscured by slough and/or eschar
  
11. Which of the following is not a characteristic of a Stage II pressure ulcer?
  - a. Red or pink wound bed without slough
  - b. Excoriation or maceration of the skin
  - c. An open serous fluid filled blister
  - d. Partial thickness, shallow, open ulcer
  
12. The National Database for Nursing Quality Indicators (NDNQI) is the reporting agency TriHealth submits pressure ulcer prevalence rates for comparison to other facilities. The NDNQI benchmark and our goal at TriHealth is to maintain hospital acquired pressure ulcer prevalence below what percentage?

- a. 1%
  - b. 1.75%
  - c. 2 %
  - d. 2.5%
  - e. Varies month to month
13. Current evidence based practice have demonstrated the sacral silicone foam dressing to be:
- a. Clinically relevant for the reduction of pressure ulcer prevalence
  - b. An adjunctive therapy to best practices for the prevention of pressure ulcers in hospitalized patients
  - c. Another intervention combined with early risk assessment to prevention pressure ulcers
  - d. All of the above
14. A 68-year old female patient was admitted to the ICU after a 3-hour complicated bowel resection. The patient is intubated and on mechanical ventilation, she has levophed (vasopressor) and a sedative infusing, and is bedrest with bilateral soft wrist restraints on. She has a history of diabetes, hypertension, and smoking 1 pack per day x 25 years. After 4 days in the ICU the patient is now extubated on 2L nasal cannula, hemodynamically stable, and just started a clear liquid diet today. She is now ready to transition to a surgical unit. On her transfer you complete the Mepilex® risk assessment. Based upon the information provided does this patient need a Mepilex® dressing?
- a. Yes, based on the medical care she has received during this admission she continues to be at risk for pressure ulcers even though she is doing better.
  - b. No, now that she is on the surgical unit, she does not meet the criteria for a Mepilex dressing.
  - c. Not sure
15. Pressure ulcers present on inpatient admission require the nursing team to do all of the following except:
- a. You do not need to document wounds present on admission, because they occurred outside of the hospital and we are not responsible for them
  - b. Notification of pressure ulcer or wound to the MD
  - c. Wound Care Team consult
  - d. Activate Wound Care Order Set
  - e. Document all POA pressure ulcers and wounds with admission assessment



## Appendix D

### Sacral Silicone Foam Dressing Algorithm Fidelity Scale: Inpatient Chart Review Form

Code Number: \_\_\_\_\_

Site: Bethesda North    Good Samaritan

Unit: \_\_\_\_\_

Date Chart Reviewed: \_\_\_\_/\_\_\_\_/\_\_\_\_

To be included in chart review, a patient must meet these criteria:

Admitted to TriHealth and classified with an inpatient status Yes    No

**P1. Admission Skin Assessment:** A comprehensive head-to-toe skin assessment completed by two staff RNs within 4 hours of patient’s admission to the perspective unit (“Four eyes in four hours”).

- A. Skin assessment completed on admission Yes    No
- B. Timely assessment completed in 4 hours of admission to the admitted unit? Yes    No
- C. Did patient have a sacral pressure ulcer present on admission Yes    No



**Complete    Incomplete**

**P2. Sacral Silicone Foam Dressing Application Criteria:** All applicable sacral silicone foam dressing criteria selected by nurse, indicating reason for dressing application.

A: Mepilex Application Criteria

RN Document

High Risk Criteria (1 or more)	Yes	No
Surgical procedure or cumulative surgeries lasting greater than 4 hours per current admission		
Cardiopulmonary arrest or rapid response this admission		
Vasopressors administration		
BMI: greater than 40 or less than 18		
Mechanical ventilation		
Quadriplegia or Spinal Cord Injury		
Drive Lines (LVAD, RVAD, IABP, ECMO)		
Rotoprone		

CRRT		
CPAP/BIPAP		
Braden Score: 13 or less		
Past history of pressure ulcers		
Sedation/Paralytics greater than 12 hours		
Restraints		
Moderate Risk (5 or more)		
Weeping edema/Anasarca		
Traction		
Age greater than 65 y.o.		
Diabetes Mellitus		
Bed Rest		
Malnutrition (Prealbumin: <20, Albumin: <2.5, NPO greater than 3 days)		
Fecal/urinary incontinence <b>controlled</b> by indwelling catheter/fecal management device		
Age greater than 65 y.o.		

B. No Mepilex Application criteria were applicable

Yes No

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**Complete Incomplete**

**P3. Pressure Ulcer Prevention Interventions**

- A. Has patient received a prophylactic sacral silicone foam dressing
- B. PUP sign on door
- C. Other (N/A- if not applicable)

Yes No  
Yes No

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**Complete Incomplete**

**P4. Maintenance of Sacral Silicone Foam Dressing:** Date of dressing change due; every 72 hours or when soiled.

A. Date sacral silicone dressing change due documented

Yes No

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Complete Incomplete

**P5. Dressing Intervention:** Interventions include new dressing, peeled back for skin inspection, dressing removed, or other.

A. Every shift, were the dressing interventions documented

Yes No

--	--

Complete Incomplete

**P6. Site Assessment:** Site assessment is documented as “Within Defined Limits (WDL)” Documentation includes skin temperature, moisture level, integrity, and characteristics defined as “Skin warm, dry, and intact. Color appropriate and even. Skin rises easily and returns to place immediately. Skin is free of any lesions, wounds, bruises, abrasions, avulsions, rashes or other abnormalities.” Or site assessment is documented as “Exceptions to Within Defined Limits- see wound LDA”

A. Was the sacral skin assessment documented

Yes No

B. If “Exceptions to Within Defined Limits-see wound LDA” was selected, did it result in the documentation of a “wound LDA”

Yes No

--	--

Complete Incomplete

**P7. Plan of Care:** “Potential for Compromised Skin Integrity” plan of care initiated

A. Did the Best Practice Advisory trigger, result in the nurse adding the “Potential for Compromised Skin Integrity” to individualize the patient’s Plan of Care?

Yes No

--	--

Complete Incomplete

**This portion should be filled out with the Sacral Silicone Foam Dressing Algorithm Fidelity Scale: Inpatient Chart Review Forms. Indicate whether the nursing documentation were satisfactory by marking each item with a (+) or (-) in the following tally sheet.**

<b>Fidelity Item</b>	<b>Complete (+)</b>	<b>Incomplete (-)</b>
<b>P1: Admission Skin Assessment</b>		
P1A		
P1B		
P1C		
<b>P2: Sacral Silicone Foam Dressing Application Criteria</b>		
P2A		
P2B		
<b>P3: Pressure Ulcer Prevention Interventions</b>		
P3A		
P3B		
P3C		
<b>P4: Maintenance of Sacral Silicone Foam Dressing</b>		
<b>P5: Dressing Intervention</b>		
<b>P6: Site Assessment</b>		
<b>P7: Plan of Care</b>		

$[(\text{Number Fidelity Items Complete}) / (7 \text{ total Fidelity Items})] \times 100 = \% \text{ complete}$

Likert Scale Rating                    1            2            3            4            5

5= 90% or more documentation complete

4= 70%-89% documentation complete

3= 50%-69% documentation complete

2= 11%-49% documentation complete

1= 10% or less documentation complete

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