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Development of a Tool for Pressure Ulcer Risk Assessment and Preventive Interventions in Ancillary Services Patients

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Development of a Tool for Pressure Ulcer Risk Assessment and Preventive Interventions in Ancillary Services Patients

by

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Dedication

I wish to dedicate this dissertation to my greatest supporter and unwavering champion throughout the years of this pursuit; my beloved husband, James. You have truly been the wind beneath my wings, and without you there would not have been the incredible lift required for such a lofty flight.

There is a very special lady looking down from heaven to whom I owe all that I am or will ever achieve. This degree is in part a fulfillment of her lifetime dream that her children would have the opportunity to become or achieve whatever they were capable of. Completing only through the 11th grade of school due to illness, Esther Gadway Shutts was a closet scholar, reading Homer, Plato and Dante Alighieri for recreation. She instilled in her children an insatiable quest for knowledge. This dissertation is a reflection of that quest and, I hope, of that great lady.

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Abstract

The incidence of nosocomial pressure ulcers has continued to increase in U.S. hospitals over the past 15 years despite the implementation of national preventive guidelines and the wide-spread use of validated risk assessment tools. The majority of preventive efforts and tools have been focused primarily on patients who are bed-ridden or immobile for extended periods. What has not been well studied or identified is the potential risk for pressure injury to patients undergoing diagnostic procedures in hospital ancillary units where extrinsic risk factors such as high interface pressures on procedure tables and friction and shear from positioning and transport can greatly magnify the effect of patient-specific intrinsic risk factors which might not otherwise put these patients at high risk on an inpatient unit. The purpose of this study was to develop a risk assessment tool designed explicitly to quantify the combination of these intrinsic and extrinsic risk factors in individual patients undergoing ancillary services procedures, and to identify targeted preventive interventions based on the individual level of risk.

Empirically and theoretically-derived risk factors for the tool were tested in a nation-wide hospital database of over 6 million patient discharge records using bivariate and multivariate analysis to identify significant predictors of pressure ulcer outcomes. The statistically significant factors emerging were then used to develop the risk assessment scale. These predictors included; advanced age, diabetes, human immunodeficiency virus infection, sepsis, and fever. The scale was tested for internal validity using the split-sample cross-validation method, and for accuracy using the area

under the Receiver Operating Characteristics curve. The optimum score cut point was identified to provide a predictive accuracy of 71 percent. Interventions for the tool were identified from national clinical practice guidelines and aligned in sets based on patient levels of risk identified by the scoring portion of the tool. The entire tool was evaluated for content validity by a panel of five international nurse experts in pressure ulcer prevention and tool development. The content validity index calculated from their ratings was .91 indicating excellent agreement on content validity.

This study contributes a risk assessment tool for further testing to address an important and poorly-appreciated risk for pressure injury in hospital clinical areas too long ignored.

Chapter One

Introduction

Nosocomial pressure ulcers continue to be a significant cause of patient morbidity and mortality in acute care hospitals despite considerable international focus and effort to reduce their incidence. Nearly 60,000 U.S. hospital patients are reported to die each year from complications due to hospital-acquired pressure ulcers (Ayello, 2008; Reddy, Gill, & Rochon, 2006). The annual cost for treating pressure ulcers in the U.S. is approximately $11 billion (Reddy et al.).

Although pressure ulcer prevention has received increasing attention in the literature since the 1960s, little has been published about the risk of pressure injury to patients undergoing procedures in diagnostic and interventional ancillary units (e.g., radiology, renal dialysis, gastrointestinal, cardiac and vascular procedure labs) (Halfens & Haalboom, 2001; Reddy et al., 2006). In the only research study found in this population, the incidence of pressure injury in patients undergoing lengthy radiology procedures was nearly 54% (Brown, 2002). Although the full study has not been published, obviating assessment for scientific merit, this incidence is well in excess of the 4% to 38% reported for patients in hospitals (Cuddigan, Ayello, & Sussman, 2001).

Unfortunately, statistics are not reported independently for pressure ulcer incidence in hospital ancillary services units. This is perhaps because there is no established protocol to assess patients' skin integrities before, during or after ancillary diagnostic and treatment interventions. Furthermore, tissue pressure injury often does not

manifest overtly in superficial tissue until 48-72 hours post injury (Aronovitch, 2007; Bouten, Oomens, Baaijens, & Bader, 2003). Thus, the true incidence of pressure ulcers incurred during ancillary services procedures is unknown. However, in a recent initiative in a 300-bed acute care hospital in Minnesota, Haugen et al (2011) identified several potential factors thought to contribute to pressure ulcer risk, including care in diagnostic or interventional departments. A root-cause analysis revealed that 76% of their hospital patients who developed pressure ulcers in 2008 had undergone three or more procedures such as x-rays. They found that patients undergoing procedures ultimately could be in the same position on sub-optimal support surfaces for 6-8 hours. Using a multidisciplinary education and interventions program which included staff in ancillary units, their initiative resulted in a significant reduction in overall hospital-acquired pressure ulcers in this facility.

Despite focused prevention programs published by U.S. government and other major health care organizations, and the publication of clinical practice guidelines by the Agency for Health Care Policy and Research (Panel for the Prediction and Prevention of Pressure Ulcers in Adults, 1992), the nosocomial pressure ulcer incidence in U.S. hospitals rose 63% from 1993 to 2003 (Ayello, 2008). In addition, in 2006 there were 503,300 hospital stays during which pressure ulcers were noted—a 78.9% increase from 1993 (Russo, Steiner, & Spector, 2008). If pressure ulcer risks to patients undergoing ancillary procedures can be better managed, the potential impact on the overall nosocomial incidence may be significant.

The Risk of Pressure Tissue Injury in Ancillary Units

The Role of Pressure

Pressure ulcers are primarily manifestations of tissue injury incurred when soft tissues are compressed between two firm surfaces (Krouskop, 1983; Schubert, 1994). This occurs most commonly over bony prominences on the body where soft tissue is compressed between an external surface, such as a bed, chair, or exam table, and an internal unyielding surface of bone. When pressures on internal tissues exceed capillary closing pressure (CCP) of 32-47 mm Hg for longer than two hours, circulation is compromised and tissue anoxia and death can ensue (Defloor, 1999; Maklebust & Sieggreen, 2001). Capillary closing pressure is the pressure required on the capillary bed to completely occlude blood flow in the capillaries.

It is generally accepted from early studies that interface pressures (perpendicular force per unit area between the body and support surface) of 60 - 70 mm Hg for 1-2 hours may lead to soft tissue pressure injury (Defloor, 1999; Kosiak, 1959). There is also a credible scientific basis for the statement that support surfaces commonly used for patients in ancillary services units such as radiology, hemodialysis and interventional diagnostic laboratories generate interface pressures well above those required to cause tissue injury. In a prospective study of interface pressures on x-ray tables, Justham, Michael and Harris (1996) measured these pressures at known pressure points in 16 healthy volunteers. They found mean interface pressures ranging from 97.7 mm Hg on the sacrum, to 126.9 mm Hg on the heel on the standard x-ray table surface. Equally hazardous interface pressures have been demonstrated in prospective studies conducted in patients undergoing surgical procedures in the operating room (Deane et al., 2008; Grous,

Reilly, & Gift, 1997; Schoonhover, Defloor, van de Tweel, Buskens, & Grypdonck, 2002; Schultz, 2005; Stordeur, Lauren, & D'Hoore, 1998; Stotts, 1999), where support surfaces are similar to those in diagnostic and interventional ancillary procedure units. The results of studies of intraoperatively acquired pressure ulcers reveal an overall incidence ranging from 12 - 66% in this population (Aronovitch, 2007). These statistics are significant to this study as the surgical environment has many extrinsic risk factors in common with ancillary services units such as high interface pressures, positioning friction and shear, forced immobility, and anesthesia and sedation.

While these studies are mostly descriptive in nature and cannot establish a definite causal relationship between interface pressures and formation of pressure ulcers, they are important because they demonstrate how great the pressures on human tissue may be in ancillary patient care areas. This may be particularly applicable to patients undergoing lengthy ancillary procedures on exam surfaces where interface pressures reach 126 - 170 mm Hg (Justham, Michael, & Harris, 1996; Keller, Lubbert, Keller, & Leenen, 2005).

Historically pressure injury was presumed to be primarily a result of compression of soft tissue beyond the level of capillary closing pressure (32 mm Hg) for an extended period of time (>2 hours) (Maklebust & Sieggreen, 2001). Based on this premise, early pressure ulcer prevention efforts were focused on risk identification and preventive interventions in areas where patients remained recumbent for extended periods, such as inpatient hospital units, extended care facilities and spinal cord injury units. Much has since been learned about pressure ulcer etiology. Studies have now shown that exposure to high interface pressures for short periods can cause injury in patients whose tissue tolerance for pressure is impaired (Gefen, 2008).

The Role of Shearing Forces

Shear is defined as mechanical stress directed parallel to the plane of interest (Maklebust & Sieggreen, 2001). These parallel forces, a combination of gravity and friction, result in distortion and damage to blood and lymph vessels attached to muscle fascia which leads to what is now described as an inverted cone of deep tissue injury (Bliss, 1998; Donnelly, 2001; Pieper, 2000). The magnitude of the additive effect of shear forces on the development of pressure injury has been well documented in a number of scientifically executed animal studies. These studies have demonstrated that the presence of shearing forces can reduce the time and intensity of pressure required to produce tissue injury by 50 percent (Bennett & Lee, 1988; Gefen, Gefen, Linder-Ganz, & Margulies, 2005; Linder-Ganz & Gefen, 2007; Palevski, Glaich, Portnoy, Linder-Ganz, & Gefen, 2006; Stekelenburg, Strijkers, Parusel, Bader, Nicolay, & Oomens, 2007).

From the literature reviewed, a sound thesis is that pressure and shearing forces inherent in the transport and positioning of ancillary procedures patients on support surfaces that already generate interface pressures well in excess of CCP place these patients at high risk for pressure injury. The additive effects of intrinsic factors and co-morbidities that diminish tissue tolerance for pressure and shear further escalate the risk in this patient population.

The Role of Ischemia: The Third Rail of Pressure Pathology

There is yet another critical factor to consider in the pathophysiology of pressure injury. An emerging theory of pressure ulcer etiology is related to tissue ischemia. Two commonly posited mechanisms of this pressure-induced ischemia are; (a) failure of the *autoregulatory* capacity of soft biological tissues in the face of an external loading

challenge, and (b) the *interstitial theory* of pressure-induced changes in interstitial pressure resulting in a disturbance of tissue metabolic equilibrium and an accumulation of toxic wastes.

Pressure-induced vasodilation (PIV). An important physiological mechanism that protects healthy skin from pressure-induced ischemic injury is that of PIV. This mechanism employs both small sensory nerve fibers and endothelial function to maintain adequate tissue perfusion in the face of an external pressure challenge to capillary flow. The phenomenon of increased capillary closing pressures (CCP) in response to external loading pressures has been well-documented in the literature (Barbenel, 1991; Daly, Chimoskey, Holloway, & Kennedy, 2006; Fromy et al., 2010; Landis, 1930; Miller & Seale, 1981). This mechanism is thought to be one of the primary explanations for the reduced risk for pressure injuries in healthy patients enduring prolonged episodes of interface pressures in excess of CCP, such as lengthy operative procedures.

Factors that impair the PIV mechanism, such as aging, diabetes, and paralysis are hypothesized to significantly increase the risk of pressure injury. Fromy et al. (2010) compared PIV in non-neuropathic and neuropathic subjects 60-75 years of age with younger subjects 20-35 years of age using laser Doppler flowmetry to evaluate cutaneous responses to local pressure application. The non-neuropathic older subjects demonstrated impaired PIV (12 ± 7% increase in blood flow with pressure) compared to younger subjects (62 ± 4%, $p < .001$). In older subjects with neuropathy, PIV was totally absent (-31 ± 10%, $p < .001$). Similar impairment in diabetics was demonstrated earlier by Fromy et al. (2002) using laser Doppler flowmetry.

The interstitial theory. Growing in acceptance, this theory is based on the assumption that external pressure on soft tissues changes interstitial pressure, interstitial fluid flow, and homeostasis of molecules and ions within this system. The resulting disequilibrium leads to impaired transport of nutrients to the cell and interruption of lymphatic drainage of metabolic waste products (Krouskop, 1883; Miller & Seale, 1981; Reddy, Cochran, & Krouskop, 1981). Researchers have attempted to describe the link between external loading and the mechanical conditions and physiological changes within the cells and interstitium (Dodd & Gross, 1991). Reddy et al. developed and employed a mathematical model to investigate the effects of external pressure on interstitial fluid dynamics. Although this work supported the theory that slow viscous flow of interstitial fluid plays a role in tissue necrosis, the interstitial theory of tissue damage has yet to be definitively demonstrated as related to the onset of pressure ulcers. It is acknowledged here as an area of much interest for future research.

The Role of Tissue Tolerance

Advances in empirical knowledge of pressure ulcer pathophysiology in the decades following 1970 produced the new concept of *tissue tolerance* as a significant factor in determining patients' risks for pressure injury. Tissue tolerance in pressure ulcer development is simply the tissue's resistance to mechanical stress; that is, its ability to maintain integrity and function without adverse sequelae in the face of the exertion of pressure and shear forces. Tissue tolerance includes factors known to impact the risk of a patient developing a pressure ulcer, without directly impacting the degree and duration of pressure and/or shearing forces (Defloor, 1999).

Factors affecting tissue's resistance to the effects of pressure are generally divided into two groups; (a) systemic (nutrition, mobility/activity, oxygen intake and delivery, and existing diseases/disability) which affect tissue integrity indirectly, and (b) local factors (nerve control, immunity, metabolism, circulation and tissue structure/composition) which affect underlying tissue viability directly. Aging is known to adversely influence both the systemic and local intrinsic tissue tolerance factors (Hagisawa & Shimada, 2005). As a result of the variability of these systemic and local factors, the intensity and duration of pressure required to cause damage depends on the individual's tissue tolerance.

Conceptual Model for Risk Factor Analysis in Ancillary Services Patients

The pathophysiologically based conceptual scheme for the study of pressure ulcer etiology published by Braden and Bergstrom (1987) provided the conceptual foundation for the Braden Scale for predicting pressure ulcer risk and proposed the concept of tissue tolerance as a *causative* factor in the development of a pressure ulcer (Braden & Bergstrom). The theoretic model of Defloor (1999) further refined this conceptual scheme, pointing out that tissue tolerance is not a *cause* of pressure injury as posited by Braden and Bergstrom but an intermediate variable. What determines the tissue response to pressure and shearing forces is the individual's tissue tolerance at that point in time. Therefore, risk factors include not just exposure to pressure and shear of sufficient intensity and duration to cause injury, but patient-specific and environmental factors which affect the tissue's event-specific tolerance of the pressure insult. Pressure injury has been documented from as little as 20 mm Hg interface pressure in some elderly and

high-risk patients (Bennett & Lee, 1985; Morison, 2001). Yet, many patients sustain pressures well above CCP for >10 hours in surgery and do not develop pressure injury.

Over 100 risk factors for pressure ulcer development are reported in the literature (Lyder, 2003). Identifying the most significant risk factors and being able to predict which individuals are most at risk during ancillary diagnostic and treatment procedures are key elements of prevention in this patient population. The amended conceptual scheme as outlined by Defloor includes a series of risk factors known to predispose patients to pressure injury independent of the intensity and duration of pressure and shearing forces. The majority of these factors (e.g., mobility, sensory perception, moisture, age, nutrition, medication, diseases) form the risk scoring categories already woven into the Braden Scale for Predicting Pressure Sore Risk instrument, a validated tool currently in use by nurses on many hospital inpatient units. However, the Braden Scale was never purported to assess risks during the operative period (Bergstrom, 2005) and has in fact been shown to be a poor predictor of pressure injury for short-term exposures to high interface pressures like those experienced by patients on operating tables (Connor, Sledge, Bryant-Wiersma, Stamm, & Potter, 2010; Grous, Reilly, & Gift, 1997; Karadag & Gümüskay, 2006; Nixon, Cranny, & Bond, 2007). With the similarity between the extrinsic risks in the operating room and those in ancillary services units, the conceptual framework for an effective risk assessment instrument for the environments of ancillary services must be based on the unique risks engendered therein.

To facilitate selection of the pressure ulcer risk factors with the highest predictive value for the specific population of ancillary services patients, a conceptual model adapted from the conceptual scheme outlined by Defloor (1999) was developed by the

investigator. The model focuses on the linear relationships among intrinsic and extrinsic factors identified from the literature and the associated risk for pressure injury outcomes (Figure 1). These factors formed the matrix for the development of an ancillary services pressure ulcer risk assessment tool.

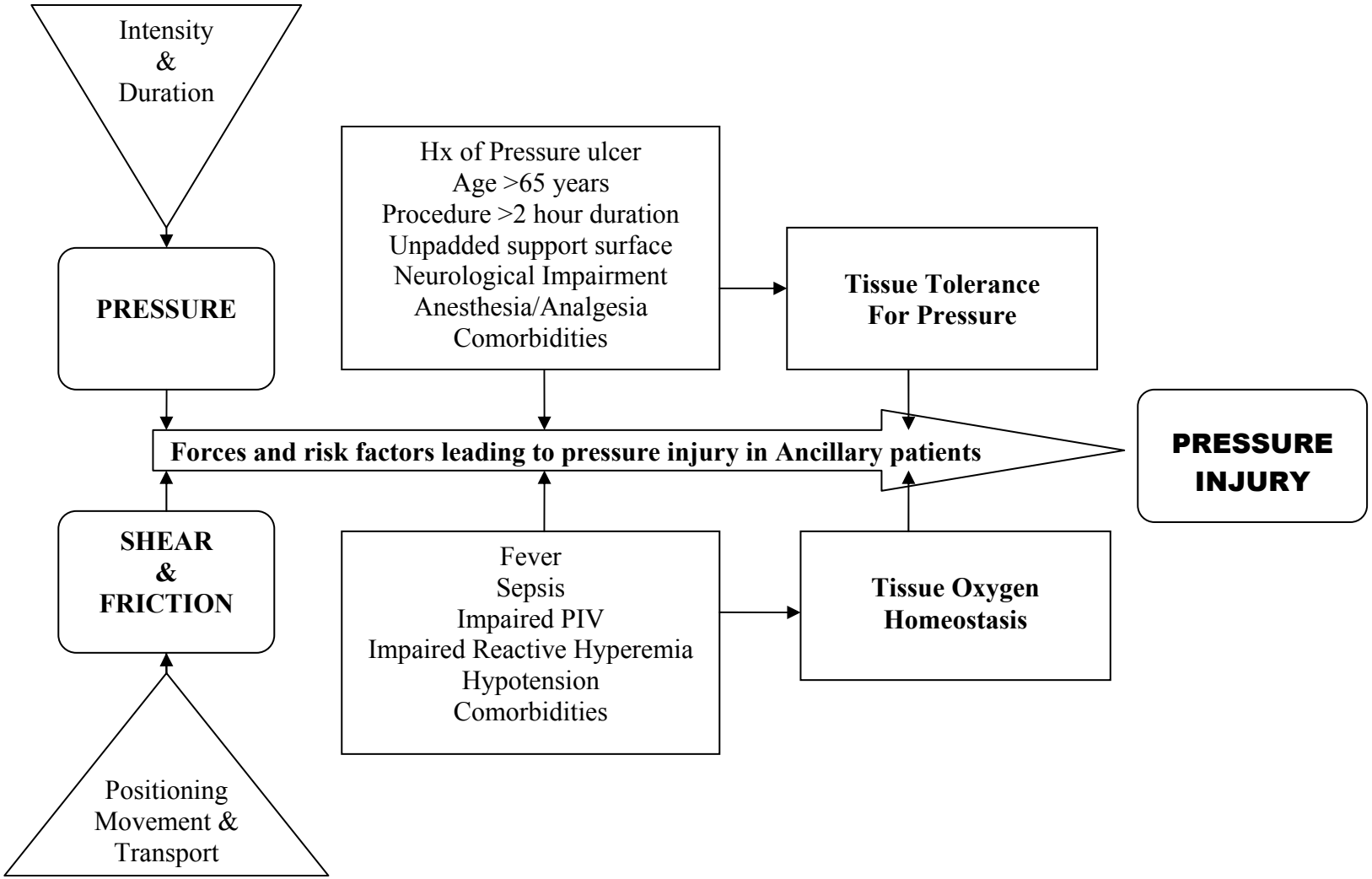


Figure 1. Ancillary Procedures Pressure Ulcer Risk Conceptual Model.

The Research Problem

Nearly 60,000 U.S. hospital patients are reported to die each year from complications due to hospital-acquired pressure ulcers. Patients are considered at-risk for pressure injury when interface pressures exceed capillary closing pressure of 32-47 mm Hg for longer than two hours. This may be particularly significant in patients undergoing lengthy ancillary procedures on exam table surfaces where interface pressures can reach 126 - 170 mm Hg. Yet, this important clinical area has been largely ignored by researchers and clinicians. To date, the focus of pressure ulcer risk assessment tools has been almost exclusively on inpatient units, long-term care facilities, and spinal cord rehabilitation units. The current risk assessment tools designed for these populations are targeted at factors that put patients at risk for pressure injury from extended exposure to lower interface pressures and shear such as incontinence, malnutrition, and immobility. These tools are poorly suited to identify patients at risk for poor tissue tolerance of the shorter-term exposure to very high interface pressures and shear encountered during the ancillary procedures process. There is a compelling need for a pressure ulcer risk assessment tool that can effectively identify patients at high risk for pressure injury during ancillary services procedures so that prevention strategies may be implemented.

Purpose, Objectives and Research Questions

Purpose

The overarching purpose of this study was to develop an instrument that can be used by physicians, nurse practitioners, physicians' assistants and registered nurses to assess the specific risks for pressure injury in adult patients undergoing lengthy ancillary

services procedures. The tool also contains targeted intervention strategies for the prevention of pressure injury in this patient population.

Objective and Research Questions

The objective of this study was to develop an adult pressure ulcer risk assessment and preventive interventions instrument for ancillary services patients. To accomplish this objective the study focused on the following research questions:

1. Which specific intrinsic and extrinsic risk factors for pressure ulcer development identified from the literature are most likely to predict pressure injury in adult patients during lengthy diagnostic and treatment procedures in hospital ancillary services units?

2. What specific interventions can be identified from the literature that will be effective in preventing pressure injury during transport and care of patients undergoing procedures in ancillary services units?

Significance of the Study

The Gap in Research and Practice

To date, the focus of hospital pressure ulcer prevention (PUP) efforts has been almost exclusively on nursing services personnel (Institute for Healthcare Improvement, 2008). Despite qualitative evidence of the risk of pressure injury to patients undergoing lengthy procedures in hospital ancillary services units, this important clinical area has been largely ignored by pressure ulcer prevention clinicians, researchers and educators (Halfens & Haalboom, 2001). The only formally validated PUP risk assessment instruments currently in clinical use are designed for use by nurses in healthcare areas where patients are recumbent for extended periods, such as inpatient hospital units, long-

term care facilities and spinal cord units (Bergstrom, 2005; Lyder & Ayello, 2008). The design and constructs of these tools aim to address factors that impact patients' tolerances for long-term exposure to lower interface pressures (such as hospital beds), and the long-term impact on tissue tolerance of variables such as moisture, immobility, nutrition, and sensory perception (Braden & Bergstrom, 1987). These tools do not identify specific factors that reduce patients' tissue tolerances for shorter-term exposure to the very high interface pressures and shear sustained during ancillary services procedures. In recognition of this deficit a risk assessment tool for intraoperative pressure ulcers was developed and tested by Price, Whitney and King (2005). However, a pilot test of this tool failed to demonstrate acceptable interrater reliability, with several variables scoring kappa coefficients of 0.3 or lower. No risk assessment tool, even in a developmental stage, was found that was appropriate for the specific and temporal risks engendered in ancillary services units.

The successful development of a valid and reliable tool to identify patients at high risk for pressure injury during lengthy ancillary services procedures and posit appropriate preventive interventions to attenuate these risks could serve to significantly reduce pressure injury in this vulnerable population.

Summary

Chapter one discusses the mechanisms of the extreme soft tissue interface pressures endured by patients undergoing lengthy diagnostic and interventional procedures in hospital ancillary services units (radiology, cardiac labs, renal dialysis, etc.). It then posits the potential for these pressures to result in pressure injury in this patient population, including a conceptual model for these relationships. This risk has

been largely ignored by researchers and clinicians and, as a result, no risk assessment tools exist to identify patients at risk for pressure injury in this important area of hospital services. This chapter also includes a statement of the research problem, two research questions to be attended to, and the intent (objective) to develop an ancillary services-specific risk assessment and preventive intervention tool to address this important gap in research and practice. Chapter two will follow with an in-depth search of the relevant literature from which the most predictive patient risk factors will be identified for integration into the study's assessment tool matrix. In addition, the literature is reviewed for preventive interventions appropriate for the attenuation of the specific risks to patients from exposure to the high interface pressures and shear engendered in the transport and ancillary services procedure processes.

Chapter Two: Review of the Literature

Although more than 1200 pressure ulcer research studies have been published in the past 15 years, little has been published about the risk of pressure injury to patients undergoing procedures in diagnostic and interventional ancillary units (e.g., radiology, renal dialysis, gastrointestinal, cardiac and vascular procedure labs). In the only research study found in this population, the incidence of pressure ulcer injury in patients undergoing lengthy radiology procedures was nearly 54%. Forty-three out of eighty high-risk patients in the study developed some degree of pressure injury during their radiology procedure (Brown, 2002). This is well in excess of the 4% to 38% reported for patients in the general hospital setting (Cuddigan et al., 2001). Over 100 risk factors for pressure ulcer development are reported in the literature (Lyder, 2003). Identifying the most significant risk factors and being able to predict which individuals are most at risk during ancillary diagnostic and treatment procedures are key elements of pressure ulcer prevention in this patient population.

The purpose of this review of literature was to identify the empirically supported intrinsic and extrinsic factors that are most likely to put ancillary services patients at risk for pressure injury during their procedures in these specialized units. In addition, the review will identify from published clinical practice guidelines and empirical literature, the most effective preventive interventions with the greatest potential to attenuate the risk of pressure injury in this patient population. Given the known exposure to excessive interface pressures on the support surfaces in these units, what other patient-specific and

environmental factors are most predictive of vulnerability for pressure injury? Once identified from the literature, these factors will then be woven into the conceptual schema for construction of the pressure injury risk assessment and prevention instrument developed in this study.

Conceptual Model for Risk Factor Analysis

Historically pressure injury was presumed to be primarily a result of compression of soft tissue beyond the level of capillary closing pressure (32 mm Hg) for an extended period of time (>2 hours) (Maklebust & Sieggreen, 2001). Based on this premise, early pressure ulcer prevention efforts were focused on risk identification and preventive interventions in areas where patients remained recumbent for extended periods, such as inpatient hospital units, extended care facilities and spinal cord injury units. Much has since been learned about pressure ulcer etiology.

The conceptual scheme for the study of pressure ulcer etiology published by Braden and Bergstrom (1987) provided the conceptual basis for the Braden Scale for predicting pressure ulcer risk in hospital inpatients and nursing home residents. The authors also proposed the concept of tissue tolerance as a *causative* factor in the development of a pressure ulcer (Braden & Bergstrom). The conceptual model of Defloor (1999) further refined this conceptual scheme; however, Defloor points out that tissue tolerance is not a *cause* of pressure injury as posited by Braden and Bergstrom, it is an intermediate variable; tissue tolerance does not itself cause pressure injury (see Figure 2). As Defloor posited; sufficiently high pressure for a sufficiently long time will cause pressure injury. What determines the tissue response to the time-intensity curve of pressure is the individual's tissue tolerance at that point in time.

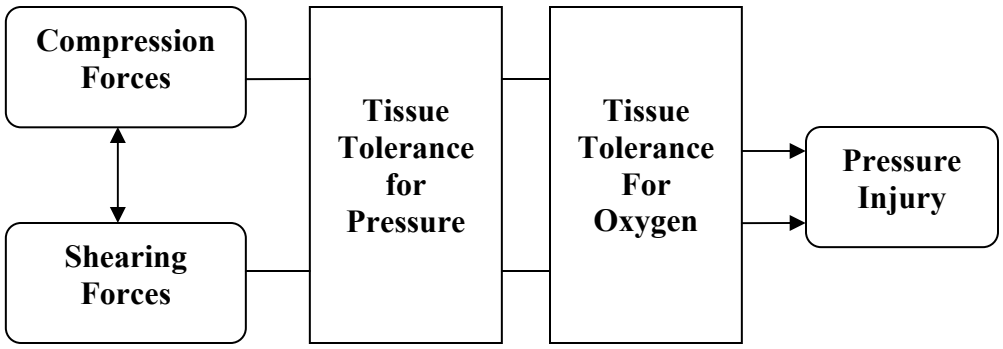


Figure 2. Conceptual Scheme for Pressure Injury (adapted from Defloor, 1999, p. 208).

Thus, it seemed appropriate to begin the quest to identify specific pressure ulcer risk factors in the ancillary services patient population with a review of the scientific literature concerning pressure, shearing forces, tissue tolerance for pressure, tissue oxygen homeostasis, and the interactions among these factors that predispose to individual variations in patient vulnerability. To better depict the physiological processes involved in the effects of risk factors on tissue oxygen demand and supply, the investigator has chosen *tissue oxygen homeostasis* to supplant Defloor's construct of "tissue tolerance for oxygen" (*vide supra*). Tissue oxygen homeostasis is here defined as the organism's physiological ability to maintain appropriate tissue oxygenation in the face of alterations in oxygen supply or demand.

