RISK FACTORS FOR PRESSURE ULCER DEVELOPMENT IN NON-CRITICAL AEROMEDICAL EVACUATION TRAUMA PATIENTS

by

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DEDICATION

This work is dedicated to the men and women of the United States military for whom I am eternally grateful.

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ABSTRACT

Background: The military in-flight care environment is unique. Non-critical Aeromedical Evacuation (AE) trauma patients are at risk for developing pressure ulcers (PUs) in-flight. This study examines the incidence of in-flight PU development and analyzes factors that may contribute to them.

Methods: This study employed a retrospective case-control cohort analysis of electronic data from January 1, 2008 through December 31, 2012 comparing non-critical AE trauma patients who did and did not develop PUs within three days post-flight. The Department of Defense Trauma Registry identified 15 PU patients. Using the Aeromedical Evacuation Registry (AER), PU patients were matched four-to-one with non-PU patients (n=60) that had been flown within plus or minus one year of the event to control for changes in practice over time. Independent variables examined included demographics, diagnoses, care requirements, flight information, and the number of AE crew.

Results: The mean age for the PU patients was 26.20 (SD=8.10); non-PU patients 26.98 (SD=8.16), with a range of 15-54 years old. Age was not significantly different ($t(73) = .740$, $p >$ .05) between the PU and non-PU patients. All of the PU patients were male (n=15, 100%) and 96% (n=57) of the non-PU patients were male. Fisher's exact test was conducted for a between group comparison, which was not significant ($p = 1.00$). The PU incidence rate was calculated as .02 (<1%) based on 73,377 patients discharged during the time period. A binomial Firth conditional logistic regression was performed in the face of PUs as a rare event (n=15; incidence rate <1%). The regression showed statistical significance in two of the 12 variables used in the model, namely the use of intravenous (IV) therapy (p = .04) and pulse oximetry (p = .01).

Conclusion: As PUs are a Nurse Sensitive Quality Indicator, a PU incidence rate of <1% illustrates the outstanding quality of care that is being conducted in the U.S. Air Force Aeromedical Evacuation System. Identification of the risk factors that lead to PUs can help mitigate future PU development on the quest to zero PUs.

CHAPTER 1: INTRODUCTION

Since 2001 and the start of medical operations in support of military involvement in Iraq and Afghanistan, there have been over 180,000 patients transported for over 300,000 patient movements in the United States Air Force (USAF) Aeromedical Evacuation (AE) system (Booz Allen Hamilton, 2016). Due to advances in enroute care, overall mortality rates have declined despite patient injury severity increasing (Eastridge et al., 2011; Kelly et al., 2008; Ling, Rhee, & Ecklund, 2010). To date, the majority of the literature addressing AE patient outcomes has focused on the critically injured or ill patients; however, critical care patients comprise only 10% of the AE patient population (Booz Allen Hamilton, 2016; Harman, Hooper, & Gackstetter, 2005), leaving the remaining 90% of the non-critical AE patient population unstudied. Therefore, in order to begin to evaluate the quality of patient care during AE, patient outcomes focused research is needed.

The AE patient care environment is unique due to the effects of the stresses of flight, such as hypoxia, vibration, and decreased humidity, in addition to other considerations such as immobility associated with long flight durations, which may place patients at risk for pressure ulcer (PU) development. Nosocomial PU development is a nationally recognized nurse sensitive quality indicator (NSQI) (Sachs, 2014; Savitz, Jones, & Bernard, 2005). Pressure ulcers contribute to an increase in mortality, medical costs, risk of infection, tissue scarring, and surgery (Alderden, Whitney, Taylor, & Zaratkiewicz, 2011). The only existing information related to PU development in AE is evidence produced from research conducted on critically ill/injured patients transported between 2008 and 2012 (Dukes, Maupin, & Mortimer, 2014). The study named a 5% PU occurrence rate for the critically ill/injured patients and identified several PU risk factors, such as increased body mass index (BMI), abnormal vital signs, mechanical ventilation and vasoactive medication administration, the use of a vacuum spine board for spinal immobilization, long flight times, and periods of immobility. Therefore, this study will identify the risk factors associated with PU development in non-critical AE trauma patients.

Chapter 1 provides a comprehensive review of the literature including discussion on PUs as a healthcare systems problem, risk assessment, known risk factors and predictors, the study purpose, specific aims and research questions, and significance and military relevance. Chapter 2 describes the Quality Health Outcomes Model (QHOM) as the conceptual framework applied to the research study. Chapter 3 details the study methodology including the overall study design, setting and sample, procedures, data collection plan, data management plan, data analysis plan, and the protection of human subjects. Chapter 4 reports the study findings. Chapter 5 provides a discussion of the study findings, including their strengths, weaknesses, limitations, and recommendations for future research.

Review of the Literature

Pressure Ulcers as a Healthcare Systems Problem

In 2006, PUs were identified as an important national healthcare problem affecting 322,946 patients and costing the healthcare system billions of dollars ($40,381 per case) (Ling & Mandl, 2013). Pressure ulcers are attributed to increased healthcare costs and patient hospital length of stay, pain, debility, disfigurement, and other complications. Recent data on nosocomial PU expenditures suggest that PUs range from $500 to $70,000 per case, with an estimated total cost of $11 billion in the United States annually (Padula et al., 2015). The National Pressure Ulcer Advisory Panel (NPUAP) was created to “serve as the authoritative voice for improved patient outcomes in PU prevention and treatment through public policy, education and research" (Panel, 2014). Pressure ulcer development is one of the patient outcomes that is identified as a NSQI and one that is typically addressed from a systems perspective, because PUs can develop quickly, the attribution of PU development is difficult to isolate, and because prevention and mitigation of worsening are the primary care strategies (Ling & Mandl, 2013). The NPUAP adopted a cross setting (nursing homes, home health agencies, acute care hospitals, long term care hospitals, inpatient rehabilitation facilities, and hospices) systems approach to PUs. Using a systems approach to decrease the incidence of PUs has been shown to be successful. For example, in the study by Padula et al. (2015) five (5) quality improvement focused interventions (leadership initiatives, visual tools, PU staging, skin care, & patient nutrition) resulted in significantly reducing the incidence of the most severe (Stage III & IV) nosocomial PUs in 55 academic acute care hospitals.

A nosocomial PU is defined as a newly acquired or worsening PU (Ling & Mandl, 2013). Unfortunately, for measurement and monitoring purposes, this definition is vague. There currently exists no one consistent standard for calculating and reporting the prevalence and incidence of PU. The NPUAP (2014) provides a list of seven (7) recommendations for prevalence and incidence reporting including considerations such as employing rigorous methodological study design with consistent and reliable variable measurement and using previously published evidence from similar study designs from which to compare and/or benchmark.

In addition, for the purposes of consistent assessment and reporting, the NPUAP developed an internationally accepted PU classification system, and prevention and treatment guidelines. Pressure ulcers are classified according to the degree of injury. The PU staging classifications are: (a) Stage I, Non-blanchable erythema; (b) Stage II, Partial thickness skin loss; (c) Stage III, Full thickness skin loss; (d) Full thickness tissue loss; (e) Unstageable, depth unknown; and (f) Suspected deep tissue injury, depth unknown.