Review Methodology and Design

To identify sources of scientific knowledge of risk factors for pressure ulcer development in ancillary services patients, a literature review from 1959 to present was conducted. The year 1959 was selected because this was the year Kosiak (1959) published his seminal time-intensity study of pressure injury etiology. In addition, literature examining the efficacy of pressure ulcer prevention interventions was reviewed

from 1992 to present. The year 1992 was selected for this portion of the review as it was the publication year of the first national pressure ulcer prevention guidelines in the U.S. (Panel for the Prediction and Prevention of Pressure Ulcers in Adults, 1992). For the risk factor review, databases of CINAHL, PubMed, MEDLINE and Cochrane were searched using the key words pressure ulcer, pressure sore, decubitus ulcer, epidemiology, etiology, pathophysiology, risks factors, shear, and tissue tolerance. For the intervention review the same databases were searched using the key words pressure ulcer prevention, pressure ulcer guidelines, pressure sore prevention, and pressure ulcer clinical practice guidelines. An extensive hand search was also conducted using sources identified from international pressure ulcer bibliographies and references from seminal studies and articles. For the risk factors, studies were selected that specifically addressed pressure ulcer risk factors, pathophysiology and mediating factors, and had pressure injury as an outcome measure. Forty-three studies were found that met the review criteria. From the interventions literature, studies, national and international protocols, major pressure ulcer organizational policies and procedures, and national and international clinical practice guidelines were selected for review. Published pressure ulcer prevention guidelines were found from 15 national and international agencies or organizations.

Review of the relevant literature for this study will be presented in a narrative, thematic format design, exploring the etiology and risk factors for development of pressure ulcers under the separate themes of; (a) pressure and shear forces, and (b) factors affecting tissue tolerance. Subsequently, the findings from the prevention literature review will be presented, including notation of the strength of evidence for

recommendations of individual interventions as recorded by the original reviewing and publishing entities.

Pressure and Shear Forces

The Effects of Pressure

Pressure is defined as the load applied at right angles to the tissue interface (Krouskop, 1983). The most critical factor in the development of pressure ulcers is unrelieved pressure when soft tissues are compressed between two firm surfaces (Schubert, 1994). This occurs most commonly over bony prominences on the body where soft tissue is compressed between an external surface, such as a bed, chair, or exam table, and an internal unyielding surface of bone. It is generally thought that when pressures on internal tissues exceed capillary closing pressure (CCP) of 32 mm Hg for longer than two hours, circulation is compromised and tissue anoxia and death can ensue (Maklebust & Sieggreen, 2001). The value of 32 mm Hg became the benchmark for judging at what interface pressure intensity patients were at risk for pressure injury. However, this value emerged from a study by Landis (1930) who measured the pressures within a capillary loop in healthy human fingernail beds. This was done by cannulating the loop and attaching a micropipette connected to a double mercury manometer that measured both high and low intracapillary pressures. The validity of these findings has since been questioned because the cannulation of the capillaries could have resulted in lower pressure readings than those found in fully enclosed vessels (Thompson, 2005). More recent technology using digital pressure readings in intact capillaries demonstrates the average capillary closing pressure to be 47 mm Hg (Defloor, 1999). What these research disparities point out is that the use of CCP as a single measure of risk is

imprudent as CCP often depends on the blood flow through the capillary bed, the general health of the tissue (e.g., edema), and the vagaries of centrally mediated vasoactivity.

In vivo human studies have been somewhat helpful in identifying the changes in tissue resulting from pressure injury. Most studies in humans, however, have examined tissue changes in existing pressure ulcers and thus are of limited predictive value (Arao, Obato, Shimada, & Hagisawa, 1998; Edsberg, Cutway, Anain, & Natiella, 2000; Witkowski & Parish, 1982). Of note in the human *in vivo* studies were the dermal papillae and collagen fiber changes seen in Stage III pressure ulcers examined by Hagisawa and Shimada (2005) and Witkowski and Parish (1982). These changes suggest that the network of collagen and elastin fibers in the papillary and reticular layers may play a significant role in preventing compressive pressures from being transmitted from the skin surface to deeper tissues. This may well explain why patients who have once sustained a pressure ulcer are at very high risk for recurrence. With the over-expression of collagen and the fibrosis that occur in the process of wound healing, the repaired tissue from the previous injury would have a significantly diminished elastic capacity to distribute pressure away from deeper tissues.

In vivo animal studies provide important information about the changes occurring in normal tissue as a result of the pressure applied. Kosiak's (1959) seminal study using healthy dogs subjected to femoral trochanteric and lateral ischial tuberosity pressures of varying mm Hg for varying lengths of time showed that 60 mm Hg pressures for only 1 hour produced histologic evidence of tissue injury. Kosiak was the first to note that the ulceration from pressure injury tended to develop first in the deep tissues over bone and extend upward to eventually involve superficial tissue. In a similar experiment in rats,

Husain (1953) found muscular necrosis, edema, and fiber destruction present after application of a pressure of 100 mm Hg for 2 hours.

The major contribution of research investigating the time-intensity relationship in pressure injury has been the discovery that higher pressures for short periods can produce as much tissue injury as lower pressure for extended periods. These studies are important because they predict how great the changes in human tissue may be in the face of even a modest pressure insult. This would be particularly significant in patients undergoing lengthy ancillary procedures on exam table surfaces where interface pressures may reach 170 mm Hg (Keller, Lubbert, Keller, & Leenen, 2005). The very high incidence (53.8%) of pressure ulcers found in Brown's (2002) between-subjects design prospective study of 80 patients undergoing prolonged interventional radiology procedures in a hospital setting, is less surprising in light of these animal studies. Unfortunately, the Brown study was never published *in toto*, making the strength of evidence difficult to determine from the abbreviated version available.

In the only study found that reports interface pressures on x-ray tables, Justham, Michael and Harris (1996) measured these pressures at known pressure points in 16 healthy volunteers. They found mean interface pressures ranging from 97.7 mm Hg on the sacrum, to 126.9 mm Hg on the heel on the standard x-ray table surface. They also found the use of a 55 mm mattress on the x-ray tables brought all mean interface pressures down to below CCP ($p < .001$), without attenuation of x-ray film quality.

In view of the similarities of extrinsic risk factors for pressure injury between the surgical suite and ancillary units, and the absence of risk research in ancillary units, review of studies examining risk factors in surgical patients is particularly cogent to the

theoretical foundation for the proposed ancillary services tool. In 1999 a comprehensive review of existing literature on pressure ulcer risk factors in surgical patients was published by Stotts, an established expert in pressure ulcer risk assessment. Although Stotts noted pressure ulcer incidence rates in surgical patients ranged between 19% and 66%, no clearly supported common risk factors could be identified in the review due to the methodological problems with existing studies. A later review of the surgical pressure ulcer literature done by Schultz (2005) yielded a similar conclusion; that the methodological concerns and contradictory findings in these studies make it difficult to identify specific perioperative risk factors for postoperative pressure ulcer development.

Review of the more current surgical literature by this investigator did reveal trends in identification of some common risk factors. Despite methodological differences, common pressure ulcer predictors in these studies were advanced age, diabetes, and longer operating room times. However, descriptive designs and methodological variations continue to obviate any definitive assignment of cause and effect from these studies. Table 1 contains a summary of a representative sample of surgical risk factor research studies.

Table 1.

Summary of Representative Sample of Operating Room Pressure Ulcer Risk Factor Studies

Author/Year/Title	Purpose	Research Design	Measures	Findings
Aronovitch (1999) Intraoperatively acquired pressure ulcer prevalence: A national study.	Determine prevalence and identify comorbid conditions as risk factors.	Multisite descriptive survey of 1128 patients undergoing surgical procedures of ≥ 3 hours.	Data collection by WOCNs in hospitals in 33 states using study data forms.	Prevalence was 8.5% As length of surgery increased so did the percentage of patients with pressure ulcers. No significant correlation found with comorbidity.
Aronovitch (2007) Intraoperatively acquired pressure ulcers: Are there common risk factors?	Determine the rate and risk factors for intraoperatively acquired pressure ulcers.	Prospective survey of 281 postoperative patients in 37 U.S. hospitals (cross-sectional 1-day).	Data collection and skin assessments by WOCNs using study survey forms.	Incidence 9/281 (3.5%) 6/9 (66.7%) had morbid conditions and warming devices used and mean OR time of 4.48 hours.
Connor, Sledge, Wiersema, Stamm, & Potter (2010). Identification of pre-operative and intra-operative variables predictive of pressure ulcer development in patients undergoing urologic surgical procedures.	Identify peri-operative risk factors predictive of pressure ulcers.	Prospective, descriptive, correlation study of 498 urology surgery patients with random sampling.	Data collection, skin assessment and Braden Scale score by trained nurses, in PAR and on PODs 1, 2 & 3.	Incidence 5% Stage I Bryant-ulcers post operatively. Significant predictors; time diastolic BP <50 mm Hg (p = .046) and anesthesia duration (p = .038). Low Braden scale score not predictive.

Table 1 (Continued).

Summary of Representative Sample of Operating Room Pressure Ulcer Risk Factor Studies

Author/Year/Title	Purpose	Research Design	Measures	Findings
Grous, Reilly, & Gift (1997). Skin integrity in patients undergoing prolonged operations.	Identify pressure ulcer risk factors in patients undergoing prolonged surgeries.	Descriptive study of 33 patients scheduled for surgeries of ≥ 10 hours duration.	Preoperative risk assessment with Braden Scale and skin assessments.	15/33 (45%) incidence of pressure ulcers. Braden Scale score not predictive. Only significant risk factor was use of a warming blanket in those patients who got ulcers (χ^2 4.3, $p < .05$).
Karadag & Gümüskay (2006). The incidence of pressure ulcers in surgical patients: A sample hospital in Turkey.	Determine incidence of pressure ulcers in adult elective surgery patients.	Prospective descriptive study of 84 patients undergoing elective surgeries of ≥ 2 hours duration in a Turkish hospital.	Braden Scale score, to determine absence of risk for pressure ulcers. Skin assessments, data collection	Incidence of pressure ulcers was 46/84 (54.8%). All were Stage I ulcers. No correlation with risk factors data presented.
Lindgren, Unosson, Krantz, & Ek (2005). Pressure ulcer risk factors in patients undergoing	Identify pressure ulcer risk factors in surgery patients.	Prospective comparative study of 286 adult patients undergoing surgery of ≥ 1 hour (Sweden).	Skin assessments, RAPS scale scores, and data collection by RNs.	41/286 (14.3%) of patients developed pressure ulcers. Significant risk factors surgery. were female gender ($p < .001$), low ASA scores ($p = .011$), and low food intake ($p = .022$) None of the other peri-operative variables measured were statistically significant risk factors.

Table 1 (Continued).

Summary of Representative Sample of Operating Room Pressure Ulcer Risk Factor Studies

Author/Year/Title	Purpose	Research Design	Measures	Findings
Nixon, Cranny, & Bond (2007). Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: A cohort study.	Identify predictors of ≥ Grade 2 pressure ulcers in surgical patients.	Prospective cohort of major surgical patients age > 55 years with expected OR time of ≥ 90 min. and LOS ≥ 5 days. N = 97 in a UK hospital.	Data collection, Braden Scale scores, and skin assessments.	Ulcer incidence 15.5%. Independent predictors of pressure ulcers were non-blanching erythema (p = .002); preop albumin (p = .009); preop weight loss (p =.092); and low diastolic BP (p = .205). Low Braden scores were not predictive in sample.
Schoonhoven, Defloor, & Grypdonck (2002). Incidence of pressure ulcers due to surgery.	Describe incidence of pressure ulcers in patients undergoing surgery.	Prospective descriptive study in the Netherlands; 208 patients scheduled for surgeries lasting > 4 hours, including nine surgical specialties.	Data collection, skin assessments and photographs. 14-day followup.	44 patients (21.2%) developed ulcers in the first 2 days post op; 59% were heel ulcers, 15.7% were sacral ulcers.
Schultz, Bien, Dumond, Brown, & Myers (1999). Etiology and incidence of pressure ulcers in surgical patients.	Identify etiology of pressure ulcers; trial of specialty OR mattress.	Randomized controlled trial of special OR mattress. Group X = N 206; O = 207. Groups equivalent. OR Time ≥ 2 hours in either lithotomy or supine position	Experimental group on special mattress; control group got "usual care." Braden scale score, data collection and skin assessments.	Ulcer incidence 21.5%. Advanced age, diabetes, lower body mass, and use of study mattress were predictive of ulcer development (p < .05). Braden predictive (p=.013).

In examining the research literature on the physiologic effects of pressure on soft tissue, there is credible support for the thesis that in patients undergoing procedures on non-pressure-reducing surfaces such as those in surgical, diagnostic, and interventional treatment units, the combination of pressure intensity and duration may be an independent risk factor for pressure ulcer formation.

The Effects of Shear

Shear is defined as mechanical stress directed parallel to the plane of interest (Salcido, 2006). These parallel forces, a combination of gravity and friction, result in distortion and damage to blood and lymph vessels attached to muscle fascia which leads to what is now described as an inverted cone of deep tissue injury (Bliss, 1998; Donnelly, 2001; Pieper, 2000). The most common occurrence of shear in patients is when the body is dragged over a stationary surface (e.g., pulling a patient up in bed), or when the body slides down from a Fowler or Semi-Fowler position.

To determine the impact of shear on pressure ulcer development, Dinsdale (1974) tested the effects of pressure alone, and pressure in combination with shear forces in normal and in paraplegic pigs. He found that a pressure (when used without shear) of 290 mm Hg was required to produce pressure ulcers; whereas, the combination of shear with pressure required only 45 mm Hg to produce similar injury. Although the report lacks a description of exactly how the shear was applied, the findings were considered an important contribution to the understanding of pressure ulcer etiology at the time.

In an enlightening study published in 1979, Bennett, Kavner, Lee, and Trainor developed an instrument to measure not only external pressure, but shear forces and arterial pulsatile arteriolar blood flow in human tissue. They measured the reduction in

pulsatile arteriolar blood flow over the thenar eminence in four healthy subjects, concluding that the combination of pressure with shear produced occlusion with half the pressure required without the shear forces present. From this and a later study by Bennett and Lee (1988) it was posited that earlier studies of pressure intensity did not account for the effects of shear forces, rendering their injury threshold pressure findings higher than they should have been.

The magnitude of the additive effect of shear forces on the development of pressure injury has been well-documented in a number of scientifically executed and well-controlled animal studies (Gefen, Gefen, Linder-Ganz, & Margulies, 2005; Linder-Ganz & Gefen, 2004; Linder-Ganz, & Gefen, 2007; Palevski, Glaich, Portnoy, Linder-Ganz, & Gefen, 2006; Stekelenburg et al., 2007). These effects were borne out in several studies in human subjects as well. As a result of their observations of rhabdomyolysis occurring after prolonged laparoscopic procedures in the flank position, Deane et al. (2008) measured interface pressures in two matched groups of 10 subjects each on the operating table. Pressures were significantly higher in the two positions that created the greatest degree of tissue deformity (internal shear), and well beyond the safe CCP threshold ($p < .0001$). In a descriptive study of 581 patients in acute care hospitals, Fisher, Wells, and Harrison (2004) identified friction/shear as a statistically significant factor associated with pressure ulcer formation in this population.

Song and Choi (1991) studied factors contributing to the development of pressure ulcers in 146 hospital patients admitted with neurological problems. They found no correlation between paralysis, laboratory parameters or age with pressure ulcer development; however, they cited friction and shear as being statistically associated with

pressure ulcer development in these patients. Three experimental studies in human subjects, using validated instruments to measure the parameters of shear forces, demonstrated significant correlation between shear forces and pressure injury (Fontaine, Risley, & Castellino, 1998; Goossens, Zegers, Hoek van Dijke, & Snijders, 1994; Schubert & Heraud, 1994). The study by Fontaine et al. was particularly revealing in its finding of significantly lower pressure and shear forces on the non-powered fluid overlay device versus the powered air-filled mattress (p =.017 and p =.015 respectively). The powered air-filled mattress consists of a series of air chambers and an electric pump mechanism that alternates the pressures in the chambers at regular intervals. The static fluid overlay relies on a layer of enclosed fluid over a foam base where pressure changes occur as a result of changes in patient position much like a commercial water mattress. The clinical significance of this finding is notable because the powered air mattress is the more commonly used device in U.S. hospitals for patients at high risk for pressure ulcers.

From the literature reviewed, it appears that the shearing forces inherent in the transport and positioning of ancillary procedures patients on support surfaces that already generate interface pressures well in excess of CCP place those even not acutely ill at risk for pressure injury. The additive effects of intrinsic factors and co-morbidities that diminish tissue tolerance for pressure and shear further escalate the risk in ancillary services procedure patients.

Factors Affecting Tissue Tolerance

The factors affecting tissue tolerance for pressure injury due to conditions adversely affecting tissue oxygen homeostasis are better understood and more widely studied in the context of their impact on disease processes rather than for their impact on

tissue tolerance for pressure. However, the conceptual framework identifying and supporting the major intrinsic factors that put patients at risk for pressure ulcers has already been well-documented as foundations of the pressure sore conceptual models of Braden and Bergstrom (1987) and Defloor (1999) and need not be elaborated in this review (see Figure 3). The task that remains is to examine the scientific literature addressing the specific physiologic mechanisms that would likely increase patients' vulnerability to pressure injury in the relatively short periods of exposure to high interface pressures and shear encountered in ancillary procedure environments.

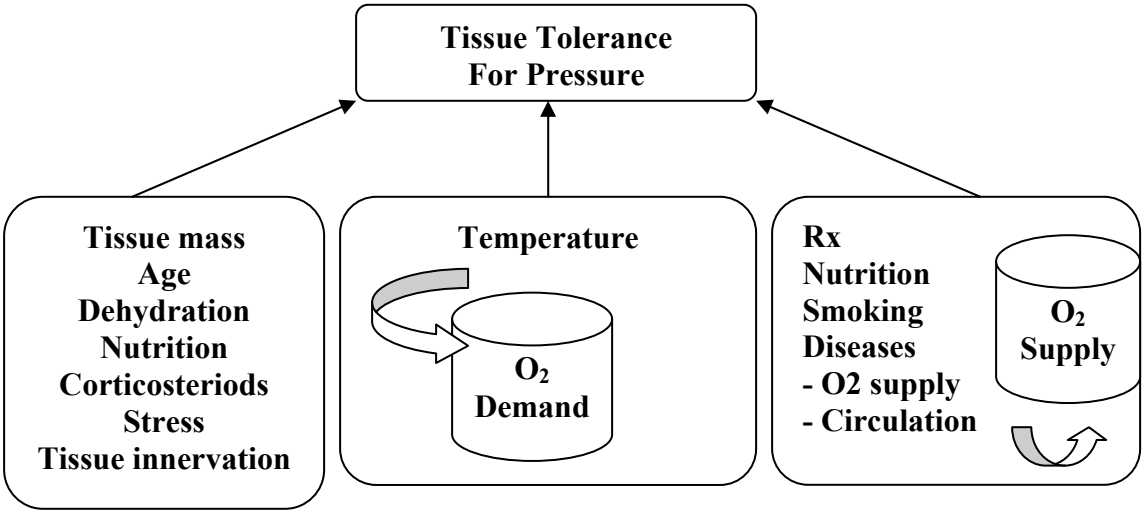


Figure 3. Factors Affecting Tissue Tolerance for Pressure and Tissue Oxygen Homeostasis (adapted from Defloor, 1999, p. 211).

In the manner of Defloor (1999), the risk factors to be examined will be subdivided into those that affect the capacity of the tissue to redistribute pressure (tissue tolerance for pressure), and those that affect the oxygen distribution and demand within the tissues (tissue oxygen homeostasis).

Tissue Tolerance for Pressure

Tissue tolerance is a critical factor in the spectrum of pressure injury. Normal human tissue possesses protective mechanisms both in structure and function. The research of Kosiak (1959; 1961) demonstrated that 70-80% of external pressure on tissue is transferred and redistributed through the biomechanical properties of elastin and collagen. Conditions that alter this important function can put patients at significant additional risk for pressure injury. Aging is the most prominent risk factor causing loss of this protective mechanism. Collagen synthesis decreases with aging, resulting in less pliable tissue that cannot properly redistribute pressure (Ek & Boman, 1982; Foreman, Theis, & Anderson, 1993).

Early warnings of tissue ischemia from pressure in normal subjects engage a sensorimotor feedback system that produces unconscious adjustments in body position to relieve the offending pressure (Maklebust & Sieggreen, 2001). Studies have shown that factors or conditions that subvert this feedback mechanism, such as aging and neurological impairment, place patients at high risk for pressure injury (Barbenel, Ferguson-Pell, & Beale, 1985; Exton-Smith, 1982). The loss of this mechanism is a well-established risk factor in spinal cord injury and post-stroke patients. What is seldom considered, and apparently has not been studied in the ancillary procedures population, is the loss of this mechanism due to anesthesia and potent analgesics. These effects have been noted to be correlated with incidence of pressure ulcers in surgical, ICU, and elderly patients (Lindquist, Feinglass, & Martin, 2003; Ramsay, 1998; Schoonhoven, Defloor, van de Tweel, Buskens, & Grypdonck, 2002; Stotts, 1999). With the routine use of general anesthesia and conscious sedation for patients undergoing interventional

procedures in ancillary units (e.g., interventional radiology procedures), the loss of this protective sensorimotor mechanism while the patient is positioned on a support surface with very high interface pressures may be a significant risk factor for pressure injury.

Tissue Oxygen Homeostasis

Common diseases and conditions that alter oxygen supply to tissues have been identified and already woven into established pressure ulcer risk assessment tools in use for patients in hospitals and long-term care facilities (Braden & Bergstrom, 1987; Defloor, 1999). This review, therefore, will focus on those factors specifically applicable to the temporal exposure of patients in ancillary procedures settings. The most relevant risk factors that would uniquely increase risk during the limited time exposure to pressure in this population appear to be: (a) temperature regulation; (b) impaired reactive hyperemia, (c) sepsis, (d) hypotension, and (e) impaired pressure-induced vasodilation.

Temperature regulation. Oxygen demand in cells is known to increase in the presence of fever. For each degree of temperature increase, metabolism is raised by 10% (Maklebust & Sieggreen, 2001). According to a consensus statement by an expert international working group, raised body temperature is a recognized risk factor for pressure sores (International Review, 2010). Similarly, externally applied heat increases tissue metabolic rate and thus the demand for more oxygen and nutrients. Kokate et al. (1995) examined the relationship between applied temperature, applied pressure, and time of application in the formation of pressure ulcers in the swine model, controlling temperatures at either 25, 36, 40, or 45 degrees C. The extent of pressure injury correlated with an increase in temperature. All other variables held constant, temperatures above 35 degrees C. resulted in both superficial and deep tissue damage and

ultimate necrosis. There was high reproducibility in the outcomes in over 64 sites per temperature, and 16 animals. In a prospective study to identify risk factors for pressure ulcers in 33 patients undergoing prolonged surgical procedures (> 10 hours), Grous, Reilly, and Gift (1997) found that of the 15 patients who developed pressure ulcers, 75% had been placed on a warming blanket during the procedure ($p < .05$). They recommend avoiding routine use of the warming blanket in lengthy procedures.

Impaired reactive hyperemia. Impaired reactive hyperemia is a little-known risk for pressure ulcer vulnerability. The phenomenon of reactive hyperemia is a protective physiologic mechanism which causes local vasodilatation to restore blood flow to replenish oxygen deficit and remove hypoxic metabolic wastes following ischemic insults (Bliss, 1998). The integrity of this important physiological mechanism is of particular significance in ancillary services patients as their exposure to pressure is relatively transient, albeit intense. Without concomitant risks, a normal reactive hyperemia response should theoretically help to protect the ancillary patient from pressure injury. However, factors that interfere with this sympathetically mediated mechanism such as β-blockers, which are known to reduce skin blood flow by 20-30%, or spinal cord injury with its attendant impairment of microvascular reflexes, can put patients at higher risk for pressure injury (Defloor, 1999) even in the face of transient pressure exposure.

Another population seldom identified with impaired reactive hyperemia is that of HIV-infected patients. Noting that there was evidence from pathology-based studies identifying the existence of coronary and arterial vasculopathy in HIV-infected patients, Monsuez, Dufaux, Vittecoq, and Vicaut (2000) tested vascular reactivity using laser Doppler flow measurement in 10 HIV-infected patients with cardiac symptoms, 19 HIV-

infected patients without evidence of cardiac disease, and 19 healthy control subjects. Laser-Doppler flow was measured in all three groups at baseline and during the reactive hyperemic phase following transient occlusion of brachial blood flow. Post-ischemic blood flow was found to be significantly lower in both the HIV-infected groups than in the control group ($p \leq .0001$). The abnormality was most pronounced in the symptomatic HIV patients. The hyperemic response was assessed by the curve of area under the flow versus time from deflation to the end of the hyperemic response.

Other disease processes known to impair reactive hyperemic response include type 2 diabetes (Meyer, Lieps, Schatz, & Pfohl, 2008), multiple sclerosis (Hagisawa, Ferguson-Pell, & Herbert, 1994), and sclerosing diseases such as scleroderma and rheumatoid arthritis (Boignard et al., 2005). Much is yet to be learned about which populations are at risk for this dysfunction.

Sepsis. Sepsis is an often-overlooked risk for pressure ulcers. The complex physiologic effects of sepsis commonly involve two previously identified risk factors; fever, and low blood pressure. However, these factors alone do not adequately explain the significant reduction in post-ischemic transcutaneous oxygen tensions found in this population. Young and Cameron (1995) compared the control of skin blood flow with laser Doppler in 11 septic, 19 recovering coronary artery bypass patients, nine healthy young volunteers and 10 elderly volunteers. Patients with sepsis had a mean skin blood flow of 6.24 (3.48) ml min-1 per 100 g tissue compared with 4.35 (1.41) ml min-1 per 100 g tissue for the patients after coronary artery bypass grafting ($p < .05$), a decreased peak hyperemic response, and a prolonged time for recovery from hyperemia (22.8 (12.7) versus 11.7 (8.5) seconds, $p < .05$).

In addition, there are a number of descriptive studies in which sepsis was positively correlated with pressure ulcer development in patients (Chan, Tan, & Lee, 2005: Compton et al., 2008; Fogerty et al., 2008; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005). It is not uncommon for septic patients to undergo diagnostic or interventional ancillary procedures. The presence of sepsis could significantly reduce their tolerance for the combination of high pressures and shear generated on ancillary unit support surfaces.

Hypotension. In an investigation of the effect of low blood pressure on risk for pressure injury, Schubert (1991) measured systolic, diastolic, and mean blood pressures in hospitalized geriatric patients; 30 with, and 100 without pressure ulcers. Additionally, 18 hospitalized geriatric patients without pressure ulcers were compared with 10 healthy elderly subjects. Blood pressure was compared to skin blood cell flux evaluated with laser Doppler, at baseline, and during postocclusive reactive hyperemia over the sacral area. There was a significant ($p < .05$) correlation between low systolic and mean blood pressure in the elderly hospitalized patients and impaired reactive hyperemia. There are other studies which have demonstrated a correlation between the number of hypotensive periods in patients and incidence of pressure ulcers (Bergstrom & Braden, 1992; Connor, Sledge, Bryant-Wiersema, Stamm, & Potter, 2010; Haleem, Heinert, & Parker, 2008; Jerusum, Joseph, Davis, & Suki, 1996; Stordeur, Laurent, & D'Hoore, 1998). From the literature it appears hypotension is a risk factor for pressure injury during lengthy ancillary procedures.

Impaired pressure-induced vasodilation (PIV). When external pressure is applied to the human body an autoregulatory process (PIV) is invoked by activation of

sensory C-fibers, resulting in release of neurotransmitters that act at the endothelial level to cause release of endothelial factors to induce smooth-muscle relaxation of the cutaneous microvessels (Fromy et al., 2010). Several studies have demonstrated the presence and characteristics of this phenomenon (Abraham, Fromy, Merzeau, Jardel, & Saumet, 2001; Fromy et al., 2002; Fromy, Abraham, & Saumet, 1998; Garry et al., 2005). Landis (1930) demonstrated that within one minute from the time of application of external pressure (60 mm Hg) an increase in arteriolar pressure occurs, stabilizing at roughly 9-10 mm Hg higher than the external pressure. Although the duration of this mechanism has not yet been well demonstrated empirically, it is considered a putative protective reflex against tissue injury from external pressure loading.

Given the similarity of the external environments and extrinsic risk factors in the operating room to those in ancillary services units, a 1997 study by Sanada et al. is of significance. They examined skin blood flow over iliac and sacral pressure points in 24 patients undergoing lengthy surgical procedures (of similar duration) using laser Doppler flowmetry to compare pre-and-intraoperative rates between patients who did and did not develop intraoperative pressure ulcers. They found that patients who did not develop ulcers had a 500% mean increase in blood flow during the procedures as compared to preoperative levels; whereas, blood flow rates actually decreased during surgery in patients who developed ulcers.

Of particular interest is the documented impairment of this important mechanism in diabetes and in aging. Fromy et al. (2002) measured skin blood flow by laser Doppler flowmetry in response to local pressure applied at 5.0 mm Hg/min in three groups of diabetic patients (one group with clinical and another with subclinical neuropathy, and

one group without neuropathy) and in healthy matched control subjects. There were 15 subjects in each of the four groups. Measurements were done at usual room temperature and the diabetic groups included only those subjects without potentially confounding co-morbidities. The researchers found that skin blood flow decreased significantly from baseline with much lower applied pressure (6.3 - 7.5 mm Hg) in diabetic patients (with and without neuropathy) than in the matched controls (48.8 mm Hg - $p < .05$). Koitka et al. (2004) published similar findings from their study in young adults with type 1 diabetes using laser Doppler flowmetry and applied pressure at 5.0 mm Hg. Again using laser Doppler flowmetry, Fromy et al. (2010) studied PIV response to pressure comparing non-neuropathic and neuropathic older subjects (60-75 years) with young subjects (20-35 years). They measured cutaneous responses to local pressure application, acetylcholine, and local heating. The non-neuropathic older subjects had impaired increase in blood flow with pressure (12 ± 7%) compared to young subjects (62 ± 4%, $p < .001$). Older subjects with neuropathy showed no PIV response to pressure, resulting in early cutaneous ischemia (-31 ±10%, $p < .001$). In addition to the previously described loss of tissue tolerance for pressure due to age-related collagen degradation in the elderly, this inability of the skin to adapt to localized pressure further compounds the risk of pressure injury in this population during extended ancillary procedures.

Selecting Measureable Indicators for Pressure Ulcer Risk

Regrettably, published human research of sufficient scientific rigor to establish definitive cause-effect relationships between identified risk factors and development of pressure ulcers virtually does not exist. Therefore, the researcher is left to determine these relationships from a preponderance of lower level evidence. Such is the case in the measureable risk indicators enumerated in Table 2. The support for these indicators consists mainly of descriptive studies in humans, experimental studies in animal models, and indicators identified by national and international expert reviewers as published in official clinical practice guidelines. Clearly, the ultimate proof of these indicators will be in their predictive validity in the clinical setting.