Risk Assessment

A variety of PU risk assessment tools have been created to facilitate early detection of PUs and identify patients who may be at increased risk for PU development. Pressure ulcer risk assessment tools tend to be patient population focused to address factors unique to the group. The Braden Scale is a PU risk assessment tool that has been used in a variety of patient populations and care settings (Källman & Lindgren, 2014; Pancorbo-Hidalgo, Garcia-Fernandez, Lopez-Medina, & Alvarez-Nieto, 2006; Park & Park, 2014; Wang et al., 2015). The Braden Scale is comprised of six (6) subscales: sensory perception, activity, mobility, nutrition, moisture, and friction/shear. The total score ranges from '6' to '23,' with lower scores indicating greater risk for PU development. The total Braden Score is often depicted in terms of low (15-18), moderate (10-12), or high (9 or less) degree of risk. The total score has been shown to have only moderate predictive validity and there is limited information to support the degree to which each of the subscales contributes to the overall risk (Cox, 2011; Park & Park, 2014; Tescher, Branda, Byrne, & Naessens, 2012). Therefore, Braden Scale scores should not be used as an independent risk factor.

Also, there is debate on when and how frequently risk assessments should be completed. The NPUAP states that initial PU risk assessments should be conducted "as soon as possible" after patient admission, but no longer than eight (8) hours. Some experts criticize that this eight hour maximum timeframe for PU assessment places patients at an undue risk for PU development considering that PU development has been documented within one (1) hour of immobility (Sharp, 2015). Additionally, the guidelines only generally recommend skin assessment and/or PU risk reassessment with significant changes in patient condition and as part of regular care assessments (National Pressure Ulcer Advisory Panel, 2014). Regardless, experts agree that an important part of successful PU prevention is a structured PU risk assessment program. Of note, is that while PU prevention interventions are a part of regular patient care, currently there is no structured PU risk assessment program in the AE system.

Risk Factors and Predictors

Other than tissue perfusion and friction/shear, there is currently no consensus on which risk factors are the primary contributors to PU development. However, patients with existing PUs are recognized as being at high risk of new or worsening PUs (National Pressure Ulcer Advisory Panel, 2014). Other commonly identified PU risk factors are physical condition, physical activity, and moisture (Cox, 2011; Dukes, Maupin, & Mortimer, 2014; Källman & Lindgren, 2014). In addition, other factors are noteworthy related to PU risk, namely surface, elevated head of bed, and nurse staffing (Alderden et al., 2011; Ma & Park, 2015; Peterson et al., 2008).

Physical Condition

A wide variety of patient populations are considered at high risk for PU development, especially medically unstable (critically ill/injured), bariatric, post-operative, diabetic, and patients with a history of cardiovascular disease (Cox, 2011). For example, trauma and surgical patients are at an increased risk of PU development due to the inherent associated changes to tissue perfusion and the application of medical assistive devices, such as wraps, casts, and dressings. The increased risk of PU development is of significant concern in the unique AE care environment because of the large number of AE patients who have a trauma diagnosis. Since the average military evacuation time from point of injury to definitive care is 28 hours, it is highly likely that the trauma patients undergoing AE transport are within the 48-hour time period of increased post-operative PU risk.

Critically ill/injured patients are considered at high risk for PU development. However, in a recent study by Lahmann, Kottner, Dassen, and Tannen (2012), when critical care and hospital ward patients were compared and controlled for various PU risk factors (surface, reposition, immobility, shear forces, age, & gender), there was little difference in the PU rate between the two groups (odds ratio 1.5; CI 1.2-1.7). These results suggest that the factors (immobility, patient condition) that are attributed to increased risk of PU development are similarly responsive to prevention strategies such as repositioning and specialized pressure reduction surfaces (Lahmann, Kottner, Dassen, & Tannen, 2012).

Immobility

Immobility has been identified as a factor in PU development, especially on areas of increased pressure such as bony prominences. As mentioned, the NPUAP guidelines do not make definitive recommendations for the timing and frequency for PU risk assessment, skin assessment, or specific prevention interventions, begging the question, “how long does it take for a patient to develop a pressure ulcer” in relationship to optimal timing and frequency of risk assessments? Most studies address the PU timing in relationship to length of immobility, degree of pressure, which is also associated with the type of surface and the position (sitting or lying) the patient is exposed to. For example, post-operative patients are at increased risk for PU development because of the extended time they are immobile (anesthetized/sedated) on a hard surface (surgical table) (Alderden et al., 2011).

Gefen (2008) conducted a study in which he performed an integrated review of human, animal, and in vitro research of patients in the supine position to determine the time of PU onset. The review revealed that PU onset at bony prominences tends to occur between one and six hours after sustained pressure loading on the tissue. This PU onset timeframe is of particular interest in the AE care environment because the average AE flight duration is seven to thirteen hours with periods of immobility at nine to fifteen hours (Dukes, Maupin, & Mortimer, 2014), double the immobility duration (1 to 6 hours) identified for increased risk of PU development. Unfortunately, there are little data related to PU development in seated patients, such as those who are wheelchair bound. Also, of concern is that AE litter and seated ambulatory patients are strapped to the litter or seat for in-flight safety in the event of turbulence, sudden aircraft position changes, and the possibility of rapid decompression scenarios, which further limits patient movement and repositioning.

Moisture

Skin moisture is a factor in PU development because it decreases the skin’s resistance making it prone to maceration and tissue necrosis (Rubayi, 2015). In the typical clinical context, moisture can occur due to incontinence, sweating, vaginal/penile discharge, and wound drainage, among others. In AE, environmental thermal regulation can be a challenge. For instance, runway temperatures in the summer in Iraq can exceed 120 degrees Fahrenheit causing patients to sweat prior to take-off, increasing clothing and linen moisture. Aircraft cabin temperature control is highly variable depending on the aircraft and other environmental and situational conditions, making patient temperature regulation and moisture control as a PU prevention strategy difficult.

Surfaces

As discussed, impedance of blood flow results in decreased tissue oxygenation and cell damage or necrosis. An external compression pressure of 25 to 32 mm Hg is generally accepted as the point at which capillary closure occurs. Both the degree of compression and its duration effect PU development, supporting frequent position changes for pressure relief as a primary PU prevention strategy (Kosiak, 1961). Another PU prevention strategy is to employ pressure reducing surfaces, such as low air flow mattresses; however, providing pressure reducing surfacing in the AE environment is difficult since bed-fast patients are transported on North Atlantic Treaty Organizations (NATO) litters and air flow mattresses cannot be used in-flight due to the gas expansion that occurs at altitude (Grissom, 2003).

Peak skin interface pressures for the NATO litter were studied by Bridges, Schmelz, and Mazer (2003) and revealed that peak pressures exceeded 30 mm Hg for all body surfaces; however, the addition of an AE litter mattress pad significantly reduced the peak pressures. That being said, the peak pressures on the NATO litter with an AE mattress pad were still 25% to 65% higher than the Maxifloat pressure-reducing mattress.

Despite the evidence that the NATO litter AE mattress pads produce pressure reduction, AE litter pads are a limited resource and may not be available for patient use, especially in contingency scenarios such as in high military operational tempos (Battle of Fallujah) and humanitarian and disaster relief efforts (Hurricane Katrina) when high volumes of patients are being transported. When available, AE litter pads are applied for comfort and pressure relief and their use is prioritized based on the patient's PU risk, such as immobility and existing PUs, and other clinical and situational factors, including individual AE crewmember (AECM) clinical judgement. In addition, unless there are specific in-flight patient activity orders, many patients can move between being seated and laying on a litter if their clinical condition allows it, especially during long flights. It is unlikely that there is documentation of position changes for comfort (seated versus litter). Another challenge is that AE litter mattress pad usage is not tracked or documented. Due to the dynamic nature of AE transport, litter mattress pads are used discriminately and there is no discernable means to determine if patients who develop a PU were on a litter mattress pad or not.

In an attempt to increase the number of NATO litter mattress pads with maximum pressure reduction characteristics, a study was conducted which compared the peak skin interface pressures on the head, sacrum, and heels between six (6) prototype AE mattresses and the standard AE litter mattress pad (Bridges, 2005). Using Kosiak's (1961) interface pressure work and the average AE flight time (10 $\pm$ 3 hours), the benchmark for an adequate mattress peak pressure was established at less than 150 mm Hg, with a secondary level of analysis completed at 60 mm Hg. As a result, a mattress pad recommendation was made, which met the 150 mm Hg peak pressure maximum standard.

Elevated Head of the Bed

Elevating the head of the bed is frequently used as a clinical intervention in a variety of patient conditions, such as in respiratory compromise and aspiration prevention. However, several studies provide evidence that elevating the head of the bed 30 degrees or more increases the risk for PU development due to increased peak skin interface pressure localized in the sacral area and the friction/shear that occurs when the patient slides down the bed (Defloor, 2000; Keller, Lubbert, Keller, & Leenen, 2005). Of note, is that the risk of PU development with the elevated head of bed is increased in healthy individuals as well (Peterson et al., 2008).

Within the AE context, specially designed removable backrests fit the NATO litter to provide head elevation at 40 and 90 degree intervals. The NATO litter skin interface study mentioned previously included an evaluation of peak skin interface pressures with the 40 degree head elevation position (Bridges et al., 2003). In this position, peak skin interface pressures were higher than in any other body position tested (190 $\pm$ 9 mm Hg); however, the addition of an AE litter mattress pad decreased the peak pressures significantly (99 $\pm$ 6 mm Hg; $p = .000$) in all body positions. Therefore, the evidence supports that deliberate decisions should be made on whether to elevate the head of the bed considering the clinical context and the risk for PU development (Metheny & Frantz, 2013).

Staffing

The degree to which nurse staffing and/or workload contributes to PU development is inconclusive. In several studies, decreased nurse workload was associated with decreased PU rates (Alderden et al., 2011; Aydin, Donaldson, Stotts, Fridman, & Brown, 2015; Ma & Park, 2015; Twigg, Duffield, Bremner, Rapley, & Finn, 2011). However, other studies suggest that the impact of nursing staffing/workload does not play as significant a role in PU development (Donaldson et al., 2005; Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2002; Unruh, 2003).

The effect of nursing staffing/workload is not known in AE. There are no known studies that have investigated nurse staffing/workload on patient outcomes. AE flights are typically staffed with two or three flight nurses and three or four AE medical technicians; however, the patient load (1 to greater than 100) and acuity are widely varied depending on the aircraft type and the nature of the AE flight, for example non-combat, combat, and humanitarian operations.

Summary

This review of the extant literature has supported the need for a study identifying the risk factors for PU development in non-critical AE trauma patients. Pressure ulcer development is well-known as an important NSQI and one that has potentially profound impact on individual patients and the collective U.S. healthcare system. A systems approach to PU prevention and treatment has been shown to successfully decrease the prevalence and incidence of PUs in a variety of healthcare settings. One of the first steps in PU prevention is to identify the risk factors associated with PU development. To date, there are no known patient outcomes (except for overall mortality rates) focused studies to reflect the quality of care in the AE system.

Purpose

The purpose of this study is to explore the characteristics of non-critical AE trauma patients and identify the risk factors for PU development using existing data from the Aeromedical Evacuation Registry (AER) and the Department of Defense Trauma Registry (DODTR) between 2008 through 2012.

Specific Aims and Research Questions

The study has two specific aims with associated research questions:

Specific Aim 1

Identify the risk factors for pressure ulcer development in non-critical AE trauma patients by addressing the following research questions:

a. Is there a difference in the client characteristics (demographics, diagnoses, and care requirements) for non-critical AE trauma patients who do and do not develop PUs?
b. Is there a difference in the systems characteristics (aircraft type, flight duration, total AE transport time, flight type, total patient load) for non-critical AE trauma patients who do and do not develop PUs?
c. Is there a difference in the AE crew characteristics (number of AECMs) associated with non-critical AE trauma patients who do and do not develop PUs?
d. What is the incidence of PU (rate) development?

Specific Aim 2

Explore the association between the risk factors identified in Specific Aim 1 and the development of PUs in non-critical AE trauma patients by addressing the following research question:

a) What relationships exist between the client characteristics (demographics, diagnoses, and care requirements), systems characteristics (aircraft type, flight duration, total AE transport time, flight type, total patient load) and interventions characteristics (number of AECMs) identified in Specific Aim 1 on PU development (outcomes)?

Significance and Military Relevance

The USAF AE system is a unique and austere patient care environment. To date there is little evidence quantifying the quality of nursing care in the USAF Aeromedical Evacuation system except for overall mortality rates. The current evidence that exists focuses on critically ill/injured patients (Bridges & Evers, 2009; Dukes, Maupin, & Mortimer, 2014; Galvagno et al., 2014; Lairet et al., 2011; Mason, Eadie, & Holder, 2011), which comprises only 10% of patients cared for in the AE system (Hamilton, 2016), leaving the vast majority (90%) of the non-critical patients unstudied. Pressure ulcer occurrence is a national NSQI that can be applied to the care provided in the AE system. In addition, this study is the first one to utilize the data and associated linkage between the AER and DODTR, which has been identified as priority from the joint military research community (Shinn, 2016).

Chapter Summary

The AE patient care environment is a unique one that currently has no patient outcomes data to reflect the quality of care provided in the USAF en route care medical system for non-critical patients. Pressure ulcer development is a nationally recognized NSQI that can be addressed using a systems approach, such as is recommended by the NPUAP (NPUAP, 2014). The extant literature review provided in this chapter discusses several risk factors for pressure ulcer development, namely physical condition, immobility, moisture, surfaces, and elevated head of the bed (friction & shear) in the in-patient environment; however, to date the incidence, prevalence, and risk factors associated with AE non-critical patients have not been identified. This chapter provided a literature synthesis, which logically supported the study purpose. In addition, the study aims, research questions, and associated key variables were presented.

CHAPTER 2: CONCEPTUAL FRAMEWORK

In Chapter 2, the use of the Quality Health Outcomes Model (QHOM) will be discussed as the guiding theoretical framework for this study. According to Fawcett (1978), nursing research and theory are as interdependent as the double helix in a DNA strand. As previously stated, this study approaches PU development in AE as a NSQI from a purely systems perspective. According to Brewer, Verran, and Stichler (2008), a “systems perspective involves viewing one’s subject as a coherent but complex, dynamic structure in which all elements are interrelated” (p. 10). Therefore, the application of a systems-based framework is preferred. The QHOM developed by the American Academy of Nursing Expert Panel on Quality Healthcare (Mitchell, Ferketich, & Jennings, 1998) encompasses the constructs (person, environment, nursing, and health) of a nursing metaparadigm (Brewer et al., 2008) which meets the definition of a nursing theoretical framework (Crawford & Shang, 2015) and has been successfully utilized in a variety of systems focused patient outcomes related studies (Berry et al., 2014; Crawford & Shang, 2015; Mallow, Theeke, Barnes, & Whetsel, 2015; Mark & Harless, 2010). The QHOM is comprised of four fundamental concepts: systems, client, interventions, and outcomes and will serve as the framework to guide and organize this study. The QHOM model as adapted for the study is illustrated in Figure 1.