Table 2.

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
Impaired Pressure & Shear Tolerance		
Advanced Age	Age ≥ 40 years	(Ek & Boman, 1982; Foreman, Theis, & Anderson, 1993; Hagisawa & Shimada, 2005; Perneger, Héliot, Raë, Borst, & Gaspoz, 1998; Taylor & James, 2005)
	Age > 50 years	(Anthony, Reynolds, & Russell, 2003; Russo & Elixhauser, 2006; Schoonhoven et al., 2006)
	Age ≥ 59 years	(Fogerty, Abumrad, Nanny, Arbogast, Poulose, & Barbul, 2008)
	Age ≥ 60 years	(Casimiro, Garcia-de-Lorenzo, & Usán, 2002; Fisher, Wells, & Harrison, 2004; Nonnemacher et al., 2009; Perneger et al., 2002)
	Age ≥ 65 Years	(Lindgren, Unosson, Fredrikson, & Ek, 2004; Page, Barker, & Kamar, 2011; Piloian, 1992; Shats & Kozacov, 1996)
	Age ≥ 70 years	(Fromy et al, 2010; Margolis, Knauss, Bilker, & Baumgarten, 2003; Slowikowski & Funk, 2010)
Anesthesia/Sedation	Presence & duration Duration of loss of sensation and/or mobility > 2 hours	(Aronovitch, 1999; Aronovitch, 2007; Barbenel, Ferguson-Pell, & Beale, 1985; Connor, Sledge, Bryant-Wiersema, Stamm, & Potter, 2010; Exton-Smith, 1961; ICSI, 2010; Schoonhoven, Defloor, van deTweel, Buskens, & Grypdonck, 2002; Stotts, 1999)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
	Type anesthetic	(Angel et al., 2004; Fizanne, Fromy, Preckel, Sigaudo-Roussel, & Saumet, 2003; Ramsay, 1998; RNAO, 2005)
	Sedative drug(s)	(Boyle & Green, 2001; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005; Lamblin, Favory, Boulo, & Mathieu, 2006; Lindquist, Feinglass, & Martin, 2003; RNAO, 2005; Rodrigues Júnior & do Amaral, 2004)
Neurologic Impairment	Partial or complete paralysis	(Berlowitz & Wilking, 1989; Fogerty et al., 2008; Frankel, Sperry, & Kaplan, 2007; ICSI, 2010; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005; Maklebust & Magnan, 1994; Margolis, Knauss, Bilker, & Baumgarten, 2003; Vanderwee, Grypdonck, De Bacquer, & Defloor, 2009)
	Diabetic and other neuropathies	(ICSI, 2010; Page, Barker, & Kamar, 2011; Shats & Kozacov, 1996)
	Spasticity or contractures	(ICSI, 2010; Margolis, Knauss, Bilker, & Baumgarten, 2003; RNAO, 2005; Vanderwee, Grypdonck, De Bacquer, & Defloor, 2009)
	Peripheral vascular disease	(AMDA, 2003; ICSI, 2010; Cox, 2010; Maklebust & Magnan, 1994; NICE, 2001; Australian Wound Management Association, 2001; RNAO, 2005; Ryan, 1979; Seiler & Stahelin, 1979)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
Pressure Intensity & Duration	Procedure duration > 1 Hour; > 2 Hours	(Gefen, 2008) (Armstrong & Bortz, 2001; Aronovitch, 1999; Campbell, 1989; Daniel, Priest,& Wheatley, 1981; Dinsdale, 1974; Ek, Lewis, Zetterqvist, & Svensson, 1984; EPUAP & NPUAP, 2009; Hoshowsky & Schramm, 1994; ICSI, 2010; Kemp, Keithley, Smith, & Morreale, 1990; Kosiak, 1959; Oomens, Bader, Gefen, & Soriano, 2008; Papantonio, Wallop, & Kolodner, 1994; Ratliff & Rodeheaver, 1998; Reswick & Rogers, 1976; Stevens et al., 2004: Tweed, 2003)
	Type of support surface	(Aronovitch, 1998; Aronovitch, Wilber, Slezak, Martin, & Utter, 1999; Campbell, 1989; EPUAP & NPUAP, 2009; Hoshowsky & Schramm, 1994; Howatson-Jones, 2001; Justham, Michael, & Harris, 1996; Keller, Lubbert, Keller, & Leenen, 2005; Krouskop, 1983; Nixon, McElvinney, Mason, Brown, & Bond, 1998; Oomens, Bader, Gefen, & Soriano, 2008; RNAO, 2005; Steinmetz & Langemo, 1996)
	Patient position on table surface	(Aronovitch, 1999; Deane et al, 2008; Defloor & De Schuijmer, 2000; King & Bridges, 2006; Oomens, Bader, Gefen, & Soriano, 2008; RNAO, 2005; Schubert, & Héraud, 1994)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
	Transport surface, and duration and transfer methods (shear)	(Bennett & Lee, 1988; Bennett, Kavner, Lee, & Trainor, 1979; Dinsdale, 1974; EPUAP & NPUAP, 2009; ICSI, 2010; Knight, Taylor, Polliack, & Bader, 2001; Linder-Ganz & Gefen, 2007; Oomens, Bader, Gefen, & Soriano, 2008; Reichel, 1958; Schubert & Heraud, 1994; Song & Choi, 1991)
Impaired Tissue Oxygen Homeostasis		
Comorbidities	Diabetes	(Brandeis, Ooi, Hossain, & Lipsitz, 1994; Chauhan, Goel, Kumar, Srivastava, & Shukla, 2005; Frankel, Sperry, & Kaplan, 2007; Fromy et al., 2002; Haleem, Heinert, & Parker, 2008; ICSI, 2010; Lewicki, Mion, Splane, Samstag, & Secis, 1997; Maklebust & Magnan, 1994; Margolis, Knauss, Bilker, & Baumgarten, 2003; Papantonio, Wallop, & Kolodner, 1994; Schultz, 1999; Slowikowski & Funk, 2010; Smith, Guihan, LaVela, & Garber, 2008)
	Pulmonary disease	(ICSI, 2010; Margolis, Knauss, Bilker, & Baumgarten, 2003; Papantonio, Wallop, & Kolodner, 1994; Talley, 2010)
	Vascular disease	(Aronovitch, 1999; Australian Wound Management Association, 2001; ICSI, 2010; Frankel, Sperry, & Kaplan, 2007; Maklebust & Magnan, 1994; NICE, 2001; Nijs et al., 2009; RNAO, 2005; Ryan, 1979; Schultz et al., 1999; Seiler & Stahelin, 1979)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
	CHF/CVD	(Chan, Tan, Lee, & Lee, 2005; Cox, 2010; ICSI, 2010; Margolis, Knauss, Bilker, & Baumgarten, 2003; Pokomy, Koldjeski & Swanson, 2003; Talley, 2010; van Marum et al., 2001)
	Renal failure	(Australian Wound Management Association, 2001; Frankel, Sperry, & Kaplan, 2007; ICSI, 2010; Kruger et al, 2006; Levine, Humphrey, Lebovits, & Fogel, 2009; Linden et al., 2008; RNAO, 2005; van Marum et al., 2001)
	Dementia	(ICSI, 2010; Maklebust & Magnan, 1994; Margolis,Knauss, Bilker, & Baumgarten, 2003; Page, Barker, & Kamar, 2011; Reed, Hepburn, Adelson, Center, & McKnight, 2003)
Fever (or external heat)	Elevated body temperature	(Bergstrom & Braden, 1992; International Review, 2010; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005; Maklebust & Sieggreen, 2001; Nixon, Brown, McElvenny, Mason, & Bond, 2000; Oomens, Bader, Gefen, & Soriano, 2008; Piloian, 1992; Feuchtinger, Halfens, & Dassen, 2005; Fisher, Szymke, Apte, & Kosiak, 1978; Grous, Reilly, & Gift, 1997; Kokate et al., 1995; Rapp, 2005; Bergstrom, & Padhye, 2009; RNAO, 2005; Sae-Sia, Wipke-Tevis, & Williams, 2005; Suriadi, Sanada, Sugama, Thigpen, & Subuh, 2008; Tzen, Brienza, Karg, & Loughlin, 2010)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
Hypotension	Diastolic BP < 50 mm Hg Systolic BP ≤ 100 mm Hg	(Bergstrom & Braden, 1992; Connor, Sledge, Bryant-Wiersema, Stamm, & Potter, 2010; Feuchtinger, Halfens, & Dassen, 2005; Haleem, Heinert, & Parker, 2008; ICSI, 2010; Jerusum, Joseph, Davis, & Suki,1996; Krouskop, 1983; Levine, Humphrey, Lebovits, & Fogel, 2009; Nixon, Cranny, & Bond, 2007; Nixon, Brown, McElvenny, Mason, & Bond, 2000; RNAO, 2005; Schubert, 1991; Stordeur, Laurent, & D'Hoore, 1998; Terekeci et al., 2009; Vanderwee, Grypdonck, De Bacquer, & Defloor, 2009)
Impaired PIV	Advanced Age	(Abraham, Fromy, Merzeau, Jardel, & Saumet, 2001; Bader & Smith, 1998; Barbenel, 1991; Fromy et al, 2010; Jan, Struck, Foreman, & Robinson, 2009; McLellan et al, 2009; Sae-Sia, 2009)
	Diabetes	(Clarkson et al., 1996; Daly, Chimoskey, Holloway, & Kennedy, 2006; Demiot et al., 2006; Fromy et al, 2002; Fromy et al., 2010; Johnstone et al., 1993; Koitka et al, 2004; McLellan et al, 2009; Saumet, 2005; Sigaudo-Roussel et al., 2004; Singleton, Smith, Russell, & Feldman, 2003)
	Neurologic impairment	(Fromy et al., 2002; Fromy, Abraham, & Saumet, 1998; Fromy et al., 2010; Garry et al., 2005; Koitka et al., 2004; Landis, 1930; Mawson et al., 1993; Miller & Seale, 1981).

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
	Vasoactive drugs	(Cox, 2010: Feuchtinger, Halfens, & Dassen, 2005; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005; Levine, Humphrey, Lebovits, & Fogel, 2009; Nijs et al., 2009; RNAO, 2005; Sae-Sia, 2009; Stordeur, Laurent, & D'Hoore, 1998; Theaker, Mannan, Ives, & Soni, 2000)
Impaired Reactive Hyperemia	Advanced age	(Meijer, Germs, Schneider, & Ribbe, 1994; Schubert & Fagrell, 1991a; Tikhonova, Tankanag, & Chemeris, 2010)
	HIV	(Monsuez, Dufaux, Vittecoq, & Vicaut, 2000; Nicastri et al., 2004; Solages et al., 2006)
	CHF/CVD	(van Marum, et al., 2001)
	Diabetes	(Demiot, et al., 2006; Garry et al, 2005; Linden et al., 2008; Mayrovitz & Sims, 2004; McLellan et al, 2009; Meyer, Lieps, Schatz,& Pfohl, 2008; Meyer & Schatz, 1998; Newrick, Cochrane, Betts, Ward, & Boulton, 1988; Singleton, Smith, Russell, & Feldman, 2003; van Marum, Meijer, Bertelsmann, & Ribbe, 1997)
	Multiple Sclerosis & sclerosing disease	(Boignard et al., 2005; Defloor, 1999; Hagisawa, Ferguson-Pell, & Herbert, 1994; ICSI, 2010)
	Neurological impairment	(Mawson et al., 1993; Sae-Sia, Wipke-Tevis, & Williams, 2007; Schubert & Fagrell, 1991b; van Marum et al., 2001)

Table 2 (Continued).

Pressure Ulcer Risk Factors and Measureable Indicators

Risk Factor	Indicators	Reference Sources
Sepsis	Clinical Dx of sepsis	(Chan, Tan, Lee, & Lee, 2005; Compton et al., 2008; Engelberger et al., 2011; Fogerty et al., 2008; Gomes, Bastos, Matozinhos, Temponi, & Velásquez-Meléndez, 2010; Kröger, Stausberg, Maier, Schneider, & Niebel, 2005; Levine, Humphrey, Lebovits, & Fogel, 2009; Talley, 2010; Yepes & Perez, 2009; Young & Cameron, 1995)

Pressure Ulcer Prevention Interventions

State of the Evidence for Preventive Interventions

Since the predictive validity of most identified risk factors for pressure ulcer development has yet to be established by rigorous scientific evidence, it is not surprising that most of the commonly employed preventive interventions suffer the same deficiencies. In fact, the time-honored nursing care intervention of turning patients every two hours to prevent pressure injury has been repeatedly challenged by compelling studies and reviews indicating lack of empirical support for this time interval (Clark, 1998; Defloor, De Bacquer, & Grypdonck, 2005; Krapfl & Gray, 2008; Reddy, Gill, & Rochon, 2006; Venderwee, Grypdonck, De Bacquer, & Defloor, 2006).

Perhaps the most widely recognized prevention recommendations are those contained in the recent combined guidelines of the European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisor Panel (EPUAP & NPUAP, 2009). Of scientific note, however, is the fact that of the 68 preventive recommendations in these guidelines that are annotated with strength of evidence, 50 are rated C; supported by indirect evidence (e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion. Only six of the 68 recommendations are rated A (supported by level 1 studies). Such is the state of the science in pressure ulcer research.

In an extensive systematic review of the evidence examining interventions to prevent pressure ulcers, Reddy et al. (2006) found the methodological quality of RCTs evaluating preventive interventions to be suboptimal. They did, however, state that use of appropriate support surfaces (mattress overlays on operating tables, specialized foam

overlays), optimizing nutritional status, and moisturizing sacral skin were the most promising interventions. They recommended that further study is needed to confirm the effectiveness of preventive interventions in different patient populations and settings.

Despite the absence of Level I evidence for many of the currently employed pressure ulcer preventive interventions, AHRQ publications state that there is a growing level of evidence that pressure ulcer prevention can be effective in all health care settings (Lyder &Ayello, 2008).

Current international pressure ulcer prevention guidelines. In 1992 the U.S. Agency for Healthcare Research and Quality (AHRQ) published its first clinical practice guidelines on prevention of pressure ulcers. Although much of the evidence contained therein was based on Level 3 evidence, expert opinion, and NPUAP consensus, it provided a foundation for clinical preventive practices (Lyder & Ayello, 2008). In 2009 the product of a 4-year collaborative effort between the European Pressure Ulcer Advisory Panel (EPUAP) and the NPUAP of the U.S. was published as clinical practice guidelines for the prevention and treatment of pressure ulcers. According to the introduction in the guideline document, an explicit scientific methodology was used to evaluate related research. While the document authors fully acknowledge that in the absence of definitive evidence, expert opinion was used to make recommendations, the recommendations reflect the accumulated wisdom of over 900 stakeholders and 146 organizations in 63 countries. The guideline authors state "Because of the rigorous methodology used to develop this guideline, the NPUAP and EPUAP believe that the research supporting these recommendations is reliable and accurate" (EPUAP & NPUAP, 2009, p. 3).

The EPUAP & NPUAP guidelines address the following as major elements of a pressure ulcer prevention plan; (a) risk assessment, (b) skin assessment, (c) nutrition for pressure ulcer prevention, (d) repositioning for pressure ulcer prevention, (e) support surfaces, and (f) special population-patients in the operating room. Of these elements, all but nutrition were employed in the development of recommended prevention interventions for the ancillary services tool.

Pressure ulcer prevention interventions in ancillary services' patients. As with the literature on ancillary services risk factors, no studies were found examining the efficacy of preventive measures in ancillary services' patients; nor do there appear to be any published prevention practice guidelines for this specific population. The majority of preventive interventions are intended for patients who are hospitalized, have SCI, or are residents in long-term care facilities. Similar to currently available pressure ulcer risk assessment scales, these interventions are targeted at the risks engendered by exposures to lower pressures for extended periods, such as those encountered by hospitalized patients. Thus these guidelines focus heavily on issues such as nutrition, continence management, and hygiene. The majority of these prevention guidelines are poorly suited to the unique risks of shorter-term exposure to high shear and extreme interface pressures encountered by patients undergoing ancillary procedures.

There are a number of widely accepted clinical practice guidelines for pressure ulcer prevention. Since the publication of the 1992 prevention guidelines by the AHCPR (Panel for the Prediction and Prevention of Pressure Ulcers in Adults), guidelines have been published by 14 other national and international organizations. Newer guidelines have added recommendations for multidisciplinary involvement in pressure ulcer

prevention; however, none was found to have specific recommendations for preventive care of patients during transport and ancillary procedures. The Australian Wound Management Association guidelines (2001) do recommend a skin assessment be done prior to, during and following prolonged procedures which involve reduced mobility and hardened surfaces.

Regarding the state of the evidence for the 2009 EPUAP & NPUAP guidelines section for patients in the operating room, of the five recommendations contained in this section, only one (use of pressure-redistributing mattress on the operating table for at-risk patients) is rated strength of evidence B (supported by Level 2, 3, 4, & 5 studies). The other recommendations are rated as strength of evidence C. However, the NPUAP recommendations are the most widely accepted foundation for PU preventive care in the U.S., and most of these operating room recommendations are appropriate for the unique risks to patients in ancillary unit environments.

Filling the Gap: Identifying Prevention Interventions for Ancillary Services Patients

Conceptually, pressure ulcer prevention interventions for at-risk patients undergoing ancillary services procedures should be based on two primary considerations; (a) the individual patient's existing impairments in tissue tolerance for the specific risk factors engendered by these procedures, and (b) the particular extrinsic risk factors the patient may encounter during the procedure and transport processes. The ancillary services risk assessment tool is intended to provide an individualized quantification of the patient's level of risk. This risk assessment tool includes the major extrinsic risk factors involved, such as transport surface, transfer shear risks, ancillary unit support surface, procedure duration, use of anesthesia or sedation, and patient position. Given the short-

term nature of these exposures, it is reasonable to assume preventive actions should focus on those factors that can be manipulated directly to reduce the extrinsic risks for that specific ancillary services encounter. Extrinsic risks unique to the transport process and ancillary unit environment can be attenuated more easily than patient-specific risks such as age, sepsis, fever, and comorbid conditions. Precedent has already been set for postponing or altering the actual procedures based on individual levels of patient intrinsic risk factors (Haugen et al., 2011). Thus, the preventions portion of the tool was crafted with a built-in "consider no-go" risk category alert when the calculated risks of pressure injury to that patient appear to exceed the potential benefit of doing the procedure.

The key to developing the preventive interventions section of the ancillary services tool was a design that could quickly capture a snapshot of the overall level of risk for a given patient for a given procedure in a given facility. While indicators for the intrinsic patient-specific risks could be gleaned from the literature and quantitatively validated, a methodology for identifying procedure-specific (extrinsic) risks became more challenging. The tool interventions section development process involved two separate steps; (a) identification of evidence-based preventive interventions from the literature and clinical practice guidelines that are applicable to ancillary services patient encounters (see Table 3 for a sample of these interventions), and (b) soliciting guidelines and practices from ancillary unit professional organizations to identify intervention sets that have the widest applicability to potential user hospitals.

Table 3.

Sample of Preventive Interventions for Ancillary Services Patients

Intervention	Source	Strength of Evidence
Use a pressure-redistributing mattress on the table for all patients identified as at-risk for PUs	EPUAP & NPUAP, 2009	(B)
Position patient to reduce risk of PU development during the procedure	"	(C)
Elevate heels completely (offload them)	"	(C)
Reposition to reduce duration and magnitude of pressure over vulnerable areas of body	"	(A)
• The use of repositioning as a prevention strategy must take into consideration the condition of the patient and the support surface in use	"	(C)
• Frequency of repositioning will be influenced by variables concerning the individual and the support surface in use	"	(C) (A)
Use transfer aids to reduce friction and shear	"	(C)
Pay attention to pressure redistribution prior to and after procedure	"	(C)
• After procedure reposition patient in position other than the procedure position	MHA, 2009	Not stated
• Consider pressure redistribution surface for stretcher	"	Not stated
Change or shorten long procedures when clinically appropriate	Haugen et al., 2011	Not stated
Provide break between tests when possible with return to room if possible to reposition off area patient was on for test	"	"
Avoid extremes in skin temperature by avoiding skin contact with plastic support surfaces.	AWMA, 2001	Consensus statement

Note. Levels of evidence are defined as: **A** = Recommendation supported by direct scientific evidence from Level 1 studies; **B** = Recommendation supported by direct scientific evidence from Level 2, 3, 4, or 5 studies; **C** = Recommendation supported by indirect evidence (e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models) and/or expert opinion.

In an attempt to identify ancillary-unit-specific environmental and transport risks and preventive interventions a search was made for published specialty practices and guidelines from the major ancillary services specialty societies and organizations. These included; (a) Alliance of Cardiovascular Professionals, (b) American Academy of Ambulatory Care Nursing, (c) American Nephrology Nurses Association, (d) Association of Perioperative Registered Nurses, (e) Association for Radiologic & Imaging Nursing, (f) Society for Vascular Nursing, and (g) Society of Gastroenterology Nurses and Associates. Although assessment of skin condition was mentioned in two of the ancillary services nursing organization practice guidelines, no specific guidance was found relating to pressure ulcer risk assessment or prevention. The notable exception was the Association of Perioperative Registered Nurses (AORN) clinical practice guidelines. This organization publishes an extensive text annually titled "(year) Perioperative Standards and Recommended Practices" (AORN, 2009). The section in that text that addresses the recommended practices for positioning the patient in the perioperative practice setting contains several important recommendations related to pressure ulcer prevention in the operating room. Given the similarity between the OR environment and that of ancillary units, these AORN guidelines were adapted for use in the ancillary services tool.

The search for other established pressure ulcer prevention clinical practice guidelines (CPG) that would be appropriate for the ancillary services setting was then widened to include national and international wound care organizations and the Agency for Healthcare Research and Quality (AHRQ). Applicable pressure ulcer prevention CPGs were found in a publication by the Association for the Advancement of Wound

Care (AAWC, 2011), and in the AHRQ publication "Preventing Pressure Ulcers in Hospital: A Toolkit for Improving Quality of Care" (2011). Within the AHRQ toolkit there was an internet link to the Minnesota Hospital Association 2009 guidelines for prevention of pressure ulcers in OR patients. The AAWC preventive interventions were targeted at a more general patient population; however, they contained specific guidelines for use of pressure-redistributing support surfaces, positioning patients to reduce pressure during procedures, off-loading pressure points, and avoidance of products such as donuts, sheepskins, blanket rolls, or water-filled gloves. The Minnesota OR recommendations were targeted to an environment similar to that of ancillary procedure units. They addressed risk assessment, skin inspection, intraoperative surface selection, avoiding shear during patient transfer and positioning, and proper management of items such as cooling blankets and warming devices to avoid pressure injury. While the Minnesota recommendations did not list level of evidence, most could be cross-checked with the AAWC guidelines which did. With the use of preventive intervention recommendations from these various sources, a well-supported set of preventive recommendations were constructed for the ancillary services tool, with levels of interventions tied specifically to individual patient level of pressure ulcer risk. The process for development of this portion of the tool will be more fully explicated in the Methods chapter.

Summary

To answer the question; which specific risk factors for pressure ulcer development are most likely to place the ancillary procedures patient population at high risk for pressure injury, pressure ulcer literature was reviewed following the conceptual model of Defloor (1999). The etiology and risk factors for development of pressure

ulcers were explored under the domains of: pressure and shear forces; and, factors affecting tissue tolerance. Although many of the foundational studies in the field employ animal models, significant technologic improvements in measurement instrumentation of pressures, oxygen tensions, and blood flow have yielded a number of very credible studies. While many of the human subject studies had small samples and varied widely in parameters measures, sufficient credible evidence was found to support the following as specific risk factors for pressure injury in patients undergoing ancillary diagnostic and treatment procedures: (a) high interface pressures on ancillary support surfaces; (b) shear incurred from patient movement and positioning; (c) advanced age; (d) severe neurologic impairment; (e) anesthesia and sedation; (f) fever; (g) impaired reactive hyperemia response; (h) sepsis, (i) hypotension, and (j) impaired pressure-induced vasodilation response. Whether each of these factors constitutes an independent risk could not be determined from this review. However, in the ancillary services environment two of the factors are likely to be always present; interface pressures well above CCP, and shear forces from movement and positioning.

The state of the science for pressure ulcer prevention interventions was examined through a review of current literature and practice guidelines, and a review provided for those guidelines that were chosen to comprise the recommended interventions section of the ancillary tool. It is clear from the material reviewed there is a compelling need for more focused attention and research into the risk of pressure injury in patients undergoing ancillary hospital procedures, and into appropriate preventive interventions in this understudied patient population.

Chapter Three

Methods

This chapter describes the methodology used in the study, including research design, sample, instrumentation, data preparation and analysis procedures, and the procedures used for construction and evaluation of the pressure ulcer risk assessment and interventions instrument.

The purpose of this study was to develop and validate a pressure ulcer risk assessment and preventive interventions tool for adult patients undergoing hospital diagnostic and treatment procedures in ancillary services units such as radiology, cardiac, vascular, and GI labs, and renal dialysis units.

Specific Aims

The specific aims of the study were to: (a) determine the combination of intrinsic and extrinsic factors which best predicts the risk of developing pressure ulcers among adult hospital inpatients undergoing ancillary services diagnostic and treatment procedures; (b) determine an appropriate weight for each risk factor; (c) determine the most appropriate and effective preventive interventions based on levels of pressure ulcer risk in ancillary services' patients; and (d) construct a concise and user-friendly risk assessment & preventive interventions tool for daily use by hospital professional staff.

Design

The research design consisted of two components. A qualitative review of literature approach was used to investigate the relationships between theoretically derived

risk factors and pressure ulcer development, and to identify the most appropriate and empirically supported pressure ulcer preventive interventions for the ancillary services patient population. A quantitative analysis was then conducted of the predictive power of selected risk factors based on logistic regression models and areas under the Receiver Operating Characteristic curves. This was a retrospective analysis using an existing large national database of de-identified hospital discharge cases. The dependent variable of interest was existing pressure ulcer cases as coded in the hospital discharge records, without regard for ulcer stages or anatomical locations. The independent variables were intrinsic and extrinsic factors identified from the literature as potential risk factors for pressure ulcer development in this patient population.

Sample and Setting

The sample for the quantitative analyses component of the study was obtained from the AHRQ Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS) database. Each year the NIS provides information on approximately 5 million to 8 million inpatient hospitalizations from about 1,000 hospitals. The NIS is designed to approximate a 20-percent sample of U.S. community hospitals (non-Federal, short-term, general, and other specialty hospitals). Included in the sampling are specialty hospitals such as obstetrics-gynecology, ear-nose-throat, long-term acute care facilities, orthopedic, and pediatric institutions. Public hospitals and academic medical centers are also included in the sampling. The universe of U.S. community hospitals is divided into strata using five hospital characteristics relating to ownership, bed size, teaching status, urban/rural location, and U.S. region. The NIS is a stratified probability sample of hospitals in the frame, with sampling probabilities proportional to the number of U.S.

community hospitals in each stratum. Inpatient stay records in the NIS include clinical and resource use information typically available from discharge abstracts (HCUP Databases, 2011). The NIS database for the year 2007 was selected for use in this study as it was the most recent database for which pressure ulcer statistics had been analyzed and published by HCUP. The researcher ensured compliance with the NIS Data Use Agreement (DUA), including the completion of the Data Use Agreement online training for members of the research team who accessed the NIS 2007 database.

The 2007 NIS database contained 8,043,415 cases, including pediatric and newborns. All cases of patients less than 18 years of age were eliminated from the database for study statistical operations. After initial bivariate analyses, the database was randomly partitioned into quartiles and two quartiles selected for analyses; one to serve as the training sample for developing the predictors, and the other to serve as a cross-validation sample for testing the validity of the prediction model. The two selected samples were then checked for comparability prior to start of statistical modeling. Table 4 displays the comparison of some key population and morbidity characteristics of interest in the training and validation samples.

Table 4.

Training and Validation Sample Characteristics

	Training (N =1,661,553)	Validation (N =1,659,508)
Mean Age	56.47	56.47
Female Gender	1,012,699 (60.9%)	1,010,620 (60.9%)
Patients with HIV	12,014 (0.7%)	12,031 (0.7%)
Patients with Diabetes	104,950 (6.3%)	104,431 (6.3%)
Patients with Sepsis	274,373 (16.5%)	272,231 (16.4%)
Patients with Fever	277,038 (16.7%)	274,892 (16.6%)
Patients with Pressure Ulcers	26,296 (1.6%)	26,868 (1.6%)

Procedures

Phase I: Tool Development

This research study was accomplished in two distinct phases. The first phase (Phase I) involved the development of the research instrument. This evolved through theoretical (qualitative) identification from the literature review of those intrinsic and extrinsic variables that appeared to have the greatest potential for predictive validity of patients' risks for pressure injury during their tenure in diagnostic and interventional ancillary services units, including risks involved in patient transport and transfers. Included in phase I was development of a conceptual model for identification of the research domains and the variables relevant to the domains (Figure 1). These variables were then translated into representative constructs and the constructs operationalized into measurable items for the risk assessment tool (Table 2).

Using the selected variables, a content domain matrix was constructed (Appendix A) and subjected to review by the study's expert consultant Dr. Nancy Stotts, a nationally recognized nurse expert in pressure ulcer risk assessment and prevention (Appendix B and Appendix C). Berk (1990) demonstrated the utility of the content domain matrix to enhance content validity as the first step in instrument development. The *a priori* explication of domains and constructs in the form of a blueprint matrix is particularly helpful in meeting Standard 1.6 of the Standards for Educational and Psychological Testing (AERA, APA, & NCME, 1999). This standard requires that:

> When content-related evidence serves as a significant demonstration of validity for a particular instrument use, a clear definition of the universe represented, its

relevance to the proposed tool items, and the procedures followed in generating content items to represent the domains to be described. (AERA et al.1999, p. 14)

Based on the expert review, the variables judged to be the most relevant to pressure ulcer risk were selected for statistical testing for inclusion in the final assessment scale. Due to the limitations engendered in using a retrospective database, variables selected for statistical examination were limited to those that were coded in the HCUP database. The independent variables (IVs) selected for initial examination were; (a) advanced age, (b) anesthesia and sedation, (c) cognitive impairment, (d) neurological impairment, (e) diabetes mellitus, (f) spasticity and/or contractures, (g) PVD and other vascular diseases, (h) pulmonary disease, (i) cardiac diseases, (j) renal failure, (k) sepsis, (l) fever, (m) hypotension, (n) HIV, (o) multiple sclerosis and other sclerosing diseases, (p) paralysis, and (q) malnutrition.