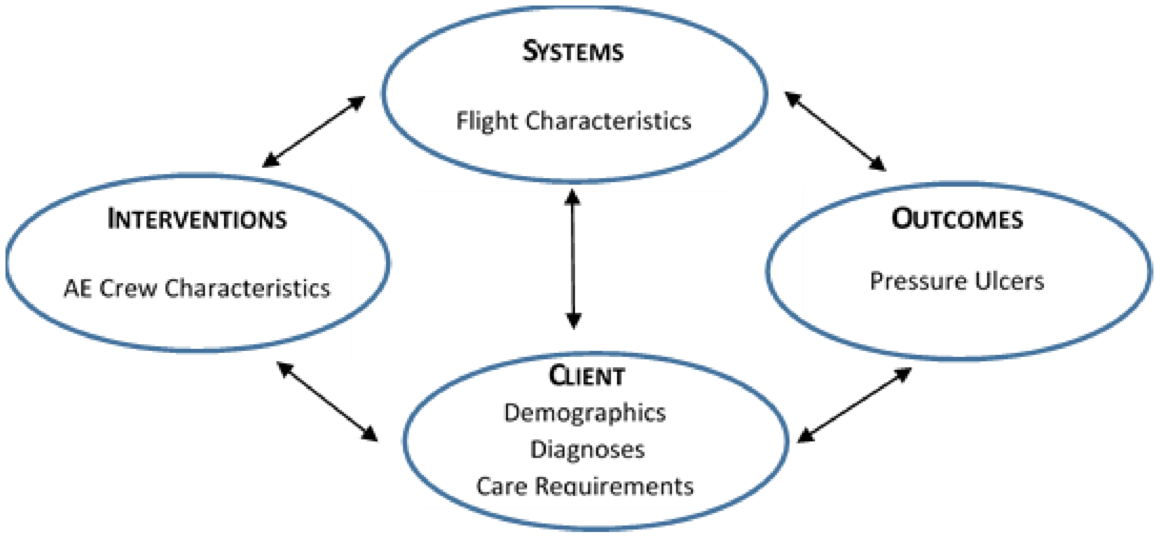

FIGURE 1. Application of the quality health outcomes model to identifying risk factors for pressure ulcer development in non-critical aeromedical evacuation trauma patients. (Mitchell et al., 1998)

The QHOM is based on Donabedian's (1966) structure, process, outcome, healthcare quality framework shown in Figure 2. Donabedian's work shows a linear depiction of how organizational structures and client characteristics influence processes resulting in a direct impact on outcomes. In the Donabedian framework, structures refer to the facilities, equipment, and other resources required to provide care. Client characteristics describe the clients' demographics, illness/wellness, values, and other unique characteristics which potentially impact the care provided (processes). The processes are: the care provided, the technical skill, evidence-based practice, and other quality of care indicators (appropriateness, completeness, and redundancy) (Crawford & Shang, 2015; Donabedian, 1966). Finally, the outcomes are the result of the structures/client characteristics and processes and are measured by the degree of client "recovery, restoration of function, and survival" (Donabedian, 1966, p.692). Unfortunately, the relationships are unidirectional and do not account for reciprocal relationships (feedback) among the concepts nor do they capture the complexity of organizations, such as the USAF AE system.

The QHOM expounds on Donabedian's (1966) structure, process, outcomes, healthcare quality framework by addressing the dynamic multi-dimensional nature of healthcare organizations.

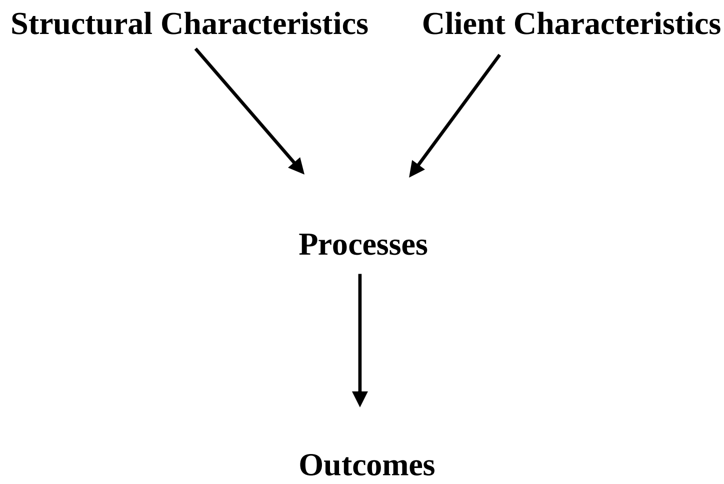

FIGURE 2. Donabedian's (1966) linear relationships in the structure, process, outcomes healthcare quality model. (Mitchell et al., 1998)

Quality Health Outcomes Model

System Characteristics

Based on an "organized agency" such as the AE system, structural and process components include facilities, space, equipment, and other resources (Mitchell et al., 1998, p. 44). The processes used to deliver care, the care providers and the associated skills sets they offer are also included as system characteristics. In this study, the systems characteristics domain reflects the unique AE care environment. Some examples of systems characteristics in the AE care environment are the flight characteristics (aircraft type, flight duration, total AE transport time, flight type, total patient load). For instance, Dukes et al. (2014) identified increased flight duration (10 ± 3 hours) and immobility duration (12 ± 3 hours) with PU development in critically ill/injured AE patients.

Interventions

The QHOM describes interventions as direct and indirect processes and activities used in care delivery (Mitchell et al., 1998). For example, while it is commonly known that patient repositioning is an effective PU prevention strategy (Lahmann et al., 2012), AE does not currently utilize a formalized repositioning/turning program, therefore it will not be included as an intervention for this study. However, of note is that patient repositioning in-flight is a frequently used PU prevention strategy and is recognized and applied as a nursing standard of care. Unfortunately, patient documentation reflecting nursing interventions in-flight, including a variety of PU prevention strategies, such as the application of a litter pad as discussed in chapter 1 is not available. In this study, the AE crew characteristics, specifically the number of AE crew per mission will be measured as interventions.

Client Characteristics

Mitchell et al. (1998) included patient demographics, health state, and disease risk factors within the client characteristics concept because these characteristics tend to impact outcomes. For the purposes of this study, the terms client and patient are used interchangeably. In the study by Dukes et al. (2014), client characteristics that were identified as risk factors for PU development in critical AE patients were high BMI and abnormal vital signs (elevated heart rate, elevated systolic blood pressure, low mean arterial blood pressure, and low oxygen saturation). Other client characteristics such as age and gender were not associated with PU development; however, age and gender will be measured in this study to determine the effect of demographics on the outcome variable.

The diagnoses variables within the client characteristics domain incorporates variables that reflect the type and severity of the patient’s illness/injury. These include the injury type, mechanism of injury, transport precedence, multiple movements, and ICD-9 trauma diagnosis code.