Using IBM SPSS for Windows Versions 19 and 20 software (IBM Corporation, Armonk, New York), the HCUP 2007 NIS database was downloaded into SPSS and dichotomous (yes/no = 1/0) variables were created for each of these risk factors from the existing ICD-9-CM, CPT-4 and NIS Clinical Classifications Software (CCS) category codes in the database (see Table 5). To code the age variable, the frequencies of pressure ulcers (PU) by age were calculated and examined for patterns or clustering. There were clear patterns of PU occurrence which fell into four distinct categories: ages low to 49= group1; ages 50 to 65= group 2; ages 66 to 81= group3, and ages 82 and above= group 4 (see Table 6). Although there is always a concern about loss of data when continuous variables such as age are collapsed into categories, the frequency pattern in these data was distinct enough to override this concern. The dependent variable (pressure ulcer

patients) was created by collapsing all cases with secondary ICD-9-CM codes for pressure ulcers into a single dichotomous variable in the database.

Table 5.

ICD-9 and HCUP CCS Codes Used to Create Study Variables in Database

Risk Factor	ICD-9-CM & CPT Codes	HCUP CCS Codes
Anesthesia	00100-01999 (CPT)	232
Cognitive Impairment	290-294; 780.03; 780.0	85; 109; 110; 113; 233; 241; 653
Neurological Impairment	V17.1; 330-337; 343; 334-348 320-389; 430-438; 780.072; 728.3	227; 81; 82; 85; 95; 233; 216
Diabetes Mellitus	249; 250; 250.6; 356; 357.1; 337; 443; 81; 648; 710; 714	50; 51
Peripheral & other Vascular Diseases	440; 443; 443.9; 444-448	109; 110; 111; 113; 114; 116; 117
Spasticity/Contractures	333; 337; 728.25	79; 201; 202; 212; 226
Pulmonary Diseases	82; 83; 89; 415-417; 490-496; 514; 515; 518.81	122; 127; 129; 131; 132; 133
Cardiac Diseases	410-414; 420-438	97; 100; 101; 103; 104; 107; 108; 213
Renal Failure	584; 585; 586	157; 158
Sepsis	0-038.9	002; 2; 249
Fever (as FUO)	780.60-780.61	3; 246
Hypotension	796.3	249
HIV	042; V08	5
MS & other Sclerosing Diseases	340; 341; 710.1	80; 210; 211
Malnutrition	260-269	52; 58
Paralysis		82
Pressure Ulcers	707.00-707.09	

Note. In all variables except Pressure Ulcers, ICD-9-CM and CPT-4 codes were located in the HCUP database Clinical Classifications Software (CCS) category variables and the study variables were coded using the appropriate CCS code. The Pressure Ulcers dependent variable for the study was created using the HCUP DX1-DX15 principal and secondary ICD-9-CM codes data in the database.

Table 6.

Pressure Ulcer Frequencies by Collapsed Age Categories

Age Range	Group	PU Pts	% in Age Group	% of Total PUs
Lo thru 49	1	2806	0.4%	10.7%
50 thru 65	2	5165	1.4%	19.6%
66 thru 81	3	9653	2.3%	36.7%
82 thru Hi	4	8672	3.8%	33.0%

A descriptive correlational design was employed at this point applying bivariate and multivariate statistical procedures using the HCUP NIS 2007 database of hospital discharge cases to investigate the relationships between the identified risk factors (IVs) and the outcome variable pressure ulcer occurrence (DV). All IVs were initially tested in the entire adult database (N = 6,639,401) for their relationship with pressure ulcer outcomes using the SPSS Crosstabs feature with Pearson's chi square for categorical variables. Chi square is used to test the null hypothesis that the tested categorical variables are independent of each other and that any observed relationship between the variables is due to chance.

While the chi square test will identify if a non-chance relationship exists between variables, it overestimates the effect in large samples, and it will not necessarily identify the strength or direction of that relationship. Therefore, the SPSS Cochran-Mantel-Haenszel (CMH) test was also used to calculate the common odds ratios, confidence intervals and significance levels. This statistic provides a chi-squared test of the null hypothesis that the common odds ratio is 1. Odds ratio (OR) is commonly used as a measure of risk in retrospective studies and is the change in odds of being in one of the categories of outcome when the predictor value changes by one unit. The CMH statistic

provides a logit estimate of the common odds ratio which is less skewed than the Pearson chi square (Agresti, 2002).

Independent variables testing at a significance level of $p \leq .05$ and OR > 1 for positive predictive value in bivariate analysis were then offered to a binary logistic multiple regression (LR) screening procedure in a forward, stepwise fashion, with a significance level to retain in the model set at $p \leq .05$. The initial LR screening was done in the training sample. The logistic regression procedure provides for multiple regression analysis of dichotomous variables by mathematically transforming the dichotomous variable value into a continuous variable in the form of a logit (natural log) of the odds of the dependent variable (event). The natural log of the odds of an event equals the natural log of the probability of the event occurring divided by the probability of the event not occurring. In multiple LR, the null hypothesis underlying the overall model states that all regression coefficients (β) equal zero. Rejection of the null hypothesis implies at least one $\beta \neq 0$ in the population. This means the LR equation predicts the probability of the outcome better than the mean of the dependent variable (e.g., PUs) (Peng, Lee, & Ingersoll, 2002).

The forward stepwise LR method provides a rapid and efficient approach to screening multiple IVs; however, it runs the risk of introducing noise in the data and thus a final *Enter* method was used thereafter to test the LR model. Forward selection starts with the constant (DV) only in the regression then adds IVs one at a time in the order of the next best based on a predefined criterion (e.g., $p \leq .05$) until the step at which all variables not in the model have a significance level of greater than $p = .05$ (Tabachnick & Fidell, 2007). The *Enter* method offers all variables to the regression in one block.

Those IVs (predictive risk factors) testing as significant at $p \leq .05$ in the final LR run ultimately formed the predictive model for the quantitative portion of the risk assessment scale. These statistically significant risk factors included: (a) age group 4 (ages 82 and above); (b) age group 3 (ages 66-81); (c) HIV; (d) diabetes; (e) sepsis; (f) fever; and, (g) anesthesia/sedation.

Weighting the quantitatively derived risk factors for the tool. To determine an appropriate scoring weight for each of the quantitatively derived risk factors, the odds ratio output statistic from the final LR in the training sample was used as a guide to the relative contribution each independent variable (risk factor) made to overall pressure ulcer risk. Odds ratios (OR) are effect size measures and reflect the factor by which the odds of the outcome event (DV) change for a one-unit change in the IV. The 95% confidence intervals for the odds ratios were examined to ensure none were selected that contained the value of 1.0. When the 95% confidence interval around the odds ratio includes this value, it indicates that a change in the value of the IV is not associated in a change in the odds of the DV assuming a given value, and thus it is not a useful predictor (Tabachnick & Fidell, 2007).

Selecting the qualitatively derived risk factors and interventions for the tool. Selection of applicable risk factors and preventive interventions for the ancillary services tool involved consideration of how to categorize the factors by derivation methodology for this study so that reviewers may make informed judgments on the strength of evidence for all the elements of the tool. There are three levels (categories) of risk factors and preventive interventions included in the tool: (a) risk factors empirically supported by the statistical analyses of the NIS 2007 data in this study; (b) risk factors

and preventive interventions supported in the literature by Level A & B evidence; and (c) risk factors and interventions recommended by national pressure ulcer guidelines and agencies as highly relevant but supported only by Level C evidence (see Table 3 for recommended preventive interventions and definitions of evidence Levels).

There are important intrinsic and extrinsic risk factors identified from the literature that could not be empirically tested in the HCUP NIS database as they would require access to complete patient hospital records. The intrinsic risk factors include: (a) use of vasopressor agents (norepinephrine, epinephrine, phenylephrine, vasopressin or dopamine); (b) hypotension (diastolic BP <50 mm Hg/Systolic BP < 100 mm Hg); (c) severely impaired sensory perception (stroke, paralysis, neuropathy); (d) severe vascular insufficiency; (e) use of general anesthesia or heavy sedation in procedures lasting more than 2.5 hours. All five of these risk factors have already been identified and supported in the 2009 EPUAP & NPUAP guidelines. Although some of these factors were statistically tested by the researcher in the HCUP database, coding issues obviated an accurate identification of all patients in the database who may have had these risk factors.

Critical extrinsic risk factors in the ancillary services population include: (a) pressure in excess of CCP from transport and ancillary unit support surfaces; (b) friction and shear during transport, transfers, and positioning for procedures; and (c) moisture. All three of these extrinsic factors are supported by Level A evidence in the EPUAP & NPUAP 2009 CPGs. These factors were not included in the scored tool as they are assumed to apply equally to all patients undergoing hospital ancillary procedures. The interventions section of the tool was designed to accommodate these universal risk factors for all ancillary procedure patients regardless of individual patient risk scores.

Formatting the ancillary services tool. The tool was initially designed in four sections and is two pages in length. The first section contains the six risk factors identified from the NIS database analysis as independent predictors of pressure ulcer risk. They are in a predictive summary rating scale format with each factor assigned a weighted score based on its strength of association from the OR output (Appendix D). This score is then summed over the six factors. Weighted risk factor scores range from 0 (no risk factor) to 6 (age 82 or above) and the summed total potential score possible for a patient is 15-16 points (depending on the age category selected). The higher the risk score, the greater the predicted risk of pressure ulcer vulnerability. The next section of the tool contains the five risk factors identified from the NPUAP guidelines as significant predictors. The presence of any one of these factors places the patient at least in the *moderate risk* category. The third section contains the identification of risk level by patient total score on the risk factors, and identifies an interventions' set (I through IV) targeted specifically at that patient's individual level of risk. The final section, which occupies page 2 of the tool, is the specific list of preventive interventions recommended for each level of risk (see Appendix D (Continued)).

Phase II: Internal and Content Validity Assessment of the Tool

Phase II of the study involved the internal validity assessment of the instrument using split-sample cross-validation statistical analysis procedures, the assessment of predictive accuracy of the empirically derived risk factor model, calculation of cut-off points for the risk scores, and content validity assessment of the tool by a panel of five internationally recognized experts in pressure ulcer risk assessment and prevention.

Split-sample cross-validation assessment of internal validity. Using the same sample to build a prediction model and to then evaluate the model's predictive accuracy invites intrusion of a bias called over-fitting. Over-fitting occurs when the model requires more information than the data can provide. This leads to exaggeration of the parameter estimates and downward biasing of prediction error estimates (they will indicate less prediction error and better model fit than is actually true). This problem results from evaluation of predicted values against the actual outcome values that were used to build the model. A common strategy to overcome this problem is the use of split-sample cross-validation (Bagley, White, & Golomb, 2001). As previously mentioned, the dataset for analysis was split into random samples with one being used for development of the prediction model and another used for validation of that model. The LR model coefficients from the training sample analysis were applied to the validation sample using the SPSS procedure for scoring data with predictive models. The predicted probabilities resulting from this analysis were then entered into a ROC curve analysis. The *p*-values were visually compared between the training and validation samples' LR outputs for individual variables and the model as a whole to ensure none exceeded the .05 level. The classification accuracy of the two models was compared with the goal that the accuracy rate of the validation sample would be within 10% of the training sample.

Assessment of predictive accuracy of the scoring model. The predictive accuracy of the risk score model (summary scale) was examined by calculating the area under the Receiver Operating Characteristic (ROC) curve in both the training and validation samples using the SPSS ROC program. The common quantitative index describing an ROC curve is the area under it. The SPSS program uses a non-parametric,

distribution-free method for calculating the standard error of the area under the curve (AUC) without any distributional assumptions. The AUC represents the probability that a randomly chosen patient with a PU is correctly rated with a higher risk score than that of a randomly chosen patient without a PU. The accuracy as measured by the area under the ROC curve can take on any value from 0 to 1. An area of 1 represents a perfect prediction; an area of .5 is equivalent to pure chance. The area under the ROC curve (AUROC) measures discrimination, that is, the ability of the risk scale score to correctly classify those who will develop PUs and those who will not. This curve can be constructed by correlating true-and-false positive rates (sensitivity and 1-minus specificity) (Polit & Beck, 2008).

In order to calculate the ROC a variable was created in each of the two samples in SPSS to calculate each patient's risk score using the syntax: COMPUTE PURISK = (Age4*6) + (Age3*5) + (HIV*4) + (DIAB*3) + (Sepsis*2) + (Fever*1). The ROC procedure was then run on the scoring model using the variable PURISK.

Calculation of scale cut points to identify risk levels in the tool. Cut point analyses were accomplished using calculations of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Youden index for each possible scale score. Each possible individual score level (0-16) for the summary risk scale was constructed as a separate variable in the NIS database using the SPSS syntax PURISK (lowest thru 3 = 0) (4 thru highest = 1) INTO Rocut2. The AUROC could then be calculated for each cut point of the scores to determine which scores yielded the best balance between sensitivity (number of true positive predictions/number of actual PU cases) and specificity (number of true negative predictions/the number of cases without

PU) for discriminating among no, low, medium, and high risk categories. Positive predictive value (PPV) is defined as the probability that a patient with a high risk score will develop a PU and was calculated for each score using the formula PPV= true positive / (true positive + false positive). The NPV is defined as the probability that a patient with a low risk score will not develop a pressure ulcer and was calculated using the formula NPV = true negative / (false negative + true negative) (Gordis, 2004).

To further identify the optimal cut point for the scale scores, the Youden index was calculated. This index is defined as (sensitivity + specificity - 1), where sensitivity and specificity are calculated as proportions. The Youden index has minimum and maximum values of -1 and +1, respectively, with a value of +1 representing the optimal value for the index. The aim of the Youden index (*J*) is to maximize the difference between the true positive rate (TPR) and the false positive rate (FPR) to identify the optimal cut-off point to discriminate the disease or condition (e.g., PU) from non-disease (no PU). Put simply, the Youden index is commonly used because it reflects the intention to maximize the correct classification rate (Youden, 1950).

Content validity assessment of the tool by a panel of experts. The completed tool was subjected to a content validity assessment (CVI) by a panel of five experts in pressure ulcer risk assessment and prevention. Using the method recommended by Waltz and Bausell (1981), the tool items were overlaid in a matrix with a 4-option rating scale (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant; 4 = highly relevant) (see Appendix E). The panel of experts was recruited with the assistance of the study consultant, Dr. Nancy Stotts, and was comprised of Dr. Stotts, Dr. Elizabeth Ayello, Dr. Janet Cuddigan, Dr. Lena Gunningberg, and Dr. Diane Krasner. Appendix F contains a

brief biographical sketch of each panel member including the reviewer's expertise in the area of pressure ulcers. The risk assessment and preventive interventions tool, CVI process instructions, and a CVI rating scale developed by the investigator were emailed to the content experts for completion and return (Appendix G).

This stage in developing content validity is the "judgement-quantification" stage (Lynn, 1986, p. 383). Content validity is defined as "…whether or not the items sampled for inclusion in the tool adequately represent the domain of content addressed by the instrument" (Waltz, Strickland, & Lenz, 2005, p. 155). There are two steps in the judgement-quantification phase of validity testing; the assertion by a panel of content experts that the individual items are content valid; and, that the entire instrument is content-valid. The task of the expert panel is to judge whether the items included in the tool adequately represent the domains of interest. The first task to be completed in the judgement-quantification stage is to determine the number of experts needed for the content validity review. There are varying opinions on what constitutes a minimum number of experts for such a panel. The seminal work by Lynn (1986) on this topic has provided nurse researchers with a commonly used algorithm since its publication. Lynn's recommendation is that a range from three to ten experts should be used. The process for the review by the expert panel was essentially the same as for the matrix review, with provision of the Validity Assessment Tool and instruction packet to the content experts. The primary difference between the matrix review and completed tool review process was the selection of a panel of pressure ulcer prevention and tool development experts to assess not only the relevance and validity of the content, but also the appropriateness and practicality of the tool's applications in clinical practice.

Although it is ideal to convene the review panel to provide instructions and an overview of the research study, this process was conducted by email since the experts were located in geographically divergent areas. The Content Validity Index (CVI) statistic was subsequently used to assess the degree of reviewers' agreement on the relevance of the scale items and of the entire scale.

Data analysis for content validity. Interrater Agreement (IRA) on content items was calculated first using a multirater kappa statistic to determine the extent to which the panel experts were reliable in their ratings (Polit & Beck, 2008; Waltz, Strickland, & Lenz, 2005; Wynd, Schmidt, & Schaefer, 2003). A key feature of the kappa statistic, and a primary distinction from the CVI, is that it is a measure of agreement which statistically controls for chance. Kappa is generally thought to be a more robust measure of interrater agreement than a simple proportion of agreement like the CVI (Wynd et al.). Although several published tables exist for interpreting the kappa statistic, the consensus is that kappa values above 0.75 constitute a high degree of agreement beyond chance (Wynd et al.). Table 7 illustrates commonly accepted parameters for interpreting the kappa statistic values.

Table 7.

Interpreting Kappa Values

Strength of Agreement:	Poor	Fair	Good	Excellent
Kappa Statistic	<0.40	0.40-0.59	0.60-0.74	0.75-1.0

Results from the returned content review forms were analyzed using both the content validity s*cale* (S-CVI) and *item* (I-CVI) indexes. Risk assessment variables and preventive interventions that scored below an I-CVI of 0.80 or kappa coefficient of 0.75

were considered for revision, or elimination from the tool if this did not compromise validity of the overall content domain matrix.

Institutional Review Board and Human Subjects Protection

Approval was obtained for this study from the University of South Florida (USF) Institutional Review Board (IRB) (Appendix H). The study was deemed *exempt* as it did not involve interaction with human subjects or use of information or procedures that posed issues in human subject protection. The data used in the study were de-identified publicly available data and were used and maintained in strict compliance with the HCUP NIS data use requirements.

Summary

This chapter described the design and procedures for the development of the pressure ulcer risk assessment and preventive interventions tool and the assessment of its content validity and clinical relevance. The process of identifying and statistically ranking measureable indicators for pressure ulcer risk in the ancillary procedures patient population was described, including the methodology for weighting risk factors and deriving a total patient risk score. In addition, appropriate prevention interventions based on levels of patient risk were identified for the tool. Also described were the processes for assessing internal validity of the scored risk factors in the scale using a split-sample cross-validation procedure, and content validity assessment of the finished tool by a panel of pressure ulcer and tool development experts. The desired outcome of this research is a tool that accurately predicts the individual PU risks for hospital ancillary procedures' patients, demonstrates predictive validity in subsequent clinical studies, and focuses clinical and research attention on this much neglected patient risk issue.

Chapter Four

Results

This chapter will summarize and analyze the study data and procedures, including characteristics of the samples, outcome of expert evaluation of the tool content domain matrix, statistical and theoretical bases for risk factor selection, weighting and scoring system development, results of cross-validation of the assessment scale's internal validity, and outcome of the expert panel assessment of the scale's content validity.

Sample Characteristics

The characteristics of interest of the subjects in both the training and validation samples were covered in some detail in Chapter Three (see Tables 4 and 6). However, it is important to stress at this point that subjects in the NIS 2007 database who had a primary (admitting) diagnosis of PU (ICD-9-CM 707.00 - 707.09) were excluded from the dependent variable group unless they also had a secondary PU diagnosis coded. Elimination of the patients with only a primary diagnosis of PU from the numerator is a standard practice by HCUP for estimating hospital-acquired ulcers from the NIS data. The percent of patients in each of the two samples coded with secondary pressure ulcers was 1.6. Approximately 38,000 (2.3%) of patients in each of the samples were excluded due to having only primary diagnosis codes for PUs. This would make the total PU prevalence in the samples ≈4% which is within the range of published findings for similar samples (Cuddigan et al., 2001; Russo et al., 2008).

Age data. The prevalence of PUs varied significantly among age groups, with the frequency of subjects *(n)* per group decreasing in older age groups but the PU prevalence increasing disproportionately to the *n* of subjects in the groups (Figure 4).

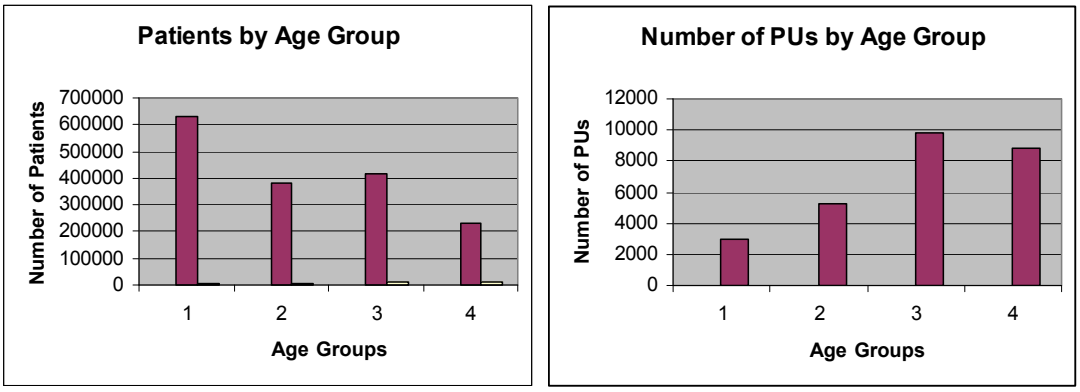


Figure 4. Validation Sample Comparison of Number of Patients by Age Group and Number of Pressure Ulcer Cases by Age Group.

The training and validation samples did not differ significantly in age or other variables of interest in the study (lowest chi square *p* value = .225). Patients over 65 years of age accounted for only ≈38% of total hospital cases but accounted for ≈70% of pressure ulcer cases in each sample (Figure 5). See Appendix I for further training sample description.

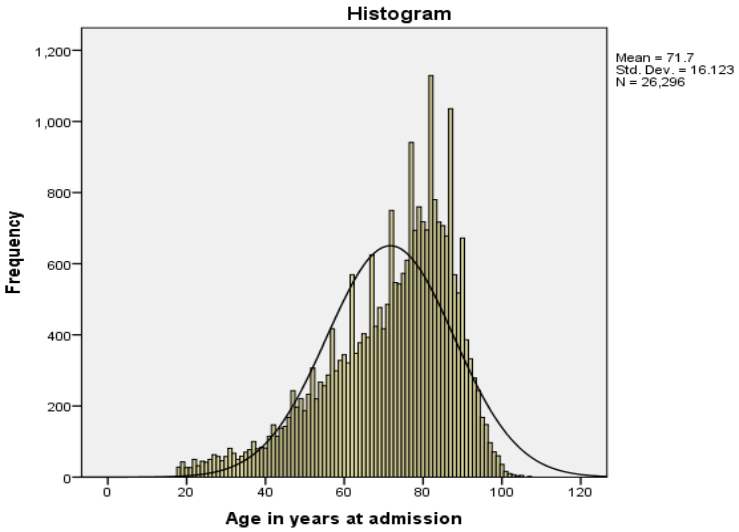


Figure 5. Training Sample Distribution of Pressure Ulcers by Patient Age

Content Domain Matrix Evaluation

As a result of the expert consultant's review of the content domain matrix, the domains, constructs, and measureable risk factors contained in the matrix were distilled to 16 items. See Table 8 for Items rated by Dr. Stotts as *quite* (score 3) or *highly* (score 4) relevant from the Content Domain Matrix. Those measureable risk factors from the revised matrix that could be statistically tested in the NIS database were then selected for the bivariate and multivariate analyses.

Table 8.

Domain Matrix Factors Rated as Quite or Highly Relevant by Consultant

Risk Factor	Rating	Risk Factor	Rating
Advanced age tissue changes	4	Tissue tolerance	4
Body build/BMI	3	PVD (soft tissue changes)	4
Neurological impairment	4	Diabetes mellitus	4
Patient positioning on surface	3	Dementia/cognitive impairment	3
Type procedure table	3	Dehydration (severe)	4
Immobility	4	Tissue oxygen homeostasis	4
Impaired sensory perception	4	CHF/CVD	4
Transport (duration, position, surface)	3	Hypotension	3
Friction & Shear (duration & intensity)	4	Impaired PIV	3
Moisture of skin and support surface	3	Impaired reactive hyperemia	3
Patient transfer techniques	4	Renal failure	3
Sepsis	3	Other vascular diseases	4

There were four risk factors rated by Dr. Stotts as 2 (somewhat relevant) that were retained by the researcher for statistical testing due to strong evidence in empirical studies as to their relationship with pressure ulcer vulnerability. These were; (a) fever, (b) pulmonary diseases, (c) use of vasopressor agents, and (d) anesthesia and sedation.

Bivariate and Multivariate Analysis Results

The following risk factors were coded into the full adult NIS database (N = 6,639,401) and subjected to bivariate chi square analysis test for independence as IVs with the DV as pressure ulcer cases; (a) advanced age, (b) anesthesia/sedation, (c)

cognitive impairment, (d) neurological impairment, (e) diabetes mellitus, (f) spasticity and/or contractures, (g) PVD and other vascular diseases, (h) pulmonary disease, (i) cardiac diseases, (j) renal failure, (k) sepsis, (l) fever, (m) hypotension, (n) HIV, (o) multiple sclerosis and other sclerosing diseases, (p) paralysis, and (q) malnutrition. The CMH chi square, ORs and significance levels were used to identify the predictors with selection criteria of OR >1 and significance of $p \leq .05$. Independent variables demonstrated as having a significant relationship with pressure ulcer outcomes were advanced age (age over 65), patients receiving general anesthesia or sedation, diabetes mellitus, presence of fever, HIV disease, pulmonary disease, and sepsis. Table 9 displays the bivariate analysis outcomes for these variables.

Table 9.

Bivariate Analysis of Risk Factors with Pressure Ulcer

Risk Factor	*N*	χ^2	Odds Ratio	OR 95% CI	*p*-Value
Age 66-81	1,665,311	7782.67	1.751	1.729 - 1.773	<.001
Age 82 and above	918,673	32962.89	3.137	3.097 - 3.178	<.001
Anesthesia/Sedation	718,948	223.13	1.151	1.130 - 1.173	<.001
Diabetes mellitus	419,557	8982.95	2.326	2.285 - 2.369	<.001
Fever	1,105,761	12148.24	2.090	2.062 - 2.118	<.001
HIV	48,339	67.43	1.301	1.221 - 1.385	<.001
Pulmonary disease	1,293,645	1893.47	1.365	1.146 - 1.384	<.001
Sepsis	1,095,152	12138.86	2.093	2.065 - 2.121	<.001

Note. χ^2 = chi square test; OR = odds ratio; CI = confidence interval.

The eight variables identified as having a significant association with pressure ulcer outcomes ($P \leq .05$) from bivariate analysis were then offered to a multivariate LR procedure in the training database (*N*=1,661,553). Statistically significant predictors of pressure ulcer risk from this analysis were; (a) ages 66 - 81, (b) ages 82 and above, (c) HIV, (d) diabetes mellitus, (e) sepsis, (f) fever, and (g) anesthesia/sedation. The results of this analysis are depicted in Table 10. The effect of a theoretically potential

interaction between the variables fever and sepsis was tested by introducing an interaction term into the regression. There was no notable change in the LR outcomes. The outcome for pulmonary disease (appeared protective) was likely due to over-inclusion of non-significant pulmonary conditions in the combining of ICD-9-CM codes in HCUP's composite pulmonary CCS codes. This will require further prospective study.

Table 10.

Multivariate Logistic Regression Analysis of Risk Factors in Training Sample

Variable	OR (Exp B)	OR 95% CI	*p*-Value
Age 82 and above	5.137	4.979 - 5.299	<.001
Age 66 - 81	2.981	2.892 - 3.072	<.001
HIV	2.728	2.400 - 3.101	<.001
Diabetes Mellitus	2.193	2.114 - 2.275	<.001
Sepsis	1.590	1.199 - 2.108	=.001
Fever	1.363	1.029 - 1.807	=.031
Anesthesia/sedation	1.087	1.047 - 1.129	<.001
Pulmonary Disease	.568	.545 - .592	<.001

N = 1,661,553, *df* for model = 8, *df* for each variable analysis = 1

The overall model chi square test of the multivariate LR model coefficients was significant ($\chi^2 = 16487.836$, $df = 8$, $p < .001$).

Weighting of Risk Factors for Development of Scale Scoring System

It is common practice in medicine and nursing research to use some form of either the regression coefficients or OR outcomes from LR for risk assessment tool score development. For development of the scoring system for the ancillary services risk assessment tool the researcher chose to use a formula based on the ORs of the multivariate logistic regression that was run on the training sample (set). In view of the lower OR for the variable anesthesia/sedation, and the inability to quantify type and duration of anesthesia in the NIS database, it was decided not to include this risk factor in the weighted scoring of the tool. The LR model was re-run with the six predictors

(omitting anesthesia and pulmonary disease). The only change in the outcomes was a minor increase in the Exp B (OR) for the age >81 variable (OR 5.177, 95% CI 5.018 - 5.340, p <.001). The ORs for the six remaining variables were linear in predictive potential, with fever being the lowest OR, and age over 82 years being the highest. In view of this linearity, a simple scoring system was chosen using integers 1-6, with the lowest OR being scored 1, and each successively stronger predictor receiving an additional weight in increments of 1. It was hoped this simplicity would make the tool more user-friendly for clinical application (see Table 11 for initial scoring of the tool).

Table 11.

Pressure Ulcer Risk Score Calculation

Risk Factor	Score Points	[Total Points = 15-16]
Patients of age > 81 years	6	
Patients of age = 66 thru 81 years	5	
Patients with diagnosis of HIV	4	
Patients with diagnosis of diabetes	3	
Patients with diagnosis of Sepsis	2	
Patients with Fever	1	

Note. Patient can only be in one of the two age categories with a score of either 5 or 6.

What to do with the risk factors that are identified as significant in the literature and EPUAP/NPUAP 2009 guidelines but could not be adequately tested in the NIS data posed an interesting problem. These risk factors included: (a) use of IV vasopressor agents (norepinephrine, epinephrine, phenylephrine, vasopressin or dopamine); (b) hypotension (diastolic BP <50 mm Hg/Systolic BP < 100 mm Hg); (c) severely impaired sensory perception (stroke, paralysis, neuropathy); (d) severe vascular insufficiency; and (e) use of general anesthesia or heavy sedation in procedures lasting more than 2.5 hours. Without these factors the tool would likely fail to identify many patients at risk for PUs in the ancillary procedures environment. It was decided to create a special section in the

tool to identify these patients as at a *moderate* (at least) risk for pressure injury until such time as the tool can be tested prospectively where real-time data can be collected to determine the appropriate scoring levels for these risks (see Appendix D example).

Internal Validity Assessment of the Prediction Model and Scoring

The apparent and internal validity of the predictive model were tested in the validation sample (see Table 4 for sample characteristics). To test apparent validity the selected six predictors were entered into a multivariate LR to determine if the resultant ORs would be statistically significant for predictions of PUs (see Table 12 for LR results)

Table 12.

Multivariate Logistic Regression Analysis of Risk Factors in Validation Sample

Variable	OR (Exp B)	OR 95% CI	*p*-Value
Age 82 and above	5.156	5.000 - 5.317	<.001
Age 66 - 81	2.937	2.850 - 3.026	<.001
HIV	2.569	2.257 - 2.924	<.001
Diabetes Mellitus	2.229	2.150 - 2.311	<.001
Sepsis	1.513	1.147 - 1.996	=.003
Fever	1.403	1.064 - 1.849	=.016
$N = 1{,}659{,}508$	Model $\chi^2 = 16070.581$, $df = 6$, $p < .001$		

The significance levels of the six predictor variables were each $p < .05$ in both the training and the validation samples. Differences in odds ratios between the training and validation LR results (OR in one sample model subtracted from OR in the other sample model) ranged from 0.019 (age >81) to 0.159 (HIV). Both LR models' overall significance levels were $p < .001$.

Next, to test the internal validity of the scoring model, the model parameters from the training sample LR were used to score the validation sample using the SPSS ApplyModel scoring expression. This procedure calculated predicted probabilities for

each case in the validation sample based on coefficients from the training sample LR. These probabilities were then used to produce an ROC curve analysis. The area under this ROC curve was .709 (SE .002, 95% CI .706-.712, p<.001), demonstrating minimal model shrinkage and acceptable predictive accuracy.

Assessment of predictive accuracy of the risk assessment scale scoring. To assess predictive accuracy of the constructed scores for the risk factors, the area under the Receiver Operating Characteristic curve (AUROC) was calculated in both the training and validation samples to determine how well the scoring system classified patients with and without PUs. The AUROC for the risk score model in the training sample was .710 (SE .002, 95% CI .707-.713, $p < .001$). The AUROC for the risk score model in the validation sample was .709 (SE .002, 95% CI .706-.712, $p < .001$). Figure 6 depicts the ROC curve for the validation sample. The predictive accuracy of the scoring model in the validation sample was within 99.9% of that in the training sample.

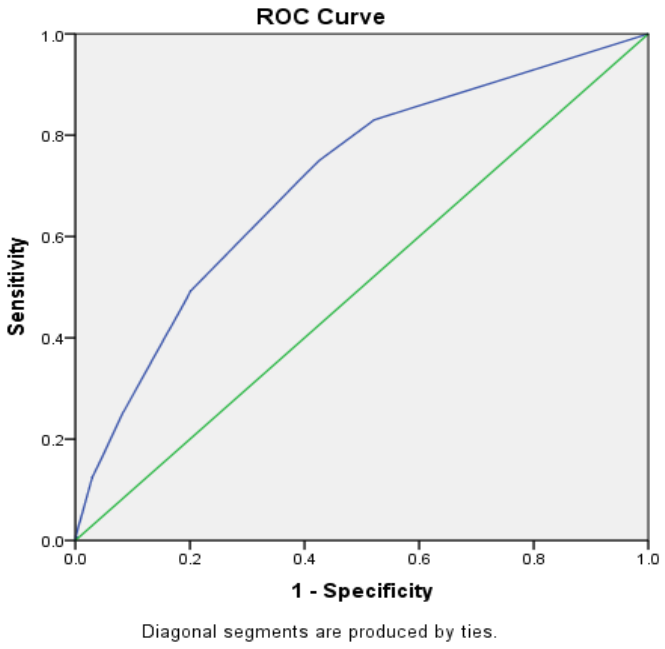


Figure 6. AUROC Curve of Risk Scores in Validation Sample. Pressure ulcer patients (positive) = 26,868. Non-pressure ulcer patients (negative) = 1,632,640.

Upon calculation and analysis of individual patient risk score it became evident that PU patients clustered heavily in the lower half of the possible total score range. While it would not be unusual for lower scores to have high sensitivity due to the higher number of patients identified as at risk, the distribution of patients was clustered, with 81% of pressure ulcer patients falling within the score scale range of 3-9 points. There was, however, a relatively clear linear trend in the proportion (prevalence in group) of pressure ulcers by risk score (see Table 13). With each risk factor in the scored portion of the tool being an independent predictor of pressure ulcer risk it appeared that small increments in the score increased the risk exponentially. This made determining cut points somewhat more difficult.

Table 13.

Linear Trend in Pressure Ulcer Patients by Risk Score in Training Sample

Risk Score	PU Patients	Total Patients	Percent with PU
0	4348	786814	0.6%
1	15	1370	1.1%
2	0	0	0.0%
3	2982	202999	1.5%
4	194	9886	2.0%
5	5852	318221	1.8%
6	6193	197681	3.1%
7	53	2075	2.6%
8	3316	90646	3.7%
9	2655	43191	6.1%
10	5	82	6.1%
11	458	6472	7.1%
12	224	2108	10.6%
13	0	1	0.0%
14	0	0	0.0%
15	1	7	14.3%
Total	26296	1661553	1.6% (in total sample)

Note: No patients in the training sample had a pressure ulcer risk score above 15.

Calculation of cut-points, sensitivity, specificity, PPV, NPV and Youden Index. The SPSS ROC program output was used to calculate sensitivity, specificity,

PPV, NPV, and the Youden Indexes for each risk scale score in the training sample. The goal was to identify the score that predicted the highest outcome of pressure ulcer and the best balance with specificity (true negatives), and then to identify scores to depict low and moderate risk levels. This was made more difficult by the clustering of PU patients within a seven-point range. The Youden Index is often chosen as the best overall indicator of balance. Table 14 displays the indicators used for the cut-point analysis in the training sample. Note that, for each individual score, the risk depicted is for all patients at or above that score level, not just the patients with that specific score.

Table 14.

Cut-Point Indicators for Determining High, Moderate, and Low Risk Scores

Score	Sensitivity %	Specificity %	Youden Index %	PPV %	NPV %
≥ 1	83.4	47.8	31.3	61.5	74.3
≥ 2	83.4	47.9	31.3	61.5	74.3
≥ 3	83.4	47.9	31.3	61.5	74.3
≥ 4	72.1	60.2	32.3	64.4	68.3
≥ 5	71.3	60.8	32.1	64.5	67.9
≥ 6	49.1	79.9	29.0	71.0	61.1
≥ 7	25.5	91.6	17.1	75.2	55.3
≥ 8	25.3	91.9	17.2	74.7	55.2
≥ 9	12.7	97.0	9.7	80.9	52.6
≥10	2.6	99.5	2.1	83.9	50.5
≥11	2.6	99.5	2.1	83.9	50.5
≥12	0.9	99.9	0.8	90.0	50.2

Note. Only nine patients in the training sample had scores above 12.

Selecting the cut-points. As would be expected, in this scale patients are identified as at risk for pressure ulcers at a very low scale score (Table 13). While the optimum score for high risk as indicated by the Youden Index would be total score = 4, (Table 14) this seemed an impractically low score at which to evoke the full array of preventive interventions in Intervention Set IV in clinical practice (see Appendix D). The next step was to examine the sets of PPV and NPV results by score level. The PPV and

NPV results for the scale scores showed a steady increase in the PPV and a steady decrease in NPV as the scale score increased (Table 14). These values were somewhat difficult to interpret given that PPV and NPV values are normally sensitive to disease/condition prevalence, with PPV increasing in higher prevalence rates, and NPV decreasing. With smaller numbers of total patients in the higher score ranges and higher prevalence of PUs within these ranges, the values of the PPV and NPV became less enticing as decision factors. In examining these scale values it appeared the most practical choice for the high-risk cut point would be a scale score of 6 (sensitivity = 49.1%, specificity = 79.9%, Youden = 29.0%, PPV = 71%, NPV = 61.1%). This cut score would identify 55.4% of the patients in the training sample as high risk who actually have PUs, whereas choosing a cut score of 5 would identify 71.3%. It was decided to test the effect size of each individual binary score variable (1-*df* tests) in a LR procedure in the training sample to provide further decision data (see results in Table 15).

Table 15.

Identification of Effect Size for Individual Risk Scores

Score Value	OR (Exp B)	OR 95% CI	*p*-Value
≥ 1	4.628	4.479 - 4.781	<.001
≥ 2	3.897	3.792 - 4.004	<.001
≥ 3	3.852	3.750 - 3.957	<.001
≥ 4	3.821	3.729 - 3.916	<.001
≥ 5	3.822	3.619 - 3.829	<.001
≥ 6	3.743	3.638 - 3.850	<.001
≥ 7	4.763	4.588 - 4.945	<.001
≥ 8	5.477	5.062 - 5.927	<.001
≥ 9	5.490	5.072 - 5.942	<.001
≥10	7.454	6.489 - 8.564	<.001
≥11	8.884	1.093 -72.211	=.041
≥12	10.365	1.248 -86.095	=.030
≥13	10.365	1.248 -86.095	=.030
≥14	4.628	4.479 - 4.781	<.001
≥15	4.632	4.483 - 4.785	<.001

Note. *df* = 1 for each test of score value. Only nine patients in this sample had risk scores >12.

After examining all the available data, it was decided to select the score of 6 (clinical practicality won out) as the *high-risk* cut-off for PU, score 1 as *low risk*, and scores 2-5 as *moderate* risk, and to revisit the scoring cut-points based on input from the expert panel review (Appendix D).

Scale Content Validity Assessment

A panel of five nurse experts in pressure ulcer prevention and care (Appendix F) reviewed the ancillary services risk tool for relevance, readability, clarity, and clinical utility. There were 32 scored items in the review matrix (see Appendix E). Only relevance was numerically scored, with comments solicited on the other review criteria. A standard 4-level summated rating scale was used for the relevance ratings as previously described. Scored items included the risk scores, the risk levels, the intervention sets, and each individual preventive intervention.

The inter-rater reliability of the panel members' ratings was calculated using a substitute for the weighted multirater kappa statistic. The IBM SPSS program computes only Cohen's kappa (two raters). According to Fleiss and Cohen (1973), "when the investigator can specify the relative seriousness of each kind of disagreement, he may employ weighted kappa, the proportion of weighted agreement corrected for chance" (p. 613). They state further that "this paper establishes the equivalence of weighted kappa with intraclass correlation coefficient under general conditions" (p. 614). The intraclass correlation coefficient for rater agreement for the five reviewers was .583 (F= 2.40, $df1$= 31, $df2$= 124, 95% CI .301-.774, p <.001). This falls into the range of *moderate* (fair) strength of agreement, short of the researcher's goal of ≥ .75. A pattern was noted in that one reviewer rated all 32 items as 4s. To examine the overall proportion of scale scoring

by individual rater, the proportion of 3 & 4 ratings was calculated by rater (see Appendix J). These proportions were .81, .75, .84, .81, and 1 ($\bar{x}$=.84), with 1 being an obvious outlier. This information has more import for future selections of these panel members than actual impact on the analysis at hand.

Two measures of the content validity indexes were calculated; the individual item index (I-CVI), and the entire scale index (S-CVI). The I-CVI/average was calculated as the number of 3 and 4 ratings (quite or highly relevant) for each item divided by the number of raters (proportion of agreement on the individual item). Collapsing the ratings into two categories (1 & 2 ratings = non-relevant) and (3 & 4 ratings = relevant) is a common and recommended practice (Polit & Beck, 2008). The outcomes for these I-CVIs are presented in detail in Appendix J. The CVI for the entire scale was calculated using both the S-CVI/average, and the S-CVI/UA methods. The S-CVI/UA (universal agreement) method is calculated using only I-CVI items whose relevancy rating achieved 100% agreement (e.g., all 3s or all 4s) as the numerator. The researcher chose to follow the advice in Polit & Beck's text and report the S-CVI/average value of 0.84. Although an S-CVI of .80 is generally considered acceptable, it is preferable to use the goal of ≥ .90 when using the S-CVI/average method. Thus the result of the panel rating of overall scale content relevance fell slightly short of that goal.

In examining the expert's ratings and comments for individual scale items three items were noted to have I-CVIs in the non-relevant range. These were the scale scored item HIV, the preventive intervention relating to use of a cooling blanket, and Risk Score = 1. In addition, comments and recommendations of the experts related to the overall scoring of the four risk levels indicated a need to revise this section. The definitions of

risk levels at scores = 0 or 1 was changed and incorporated into a single risk level of *low risk*. The *high risk* cut point was changed to 5, a better choice in view of the statistical indicators (see Table 14). In view of the expert opinion that the interventions in Set I are a minimum standard that apply to all patients, this set was chosen to be applied for patients at low risk on the scale scores. The cooling blanket intervention was removed from the tool as it applies to few patients in ancillary units and would likely be poorly understood in these environments. With item 20 (cooling blanket) removed, and the revision of item 30, the S-CVI increases to .91, a highly acceptable indicator of scale relevance. Item 3, diagnosis of HIV as a scored risk factor, was not removed at this time. Because of the strong evidence of the impairment of reactive hyperemia (a critical tissue protective mechanism against pressure injury) by protease inhibitors used to treat HIV infection and the effect size found in the study data, the researcher decided to leave this item in the scale for future study.

There were several excellent recommendations by the expert panel for changes such as: broaden the risk category of sepsis to include various types of infections as identified in the work of Fogarty (Fogarty et al, 2008); also related to sepsis, consider the use of SIRS-Sepsis-Septic Shock continuum used by many critical care groups; change example in CRF for risk factor vascular insufficiency from PVD to a more reliably severe condition of vascular insufficiency; and more clearly define parameters to identify the CRF risk factors overall. The researcher was able to make several of these changes in the tool; however, it was decided to delay any changes to items that were included, rated, or defined based on the findings from the NIS database analyses until the tool can be tested *in vivo* (see revised tool in Appendix K).

Chapter Five

Summary, Discussion and Recommendations

Summary

The Research Problem

The incidence of nosocomial pressure ulcers has continued to increase in U.S. hospitals over the past 15 years despite the implementation of national preventive guidelines and the wide-spread use of validated risk assessment tools. The majority of preventive efforts and tools have been focused primarily on patients who are bed-ridden or immobile for extended periods. What has not been well-studied or identified is the potential risk for pressure injury to patients undergoing diagnostic procedures in hospital ancillary units where extrinsic risk factors such as high interface pressures on procedure tables and friction and shear from positioning and transport can greatly magnify the effect of patient-specific intrinsic risk factors which might not otherwise put these patients at high risk on an inpatient unit. Existing PU risk assessment scales focus on factors such as incontinence, immobility, nutritional deficiencies, and sensory perception deficits that put patients at risk primarily because they are bed-ridden. They do not capture the unique physiologic factors that can impair tissue tolerance for short periods of high pressure and shear such as experienced by the ancillary procedures patient population. The purpose of this study was to develop a risk assessment scale (tool) designed explicitly to quantify the combination of these intrinsic and extrinsic risk factors in individual patients undergoing

ancillary services procedures, and to identify targeted preventive interventions based on the individual level of risk.

Method and Results

Because of the need to identify risk factors related to the special extrinsic risks in the ancillary procedures population the study began with a two-fold approach to literature review. The first was the standard approach in pressure ulcer research of identifying empirical studies that demonstrated a significant relationship between diseases and conditions and outcomes of pressure ulcers. This included studies of relationships between extrinsic risk factors inherent in the ancillary unit environments such as pressure, friction, shear, temperature, and moisture, and increased risk for pressure injury. It also included studies that identified the relationship between intrinsic factors such as diabetes, neuropathy, and malnutrition, and increased risk for pressure ulcers. The second approach to literature review was to attempt to identify from physiology studies the physiological mechanisms such as PIV and reactive hyperemia that protect normal human tissue from pressure injury. With these identified, the literature was further searched to identify which diseases and conditions interfere with these mechanisms.

The factors identified from this extensive review were statistically tested for relationship with pressure ulcer outcomes in a national inpatient database of over 6 million cases. Factors that could be studied in the retrospective data set were tested for association with existing pressure ulcer outcomes using bivariate and multivariate statistics and employing split-sample cross-validation (training and validation samples) to assess the internal validity of the findings. Factors identified in the dataset with a statistically significant association with pressure ulcer outcomes were; advanced age,

HIV, diabetes, sepsis, anesthesia/sedation, and fever. An assessment scale was constructed from the training sample data using these factors and other risk factors already well-supported in the empirical literature. The accuracy of the scale model was tested for generalizability in the validation sample and found to be a reasonably accurate predictor of the risk in this population, with a LR model accuracy significant at $p < .001$, and an area under the Receiver Operating Characteristics (ROC) curve of .710. The ROC curve statistics were used to identify cut points for the risk levels in the tool and targeted intervention sets were designed from national practice guidelines for each level of risk.

The risk scale was subjected to a content validity review by a panel of five international nurse experts in pressure ulcer prevention and tool development. With minor changes recommended by the panel the scale content validity, as measured by the S-CVI/average statistic, was calculated at .91, indicating excellent agreement on validity.

Discussion

The primary aims of this study were to; (a) identify specific intrinsic and extrinsic risk factors for pressure ulcer development that are most likely to predict pressure injury in adult patients during lengthy diagnostic and treatment procedures in hospital ancillary units, (b) identify specific preventive interventions that will likely be effective in preventing pressure injury in this population, and (c) construct a valid risk assessment and preventive intervention tool for practical clinical use by hospital professional staff. The status of achievement of the aims in this study is discussed below.

Identification of PU predictors. Seventeen risk factors were identified from the literature as potential predictors of pressure ulcer risk in the ancillary procedures patient population. In bivariate analysis eight of these factors emerged as significantly

associated with PU outcomes. Of these eight risk factors six emerged from multivariate analysis as significant predictors in two random samples totaling over 3 million patients from the NIS 2007 probability sample of 1000 U.S. hospitals' discharge cases. This aim was achieved to the degree possible in a descriptive design with retrospective data.

Identification of preventive interventions. Three sets of interventions were found that were supported in national published clinical practice guidelines and that could be titrated by patient risk level. The content validity of these interventions (and sets) was deemed good-to-excellent by a panel of international nurse pressure ulcer experts. While the aim of identifying the interventions was met, the predictive validity of the interventions could not be established by this descriptive study. A major issue in pressure ulcer prevention is the absence of valid empirical evidence of the efficacy of the majority of nursing interventions for pressure ulcer prevention (EPUAP & NPUAP, 2009). The Messer Scale tool interventions conform to current national published CPGs, thus it is reasonable to declare these interventions as valid as any currently in practice.

Construction of a valid risk assessment/preventive interventions tool. A risk assessment scale was constructed that predicted pressure ulcer outcomes with 71% accuracy in two random samples of over 3 million U.S. hospital patients. This accuracy statistic is equal to or better than currently available PU risk assessment scales (Braden, Waterflow, and Norton Scales). Table 16 compares the Messer Scale using the standard risk assessment scale performance indicators with the primary validated PU risk scales in current use world-wide, and the respective outcomes for nursing clinical judgement as published in an extensive metaanalysis by Pancorbo-Hildago, Garcia-Fernandez, Lopez-Medina, and Alvarez-Nieto in 2006. However, the accuracy of the Messer Scale was

tested in a retrospective database so cannot be directly compared to accuracy outcomes calculated in prospective predictive validity studies in the clinical setting. Therefore, the aim of developing a valid and clinically practical risk assessment/preventive interventions tool is declared only partially met pending further testing of the Messer Scale in actual clinical settings.

Table 16

Comparison of Clinical Predictive Ability of Pressure Ulcer Risk Assessment Scales

Scale	# of Studies	Sensitivity (%)	Specificity (%)	Youden Index	PPV (%)	NPV (%)
Braden Scale	20	57.1	67.5	.25	22.9	91.0
Norton Scale	5	46.8	61.8	.09	18.4	87.0
Waterflow Scale	6	82.4	27.4	.09	16.0	89.0
Clinical Nurse Judgement	3	50.6	60.1	.11	32.9	75.9
Messer Scale	1	71.3	60.8	.32	64.5	67.9

Note. Braden, Norton, Waterflow Scale and Clinical Nurse Judgement data extracted from Pancobo-Hidalgo et al., (2006).

Statistically Significant Findings

One of the most important findings from the study data analysis was the significant relationship between HIV disease and pressure ulcer outcome in the NIS sample. Patients in the NIS 2007 sample who had a coded diagnosis of HIV were 2.6 times more likely to also have a coded secondary diagnosis of PU as patients without the HIV diagnosis (OR 2.569, 95% CI 2.400-3.101, $p < .001$). This supports the conclusions from Monsuez and colleagues' 2006 study that demonstrated severely impaired reactive hyperemia in HIV infected patients. However, HIV is not a disease that has been well studied in relation to pressure ulcer risk. It is hoped the findings from this study will stimulate more interest in pressure ulcer research of this risk factor.

The large effect size for advanced age as a risk predictor supports findings from a number of published studies (Fromy et al., 2010; Lindgren et al., 2004; Page et al., 2011). However, what is unique in the findings from this study is the variation in level of risk between patients ages 66 - 81, and those ages 82 and above. Patients between the ages of 66 and 81 in the NIS sample were nearly 3 times more likely than younger patients to have a secondary diagnosis of PU (OR 2.981, 95% CI 2.892-3.072, $p < .001$). Patients in the sample who were ages 82 or above were more than 5 times more likely than younger patients to have a secondary diagnosis of PU (OR 5.137, 95% CI 4.979-2.299, $p < .001$). The ability to distinguish levels of risk among older age groups could be very helpful in clinical applications of targeted levels of preventive interventions. There was a very clear pattern of high incidence of pressure ulcers in the older group; however, what was not clear from the study data was the relative contribution of age-related co-morbidities to the pressure ulcer outcomes in this group. This requires further prospective study.

Patients in the NIS sample with a coded diagnosis of sepsis were over 1.5 times more likely to have a coded secondary diagnosis of PU than those without this diagnosis (OR 1.513, 95% CI 1.119-2.108, $p = .003$). The support of sepsis as an independent predictor of pressure ulcer risk is not surprising given its support in several other studies (Chan et al., 2005; Compton et al., 2008; Engelberger et al., 2011; Fogerty et al., 2008, Talley, 2010; Yepes et al., 2009). However, the results of studies of this variable have been inconsistent so the full import of this condition in relation to pressure ulcer risk is yet to be clearly explicated. The problem in this study was the inability to adequately identify the type, degree, and physiologic parameters of sepsis in the NIS sample patients. Without access to patient charts the researcher was forced to rely strictly on hospital

discharge coding of the diagnosis without confirmation of how the diagnoses were made in the sample patients. This decidedly detracts from the findings.

In this study, patients with a coded diagnosis of diabetes mellitus were more than twice as likely to have a secondary diagnosis code of PU as patients without this diagnosis (OR 2.229, 95% CI 2.114-2.275, $p < .001$). Diabetes mellitus has long been known as a risk factor but empirical confirmation of its predictive power has been elusive. Pressure ulcer researchers have focused primarily on diabetic patients with neuropathy and other diabetic co-morbidities as at-risk (Frankel et al., 2007; Fromy et al., 2002; Haleem et al., 2008; Smith et al., 2008). However, the physiology literature relating to the effects of diabetes on important protective mechanisms such as PIV and reactive hyperemia indicates the mere presence of the disease, without co-morbidities, may be sufficient to impair patients' tissue tolerance for pressure (Daly et al., 2006; Demiot et al., 2006; Fromy et al., 2010; Saumet, 2005). This thesis was supported to some degree by the data in this study as all patients with a diagnosis of diabetes were included in the IV. However, due to the reliance on ICD-9 coding it is impossible to determine what percentage of the diabetic patients in the study sample had co-morbidities. This should also be further studied in prospective research designs.

The support of fever as an independent predictor in this study adds to the literature on this important but poorly understood risk factor. Patients in the study with a coded diagnosis of fever were 1.4 times more likely to have a secondary diagnosis of PU than those without this coded diagnosis (OR 1.403, 95% CI 1.029-1.807, $p = .016$). Previous studies have failed to definitively identify the predictive strength of this condition (Nixon et al., 2000; Oomens et al., 2008; Bergstrom & Padhye, 2009; Suriadi et

al., 2010). Unfortunately, in this study neither the degree and duration of fever nor the source of the fever could be gleaned from the NIS database coding. This makes the predictor less useful in clinical practice. Further prospective study is needed to determine how much fever for how long is required to put a patient at high risk for PU. Although the study data were tested for a possible interaction between fever and sepsis and none was found, there is still the lingering question whether the study statistics fully identified this potential issue. This variable, also, would be best tested in a prospective study.

Additional findings. As an additional piece of the investigation, patients in the NIS database who were coded as having had non-operating room ancillary diagnostic and interventional procedures were identified and this group was tested using procedures as a predictor in the full NIS database. The CMH chi square and odds ratio were $\chi^2 = 4331.89$. *df* 1, OR = 1.585, $p < .001$. This variable remained slightly predictive when entered into a screening LR with the other predictor variables; however, the researcher did not feel sufficiently confident in the accuracy of the original CPT-4 coding of this variable in the NIS sample to pursue it further in the study. Clearly, a major goal of future research in this patient population is to identify the actual incidence of pressure ulcers occurring in ancillary services units. Currently there is only one published study of this incidence and it was conducted in a radiology department in a hospital in Ireland (Brown, 2002).

The inability to accurately identify patients with hypotension in the retrospective database was disappointing. There is growing evidence in the literature that number and degree of hypotensive episodes are important risk factors for pressure ulcer vulnerability. The problem encountered in studying this variable in a retrospective data set is the inability to determine the degree, duration, and etiology of the hypotension. Published

studies of the relationship between hypotension and PU risk have indicated that the number and duration of hypotensive episodes are determining factors in this risk. However, as Dr. Cuddigan noted in her comments on this item in the Content Validity Review Form for this study, previous studies are mixed on the effects of blood pressure. Further study of this variable will need to be done in a prospective follow-up when the Messer Scale is tested for predictive validity.

Additional cross-validation of study data. The remaining two 25% random samples from the original NIS database were too tempting to ignore. As an additional cross-check of the predictive stability of the selected risk factors and scale scores, each of the remaining samples was subjected to a LR and ROC curve analysis using the six variables identified as significant PU predictors. The resulting model coefficients and AUROCs were amazingly stable in both these samples with less than 2% shrinkage.

Limitations

In view of the retrospective nature of this study, the following limitations are acknowledged:

1. Lack of control over accuracy of the data recorded in the NIS database was a limitation. The coding system in the NIS 2007 data set made it extremely difficult to accurately identify patients with some of the diseases and conditions connected in the PU literature to impaired tissue tolerance for pressure. Even though this was attempted in the study, the statistical outcomes for the variables; cardiac disease, vascular disease, multiple sclerosis and other sclerosing diseases, malnutrition, paralysis and other neurological impairments, cognitive impairment, and spasticity and contractures, were insignificant. These factors are better suited for a prospective study, or at least a

retrospective study where patient medical records can be reviewed for more detailed evidence of the presence and degree of these factors.

2. With reliance on ICD-9-CM codes to identify risk factors it was not possible to ensure the absence of spurious correlations in the data. Analyses could not be done with adequate controls for confounders.

3. The researcher's inability to access individual patient records to identify presence, degree, and duration of diseases and conditions under study was a key weakness in the study.

4. As with much pressure ulcer research, the inability to determine whether patients in the study received PU preventive interventions was a limiting factor primarily because patients who were at risk based on the factors under study but did not get PUs may have received a different level of preventive care.

Implications of the Study

The most important implication of this study is that it identifies what has been a much-neglected clinical area where patients may be at high risk for pressure injury. One of the over-arching drivers of the research has been the researcher's conviction (based on extensive clinical experience as a pressure ulcer prevention clinical specialist) that a not-insignificant percent of hospital-acquired pressure ulcers may be occurring in ancillary services units. There currently is no clinical guideline in the U.S. that recommends skin assessments over pressure points before and after lengthy (non-operating room) diagnostic and interventional procedures. If this study at least sparks impetus toward making this a routine part of skin assessment it will have made an important contribution to clinical practice and patient care.

The further identification of HIV as an independent risk factor for pressure injury is an important contribution of this study. This risk factor has been under-studied, perhaps because its impairment of reactive hyperemia is not well known. It is hoped this study will encourage attention and study of HIV and protease inhibitors, and their physiologic affect on the critical mechanisms that protect tissue from pressure injury.

A unique contribution of this study is the incorporation of recommended preventive interventions into the risk scale itself. This has not historically been done with pressure ulcer risk scales, although it is sometimes seen in medical scales for morbidity and mortality predictions. This makes the Messer Scale not only a potential teaching tool for nurses in the clinical setting, but it also can be easily adapted into a *standing order* for providers to use to request specific assessment and preventive interventions for their patients. The down side of including interventions in the tool is the difficulty it creates in research validation of the tool. Validation of the entire tool would require research of the predictive validity of the preventive interventions as well as the risk scores. This would require major resources and thus is less likely to be attempted.

There currently is no validated risk assessment tool for surgical patients in the operating room environment. The Messer Scale is targeted at many of the same intrinsic and extrinsic factors that put patients at risk for pressure injury during surgical operations. Many of the recommended preventive interventions in the tool are also appropriate for patients undergoing procedures in the operating room. The Messer Scale could easily be adapted for the surgical patient population.

The extremely large, heterogeneous, nation-wide sample used for statistical analyses in this study improves the generalizability of the research findings despite

previously acknowledged weaknesses due to its retrospective nature. The HCUP NIS databases are a potentially rich source of pressure ulcer research data and it is hoped this study will encourage more nurse researchers to consider using the NIS data sets.

Recommendations

Based on the findings in this study, the following recommendations for future research are proposed:

1. Replication of the study in the clinical setting where real-time variable data can be collected and variable characteristics can be better described. Identification and control of potential confounders would greatly enhance this research.