In addition, care requirements will be included within the client characteristics domain. Examples of care requirements are the degree of mobility ordered for the patient (ambulatory [seated] versus litter [laying]), the use of a cardiac monitor, pulse oximetry, suction, oxygen, and intravenous therapy. Care requirements such as these, may decrease mobility, which is a known risk factor for PU development (Alderden et al., 2011; Dukes et al., 2014).

Based on the literature review discussed in chapter 1, the use of litters and backrests are two interventions unique to AE that are hypothesized to contribute to PU development in this patient population, and as such will be included as care requirements in the client characteristics domain. Since in-flight nursing documentation is not available, litter and backrest usage will be determined using pre-flight data sources. In-flight changes to patients’ litter/ambulatory status or backrest use will not be captured.

Outcomes

Mitchell et al. (1998) describe outcomes as the measurable results of systems and processes that “integrate functional, social, psychological, physical, and physiologic aspects of people’s experience in health and illness” (p. 45). In this study, the measurable result of the systems and processes is any new PU development (of any stage classification) documented within three days post AE patient transport.

Relationships among the Model Concepts

In the QHOM model, the concepts (systems, client, interventions & outcomes) have bi-directional relationships allowing for the dynamic interactions between them. In this way, multi-dimensional analysis can be performed, representing the complex nature of the AE system. However, not all of the relationships in the QHOM model will be tested as some of the relationships are not logical or applicable. For example, by virtue of the chronology of PU development, it is logical to assume that systems characteristics such as flight duration may influence PU development (outcomes); however, it is not logical that a PU acquired in-flight would influence the flight duration (systems characteristics). Similar logic applies to the relationship between systems characteristics, client characteristics, and interventions. Some relationships between the concepts apply, but some do not. Also, while flight duration and total AE transport time (systems characteristics) may affect patient care requirements (client characteristics), it is not logical that they would affect static patient demographic variables, such as age and gender.

One limitation of the QHOM is that there is no direct relationship between interventions (number of AE crew members) and outcomes (PU development) (Brewer et al, 2008; Crawford & Shag, 2015). Nursing care (interventions) is mediated by client and systems characteristics; therefore, there is no direct effect of nursing care (interventions) on patient outcomes (PU development) (Mallow et al., 2013; Mitchell et al., 1998). Despite the fact that this study investigates PUs as a NSQI, it will be the first study in a new program of AE outcomes research. The goal is to improve awareness, which has been shown to effectively improve outcomes through a systems approach, not to potentially foster a punitive environment based on independent nursing interventions (or missed nursing care). In addition, there is no accessible documentation to reflect individual in-flight patient care, making inquiry into individual nursing care interventions and their direct effect on patient outcomes difficult. Therefore, the number of AE crew members will be used as a nursing care intervention.

Chapter Summary

The QHOM is a conceptual framework that will approach the topic of PU development in non-critical AE trauma patients from a systems perspective without introducing a punitive overtone to what is currently a “no blame” culture of patient safety. The model allows for multi-dimensional analysis between the concepts (systems, client, interventions, outcomes), which adequately represents the complex nature of the AE system care environment.

CHAPTER 3: METHODS

Chapter 3 discusses the study methodology including: study design, setting and sample, procedures, data collection plan, data management plan, data analysis plan, and the protection of human subjects.

Study Design

This study employed a retrospective case-control cohort analysis of electronic data from January 1, 2008 through December 31, 2012 comparing non-critical AE trauma patients who did and did not develop PUs within three days post-flight. This date range was chosen to compliment the previous work done by Dukes et al. (2014) which focused on PU development in critical AE patients; such that, when combined, the results of both studies will offer an overall gestalt of PU development as a NSQI in the AE system during the specified period. In addition, the DODTR determined that there was a raw total of 348 patients who developed PUs between 2008 and 2012. Considering that some of the 348 patients were critical patients and others may be excluded, this date range should provide the requisite 146 PU case patients needed based on the power analysis described in the Data Management Plan below.

The retrospective case-control cohort analysis of electronic data study design was selected because it is believed that PU development will be rare (approximately 5%) and the retrospective data analysis as designed would be feasible for data collection (Dukes, Maupin, & Mortimer, 2014). The QHOM will be applied as a framework for the study design as explained in chapter two.

Setting and Sample

The care of ill or injured military personnel often includes moving patients from one medical facility to another requiring fixed wing aircraft transport. Patient movement occurs for several reasons, to receive care that is: (a) specialized, (b) not offered by the originating facility, or is (c) logistically preferential. Generally, patient movement from a war zone is necessary to take the patient to a facility offering more specialized care, because the patient’s condition precludes a return to duty, and/or rehabilitative services are needed. What makes this type of patient movement unique is the mode of transport, the distance traveled, the condition of the patient being evacuated, and limited medical personnel, supplies, and equipment compared to civilian transports. Aspects of AE missions present a unique set of challenges unlike other care environments, such as exposure to the stresses of flight (hypoxia, decreased barometric pressure, thermal changes, humidity, gravitational forces, noise, vibration, dehydration, & fatigue) the effects of acceleration/deceleration, and other safety considerations related to in-flight care. For example, ambulatory patients sit in uncomfortable webbed seating for flights up to 16 hours, not including the ground time for which they are seated on either end of the flight (pre-flight & post-flight). Instead of beds or cushioned stretchers, non-ambulatory patients are secured with straps to a NATO litter, with or without a litter pad and also with or without a backrest possibly exposing them to increased risk for PU development (Figure 3) (Holleran, 2018). As stated, this is the first research study to investigate outcomes in non-critical AE trauma patients.