2. Focused clinical research should be done to more clearly identify the effects of HIV disease and use of protease inhibitors on tissue tolerance for pressure and correlation of HIV disease and its treatment with pressure ulcer risk.

3. A large multi-center prospective study of pressure ulcer incidence in hospital ancillary services units in the U.S. is urgently needed. With the increasing incidence of nosocomial PUs it is critical to identify all hospital areas where patients are at high risk for pressure injury.

4. Wound and skin care organizations such as NPUAP and WOCN should consider including specific recommendations for routine skin assessments of pressure points in the peri-procedure period for patients undergoing lengthy ancillary diagnostic and treatment procedures.

References

AAWC (2011). Association for the Advancement of Wound Care pressure ulcer guideline: A quick reference guide for pressure ulcer prevention and treatment. *Association for the Advancement of Wound care*. Retrieved from http://aawconline.org/professional-resources/resources

Abraham, P., Fromy, B., Merzeau, S., Jardel, A., & Saumet, J. L. (2001). Dynamics of local pressure-induced cutaneous vasodilation in the human hand. *Microvascular Research*, *61*(1), 122-129.

AERA, APA, & NCME: Joint Committee (1999). *Standards for educational and psychological testing*. Washington, DC: American Psychological Association.

Agresti, A. (2002). *Categorical data analysis* (2nd ed.). Hoboken, NJ: Wiley.

AHRQ (2011). Preventing pressure ulcers in hospital: A toolkit for improving quality of care. *Agency for Healthcare Research and Quality*. Retrieved from http://www.ahrq.gov/research/ltc/pressureulcertoolkit/

American Medical Directors' Association (AMDA) (2003). *Pressure Ulcers in the Long Term Care Setting*. American Medical Directors' Association, Tag 314, Columbia, MD.

Angel, D., Sieunarine, K., Hunduma, N., Clayton, M., Abbas, M., & Ponosh, S. (2004). Postoperative pressure ulcers in vascular patients after epidural analgesia: Case reports. *Primary Intention*, *12*(1), 35-38.

Anthony, D., Reynolds, T., & Russell, L. (2003). A regression analysis of the Waterflow score in pressure ulcer risk assessment. *Clinical Rehabilitation*, *17*(2), 216-223.

Arao, H., Obato, M., Shimada, T., & Hagisawa, S. (1998). Morphological characteristics of the dermal papillae in the development of pressure sores. *Journal of Tissue Viability*, *8*(3)*,* 17–23.

Armstrong, D., & Bortz, R. (2001). An integrative review of pressure relief in surgical patients. *Journal of the Association of Perioperative Registered Nurses*, *73*(3), 645-674.

Aronovitch, S. A. (1998). A comparative, randomized, controlled study to determine safety and efficacy of preventive pressure ulcer systems: Preliminary analysis. *Advances in Wound Care*, *11*(3 Suppl), 15-16.

Aronovitch, S. A. (1999). Intraoperatively acquired pressure ulcer prevalence: A national study. *Journal of Wound, Ostomy, and Continence Nursing*, *26*(3), 130-136.

Aronovitch, S. A. (2007). Intraoperatively acquired pressure ulcers: Are there common risk factors? *Ostomy Wound Management*, *53*(2), 57-69.

Aronovitch, S. A., Wilber, M., Slezak, S., Martin, T., & Utter, D. (1999). A comparative study of an alternating air mattress for the prevention of pressure ulcers in surgical patients. *Ostomy Wound Management*, *45*(3), 34-40, 42-44.

Australian Wound Management Association (AWMA) (2001). *Clinical Practice Guidelines for the Prediction and Prevention of Pressure Ulcers*. West Leaderville, WA: Cambridge Publishing.

Ayello, E. A. (2008). A new era of pressure ulcer accountability in acute care. *Advances in Skin & Wound Care*, *21*(3), 134-140.

Bader, D. L., & Smith, S. H. (1998). The viability of soft tissues in elderly subjects undergoing hip surgery. *Age and Ageing, 27*(2), 217-221.

Bagley, S. C., White, H., & Golomb, B. A. (2001). Logistic regression in the medical literature: Standards for use and reporting, with particular attention to one medical domain. *Journal of Clinical Epidemiology*, *54*(10), 979-985.

Barbenel, J. C. (1991). Pressure management. *Prosthetics and Orthotics International*, *15*, 225-231.

Barbenel, J. C., Ferguson-Pell, M. W., & Beale, A. Q. (1985). Monitoring the mobility of patients in bed. *Medical and Biological Engineering and Computing*, *23*(5), 466-468.

Bennett, L., Kavner, D., Lee, B. Y., & Trainor, F. A. (1979). Shear vs. pressure as causative factors in skin blood flow occlusion. *Archives of Physical Medicine and Rehabilitation*, *60*(7), 309-314.

Bennett L., & Lee, B. (1985). Pressure versus shear in pressure sore causation. In: B. Lee (Ed.) *Chronic ulcers of the skin* (1st ed.), (pp. 39-56). New York, NY: McGraw-Hill.

Bennett, L., & Lee, B. Y. (1988). Vertical shear existence in animal pressure threshold experiments. *Decubitus*, *1*(1), 18-24.

Bergstrom, N. (2005). The Braden Scale for predicting pressure sore risk [Letter to the editor]. *Journal of Wound*, *Ostomy, and Continence Nursing*, *32*(1), 79-80.

Bergstrom, N., & Braden, B. (1992). A prospective study of pressure sore risk among institutionalized elderly. *Journal of the American Geriatric Society*, *40*(8), 747-758.

Berk, R. A. (1990). Importance of expert judgement in content-related validity evidence. *Western Journal of Nursing Research*, *12*(5), 659-671.

Berlowitz, D. R., & Wilking, S. V. (1989). Risk factors for pressure sores. A comparison of cross-section and cohort-derived data. *Journal of the American Geriatric Society*, *37*(11), 1043-1050.

Bliss, M. R. (1998). Hyperaemia. *Journal of Tissue Viability*, *8*(4), 4-12.

Bliss, M. R. (1998). Pressure injuries: Causes and prevention. *British Journal of Hospital Medicine*, *59*(11), 841-844.

Boignard, A., Salvat-Melis, M., Carpentier, P. H., Minson, C. T., Grange, L., Duc, C.,… Cracowski, J. L. (2005). Local hyperemia to heating is impaired in secondary Raynaud's phenomenon. *Arthritis Research & Therapy*, *7*(5), R1103-R1112.

Bouten, C. V., Oomens, C. W., Baaijens, F. P., & Bader, D. L. (2003). The etiology of pressure ulcers: Skin deep or muscle bound? *Archives of Physical Medicine and Rehabilitation*, *84(*4), 616-619.

Boyle, M., & Green, M. (2001). Pressure sores in intensive care: Defining their incidence and associated factors and assessing the utility of two pressure sore risk assessment tools. *Australian Critical Care*, *14*(1), 24-30.

Braden, B., & Bergstrom N. (1987). A conceptual schema for the study of the etiology of pressure sores. *Rehabilitation Nursing*, *12*(1), 8-12.

Brandeis, G. H., Ooi, W. L., Hossain, M., Morris, J. N., & Lipsitz, L. A. (1994). A longitudinal study of risk factors associated with the formation of pressure ulcers in nursing homes. *Journal of the American geriatric Soc*iety, *42*(4), 388-393.

Brown, A. (2002, September 20). *Pressure ulcer prevention in x-ray departments*. Paper presented at the Sixth European Pressure Ulcer Advisory Panel Open Meeting, Budapest, Hungary. Retrieved from http://www.epuap.org/review5_1/page5c.html

Burns, N., & Grove, S. (2005). *The practice of nursing research* (5th ed.). St Louis, MO: Elsevier.

Campbell, K. (1989). Pressure points in the operating room. *Journal of Enterostomal Therapy*, *16*(3), 119-124.

Casimiro, C., Garcia-de-Lorenzo, A., & Usán, L. (2002). Prevalence of decubitus ulcers and associated risk factors in an institutionalized Spanish elderly population. *Nutrition*, *18*(5), 408-414.

Chan, E. Y., Tan, S. L., Lee, C. K., & Lee, J. Y. (2005). Prevalence, incidence and predictors of pressure ulcers in a tertiary hospital in Singapore. *Journal of Wound Care*, *14*(8), 386-388.

Chauhan, V. S., Goel, S., Kumar, P., Srivastava, S., & Shukla, V. K. (2005). The prevalence of pressure ulcers in hospitalized patients in a university hospital in India. *Journal of Wound Care*, *14*(1), 36-37.

Clark, M. (1998). Repositioning to prevent pressure sores - what is the evidence? *Nursing Standard, 13*(3), 58-64.

Clarkson, P., Celermajer, D. S., Donald, A. E., Sampson, M., Sorensen, K. E., Adams, M.,… Deanfield, J. E. (1996). Impaired vascular reactivity in insulin-dependent diabetes mellitus is related to disease duration and low density lipoprotein

cholesterol levels. *Journal of the American College of Cardiology*, *28*(3), 573-579.

Compton, F., Hoffmann, F., Hortig, T., Strauss, M., Frey, J. Zidek, W., & Schäfer, J. H. (2008). Pressure ulcer predictors in ICU patients: Nursing skin assessment versus objective parameters. *Journal of Wound Care*, *17*(10), 417-420, 422-424.

Connor, T., Sledge, J. A., Bryant-Wiersema, L., Stamm, L., & Potter, P. (2010). Identification of pre-operative and intra-operative variables predictive of pressure ulcer development in patients undergoing urologic surgical procedures. *Urologic Nursing*, *30*(5), 289-295, 305.

Cox, J. (2010). Predictors of pressure ulcer development in adult critical care patients. (Doctoral dissertation, Rutgers University). Retrieved from http://proquest.umi.com.ezproxy.lib.usf.edu/pqdweb?index=0&did=2095151821&SrchMode=1&sid=2&Fmt=6&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1300656614&clientId=20178

Cuddigan, J., Ayello, E. A., & Sussman, C. (Eds.). (2001). *Pressure ulcers in America*: *Prevalence, incidence, and implications for the future*. Reston, VA: National Pressure Ulcer Advisory Panel. Evidence Level 1: Systematic Review/Meta-Analysis.

Daly, C. H., Chimoskey, J. E. Holloway, G. A., & Kennedy, D. (2006). The effect of pressure loading on blood flow rate in human skin. *Journal of Tissue Viability*, *16*(4), 17-21.

Daniel, R. K., Priest, D. L., & Wheatley, D. C. (1981). Etiologic factors in pressure sores: An experimental model. *Archives of Physical Medicine and Rehabilitation, 62*(10), 492-498.

Deane, L. A., Lee, H. J., Box, G. N., Abraham, J. B. A., Abdelshehid, C. S., Elchico, E. R.,…Clayman, R. V. (2008). Flank position is associated with higher skin-to-surface interface pressures in men versus women: Implications for laparoscopic renal surgery and the risk of rhabdomyolysis. *Journal of Endourology*, *22*(6), 1147-1152.

Defloor, T. (1999). The risk of pressure sores: A conceptual scheme. *Journal of Clinical Nursing*, *8*(2), 206-216.

Defloor, T., De Bacquer, D., & Grypdonck, M. H. F. (2005). The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. *International Journal of Nursing Studies*, *42*(1), 37-46.

Defloor, T., & De Schuijmer, J. D. S. (2000). Preventing pressure ulcers: An evaluation of four operating-table mattresses. *Applied Nursing Research*, *13*(3), 134-141.

Demiot, C., Tartas, M., Fromy, B., Abraham, P., Saumet, J. L., & Sigaudo-Roussel, D. (2006). Aldose reductase pathway inhibition improved vascular and C-fiber functions, allowing for pressure-induced vasodilation restoration during severe diabetic neuropathy. *Diabetes*, *55*(5), 1478-1483.

Dinsdale, S. M. (1974). Decubitus ulcers: Role of pressure and friction in causation. *Archives of Physical Medicine and Rehabilitation*, *55*(4), 147-155.

Donnelly, J. (2001). Hospital-acquired heel ulcers: A common but neglected problem. *Journal of Wound Care*, *10*(4), 131-136.

Edsberg, L. E., Cutway, R., Anain, S., & Natiella, J. R. (2000). Microstructural and mechanical characterization of human tissue at and adjacent to pressure ulcers. *Journal of Rehabilitation Research and Development, 37*(4), 463–471.

Ek, A. C., & Boman, G. (1982). A descriptive study of pressure sores: The prevalence of pressure sores and the characteristics of patients. *Journal of Advanced Nursing*, *7*(1), 51-57.

Ek, A. C., Lewis, D. L., Zetterqvist, H., & Svensson, P. G. (1984). Skin blood flow in an area at risk for pressure sore. *Scandinavian Journal of Rehabilitation Medicine*, *16*(2), 85-89.

Engelberger, R. P., Pittet, Y. K., Hugues, H., Delodder, F., Daniel, H. Chioléro, R. L.,… Feihl, F. (2011). Acute endotoxemia inhibits microvascular nitric oxide-dependent vasodilation in humans. *Shock*, *35*(1), 28-34.

European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisor Panel (EPUAP & NPUAP) (2009). *Pressure Ulcer Prevention: Quick Reference Guide*. Washington, DC: National Pressure Ulcer Advisory Panel.

Exton-Smith, A. N. (1961). The prevention of pressure sores. Significance of spontaneous bodily movements. *Lancet*, *2*(7212), 1124-1126.

Feuchtinger, J., Halfens, R. J., & Dassen, T. (2005). Pressure ulcer risk factors in cardiac surgery: A review of the research literature. *Heart & Lung*, *34*(6), 375-385.

Fisher, A. R., Wells, G., & Harrison, M. (2004). Factors associated with pressure ulcers in adults in acute care hospitals. *Holistic Nursing Practice*, *18*(5), 242-253.

Fisher, S., Szymke, T. E., Apte, S. Y., & Kosiak, M. (1978). Wheelchair cushion effect on skin temperature. *Archives of Physical Medicine and Rehabilitation*, *59*(2), 68-72.

Fizanne, L., Fromy B., Preckel, M. P., Sigaudo-Roussel, D., & Saumet, J. L. (2003). Effect of isoflorane on skin-pressure-induced vasodilation. *Journal of Vascular Research, 40*(4), 416-422.

Fleiss, J. L., & Cohen, J. (1973). The equivalence of weighted kappa and the intraclass correlation coefficient as measures of reliability. *Educational and Psychological Measurement*, *33*, 613-619.

Fogerty, M., Abumrad, J. N., Nanney, L., Arbogast, P. G., Poulose, B., & Barbul, A. (2008). Risk factors for pressure ulcers in acute care hospitals. *Wound Repair and Regeneration*, *16*(1), 11-18.

Fontaine, R., Risley, S., & Castellino, R. (1998). A quantitative analysis of pressure and shear in the effectiveness of support surfaces. *Journal of Wound, Ostomy, and Continence Nursing*, *25*(5), 233-239.

Foreman, M. D., Theis, S. L., & Anderson, M. A. (1993). Adverse events in the hospitalized elderly. *Clinical Nursing Research*, *2*, 360-370.

Frankel, H., Sperry, J., & Kaplan, L. (2007). Risk factors for pressure ulcer development in a best practice surgical intensive care unit. *The American Surgeon*, *73*(12), 1215-1217.

Fromy, B., Abraham, P., Bouvet, C., Bouhanick, B., Fressinaud, P., & Saumet, J. L. (2002). Early decrease of skin blood flow in response to locally applied pressure in diabetic subjects. *Diabetes*, *51*, 1214-1217.

Fromy, B., Abraham, P., & Saumet, J. L. (1998). Non-nociceptive capsaicin-sensitive nerve terminal stimulation allows for an original vasodilatory reflex in the human skin. *Brain Research*, *811*(1-2), 166-168.

Fromy, B., Sigaudo-Roussel, D., Gaubert-Dahan, M. L., Roussear, P., Abraham, P., Benzoni, D., Saumet, J. L. (2010). Aging-associated sensory neuropathy alters pressure-induced vasodilation in humans. *Journal of Investigative Dermatology*, *130*(3), 849-855.

Garry, A., Sigaudo-Roussel, D., Merzeau, S., Dumont, O., Saumet, J. L., & Fromy B. (2005). Cellular mechanisms underlying cutaneous pressure-induced vasodilation: In vivo involvement of potassium channels. *American Journal of Physiology - Heart and Circulatory Physiology*, *289*(1), H174-180.

Gefen, A. (2008). How much time does it take to get a pressure ulcer? Integrated evidence from human, animal, and in vitro studies. *Ostomy Wound Management 54*(10), 26-28, 30-35.

Gefen, A., Gefen, N., Linder-Ganz, E., & Margulies, S. S. (2005). In vivo muscle stiffening under bone compression promotes deep pressure sores. *Journal of Biomechanical Engineering*, *127*(3), 512-524.

Gomes, F. S. L., Bastos, M., A., R., Matozinhos, F. P., Temponi, H. R., & Velásquez-Meléndez (2010). Factors associated to pressure ulcers in patients at adult intensive care units. *Journal of São Paulo University School of Nursing*, *44*(4), 1065-1071.

Goossens, R. H., Zegers, R., Hoek van Dijke, G. A., & Snijders, C. J. (1994). Influence of shear on skin oxygen tension. *Clinical Physiology*, *14*(1), 111-118.

Gordis, L. (2004). *Epidemiology* (3rd ed.) Philadelphia. PA: Elsevier Saunders.

Grous, C. A., Reilly, N. J., & Gift, A. G. (1997). Skin integrity in patients undergoing prolonged operations. *Journal of Wound, Ostomy, and Continence Nursing*, *24*(2), 86-91.

Guihan, M., Garber, S. L., Goldstein, B., Holmes, S. A., & Lishan, C. (2008). Predictors of pressure ulcer recurrence in veterans with spinal cord injury. *Journal of Spinal Cord Medicine*, 31(3), 551-559.

Hagisawa, S., Fergusan-Pell, M., & Herbert, J. (1994). Reactive hyperemia response to pressure-induced localized ischemia in patients with multiple sclerosis. *Neurorehabilitation and Neural Repair*, *8*(4), 193-201.

Hagisawa, S., & Shimada, T. (2005). Skin morphology and its mechanical properties associated with loading. In D. Bader, C. Bouten, D. Colin, & C. Oomens (Eds.), *Pressure ulcer research: Current and future perspectives* (pp. 161-185). Berlin, Germany: Springer-Verlad.

Haleem, S., Heinert, G., & Parker, M. J. (2008). Pressure sores and hip fractures. *Injury*, *39*(2), 219-223.

Halfens, R. J., & Haalboom, J. R. E. (2001). A historical overview of pressure ulcer literature of the past 35 years. *Ostomy Wound Management*, *47*(11), 36-43.

Haugen, V., Pechacek, J., Maher, T., Wilde, J., Kula, L., & Powell, J. (2011). Decreasing pressure ulcer risk during hospital procedures. *Journal of Wound, Ostomy, and Continence Nursing, 38*(2), 155-159.

Hoshowsky, V. M., & Schramm, C. A. (1994). Intraoperative pressure sore prevention: An analysis of bedding materials. *Research in Nursing & Health*, *17*(5), 333-339.

Howatson-Jones, I. L. (2001). Relieving the pressure in the radiology department. *British Journal of Nursing*, *10*(4), 219-222, 224, 226.

HCUP Databases (November 2011). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: *Agency for Healthcare Research and Quality*.

Husain, T. (1953). An experimental study of some pressure effects on tissues, with reference to the bed-sore problem. *Journal of Pathology & Bacteriology*, *66*(2), 347-358.

Institute for Clinical Systems Improvement (ICSI) (2010). *Health Care Protocol*: *Pressure Ulcer Prevention and Treatment Protocol.* Bloomington, MN: Institute for Clinical Systems Improvement.

Institute for Healthcare Improvement (2008). Protecting 5 million lives from harm: Getting started kit: Prevent pressure ulcers: How-to-guide. Retrieved from http://www.ihi.org/NR/rdonlyres/5ABABB51-93B3-4D88-AE19-BE88B7D96858/0/PressureUlcerHowtoGuide.doc

International Review (2010). *Pressure Ulcer Prevention: Pressure, Shear, Friction and Microclimate in Context. A Consensus Document*. London: Wounds International.

Jan, Y. K., Struck, B. D., Foreman, R. D., & Robinson, C. (2009). Wavelet analysis of sacral skin blood flow oscillations to assess soft tissue viability in older adults. *Microvascular Research, 78*(2), 162-168.

Jerusum, J., Joseph, K., Davis, J. M., & Suki, R. (1996). Balloons, beds and breakdown. *Critical Care Nursing Clinics of North America*, *8*, 423-440.

Johnstone, M. T., Creager, S. J., Scales, K. M., Cusco, J. A., Lee, B. K., & Creager, M. A. (1993). Impaired endothelium-dependent vasodilation in patients with insulin-dependent diabetes mellitus. *Circulation*, *88*(6), 2510-2516.

Justham, D., Michael, C., & Harris, D. (1996). A healthy volunteer study of skin-surface interface pressure experienced in x-ray departments. *Journal of Tissue Viability*, *6*(4), 107-110.

Karadag, M., & Gümüskaya, N. (2006). The incidence of pressure ulcers in surgical patients: A sample hospital in Turkey. *Journal of Clinical Nursing*, *15*(4), 413-421.

Keller, B. P. J. A., Lubbert, P. H. W., Keller, E., & Leenen, L. P. H. (2005). Tissue-interface pressures on three different support-surfaces for trauma patients. *Injury*, *36*(8), 946-948.

Kemp, M. G., Keithley, J. K., Smith, D. W. & Morreale, B. (1990). Factors that contribute to pressure sores in surgical patients. *Research in Nursing & Health*, *13*(5), 293-301.

King, C. A., & Bridges, E. (2006). Comparison of pressure relief properties of operating room surfaces. *Perioperative Nursing Clinics*, *1*(3), 261-265.

Knight, S. L., Taylor, R. P., Polliack, A. A., & Bader, D. L. (2001). Establishing predictive indicators for the status of loaded soft tissues. *Journal of Applied Physiology*, *90*(6), 2231-2237.

Koitka, A., Abraham, P., Bouhanick, B., Sigaudo-Roussel, D., Demiot, C., & Saumet, J. L. (2004). Impaired pressure-induced vasodilation at the foot in young adults with type 1 diabetes. *Diabetes*, *53*, 721-725.

Kokate, J. Y., Leland, K. J., Held, A. M., Hansen, G. L., Kveen, G. L., Johnson, B. A.,… Iaizzo, P. A. (1995). Temperature-modulated pressure ulcers: A porcine model. *Archives of Physical Medicine and Rehabilitation*, *76*(7), 666-673.

Kosiak, M. (1959). Etiology and pathology of ischemic ulcers. *Archives of Physical Medicine and Rehabilitation*, *40*(2), 62-69.

Kosiak, M. (1961). Etiology of decubitus ulcers. *Archives of Physical Medicine and Rehabilitation*, *42*, 19-29.

Krapfl, L. A., & Gray, M. (2008). Does regular repositioning prevent pressure ulcers? *Journal of Wound, Ostomy, and Continence Nursing, 35*(6), 571-577.

Kröger, K., Stausberg, J., Maier, I., Schneider, H., & Niebel, W. (2005). Preexisting risk factors in intensive care patients with pressure ulcers. *Intensive Care and Emergency Medicine*, *42*(3), 270-274.

Krouskop, T. A. (1983). A synthesis of the factors that contribute to pressure sore formation. *Medical Hypothesis*, *11*(2), 255-267.

Kruger, A., Stewart, J., Sahityani, R., Riordan, E. O., Thompson, C., Adler, S.,… Goligorsky, M. S. (2006). Laser Doppler flowmetry detection of endothelial dysfunction in end-stage renal disease patients: Correlation with cardiovascular risk. *Kidney International, 70*(1), 157-164.

Lamblin, V., Favory, R., Boulo, M., & Mathieu, D. (2006). Microcirculatory alterations induced by sedation in intensive care patients. Effects of midazolam alone and in association with sufentanil. *Critical Care*, *10*(6), R176.

Landis, E. (1930). Microinjection studies of capillary blood pressure in human skin. *Heart*, *15*, 209-228.

Lewicki, L. J., Mion, L., Splane, K. G., Samstag, D., & Secic, M. (1997). Patient risk factors for pressure ulcers during cardiac surgery. *Journal of the Association of Perioperative Registered Nurses*, *65*(5), 933-942.

Linden, E., Cai, W., He, J. C., Xue, C., Li, Z., Winston, J., Uribarri, J. (2008). Endothelial dysfunction in patients with chronic kidney disease results from advanced glycation end products (AGE)-mediated inhibition of endothelial nitric oxide synthase through RAGE activation. *Clinical Journal of the American Society of Nephrology*, *3*(8), 691-698.

Linder-Ganz, E., & Gefen, A. (2004). Mechanical compression-induced pressure sores in rat hind-limb: Muscle stiffness, histology, and computational models. *Journal of Applied Physiology*, *96*, 2034-2049.

Linder-Ganz, E., & Gefen, A. (2007). The effects of pressure and shear on capillary closure in the microstructure of skeletal muscles. *Annuls of Biomedical Engineering*, *35*(12), 2095-2107.

Lindgren, M., Unosson, M., Fredrikson, M., & Ek, A. C. (2004). Immobility - a major risk factor for development of pressure ulcers among adult hospitalized patients: A prospective study. *Scandinavian Journal of Caring Sciences, 18*(1), 57-64.

Lindgren, M., Unosson, M., Krantz. A. M., & Ek, A. C. (2005). Pressure ulcer risk factors in patients undergoing surgery. *Journal of Advanced Nursing*, *50*(6), 605-612.

Lindquist, L. A., Feinglass, J., & Martin, G. J. (2003). How sedative medication in older people affects patient risk factors for developing pressure ulcers. *Journal of Wound Care*, *12*(7), 272-275.

Lyder, C. H. (2003). Pressure ulcer prevention and management. *The Journal of the American Medical Association, 289*(2), 223-226.

Lyder, C. H., & Ayello, E. A. (2008). Pressure ulcers: A patient safety issue. In *Patient Safety and Quality: An Evidence-based Handbook for Nurses*. Agency for Healthcare Research and Quality, Publication No. 08-0043: Vol. 2. Washington, DC: U.S. Government Printing Office.

Lynn, M. R. (1986). Determination and quantification of content validity. *Nursing Research, 35*(6), 382-385.

Maklebust, J., & Magnan, M. A. (1994). Risk factors associated with having a pressure ulcer: A secondary data analysis. *Advances in Wound Care*, *7*(6), 27-28, 31-34.

Maklebust, J., & Sieggreen, M. (2001). *Pressure ulcers: Guidelines for prevention and management* (3rd ed.). Springhouse, PA: Springhouse Corporation.

Margolis, D. J., Knauss, J., Bilker, W., & Baumgarten, M. (2003). Medical conditions as risk factors for pressure ulcers in an outpatient setting. *Age and Ageing*, *32*(3), 259-264.

Mawson, A. R., Siddiqui, F. H., Connolly, B. J., Sharp, C. J., Summer, W. R., & Biundo, J. J. Jr. (1993). Sacral transcutaneous oxygen tension levels in the spinal cord injured: Risk factors for pressure ulcers? *Archives of Physical Medicine and Rehabilitation*, *74*(7), 745-751.

Mayrovitz, H. N., & Sims, N. (2004). Effects of support surface relief pressures on heel skin blood flow in persons with and without diabetes mellitus. *Advances in Skin & Wound Care, 17*(4 Pt 1), 197-201.

McLellan, K., Petrofsky, J. S., Zimmerman, G., Lohman, E., Prowse, M., Schwab, E., & Lee, S. (2009). The influence of environmental temperature on the response of the skin to local pressure: The impact of aging and diabetes. *Diabetes Technology & Therapeutics*, *11*(12), 791-798.

Meijer, J. H., Germs, P. H., Schneider, H., & Ribbe, M. W. (1994). Susceptibility to decubitus ulcer formation. *Archives of Physical Medicine and Rehabilitation*, *75*(3), 318-323.

Meyer, M. F., Lieps, D., Schatz, H., & Pfohl, M. (2008). Impaired flow-mediated vasodilation in type 2 diabetes: Lack of relation to microvascular dysfunction. *Microvascular Research*, *76*(1), 61-65.

Meyer, M. F., & Schatz, H. (1998). Influence of metabolic control and duration of disease on microvascular dysfunction in diabetes assessed by laser Doppler anemometry. *Experimental and Clinical Endocrinology & Diabetes*, *106*(5), 395-403.

Miller, G. E., & Seale, J. (1981). Lymphatic clearance during compressive loading. *Lymphology*, *14*(4), 161-166.

Minnesota Hospital Association (MHA), 2009. *Pressure Ulcer Prevention in the O.R. Recommendations and Guidance.* Retrieved from http://www.mnhospitals.org/inc/data/tools/SafeSkin-Toolkit/OR-pressure-ulcer-recommendations.pdf

Monsuez, J. J., Dufaux, J., Vittecoq, D., & Vicaut, E. (2000). Reduced reactive hyperemia in HIV-infected patients. *Journal of Acquired Immune Deficiency Syndromes*, *25*(5), 434-442.

Morison, M. J., (Ed.). (2001). *The prevention and treatment of pressure ulcers* (p. 28). London: Mosby.

National Institute for Health and Clinical Excellence (NICE) (2001): *Pressure Ulcer Management.* Retrieved from http://guidance.nice.org.uk/CG29

Newrick, P. G., Cochrane, T., Betts, R. P., Ward, J. D., & Boulton, A. J. (1988). Reduced hyperaemic response under the diabetic neuropathic foot. *Diabetic Medicine*, *5*(6), 570-573.

Nicastri, E., Viale, P., Lyder, C. H., Cristini, F., Martini, L., Preziosi, G.,… Petrosillo, N. (2004). Incidence and risk factors associated with pressure ulcers among patients with HIV infection. *Advances in Skin & Wound Care, 17*(5 Pt 1), 226-231.

Nijs, N., Toppets, A., Defloor, T., Bernaerts, K., Milisen, K., & Van Den Berghe, G. (2009). Incidence and risk factors for pressure ulcers in the intensive care unit. *Journal of Clinical Nursing*, *18*(9), 1258-1266.

Nixon J., Brown J., McElvenny D., Mason S., & Bond S. (2000). Prognostic factors associated with pressure sore development in the immediate post-operative period. *International Journal of Nursing Studies*, *37*(4), 279–289.