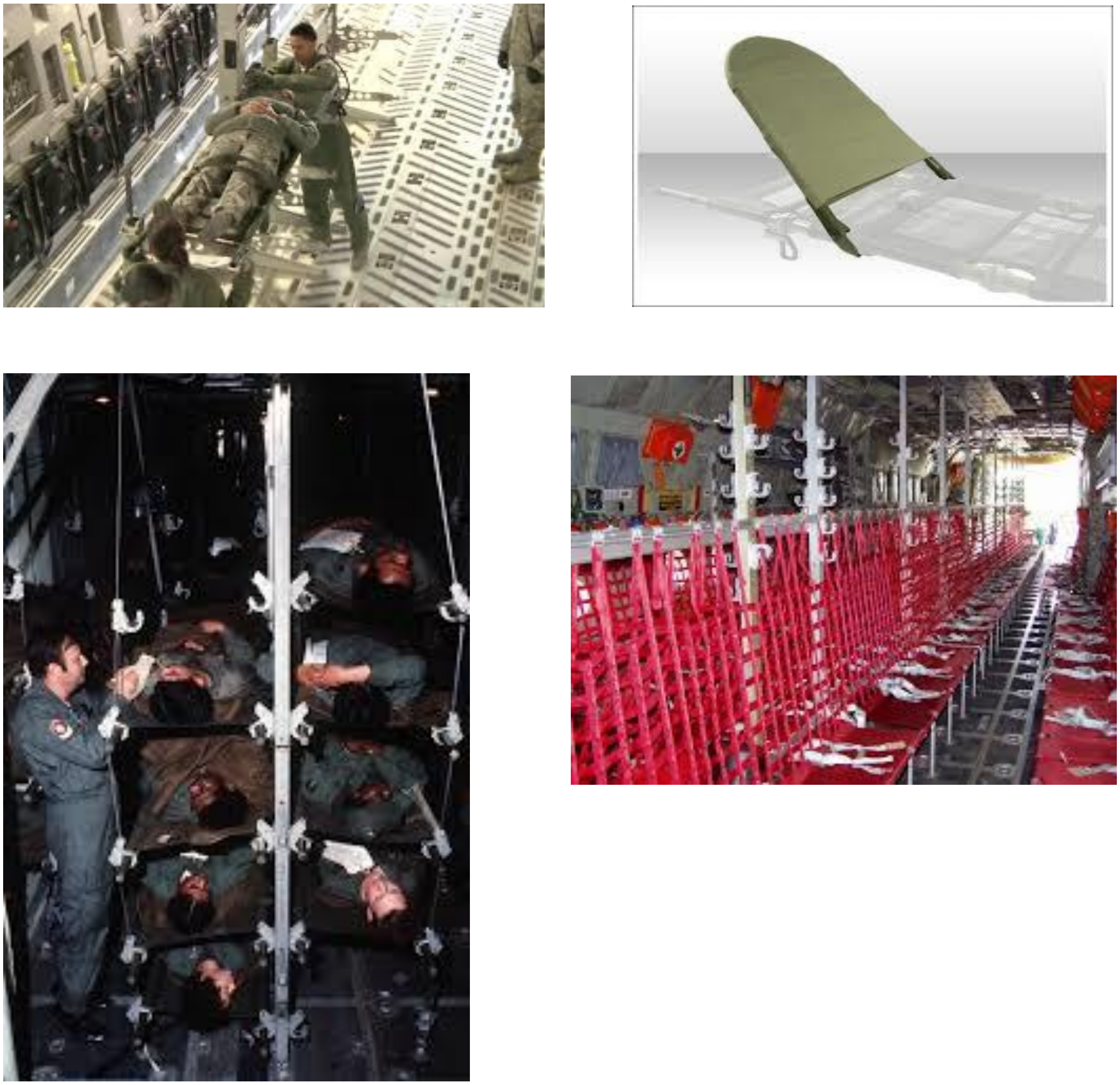

FIGURE 3. Examples of NATO litters and cargo seats used in military AE transport.

All non-critical patients between 2008-2012 identified as having a primary trauma International Classification Diagnosis (ICD-9) code who had a documented PU within three days post-flight as identified in the DODTR, as well as those who did not, were included in the study. Four-to-one comparison groups of non-critical trauma patients who did not (Control Group) and did develop PUs (Case Group) were identified using AER data (Marsh, Hutton, & Binks, 2002;

Redelmeier & Tibshirani, 2017). The control subjects were frequency matched within plus or minus one year of AE transport to the PU case group to mitigate potential bias related to practice changes over time, such as employing new pressure reducing mattresses, which were phased in globally during the study period.

Procedures

Primary data definitions and coding were used based on the individual data element's data source (AER or DODTR). Table 1 is a summary of study independent and dependent variables and outlines the variables within the QHOM framework. The study variables were chosen based on identified PU risk factors in the extant literature, AE policies and procedures, subject matter expert input, and data availability. Variables were identified and classified within the constructs of the QHOM model, namely Systems, Client, Intervention, and Outcomes variables.

Independent Variables

Client variables were divided into three sub-categories, demographics, diagnoses, and care requirements (Table 1). Some variables were identified as known risk factors for PU development in other patient populations, such as multiple AE transports, and flight duration (Dukes et al., 2014). As described in Chapter 1, immobility has long been known to be a PU risk factor. Since it is difficult to determine the degree of immobility in AE patients, the following variables were included as surrogates for immobility namely, mobility category (ambulatory versus litter), flight duration, and total AE transport time. Increased friction and shear, such as is associated with an elevated head of the bed has also been identified as a PU risk factor; therefore, the use of a back rest in-flight for litter patients was included as a client variable (Cox, 2011). Of note, is that the commonly used Braden Score, which has been shown to be a moderately valid predictor of PU development, is not included as an independent variable because the Braden Score and other PU risk assessment tools are not used in the AE system (Moore, 2014; Park & Park, 2014; Wang et al., 2015). Due to the lack of in-flight patient care documentation, the sole Interventions variable is the number of AE crewmembers.

Dependent Variables

The single dependent or patient outcome variable for the study is PU development. The DODTR stratifies, PUs as a complication into two groups by PU staging classification. The first group is PUs staged I or II and the second group is PUs staged III and IV. Pressure ulcer development as an outcome variable will be analyzed as a dichotomous (binary) variable, regardless of the PU stage; a PU developed (Yes) and was documented or a PU did not develop or it was not documented (No).

TABLE 1. *Independent and dependent variables.*

Variables	**Primary Data Source**
Independent Variables	
Client Variables:	
Demographics	AER
Last Name, First Name	
Social Security Number	
Cite Number	
Age	
Gender	
Diagnoses	AER/DODTR
Injury Type (Battle Injury/Non-Battle Injury)	
Mechanism of Injury (IED, GSW, MVA, Helo Crash, Other)	
Transport Precedence (Urgent, Priority, Routine)	
Multiple Movements (Number of times transported via AE)	
ICD-9 Trauma Diagnosis Code	
Care Requirements	AER
Mobility (Ambulatory (seated), Litter (laying))	
Back Rest	
Cardiac Monitor	
Pulse Oximetry	
Suction	
Oxygen (Ordered continuous or Stand-by)	
Intravenous Therapy	

TABLE 1 – *Continued*

Variables	Primary Data Source
Independent Variables	
Systems Variables:	
Flight Characteristics	AER
Mission Number	
Mission Date	
Flight Duration (Minutes)	
Total AE Transport Time (Minutes)	
Aircraft Type (C-21, C-130, C-141, C-17, C-5)	
Flight Type (Non-Combat, Combat, Humanitarian)	
Total Patient Load	
Intervention Variables:	
AE Crew Characteristics	AER
Number of AE Crew Members	
Dependent/Outcome Variables	
Pressure Ulcer Development (Yes/No)	DODTR

Data Collection Plan

Data collection was accomplished using two primary data sources, the United States Air Forces School of Aerospace Medicine (USAFSAM) Aeromedical Evacuation Registry (AER) and the United States Army Institute of Surgical Research (USAISR) Department of Defense Trauma Registry (DODTR) as these are two of the primary existing searchable data sources that represent data associated with the en route care phases of the military health continuum (Mortimer, 2017; System, 2017).

Aeromedical Evacuation Registry (AER)

The USAFSAM is constructing a registry that captures and integrates AE mission (flight), crew, and medical data from patients who underwent AE transport on fixed-wing aircraft between September 2001 and October 2018. The AER project was initially funded by the Joint Program Committee for Combat Casualty Care (Defense Health Agency, Research and Development). The AER project received non-human use designation (FWR2010019N) from the Air Force Research Laboratory (AFRL), Wright Patterson Air Force Base, Ohio Institutional

Review Board (IRB) as a quality improvement initiative and is designed to be a searchable database interfaced with the existing DODTR.

The AER includes all patients transported globally in the AE system, including patients of all ages with surgical/trauma, medical, and behavioral health diagnoses, critical and non-critical in severity; they may be military members or their families, contractors, U.S. or other national civilians. The volume of patients and diverse health conditions is unique to the USAF in large part because the AE system cares for patients in a variety of scenarios such as combat/wartime/contingency operations, humanitarian and disaster response, international U.S. citizen evacuation in times of political unrest and non-combat AE system operations (Bridges, Mortimer, & Dukes, 2016) making the AER the most comprehensive en route care database to date.