Nixon, J., Cranny, G., & Bond, S. (2007). Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: A cohort study. *International Journal of Nursing Studies*, *44*(5), 655-663.

Nixon, J., McElvinney, D., Mason, S., Brown, J., & Bond, S. (1998). A sequential randomised controlled trial comparing a dry visco-elastic polymer pad and standard operating table mattress in the prevention of post-operative pressure sores. *International Journal of Nursing Studies*, *35*(4), 193-203.

Nonnemacher, M., Stausberg, J., Bartoszek, G., Lottko, B., Neuhaeuser, M., & Maier, I. (2009). Predicting pressure ulcer risk: A multifactorial approach to assess risk factors in a large university hospital population. *Journal of Clinical Nursing*, *18*(1), 99-107.

Norton, D., McLaren, R., & Exton-Smith, A. N. (1962). *An investigation of geriatric nursing problems in hospital*. London: National Corporation for the Care of Old People (now Centre for Policy on Ageing).

Oomens, C., Bader, D., Gefen, A., & Soriano, J. V. (2008). *The aetiology of pressure ulcers: Preamble for EPUAP/NPUAP Pressure Ulcer Guidelines*. Retrieved from http://www.tempurpedicmed.com/images/uploads/articles/EPUAPAetiology_10_1_guidelines.pdf

Page, K. N., Barker, A. L., & Kamar, J. (2011). Development and validation of a pressure ulcer risk assessment tool for acute hospital patients. *Wound Repair and Regeneration*, *19*(1), 31-37.

Palevski, A., Glaich, I., Portnoy, S., Linder-Ganz, E., & Gefen, A. (2006). Stress relaxation of porcine gluteus muscle subjected to sudden transverse deformation as related to pressure sore modeling. *Journal of Biomechanical Engineering, 128*(5), 782-787.

Pancorbo-Hidalgo, P.L., Garcia-Hernandez, F. P., Lopez-Medina, I.M., & Alvarez-Nieto, C., (2006). Risk assessment scales for pressure ulcer prevention: A systematic review. Journal of Advanced Nursing, 54(1), 94-110.

Panel for the Prediction and Prevention of Pressure Ulcers in Adults (1992). *Pressure ulcers in adults: Prediction and prevention*. Clinical Practice Guideline Number

3. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services.

Papantonio, C. T., Wallop, J. M., & Kolodner, K. B. (1994). Sacral ulcers following cardiac surgery: Incidence and risks. *Advances in Wound Care*, *7*(2), 24-36.

Peng, C. Y., Lee, K. L., & Ingersoll, G. M. (2002). An introduction to logistic regression analysis and reporting. *The Journal of Educational Research*, *96*(1), 3-12.

Perneger, T. V., Héliot, C., Raë, A. C., Borst, F., & Gaspoz, J. M. (1998). Hospital-acquired pressure ulcers: Risk factors and use of preventive devices. *Archives of Internal Medicine, 158*(17), 1940-1945.

Perneger, T. V., Raë, A. C., Gaspoz, J. M., Borst, F., Vitek, O., & Héliot, C. (2002). Screening for pressure ulcer risk in an acute care hospital: Development of a brief bedside scale. *Journal of Clinical Epidemiology*, *55*(5), 498-504.

Pieper, B. (2000). Mechanical forces: Pressure, shear, and friction. In R. A. Bryant (Ed.), *Acute and chronic wounds: Nursing management* (2nd ed.) (pp. 221-264). St. Louis, MO: Mosby.

Piloiam. B. B. (1992). Defining characteristics of the nursing diagnosis "high risk for impaired skin integrity". *Decubitus*, *5*(5), 32-38, 42.

Pokomy, M. E., Koldjeski, D., & Swanson, M. (2003). Skin care intervention for patients having cardiac surgery. *American Journal of Critical Care*, *12*(6), 535-544.

Polit, D. F., & Beck, C. T. (2006). The content validity index: Are you sure you know what's being reported? Critique and recommendations. *Research in Nursing & Health*, *29*(5), 489-497.

Polit, D. F., & Beck, C. T. (2008). *Nursing research: Generating and assessing evidence for nursing practice* (8th ed.). Philadelphia: Lippincott Williams & Wilkins.

Price, M. C., Whitney, J. D., & King, C. A. (2005). Development of a risk assessment tool for intraoperative pressure ulcers. *Journal of Wound, Ostomy and Continence Nursing*, *32*(1), 19-30.

Ramsay, J. (1998). Pressure ulcer risk factors in the operating room. *Advances in Wound Care*, *11*(3 Suppl), 5-6.

Rapp, M. P., Bergstrom, N., & Padhye, N. S. (2009). Contribution of skin temperature regularity to the risk of developing pressure ulcers in nursing facility residents. *Advances in Skin & Wound Care*, *22*(11), 506-513.

Ratliff, C., & Rodeheaver, G. (1998). Prospective study of the incidence of OR-induced pressure ulcers in elderly patients undergoing lengthy surgical procedures. *Advances in Wound Care*, *11*(3 Suppl), 10.

Reddy, M., Gill, S. S., & Rochon, P. A. (2006). Preventing pressure ulcers: A systematic review. *The Journal of the American Medical Association*, *296*(8), 974-984.

Reddy, N. P., Cochran, G. v. B., & Krouskop, T. A. (1981) Interstitial fluid flow as a factor in decubitus ulcer formation. *Journal of Biomechanics*, *12*(12), 879-881.

Reed, R. L., Hepburn, K., Adelson, R., Center, B., & McKnight, P. (2003). Low serum albumin levels, confusion, and fecal incontinence: Are these risk factors for pressure ulcers in mobility-impaired hospitalized adults? *Gerontology*, *49*(4), 255-259.

Registered Nurses' Association of Ontario (RNAO) (2005). *Risk assessment and prevention of pressure ulcers*. Toronto: RNAO. Retrieved from http://www.rnao.org/Page.asp?PageID=924&ContentID=816

Reichel, S. M. (1958). Shearing force as a factor in decubitus ulcers in paraplegics. *Journal of the American Medical Association*, *166*(7), 762-763.

Reswick, J. B., & Rogers, J. E. (1976). Experience at Rancho Los Amigos Hospital with devices and techniques to prevent pressure sores. In: R. M. Kenedi, M. Cowden, & J. T. Scales (Eds.). *Bedsore biomechanics* (pp. 301-310). London: Macmillan Press.

Rodrigues Júnior, G. R., & do Amaral, J. L. (2004). Influence of sedation on morbidity and mortality in the intensive care unit. *São Paulo Medical Journal, 122*(1), 8-11.

Russo, C. A., & Elixhauser, A. (2006). *Hospitalizations related to pressure sores, 2003*. HCUP Statistical Brief # 3. Rockville, MD: Agency for Healthcare Research and Quality.

Russo, C. A., Steiner, C., & Spector, W. (2008). *Hospitalizations related to pressure ulcers among adults 18 years and older, 2006*. HCUP Statistical Brief #64. Rockville, MD: Agency for Healthcare Research and Quality.

Ryan, T. J., (1979). Blood supply and decubitus ulcers. *International Journal of Dermatology*, *18*(2), 123-124

Sae-Sia, W. (2009). Impaired skin microcirculation in hospitalized elderly and in patients with spinal cord injuries: a pressure ulcer risk. *Songkla Medical Journal*, *27*(2), 179-193.

Sae-Sia, W., Wipke-Tevis, D. D., & Williams, D. A. (2005). Elevated sacral skin temperature (T_s): A risk factor for pressure ulcer development in hospitalized neurologically impaired Thai patients. *Applied Nursing Research*, *18*(1), 29-35.

Sae-Sia, W., Wipke-Tevis, D. D., & Williams, D. A. (2007). The effect of clinically relevant pressure duration on sacral skin blood flow and temperature in patients after acute spinal cord injury. *Archives of Physical Medicine and Rehabilitation*, *88*(12), 1673-1680.

Salcido, R. (2006, August 10). Pressure ulcers and wound care. *Emedicine*. Retrieved from http://www.emedicine.com/pmr/topic179.htm

Sanada, H., Nagakawa, T., Yamamoto, M, Higashidani, K., Tsuru, H., & Sugama, J. (1997). The role of skin blood flow in pressure ulcer development during surgery. *Advances in Wound Care*, *10*(6), 29-34.

Saumet, J. L. (2005). Cutaneous vasodilation induced by local pressure application: Modifications in diabetes. *Bulletin de l'Académie nationale de medicine, 89*(1), 99-105.

Schoonhoven, L., Defloor, T., & Grypdonck, M. H. (2002). Incidence of pressure ulcers due to surgery. *Journal of Clinical Nursing*, *11*(4), 479-487.

Schoonhoven, L., Defloor, T., van de Tweel, I., Buskens, E., & Grypdonck, M. H. (2002). Risk indicators for pressure ulcers during surgery. *Applied Nursing Research*, *15*(3), 163-173.

Schoonhoven, L., Grobbee, D. E., Donders, A. R., Algra, A., Grypdonck, M. H., Bousema, M. T., Buskens, E. (2006). Prediction of pressure ulcer development in

hospitalized patients: A tool for risk assessment. *Quality & Safety in Health Care, 15*(1), 65-70.

Schubert, V. (1991). Hypotension as a risk factor for the development of pressure sores in elderly subjects. *Age and Ageing*, *20*(4), 255-261.

Schubert, V., & Fagrell, B. (1991a). Evaluation of the dynamic cutaneous post-ischaemic hyperaemia and thermal response in elderly subjects and in an area at risk for pressure sores. *Clinical Physiology*, *11*(2), 169-182.

Schubert, V., & Fagrell, B. (1991b). Postocclusive reactive hyperemia and thermal response in the skin microcirculation of subjects with spinal cord injury. *Scandinavian Journal of Rehabilitation Medicine*, *23*(1), 33-40.

Schubert, V., & Héraud, J. (1994). The effects of pressure and shear on skin microcirculation in elderly stroke patients lying in supine or semi-recumbent positions. *Age and Ageing*, *23*(5), 405-410.

Schultz, A. (2005). Predicting and preventing pressure ulcers in surgical patients. *Journal of the Association of Perioperative Registered Nurses*, *81*(5), 986-1006.

Schultz, A., Bien, M., Dumond, K., Brown, K., & Myers, A. (1999). Etiology and incidence of pressure ulcers in surgical patients. *Journal of the Association of Perioperative Registered Nurses*, *70*(3), 434, 437-440, 443-444, 446-449.

Seiler, W. O., & Stähelin, H. B., (1979). Skin oxygen tension as a function of imposed skin pressure: Implication for decubitus ulcer formation. *Journal of the American Geriatrics Society*, *27*(7), 298-267.

Shats, V., & Kozacov, S. (1996). Is diabetes mellitus a risk factor for pressure ulcers? *Harefuah, 131*(11), 485-486, 535.

Sigaudo-Roussel, D., Demiot, C., Fromy, B., Koïtka, A., Lefthériotis, G., Abraham, P., & Saumet, J. L. (2004). Early endothelial dysfunction severely impairs skin blood flow response to local pressure application in streptozotocin-induced diabetic mice. *Diabetes*, *53*(6), 1564-1569.

Singleton, J. R., Smith, A. G., Russell, J. W., & Feldman, E. L. (2003). Microvascular complications of impaired glucose tolerance. *Diabetes, 52*(12), 2867-2873.

Slowikowski, G. C., & Funk, M. (2010). Factors associated with pressure ulcers in patients in a surgical intensive care unit. *Journal of Wound, Ostomy, and Continence Nursing*, *37*(6), 619-626.

Smith, B. M., Guihan, M., LaVela, S. L., & Garber, S. L. (2008). Factors predicting pressure ulcers in veterans with spinal cord injuries. *American Journal of Physical Medicine and Rehabilitation*, *87*(9), 750-757.

Solages, A., Vita, J. A., Thornton, D. J., Murray, J., Heeren, T., Craven, D. E., & Horsburgh, C. R., Jr. (2006). Endothelial function in HIV-infected persons. *Clinical Infectious Diseases*, *42*(9), 1325-1332.

Song, M., & Choi, K. S. (1991). Factors predicting development of decubitus ulcers among patients admitted for neurological problems. *The Journal of Nurses Academic Society*, *21*(1), 16-26.

Steinmetz, J. A., & Langemo, D. K. (1996). Changes in occipital capillary perfusion pressures during coronary artery bypass graft surgery. *Advances in Wound Care*, *9*(3), 28-32.

Stekelenburg, A., Strijkers, G. J., Parusel, H., Bader, D. L., Nicolay, K, & Oomens, C. W. (2007). Role of ischemia and deformation in the onset of compression-induced

deep tissue injury: MRI-based studies in a rat model. *Journal of Applied Physiology*, *102*(5), 2002-2011.

Stevens, J., Nichelson, E., Linehan, W. M., Thompson, N., Liewehr, D., Venzon, D., & Walther, M. M. (2004). Risk factors for skin breakdown after renal and adrenal surgery. *Urology, 64*(2), 246-249.

Stordeur, S., Laurent, S., & D'Hoore, W. (1998). The importance of repeated risk assessment for pressure sores in cardiovascular surgery. *Journal of Cardiovascular Surgery*, *39*(3), 343-349.

Stotts, N. A. (1999). Risk of pressure ulcer development in surgical patients: A review of the literature. *Advances in Wound Care*, *12*(3), 127-136.

Suriadi, Sanada, H., Sugama, J., Thigpen, B., & Subuh, M. (2008). Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit. *Nursing in Critical Care*, *13*(1), 34-43.

Tabachnick, B. G., & Fidell, L. S. (2007). *Using multivariate statistics* (5th ed.). NY: Pearson.

Talley, M. (2010). Pressure ulcer risk factors for patients with hospital versus community acquired pressure ulcers. (Doctoral dissertation, University of San Diego). Retrieved from http://proquest.umi.com.ezproxy.lib.usf.edu/pqdweb?index=0&did=2095151821&SrchMode=1&sid=2&Fmt=6&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1300656614&clientId=20178

Taylor, R., & James, T. (2005). The role of oxidative stress in the development and persistence of pressure ulcers. In D. Bader, C. Bouton, D. Colin, & C. Oomens

(Eds.). *Pressure ulcer research: Current and future perspectives* (pp. 205-232). Berlin, Germany: Springer-Verlad.

Terekeci, H., Kucukardali, Y, Top, C., Onem, Y., Celik, S., & Okenli, C. (2009). Risk assessment study of the pressure ulcers in intensive care unit patients. *European Journal of Internal Medicine*, *20*(4), 394-397.

Theaker, C., Mannan, M., Ives, N., & Soni, N. (2000). Risk factors for pressure sores in the critically ill. *Anaesthesia*, *55*(3), 221-224.

Thompson, D. (2005). A critical review of the literature on pressure ulcer aetiology. *Journal of Wound Care*, *14*(2), 8790.

Tikhonova, I. V., Tankanag, A. V., & Chemeris, N. K., (2010). Age-related differences in the dynamics of the skin blood flow oscillations during postocclusive reactive hyperemia. *Human Physiology, 36*(2), 222-228.

Tweed, C. (2003). The role of pressure in pressure ulcer aetiology: A review of the literature. *Primary Intention*, *11*(1), 28-36.

Tzen, Y. T., Brienza, D. M., Karg, P., & Loughlin, P. (2010). Effects of local cooling on sacral skin perfusion response to pressure: Implications for pressure ulcer prevention. *Journal of Tissue Viability*, *19*(3), 86-97.

Vanderwee, K., Grypdonck, M. H. F., De Bacquer, D., & Defloor, T. (2007). Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. *Journal of Advanced Nursing*, *57*(1), 59-68.

Vanderwee, K., Grypdonck, M., De Bacquer, D., & Defloor, T. (2009). The identification of older nursing home residents vulnerable for deterioration of grade 1 pressure ulcers. *Journal of Clinical Nursing*, *18*(21), 3050-5058.

van Marum, R. J., Meijer, J. H., Bertelsmann, F. W., & Ribbe, M. W. (1997). Impaired blood flow response following pressure load in diabetic patients with cardiac autonomic neuropathy. *Archives of Physical Medicine and Rehabilitation*, *78*(9), 1003-1006.

van Marum, R. J., Meijer, J. H., Ooms, M. E., Kostense, P. J., van Eijk, J. T., & Ribbe, M. W. (2001). Relationship between internal risk factors for development of decubitus ulcers and the blood flow response following pressure load. *Angiology*, *52*(6), 409-416.

Waltz, C. F., & Bausell, R. B. (1981). *Nursing research: Design, statistics and computer analysis*. Philadelphia: F. A. Davis.

Waltz, C. F., Strickland, O. L., & Lenz, E. R. (2005). *Measurement in nursing and health research* (3rd ed.). New York: Springer.

Witkowski, J. A., & Parish, L. C. (1982). Histopathology of the decubitus ulcer. *Journal of the American Academy of Dermatology*, *6*, 1014–1021.

Wynd, C. A., Schmidt, B., & Schaefer, M. A. (2003). Two quantitative approaches for estimating content validity. *Western Journal of Nursing Research*, *25*(5), 508-518.

Yepes, D., Molina, F., Leon, W., & Pérez, E. (2009). Incidence and risk factors associated with the presence of pressure ulcers in critically ill patients. *Medicina Intensiva*, *33*(6), 276-281.

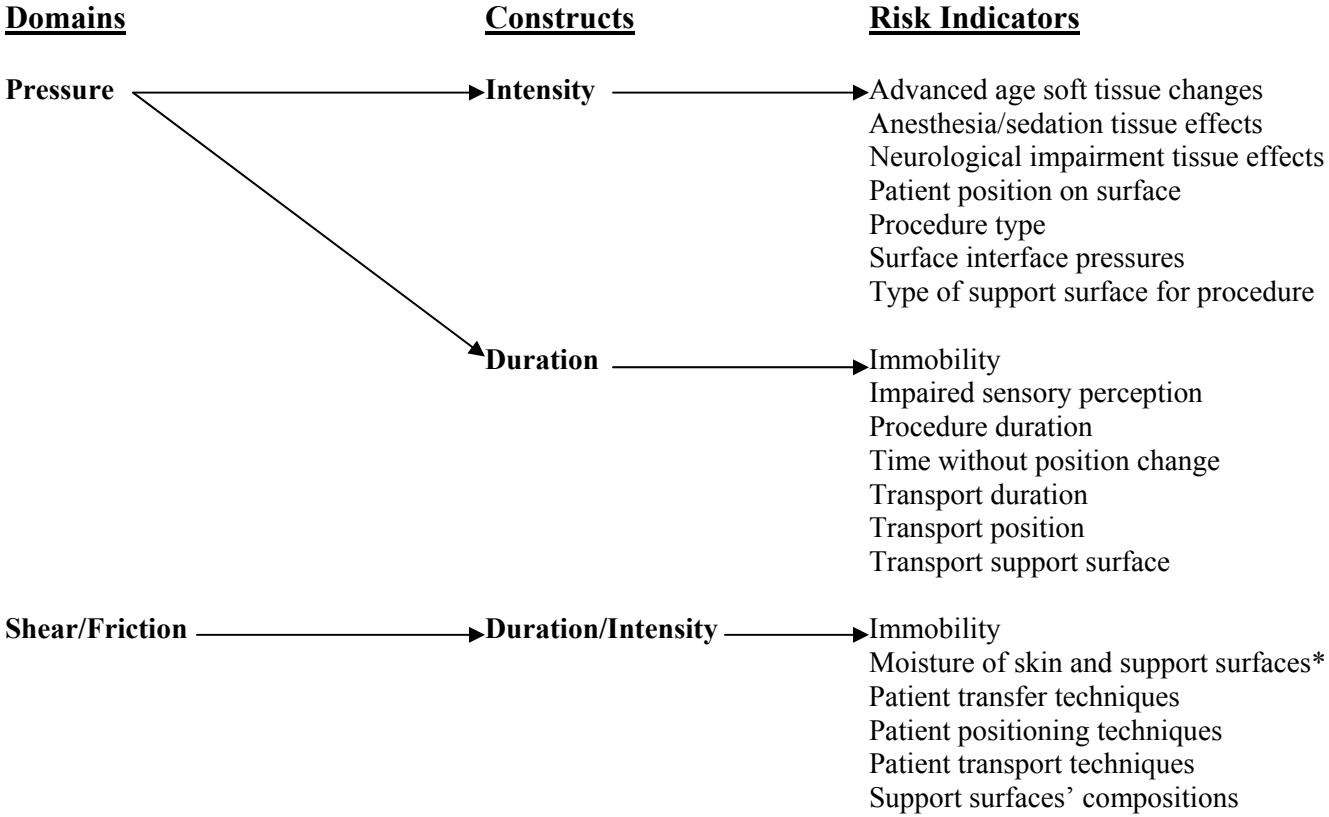
Youden, W. J. (1950). Index for rating diagnostic tests. *Cancer*, *3*(1), 32-35.

Young, J. D., & Cameron, E. M. (1995). Dynamics of skin blood flow in human sepsis. *Intensive Care Medicine*, *21*(8), 669-674.

Appendices

Appendix A

Ancillary Procedures Patients Pressure Ulcer Risk Domain Matrix



Appendix A (Continued)

Ancillary Procedures Patients Pressure Ulcer Risk Domain Matrix

Domains	Constructs	Risk Indicators
Tissue Tolerance for Pressure	**Reduced Tolerance**	Advanced age Anesthesia/sedation Dehydration (severe)* Dementia/cognitive impairment Diabetes Mellitus with neuropathy Friction/shear Hx of pressure ulcers >grade II* Moisture (excess; in contact with skin)* Neurological impairment PVD (soft tissue changes) Tissue mass loss (atrophy or malnutrition)
Tissue Oxygen Homeostasis	**Impaired Homeostasis**	CHF/CVD Diabetes Mellitus External heat &/or Fever Hypotension Impaired pressure induced vasodilation Impaired reactive hyperemia Neurological impairment Pulmonary disease or Renal failure Sepsis Shear Vascular diseases Vasoactive drugs

*** Indicators from the Conceptual Schema & subscales of the Braden Scale for Predicting Pressure Sore Risk**

Appendix B

Ancillary Procedures Patient Pressure Ulcer Risk Domain Matrix Review

Relevance Rating Scale: 1= not relevant; 2= somewhat relevant; 3= quite relevant; 4= highly relevant

Domains/Constructs	Risk Factors	1	2	3	4	Reviewer Comments
Pressure						
Pressure Intensity	1a. Advanced age tissue changes					
	2a. Anesthesia/sedation tissue effects					
	3a Body build/BMI					
	4a. Neurological impairment tissue effects					
	5a. Patient position on surface					
	6a. Procedure type					
	7a. Surface interface pressures					
	8a. Type procedure table support surface					
Pressure Duration	1b. Immobility					
	2b. Impaired sensory perception					
	3b. Procedure duration					
	4b. Time without position change					
	5b. Transport duration					
	6b. Transport position					
	7b. Transport support surface					
Shear & Friction	**Risk Factors**	**1**	**2**	**3**	**4**	**Comments**
Duration/Intensity	1c. Immobility					
	2c. Moisture of skin and support surfaces					
	3c. Patient transfer techniques					
	4c. Patient positioning techniques					
	5c. Patient transport techniques					
	6c. Support surfaces' compositions					

Appendix B (Continued)

Tissue Tolerance for Pressure	Risk Factors	1	2	3	4	Comments
Reduced Tolerance	1d. Advanced age					
	2d. Anesthesia/sedation					
	3d. Dehydration (severe)					
	4d. Dementia/cognitive impairment					
	5d. Diabetes Mellitus with neuropathy					
	6d. Friction/shear					
	7d. Hx of pressure ulcers > grade II					
	8d. Moisture (excess; in contact with skin)					
	9d. Neurological impairment					
	10d. PVD (soft tissue changes)					
	11d. Tissue mass loss (atrophy or malnutrition)					
Tissue Oxygen Homeostasis	**Risk Factors**	**1**	**2**	**3**	**4**	**Comments**
Impaired Homeostasis	1e. CHF/CVD					
	2e. Diabetes Mellitus					
	3e. External heat					
	4e. Fever					
	5e. Hypotension					
	6e. Impaired pressure induced vasodilation					
	7e. Impaired reactive hyperemia					
	8e. Neurological impairment					
	9e. Pulmonary disease					
	10e. Renal failure					
	11e. Sepsis					
	12e. Shear					
	13e. Vascular diseases					
	14e. Vasoactive drugs					

Appendix B (Continued)

Additional Reviewer Comments Here

Item #	COMMENTS AND RECOMMENDATIONS

Reviewer Demographics:

Name of Reviewer: _____

Degree(s)/Certification(s):_____
_____

Title/Affiliation:
_____

Preferred Contact Medium: □ **Email (**_____**)** □**Phone (**_____**)**

□**Fax (**_____**)** □**Postal mail (**_____**)**

Experience relevant to expertise in pressure ulcers, ancillary services, research and/or tool development and evaluation:
_____
_____
_____
_____
_____
_____
_____

Other Relevant Information you wish to include:

Appendix C

Expert Consultant Instruction Letter

Nancy A. Stotts, EdD, RN, FAAN
1233 Glacier Avenue
Pacifica, CA 94044-3822

Dear Nancy,

As you know, I am developing an instrument to measure pressure ulcer risk levels among adult patients undergoing hospital ancillary procedures such as interventional radiology, cardiac, vascular, and GI lab diagnostic and interventional procedures, and renal dialysis. As diagnostic and interventional procedures become more sophisticated, more acutely ill and higher risk patients are undergoing these procedures, often under anesthesia or sedation and on support surfaces that generate interface pressures in the range of 150 - 170 mm Hg. With the empirically established potential for tissue injury when patients are exposed to such pressures, there is a compelling need to address this issue. No pressure ulcer risk assessment tool or prevention protocol currently exists for these patients. My hope is to fill that void with a combined risk assessment and preventive interventions tool for this patient population.

You are asked to serve as a content expert because of your own extensive research and contributions in the area of pressure ulcer risk assessment and prevention. Your critical review and expert input in this first element of the tool development, the ***Content Domain Matrix*** of potential risk indicators, will be key to ensuring a valid and representative pool of scale items for the tool.

The Content Domain Matrix contains four domains, their attendant constructs and individual risk factors. It is the result of extensive review of the theoretical and empirical literature relating to the specific intrinsic and extrinsic factors that would put patients at risk for pressure injury during ancillary services procedures. I have also included a table citing the specific studies in which empirical data support selection of each of the risk factors for this matrix, and a comprehensive references section of these citations should you wish to refer to them.

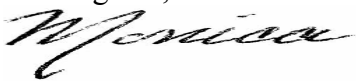
On the attached Matrix Review Form you are asked to judge the relevance (representativeness) of the each of the content domains and their constructs and risk factors on a 4-point scale. Also, providing suggested revisions for the items you find lacking would be very helpful.

After agreement on the items within the domain matrix, a combination of qualitative (review of literature) and quantitative (statistical analysis of predictive strength of risk indicators using the AHRQ Nationwide Inpatient Sample 2007 patient database) will be used to distill the item pool to those indicators with the greatest predictive potential for pressure ulcer outcomes in this population. These predictors will form the basis of the

risk assessment tool which will then be evaluated by a full panel of experts (where I will again be requesting you assistance and expertise).

Thank you profoundly for agreeing to be my expert consultant on this venture.

Best regards,



Monica S. Messer, RN, DNP, CWS
PhD Candidate, USF College of Nursing at Tampa FL
Email: msmesser@verizon.net
Phone: (813) 672-0409

Appendix D

Messer Pressure Ulcer Risk Assessment Scale©

For use in Ancillary Procedure Unit Patients
(Radiology; Cardiac, Vascular, and GI labs; Hemodialysis units)

Circle appropriate score in "Yes" or "No" column for all factors

RISK FACTORS and their POINT VALUES	Yes	No
AGE: patient is age 82 or older	**6**	0
AGE: patient is between 66 and 81 years of age	**5**	0
HIV: patient relates being diagnosed by a doctor as being HIV positive (with or without active AIDS; with or without AIDS medication)	**4**	0
DIABETES MELLITUS: patient relates being diagnosed by a doctor as having diabetes mellitus (with or without insulin dependence; with or without neuropathy or other diabetic morbidities)	**3**	0
SEPSIS: patient has clinical symptoms of sepsis -(the presence of bacteria [bacteremia] or other infectious organisms or their toxins in the blood [septicemia] or in other tissue of the body)	**2**	0
FEVER: patient currently experiencing fever (rectal temperature greater than 100.4°F [38.0°C]; oral temperature greater than 99.5° F [37.5° C]; ear [tympanic] temperature greater than 99.5°F [37.5° C] when in oral mode)	**1**	0

Patient's Total Risk Factor Score = _____

***Note:** Each of the risk factors with point scores is an "independent" predictor of pressure ulcers and thus high risk for pressure injury occurs at low total scale scores.*

SPECIAL NOTE. Additional Compounding Risk Factors (CRF): There is sufficient support in pressure ulcer empirical studies to warrant classifying a patient who has **any** of the following risk factors to be at least at **moderate risk** for pressure injury during procedures in ancillary units: (a) *requires IV vasopressor agents to maintain blood pressure*; (b) *currently hypotensive*; (c) *severely impaired sensory perception*; (d) *severe vascular insufficiency (e.g. PVD);* (e) *use of anesthesia or heavy sedation in procedures lasting more than 2.5 hours.*

(Circle CRF in the above text if it applies to this patient)

Patient has at least one Compounding Risk Factor (*Check One***)** **Yes □ No □**

RISK CATEGORIES AND PREVENTION PLAN

Total Risk Factor Score*	Risk Level	Recommended Peri-procedure Pressure Ulcer Preventive Intervention Sets (see page 2)
0	Low Risk	Intervention Set **I**
1	At Risk	Intervention Set **II**
2-5 (or +CRF)	Moderate Risk	Intervention Set **III**
6 or over	High Risk	Intervention Set **IV**

Appendix D (Continued)

Peri-procedure Pressure Ulcer Preventive Intervention Sets

♦**Instructions**: Calculate the patient's total risk score using the tool on page 1. Locate the appropriate "*Recommended Peri-procedure Pressure Ulcer Preventive Intervention Set*" on page 1 based on the patient's total score and level of risk. Go to the corresponding Intervention Set below to identify the specific peri-procedure pressure ulcer (PU) preventive care interventions for this patient.

Recommended Peri-procedure Pressure Ulcer Preventive Intervention Sets

Intervention Set I	Intervention Set II	Intervention Set III	Intervention Set IV
♦Inspect skin thoroughly before and after procedure ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves	♦Inspect skin thoroughly before and after procedure ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves **♦Reposition to reduce duration and magnitude of pressure on pressure points** **♦If cooling blanket used under patient consider a pressure-redistributing mattress on procedure support surface if procedure >2hrs long**	♦Inspect skin thoroughly before and after procedure **♦Provide pressure-redistributing mattress pad on <u>procedure</u> support surface if procedure > 2hrs long** ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves ♦Reposition to reduce duration and magnitude of pressure on pressure points	♦Inspect skin thoroughly before and after procedure **♦Provide pressure-redistributing mattress on <u>transport</u> surfaces (e.g. stretcher)** **♦Provide pressure-redistributing mattress pad on <u>procedure</u> support surface** ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves ♦Reposition to reduce duration and magnitude of pressure on pressure points **♦After procedure reposition patient in position other than the procedure position** **♦Consider shortening or postponing lengthy procedures if possible if patient's perfusion severely compromised (shock, sepsis, profound hypotension)**

Note: References for recommended interventions available from author upon request (msmesser@verizon.net)

Appendix E

Content Validity Review Form for *Messer Pressure Ulcer Risk Assessment Scale*

Instructions: Using the rating scale below, please indicate your opinion on the relevance of each pressure ulcer risk factor and preventive intervention from the Messer Scale by placing an X or √ in the review form column corresponding to your rating. Write your comments in the Comments section. ***WHEN COMPLETED***, ***PLEASE RETURN THIS FORM VIA EMAIL TO***: msmesser@verizon.net

[Rating Scale: 1= not relevant; 2= somewhat relevant; 3= quite relevant; 4= highly relevant
Please also use Comment Section to Evaluate Item Clarity and Ease of Understanding]

Relevance Rating

Risk Factor & (Score)	1	2	3	4	Comments and Recommendations
Age: Patient is age 82 or older (risk score = 6)					
Age: Patient is between 66 & 81 years of age (risk score = 5)					
HIV: patient relates being diagnosed by a doctor as being HIV positive; with or without AIDS; with or without AIDS medication (risk score = 4)					
Diabetes Mellitus: patient relates being diagnosed by a doctor as having diabetes mellitus; with or without insulin dependence; with or without neuropathy or other diabetic morbidities. (risk score = 3)					
Sepsis: patient has clinical symptoms of sepsis (the presence of bacteria [bacteremia] or other infectious organisms or their toxins in the blood [septicemia] or in other tissue of the body) (risk score = 2)					
Fever: patient currently experiencing fever (rectal temperature greater than 100.4^{o}F [38.0^{o}C]; oral temperature greater than 99.5^{o}F [37.5^{o}C]; ear [tympanic] temperature greater than 99.5^{o}F [37.5^{o}C], when in oral mode (risk score = 1)					

Requires **vasopressor** to maintain blood pressure (risk ≥ Moderate)					
Currently **hypotensive** (risk ≥ Moderate)					
Severely impaired **sensory perception** (risk ≥ Moderate)					
Severe **vascular insufficiency** (e.g. PVD) (risk ≥ Moderate)					
Risk Factor & (Score)	**1**	**2**	**3**	**4**	**Comments and Recommendations**
Use of **anesthesia** or heavy **sedation** in procedures lasting more than 2.5 hrs (risk ≥ Moderate)					
Preventive Interventions	**1**	**2**	**3**	**4**	**Comments and Recommendations**
Intervention Set I (Low Risk) **(Relevance of each intervention)** ♦Inspect skin thoroughly before and after procedure ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves **Overall Relevance of the set to the patient's risk level**					

Appendix E (Continued)

Intervention Set II (At Risk) **(Relevance of additional individual items in Set II)** ♦ (all of Set I items apply PLUS) ♦Reposition to reduce duration and magnitude of pressure on pressure points ♦If cooling blanket used under patient consider a pressure- redistributing mattress on procedure support surface if procedure >2hrs long **Overall Relevance of the set to the patient's risk level**					
Intervention Set III (Mod Risk) **(Relevance of additional individual items in Set III)** ♦ (all of Set I&II items apply PLUS) ♦Provide pressure-redistributing mattress pad on procedure support surface if procedure > 2hrs long **Overall Relevance of the set to the patient's risk level**					
Preventive Interventions	**1**	**2**	**3**	**4**	**Comments and Recommendations**
Intervention Set IV (High Risk) **(Relevance of additional individual items in Set IV)** ♦ (all of Set I, II & III items apply PLUS) ♦Provide pressure-redistributing mattress on transport surfaces (e.g. stretcher) ♦Provide pressure-redistributing mattress pad on procedure support surface ♦After procedure reposition patient in position other than the procedure position ♦Consider shortening or postponing lengthy procedures if possible if patient's perfusion severely compromised (shock, sepsis, profound hypotension) **Overall Relevance of the set to the patient's risk level**					

Appendix E (Continued)

Using the rating scale below, please indicate your opinion on the clinical appropriateness of the Risk Categories and Prevention Plan Intervention Sets.

[Rating Scale: 1= not appropriate; 2= somewhat appropriate; 3= quite appropriate; 4= highly appropriate

Score, Risk Level, & Prevention Plan (Intervention Set(s)	1	2	3	4	Comments and Recommendations
♦Score 0; Low Risk; Intervention Set I					
♦Score 1; At Risk; Intervention Set II					
♦Score 2-5 (or CRF); Moderate Risk; Intervention Set III					
♦Score 6 or over; High Risk; Intervention Set IV					

Please add any additional reviewer comments and recommendations here

Review Item	Comments/Recommendations

Appendix E (Continued)

Expert Panel Judge/Reviewer Profile Questionnaire

In accordance with the Standards for Educational and Psychological Testing (AERA et al., 1999), I will be including a profile of each expert panel judge in my dissertation. Please complete the following requested information items and return this form with your completed review package.

Name of Reviewer: _____ (withhold? y n)

Degree(s)/Certification(s):_____
_____
_____

Title/Affiliation:
_____
_____

Preferred Contact Medium:
□ **Email (_____)** □**Phone (_____)**

□**Fax (_____)** □**Postal mail**

Address for receipt of honorarium check:
_____

Experience (in years) relevant to expertise in pressure ulcers, ancillary services, research and/or tool development and evaluation:
_____
_____
_____
_____
_____
_____
_____

Other Relevant Information you wish to include:

Appendix F

Panel of Experts for Content Validity Review of Messer Tool

Nancy A. Stotts, RN, EdD, FAAN, is a Professor in the Department of Physiological Nursing at the University of California San Francisco (UCSF). Her areas of expertise include wound healing, nutrition and pain, with an emphasis in care of older persons. She completed a John A Hartford Post-Doctoral Scholar in gerontological nursing where she refined her skills and expertise in care of older persons. Dr. Stotts' program of research focuses on elucidating factors that interfere with normal wound healing, especially nutritional factors and oxygenation. Her work has examined risk factors for pressure ulcer development and impaired healing and explored the effect of various interventions to support healing. Dr. Stotts teaches in the graduate program in Critical Care/Trauma and directs the Nursing Education specialty in the Masters Program at UCSF. Dr. Stotts' work with professional and governmental groups has helped establish public policies in the area of pressure ulcer care and has set the agenda for future directions in research and patient care related to wound care and pressure ulcers. Dr. Stotts has published widely in nursing and inter-disciplinary peer-reviewed journals. She is recognized nationally and internationally for her research, creative work, and publications.

Janet Cuddigan, PhD, RN, CWCN
Associate Professor & AHI Dept Chair
Acting Dean
College of Nursing
University of Nebraska Medical Center
985330 Nebraska Medical Center
Omaha, NE 68198-5330

National Pressure Ulcer Advisory Panel Board of Directors; Co-captain of the "Pressure Ulcer Stream" for the World Union of Wound Healing Societies' Conference in Toronto, Canada, June 2008; Co-Chair, NPUAP-EPUAP International Guideline Development Panel on Pressure Ulcer Prevention and Treatment; Member, International Wound Infection Institute; Baranoski Founder's Award for Excellence in Pressure Ulcer Care, 1999

Lena Gunningberg PhD, RN [lena.gunningberg@pubcare.uu.se]
Assistant Professor, School of Nursing, University of California San Francisco
Klinisk lektor, docent
Institutionen för folkhälso- och vårdvetenskap
Uppsala universitet, Sweden.
Board Member: European Pressure Ulcer Advisory Panel
(see Gunningberg bio and publications at url below)

http://www.pubcare.uu.se/medarbetare/Vardvetenskap/Gunningberg_Lena/

Dr. Diane L. Krasner, PhD RN CWCN CWS MAPWCA FAAN.
Wound & Skin Care Consultant
212 East Market Street
York PA 17403 USA
website **www.chronicwoundcarebook.com**

Dr. Diane L. Krasner is a board certified wound specialist with experience in wound, ostomy & incontinence care across the continuum of care. She is a Fellow of the American Academy of Nursing and a Master of the American Professional Wound Care Association. Dr. Krasner is a Wound & Skin Care Consultant in York, Pennsylvania and works part-time at Rest Haven - York as the WOCN / Special Projects Nurse. Dr. Krasner is the lead co-editor of Chronic Wound Care: A Clinical Source Book for Healthcare Professionals (4th edition, 2007, HMP Communications). She currently serves as the clinical editor of the Kestrel Wound Product Source Book. Krasner is also on the editorial boards of WOUNDS, The International Journal of Wound Care and World Wide Wounds. Since 1992 Dr. Krasner has served on the Board of Directors and as an Officer of several national wound care organizations, including The American Academy of Wound Management, The Association for the Advancement of Wound Care and The National Pressure Ulcer Advisory Panel.

Elizabeth A. Ayello PhD, RN, ACNS-BC, CWON, MAPWCA, FAAN

Elizabeth A. Ayello is president of Ayello, Harris and Associates. She is a faculty member at Excelsior College School of Nursing, Albany New York, Co-Director of the International Interprofessional Wound Care Course at the University of Toronto, Toronto, Canada, and Senior Advisor at the John A. Hartford Institute for Geriatric Nursing, New York, New York. Dr. Ayello is the Executive Editor for the World Council of Enterostomal Therapists (WCET) Journal and Clinical Associate Editor for the interdisciplinary journal, Advances in Skin and Wound Care. Dr. Ayello has served in many leadership positions in several wound care organizations including Board of Directors and 1999 President of the National Pressure Ulcer Advisory Panel (NPUAP) and presently serves on the Board of Directors for the American Professional Wound Care Association (APWCA). She was one of two nurses nationally who served on the CMS panel that revised the guidance for surveyors on F Tag 314 on pressure ulcers. Most recently, she worked with CMS to develop the educational materials for MDS 3.0 section M Skin conditions and delivered the educational programs at their "Train the Trainer" national programs. She is the Chairperson for the New Jersey Hospital Association collaborative that decreased pressure ulcer incidence among its partners by 70% across care settings. Dr. Ayello is co-author/editor of the book, Wound Care Essentials: Practice Principles. She is also the recipient of numerous awards for her sustained contributions to wound care including the 2007 NPUAP Kosiac Award, 2008 John Boswick Memorial Award, Masters designation by the APWCA, and the 2010 Sharon Baranoski Founders Award

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Appendix G

Expert Review Panel Package
for review of the
Messer Pressure Ulcer Risk Assessment Scale

General Information for the Expert Judges

Thank you once again for agreeing to review my research tool. In my email to you of 9/29/11, I included a letter with a brief overview of my plan for developing an instrument to measure pressure ulcer risk among adult patients undergoing hospital ancillary procedures (radiology, cardiac, vascular and GI labs, hemodialysis, etc.). Also included was my WOCN article covering the theoretical foundation for the tool, and a copy of my conceptual model for the tool. I have not included these again here so please advise me if you wish me to resend any of that information.

This review package includes the following: (a) Instructions to Panel Judges for review and return of the instrument; (b) copy of the "Messer Pressure Ulcer Risk Assessment Scale"; (c) "Content Validity Review Form"; (d) Overview of the Tool Development Methodology; and, (e) "Expert Panel Judge/Reviewer Profile Questionnaire." References used to develop the theoretical foundation for the tool are contained in the WOCN article I sent previously. If you wish the specific references used in development of the recommended preventive interventions please so advise me. These recommendations came primarily from the AORN Perioperative Standards and Recommended Practices publication (2009), the EPUAP/NPUAP Quick Reference Guide (2009), the AHRQ Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of Care (2011), and the AAWC 2009 Pressure Ulcer Care Initiative (PUCI).

Communications between author and panel members. Unless you advise me otherwise I will assume email is our communication medium of choice. If this creates a problem for you in returning the package please let me know how you wish me facilitate your return of the material to me.

Thank you again for your support on this project. I cannot tell you how thrilled and honored I am to have such a renowned panel of experts review this instrument.

Monica S. Messer, RN, DNP, CWS
PhD Nursing Student
University of South Florida College of Nursing
Tampa, FL
Phone: (813) 672-0409
Fax: (813) 672-0508
Postal Mail: 10122 Sedgebrook Dr., Riverview, FL 33569
Email: msmesser@verizon.net

Appendix G (Continued)

Instructions for Expert Panel Judges

The **Content Validity Review Form** (sent as separate document) is a weighted list of pressure ulcer risk factors, and a list of recommended preventive interventions included in the Messer Pressure Ulcer Risk Assessment Scale research instrument. You are asked to serve as an expert in the evaluation of the content validity of these scale items.

Please **rate each factor and intervention** on a **four-point scale (1= not relevant - 4= very relevant)** according to your opinion on the relevance of these risk factors to patients' vulnerability for developing pressure injury (ulcer/sore) during transport to and from, and anatomical positioning during hospital ancillary procedures, and the relevance of each intervention as an appropriate preventive action**.** The intended **clinical setting for the tool** includes hospital diagnostic and interventional procedures in ancillary units such as radiology, cardiac, vascular, GI, and urology labs, and hemodialysis. The unique extrinsic risk in this population is exposure to very high interface pressures.

In addition to relevance, I am asking that you **evaluate each individual item** (risk factors and preventive interventions) **for clarity** and **ease of understanding**. I would also greatly appreciate your comments and any suggestions for revisions on the items in the scale.

The **Content Domain Matrix** for the risk assessment scale was reviewed and critiqued by Dr. Nancy Stotts and appropriate revisions incorporated into the development of the tool as recommended by Dr. Stotts (reviewed Matrix available upon request).

Intended users of the tool. The assessment and point ratings are intended for completion by licensed professionals (e.g. RNs, PAs, NPs, or MDs). Ideally the assessment should be done by either the ordering provider, or the attending RN on the inpatient unit when the order for the procedure is written. However, the scale may also be used by RNs or providers within the ancillary units providing the procedures. The design of the scale makes it easily convertible into a "standing order" format where ordering providers could write for any special preventive interventions for management of the patient during the periprocedure period.

For **analysis of the rating forms**, the content validity indexes will be computed using both individual-item (I-CVI) and total-scale (S-CVI) ratings using averaging across I-CVIs as recommended by Polit and Beck (2008). I will also be calculating inter-rater agreement using the multirater kappa statistic. I will provide panel members with a copy of the completed analysis of your review. Although this is not an official "Delphi" technique, I would welcome any additional reviewer feedback at that time.

The NEXT ITEM in this package is the **proposed tool** itself. I have included it in finished form so that you may **comment on** the **format**, **appearance, readability,** and overall **face validity** of the tool. I will attach the Content Validity Review Form as a separate document to facilitate return of the reviewed document to me via email.

Appendix G (Continued)

Overview of the Tool Development Methodology

Background. The original concept for this research evolved from observations made during the researcher's 30 years of clinical experience as a wound and pressure ulcer care specialist. I noted a trend in development of pressure ulcers in certain types of patients within 1-3 days after having undergone diagnostic or interventional procedures in ancillary units (radiology; cardiac, vascular, GI, and urology labs; hemodialysis units). While the risk and incidence of pressure ulcers occurring during surgical procedures has been increasingly studied by researchers, the risk to ancillary services patients has been virtually ignored. This may be because skin assessments are not routinely done before and after these procedures, and because of the delay in overt presentation of pressure injury in many of these patients.

The decision to develop a risk assessment tool rather than launch a prospective study of pressure ulcer (PU) incidence in ancillary units was parsimoniously motivated. Ready access to very large national databases of nation-wide hospital discharge cases available through AHRQ (HCUP Nationwide Inpatient Sample) enabled me to effectively analyze the associations between the study variables and pressure ulcer outcomes. Although limited to only those variables coded into the retrospective database, there were sufficient data available to credibly test the major risk factors identified from my review of the empirical literature.

Methodology. To identify which specific intrinsic and extrinsic factors could put patients at risk for pressure injury during short-term exposure to high interface pressures, an extensive review (ROL) was conducted of tissue physiology and pressure ulcer literature examining the domains of; (a) pressure, (b) friction/shear, (c) tissue tolerance for pressure, and (d) tissue oxygen homeostasis. From the ROL, risk factors that emerged as potentially predictive in this population (that could be tested in the HCUP database) were: (a) advanced age, (b) diabetes, (c) HIV, (d) renal failure, (e) sepsis, (f) pulmonary diseases, (g) cognitive impairment, (h) neurological impairment, (i) sclerosing diseases, (j) malnutrition, (k) fever, (l) vascular disease, (m) cardiac disease, (n) hypotension, (o) non-OR procedure, and (p) anesthesia. A frequency distribution of PUs by patient age showed a clear pattern of four levels of risk: patient ages low to 49; 50 to 65; 66 to 81; and 82 and above. Thus this variable was collapsed into these four levels for the analyses.

Access was obtained to the AHRQ HCUP NIS 2007 database of **8,043,415** U.S. hospital discharge cases, of which **106,810** cases contained ICD-9 CM codes for **PUs** (the count of interest was PU cases not number of PUs). To address the issue of internal validity, a **split-sample validation** approach to analysis was selected. Using IBM SPSS Version 19 for Windows, the NIS 2007 database was randomly partitioned into quartiles and appropriate checks done for sub-sample comparability. Initial analysis and model-building were done using one quartile of **1,661,553 cases** as a **training sample**, followed by testing of the model in another quartile of **1,659,508 cases** as a **validation sample**.

Appendix G (Continued)

The sampling was restricted to patients age 18 and above, and each sub-sample contained 1.6% pressure ulcer patients. Bivariate analysis of the identified variables, using chi square for categorical and t-test for continuous variables, demonstrated a statistically significant ($p \leq .05$) predictive value only for: (a) two levels of advanced age; (b) sepsis, (c) HIV, (d) diabetes, (e) pulmonary, (f) fever, (g) anesthesia, and (h) non-OR procedures. These variables were then offered to a multivariate logistic regression (LR) procedure using a forward step-wise approach. Variables emerging from multivariate analysis as **independent predictors** of pressure ulcer risk in the training sample were; (a) **age 66-81 years**, (b) **age 82 and over**, (c) **HIV**, (d) **diabetes**, (e) **sepsis**, and (f) **fever** (see **Table 1**). Odds ratios for these variables obtained from the LR were then used to develop a weighted scoring system for the tool. The predictive power of the tool was tested first in the training sample, and then in the validation sample using LR. Risk scores were calculated in the samples and the accuracy of the model analyzed using the **Receiver Operating Characteristic (ROC) Curve**. The overall accuracy of the tool (**area under the curve**) was **.710**, with **SE .002, 95% CI .707 - .713** (**Table 2**). Each score level was then subjected to ROC analysis to facilitate selection of appropriate cut-off scores for the different risk levels in the tool. The statistical outcomes for all variables and scores were remarkably stable when tested in the validation sample.

Table 1. Multivariate Logistic Regression Outcome for PU Variables

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 6[f]	Age4(1)	1.644	.016	10766.112	1	.000	5.177	5.018	5.340
	Age3(1)	1.092	.015	5034.896	1	.000	2.981	2.892	3.072
	HIV(1)	1.004	.065	235.829	1	.000	2.728	2.400	3.101
	DIAB(1)	.785	.019	1757.695	1	.000	2.193	2.114	2.275
	Sepsis(1)	.464	.144	10.370	1	.001	1.590	1.199	2.108
	Fever(1)	.310	.144	4.655	1	.031	1.363	1.029	1.807
	Constant	-5.103	.012	170589.113	1	.000	.006		

Table 2. ROC Results for Accuracy of Risk Scoring System
Area Under the Curve
Test Result Variable(s): PURISK1

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.707	.002	.000	.704	.710

The test result variable(s): PURISK1 has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

Appendix H

Institutional Review Board Letter of Approval

USF
UNIVERSITY OF
SOUTH FLORIDA

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

June 22, 2011

Dr. Monica Messer
College of Nursing
10122 Sedgebrook Dr.
Riverview, FL 33569

RE: **Not Human Research Activities Determination**

Activity Title: Development of a Tool for Pressure Ulcer Risk Assessment and Preventive Interventions in Ancillary Services Patients

Dear Dr. Messer:

I have reviewed the information you provided regarding the above referenced project and have determined the activities do not meet the USF definition of human subjects research activities; therefore, IRB approval is not required. If, in the future, you change this activity such that it becomes human subjects research activities, prior IRB approval is required. If you wish to obtain a determination about whether the activity, with the proposed changes, will be human research activities, please contact the IRB Office for further guidance.

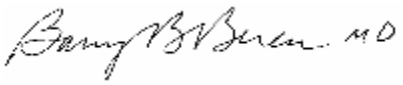
All research activities, regardless of the level of IRB oversight, must be conducted in a manner that is consistent with the ethical principles of your profession and the ethical guidelines for the protection of human subjects. As principal investigator, it is your responsibility to ensure subjects' rights and welfare are protected during the execution of this project

Also, please note that there may be requirements under the HIPAA Privacy Rule that apply to the information/data you will use in your activities. For further information about any existing HIPAA requirements for this project, please contact Vinita Witanachchi, J.D., HIPAA Program Coordinator, at 813-974-5478.

Appendix H (Continued)

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,



Barry Bercy, MD, Chairperson
USF Institutional Review Board

Appendix I

Description of Training Data Set for Logistic Regression

Patient has PU	Total Sample (*N*)	Anesthesia (*n*)	Sepsis (*n*)	Age 3 (*n*)	HIV (*n*)	Diabetes (*n*)	Fever (*n*)	Pulm (*n*)	Age4 (*n*)
Yes	26,296	179,698	274,373	416,406	12,014	104,950	277,038	324,340	230,370
No	1,635,257	1,481,855	1,387,180	1,245,147	1,649,539	1,556 603	1,384,515	1,337,213	1,431,183
Total	1,661,553								

Note: PU= pressure ulcer; Age3 = patients age 66-81; Pulm = pulmonary disease; Age4 = patients age 82 and above.

Appendix J

Results of Expert Panel Content Validity Assessment of Messer Scale

Item	J-1	J-2	J-3	J-4	J-5	# of Ratings	# 3&4 Ratings	I-CVI
				Scores				
1	4	4	3	4	4	5	5	1
2	3	3	3	4	4	5	5	1
3	3	2	2	1	4	5	2	0.4
4	4	3	2	4	4	5	4	0.8
5	4	2	2	4	4	5	3	0.6
6	4	2	3	2	4	5	3	0.6
7	3	3	3	3	4	5	5	1
8	4	3	3	4	4	5	5	1
9	4	4	2	4	4	5	4	0.8
10	3	3	3	4	4	5	5	1
11	3	2	4	4	4	5	4	0.8
12	3	4	3	4	4	5	5	1
13	3	4	4	4	4	5	5	1
14	3	3	4	4	4	5	5	1
15	3	4	4	4	4	5	5	1
16	2	3	3	1	4	5	3	0.6
17	2	4	3	4	4	5	4	0.8
18	2	3	3	4	4	5	4	0.8
19	3	3	4	4	4	5	5	1
20	2	2		1	4	4	1	0.25
21	3	3	3	3	4	5	5	1
22	4	4	4	4	4	5	5	1
23	3	4	4	4	4	5	5	1
24	2	4	4	4	4	5	4	0.8
25	3	4	4	4	4	5	5	1
26	4	3	4	4	4	5	5	1
27	3	2	4	4	4	5	4	0.8
28	3	3	4	4	4	5	5	1
29	1	2	3	4	4	5	3	0.6
30	3	2	2	1	4	5	2	0.4
31	4	3	3	1	4	5	4	0.8
32	4	4	3	4	4	5	5	1
Proportion by rater :	0.81	0.75	0.84	0.81	1			$\bar{x}$ = 0.8391

S-CVI / Average = 0.84
S-CVI / Average with item 20 removed and item 30 revised = 0.91
S-CVI / UA = 0.53
S-CVI / UA with item 20 removed and item 30 revised = 0.56

Note. J1 - J5 = Expert panel judges. I-CVI = Item content validity index; S-CVI/Average = scale content validity index using I-CVI-averaging method; SCVI/UA = scale content validity universal agreement method.

Appendix K

Messer Pressure Ulcer Risk Assessment Scale (Revised)

For use in Ancillary Procedure Unit Patients
(Radiology; Cardiac, Vascular, and GI labs; Hemodialysis units)

Circle appropriate score in "Yes" or "No" column for all factors

RISK FACTORS and their POINT VALUES	Yes	No
AGE: patient is age 82 or older	**6**	0
AGE: patient is between 66 and 81 years of age	**5**	0
HIV: patient relates being diagnosed by a doctor as being HIV positive (with or without active AIDS; with or without AIDS medication)	**4**	0
DIABETES MELLITUS: patient relates being diagnosed by a doctor as having diabetes mellitus (with or without insulin dependence; with or without neuropathy or other diabetic morbidities)	**3**	0
SEPSIS: patient has clinical symptoms of sepsis -(the presence of bacteria [bacteremia] or other infectious organisms or their toxins in the blood [septicemia] or in other tissue of the body)	**2**	0
FEVER: patient currently experiencing fever (rectal temperature greater than 100.4°F [38.0°C]; oral temperature greater than 99.5° F [37.5° C]; ear [tympanic] temperature greater than 99.5°F [37.5° C] when in oral mode)	**1**	0

Patient's Total Risk Factor Score = _____

***Note:** Each of the risk factors with point scores is an "independent" predictor of pressure ulcers and thus high risk for pressure injury occurs at low total scale scores.*

SPECIAL NOTE. Additional Compounding Risk Factors (CRF): There is sufficient support in pressure ulcer empirical studies to warrant classifying a patient who has **any** of the following risk factors to be at least at **moderate risk** for pressure injury during procedures in ancillary units: (a) *requires IV vasopressor agents to maintain blood pressure*; (b) *currently hypotensive*; (c) *severely impaired sensory perception*; (d) *severe vascular insufficiency (e.g. absence of peripheral pulses);* (e) *use of anesthesia or heavy sedation in procedures projected to last more than 2.5 hours.*

(Circle CRF in the above text if it applies to this patient)

Patient has at least one Compounding Risk Factor (*Check One***)** **Yes ☐ No ☐**

RISK CATEGORIES AND PREVENTION PLAN

Total Risk Factor Score*	Risk Level	Recommended Peri-procedure Pressure Ulcer Preventive Intervention Sets (see page 2)
0 - 1	Low Risk	Intervention Set **I**
2-4 (or +CRF)	Moderate Risk	Intervention Set **II**
5 or over	High Risk	Intervention Set **III**

Appendix K (Continued)

Peri-procedure Pressure Ulcer Preventive Intervention Sets

♦**Instructions**: Calculate the patient's total risk score using the tool on page 1. Locate the appropriate "*Recommended Peri-procedure Pressure Ulcer Preventive Intervention Set*" on page 1 based on the patient's total score and level of risk. Go to the corresponding Intervention Set below to identify the specific peri-procedure pressure ulcer (PU) preventive care interventions for this patient.

Recommended Peri-procedure Pressure Ulcer Preventive Intervention Sets

Intervention Set I	Intervention Set II	Intervention Set III
♦Inspect skin thoroughly before and after procedure ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves	♦Inspect skin thoroughly before and after procedure **♦Provide pressure-redistributing mattress pad on procedure support surface if procedure time likely to be > 2hrs long** ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves ♦Reposition to reduce duration and magnitude of pressure on pressure points	♦Inspect skin thoroughly before and after procedure **♦Provide pressure-redistributing mattress on transport surfaces (e.g. stretcher)** **♦Provide pressure-redistributing mattress pad on procedure support surface** ♦Position patient to reduce risk of PU development during the procedure (protect pressure-sensitive areas based on position on table-lateral, supine, etc.) ♦Float heels off table when patient supine ♦Use transfer aids to reduce friction and shear ♦Avoid pooling of liquids under patient ♦Avoid use of sheepskin, donuts (except plantar foot surface), blanket rolls, or water-filled gloves ♦Reposition to reduce duration and magnitude of pressure on pressure points **♦After procedure reposition patient in position other than the procedure position** **♦Consider shortening or postponing lengthy procedures if possible if patient's perfusion severely compromised (shock, sepsis, profound hypotension)**

Note: References for recommended interventions available from author upon request (msmesser@verizon.net)

About the Author

Monica Shutts Messer completed her Doctor of Nursing Practice degree in 2008 at the University Of South Florida College Of Nursing in Tampa, Florida. Dr. Messer recently served as Adjunct Faculty in the University of South Florida Graduate Nursing Education Program. She is also a published author and expert consultant in the clinical area of wound management and pressure ulcer prevention, holding national board certification as a Wound Specialist from the American Academy of Wound Management.

Dr. Messer is also retired from a 30-year career in the Air Force Nurse Corps. Her assignments ranged from bedside nursing during the Viet Nam war, to USAF IG Nurse Inspector, Clinical Nurse Specialist; and, Chief Nurse Officer at Eielson AFB Clinic, Alaska, Kirtland USAF Hospital New Mexico, MacDill USAF Hospital Tampa, and Keesler USAF Medical Center in Mississippi. Dr. Messer, a diploma nurse graduate, earned her BSN from Incarnate Word College, and her MSN from the University of California San Francisco. She was presented the E. Ann Hoefly Award for Excellence in Clinical Nursing by the Air Force Medical Association, and was awarded the Air Force Legion of Merit Medal for her role in development and implementation of the Air Force Nursing Documentation System, and for her leadership in the development and funding of ambulatory surgery units Air Force wide.