Department of Defense Trauma Registry (DODTR)

The DODTR, originally the Joint Theater Trauma Registry (JTTR), is a patient clinical database in support of quality improvement and research in the field of combat casualty care. Unlike the AER, which includes all types of patient populations, the DODTR includes only patients with specific trauma diagnoses ICD-9 codes. The DOTR currently has eight sub-specialty modules interfaced with it, namely the Acoustic, Infectious Disease, Military Orthopaedic Trauma, Pre-Hospital Trauma, Outcomes (Recovery and Rehabilitation), Traumatic Brain Injury, and Vision Registry modules (United States Army Institute of Surgical Research (UAISR), 2016). Upon completion of the AER, it will be interfaced with the DODTR like the other sub-specialty modules.

Data Management Plan

The study data were extracted by representatives from each of the respective registries (AER & DODTR) who have unlimited database access and specialized expertise. First, a list of all of the trauma patients who incurred a PU was provided to the Principal Investigator (PI) by the DODTR. To establish the control group, the PI matched PU patients to non-PU patients who were transported within plus or minus one year of the PU patients to control for practice changes in the AE system such as the use of different litter mattress pads. For every one PU patient, four control group patients were included in the study as a means to improve reliability and validity. Mobility status, flight duration, and total AE transport time will be used as surrogates for immobility. Litter patients are more immobile and have decreased range of motion in the supine position compared to seated/ambulatory patients. In addition, due to restrictions in mobility related to flight safety regulations, it is likely that longer duration flights predispose patients to longer periods of immobility (Dukes, Maupin, & Mortimer, 2014).

Subject identifiers (first name, last name, social security numbers) were used initially to match patients across the databases; however, once the study subjects were identified, the personal identifiers were removed to maintain subject privacy and confidentiality (Friedman, 2010). In addition, to maintain security of the identified data, they were stored solely on a USAF limited access secure server at the School of Aerospace Medicine using government computers. Once the data were de-identified, the data were maintained by the PI in accordance with AFRL IRB protocols.

Based on a power analysis for regression analysis and the four to one match, the study sample size was determined to be 146 case subjects and 584 control subjects (total subjects =

730). The power analysis, using G* Power statistical software, was conducted to determine the sample size using an a priori alpha a = .05 and moderate effect size ES = .3; and a standard power of .80 (Field, 2013; Grove, 2007). Because previous studies estimated a 5% pressure ulcer rate (rare occurrence), a moderate a priori effect size was established to ensure there was a large enough effect size such that the difference from the null hypothesis could be credited to the independent variable (Grove, 2007). Furthermore, the 146-sample size was corroborated with Field (2013), who states that a sample of approximately 160 is more than enough to achieve a moderate effect size suitable for logistic regression models with up to 20 independent variables (current study 21 independent variables). However, the data request from the DODTR returned only 22 PU patients, seven of which were excluded because they had not been transported via the AE system. Therefore, considering the four-to-one matching, the case group equaled 15 and the control group was 60.

Data Analysis Plan

The AER and DODTR were the data sources. Flight, crew, and patient pre- and in-flight clinical data were extracted from the AER. The outcome variable data (PU development) was extracted from the DODTR (Table 2). A priori statistical significance was evaluated at the $p \leq .05$ level (Field, 2013). Statistical analyses were performed using SPSS and SAS statistical software.

Specific Aim 1

Identify the risk factors for pressure ulcer development in non-critical AE trauma patients by addressing the following research questions:

a. Is there a difference in the client characteristics (demographics, diagnoses, and care requirements) for non-critical AE trauma patients who do and do not develop PUs? Descriptive statistics, such as frequency distribution, percentages, mean, median, and ranges, were used to characterize demographic, diagnoses, and patient care requirements. In addition, group comparisons were analyzed using t-tests, Chi-square, and Fisher's exact test (Cox, 2011; Kellar, 2013; Field, 2013).
b. Is there a difference in the flight characteristics (aircraft type, flight duration, total AE transport time, flight type, total patient load) for non-critical AE trauma patients who do and do not develop PUs? Descriptive statistics, such as frequency distribution, percentages, mean, median, and ranges, were used to characterize flight characteristics. In addition, group comparisons were analyzed using t-tests, Chi-square, and Fisher's exact test (Cox, 2011; Kellar, 2013; Field, 2013).
c. Is there a difference in the AE crew characteristics (number of AECMs) associated with non-critical AE trauma patients who do and do not develop PUs? Descriptive statistics, such as frequency distribution, percentages, mean, median, and ranges, were used to characterize AE crew characteristics. In addition, group comparisons were analyzed using t-tests, Chi-square, and Fisher's exact test (Cox, 2011; Kellar, 2013; Field, 2013).
d. What is the incidence of PU (rate) development? There are several different ways in which PU rates are calculated. The National Database of Nursing Quality Indicators (NDNQI) calculates hospital acquired PU rate based on the total number of patients who acquired a PU after admission to the hospital divided by the number of patients surveyed times 100 (Indicators, 2018). The Agency for Healthcare Research and Quality (AHRQ)

acknowledges that there are several ways to calculate PU rates; however, facilities must choose one method and use it consistently and also notes that rates that are calculated differently cannot reliably be compared ("How do we measure our pressure ulcer rates and practices?," 2014). The calculation used by AHRQ is the number of PUs per 1000 patient discharges times 100. In the study by Dukes, Maupin, Thomas, and Mortimer (2018), the PU incidence rate was calculated for critically ill/injured (CCATT) AE patients (who developed PUs within three days post-flight) based on the number of PU patients in the study sample divided by the total number of CCATT patients moved during the study period; however, these calculations do not take into account that individual patients were transported multiple times (on average 1.3 times). Patients who had more than one CCATT transport were 27 times more likely to develop a PU. Therefore, similarly to the AHRQ method, the PU incidence (rate) was determined by the number of PU per 1000 patient movement requests (the number of transports) (i.e., discharges) times 100.

Specific Aim 2

Explore the association between the risk factors identified in Specific Aim 1 and the development of PUs in non-critical AE trauma patients by addressing the following research questions:

a. What relationships exist between the client characteristics (demographics, diagnoses, and care requirements), systems characteristics (aircraft type, flight duration, flight type, total patient load, number of AECMs), and AE crew characteristics (number of AECMs) identified in Specific Aim 1 on PU development (outcomes)? Firth conditional logistic regression was used to identify the risk factors that predicted PU development. Firth conditional logistic regression was the statistical method chosen because it is used in models with a dichotomous (binary) dependent variable, rare events, and small cell sizes. The Firth conditional logistic regression method reduces the chance of a Type I error in small sample size datasets or during separation (when there are too many small cell sizes in the table) and decreases the possibility of small sample size bias (Allen, 2012; Ma, Blackwell, Boehnke, & Scott, 2013; Wang, 2014; Williams, 2019).

Protection of Human Subjects

Based on the nature of the retrospective data analysis, I requested Expedited Institutional Review Board approval from the AFRL IRB (Appendix A). Since all of the study data are DOD data, I also requested a waiver from the University of Arizona designating the AFRL IRB (Appendix B) as the study IRB of record. Individual patient consent was not required for the retrospective data review. Both the AER and DODTR required study IRB approval prior to providing data. Initially, patient identifiers were used to link data between the data sources and to match the patients for the purposes of the case control. Once the PU and control groups were delineated, all patients were de-identified and given a dummy unique identifier for use in data analysis. All identifiable data were stored and used on approved secure USAF servers and computers located at Wright Patterson Air Force Base, Ohio. Patient and other data are reported in the aggregate and with sensitivity to avoid patient identification by other means such as dates and locations of injuries.

Chapter Summary

Chapter 3 discussed the study methodology. The retrospective case-control cohort analysis study design is both logical and feasible to meet the specific aims of the study. In addition, the study setting and sample, procedures, data collection plan, data management plan, and data analysis plan were supported. The discussion regarding the protection of human subjects focused on maintaining privacy and confidentiality of subject personally identifiable information.

CHAPTER 4: FINDINGS

The following chapter describes the study findings, including a description of the cohort, non-critical aeromedical evacuation trauma patients, those with and without PUs. The independent variable results will be presented within the QHOM framework as they align to the client, systems, interventions, and outcomes variables. The degree of missing data will be reported, important considering the context of the retrospective case-control cohort analysis of electronic data study design. Next, the PU incidence (rate) will be discussed. Finally, the PU risk factors will be identified using Firth conditional logistic regression.

Sample Characteristics

Organized using the QHOM model, the sample characteristics are embodied in the three domains, client, systems, interventions, and their relationship to the case (PU) patients and control (non-PU) patients. The DODTR was queried and returned 22 trauma patients with a documented PU complication within three days of admission (post-flight). The PU patients were compared to patients in the AER to determine which of the PU patients had been transported in the AE system. Seven patients were excluded because they had not been transported via AE, leaving 15 case patients for inclusion in the study, which as stated previously was far fewer case patients than expected.

The sample, based on a four-to-one control-to-case ratio, includes 15 PU patients (case) and 60 non-PU patients (control). The case patients were matched to the control patients who were transported via AE plus or minus one year of the PU complication date. This matching procedure was chosen to decrease confounding variables that occurred due to changes in clinical practice over longer periods of time. No other matching criteria were employed so as not to decrease the potential for identifying possible risk factors for PU development in the patient population.

Client Variables

The client variables results are aligned with Specific Aim #1a and are illustrated in Table 2. According to Mitchell et al. (1998), the client (patient) characteristics include variables such as demographics and health state as these have a direct impact on client's outcomes. Therefore, the client characteristics in this study are independent variables including demographics, diagnoses, and care requirements variables (Table 1). Table 2 lists the client variables analysis findings.

TABLE 2. *Non-critical aeromedical evacuation (AE) trauma patient client variables.*

Client Variables	**Ulcer (n=15)**	**No Ulcer (n=60)**	***P* Value**	**% Missingness**
Demographics				
Age n(Mean, SD, years)	15(26.20, 8.10)	60(26.98, 8.15)	.740	0.00
Gender n(%)			1.00	0.00
Female	0(0.00)	3(5.00)		
Male	15(100.00)	57(95.00)		
Diagnoses n(%)				
Injury Type			.082	0.00
Battle Injury	11(73.33)	27(45.00)		
Disease/Non-Battle Injury	4(26.67)	33(55.00)		
Mechanism of Injury			<.001	80.00
Blank	0(0.00)	60(100.00)		
Bullet/GSW/Firearm	2(13.33)	0(0.00)		
Explosive	10(66.67)	0(0.00)		
Fall	1(6.67)	0(0.00)		
MVC	1(6.67)	0(0.00)		
Sports	1(6.67)	0(0.00)		
Transport Precedence			.270	0.00
Urgent	0(0.00)	0(0.00)		
Priority	5(33.33)	12(20.00)		
Routine	10(66.67)	48(80.00)		
Multiple Movements			.266	0.00
1	9(60.00)	22(36.67)		
2	3(20.00)	22(36.67)		
≥3	3(20.00)	16(26.67)		

TABLE 2 – *Continued*

Client Variables				
	Ulcer (n=15)	**No Ulcer (n=60)**	***P* Value**	**% Missingness**
Primary Diagnosis			.043	0.00
Amputation, Traumatic	3(20.00)	1(1.67)		
Closed Head or Traumatic Brain Injury	0(0.00)	2(3.33)		
Crushing Injury	0(0.00)	2(3.33)		
Dislocation, Open or Closed	0(0.00)	7(11.67)		
Fracture, Open or Closed	9(60.00)	24(40.00)		
Injury or Open Wound, Superficial	0(0.00)	9(15.00)		
Injury, Major Organ other than Nervous System	1(6.67)	1(1.67)		
Injury, Cranial Nerve or Spinal Cord	1(6.67)	1(1.67)		
Injury, Unspecified	1(6.67)	9(15.00)		
Sprain	0(0.00)	4(6.67)		
Care Requirements n(%)				
Mobility			.029	0.00
Ambulatory	1(6.67)	22(36.67)		
Litter	14(93.33)	38(63.33)		
Back Rest			.480	92.00
Blank	14(18.7)	55(91.67)		
No	0(0.00)	4(6.67)		
Yes	1(6.67)	1(1.67)		
Cardiac Monitor			.278	80.00
Blank	14(93.33)	46(76.67)		
No	1(6.67)	14(23.33)		
Yes	0(0.00)	0(0.00)		
Pulse Oximetry			<.001	0.00
No	5(33.33)	54(90.00)		
Yes	10(66.67)	6(10.00)		
Suction			.013	0.00
No	11(73.33)	58(96.67)		
Yes	4(26.67)	2(3.33)		
Oxygen			<.001	60.00
Blank	2(13.33)	43(71.67)		
Nasal Cannula-Adult	10(66.67)	11(18.33)		
Standby Oxygen for Transport	3(20.00)	6(10.00)		
Intravenous (IV)			<.001	45.33
Blank	1(6.67)	33(55.00)		
IV Catheter	9(60.00)	8(13.33)		
Saline Lock	5(33.33)	19(31.67)		

Demographics

Demographics included age and gender. The mean age for the PU patients (n=15) was 26.20 (SD=8.10) and the non-PU patients (n=60) had a mean age of 26.98 (SD=8.16), with a range of 15-54 years old (0% missing data). Age was not significantly different ($t(73) = .740$, $p >$

.05) between the PU and non-PU patients. All of the PU patients were male (n=15, 100%) and 96% (n=57) of the non-PU patients were male (0% missing data). Fisher's exact test was conducted for a between group comparison, which was not significant (p = 1.00).

Diagnoses

The diagnoses category consists of injury type, mechanism of injury, transport precedence, multiple movements and the patient's primary diagnoses. Injury type is determined by whether the patient had a battle related injury (BI) versus a disease/non-battle injury (DNBI). Since all of the patients in the study are trauma patients, there were no disease patients, only battle versus non-battle injury; however, the term DNBI will be used as it is the proper military nomenclature for the injury type. In this case, 73.3% (n=11) of the PU patients incurred a BI compared to 45% (n=27) of the non-PU patients. Unfortunately, none (n=0, 0%) of the non-PU patients had a documented mechanism of injury; but of the PU patients, two (13.33%) experienced gunshot wound, 10 (66.67%) explosive injury, and one (each) (6.67%) incurred a fall, motor vehicle crash, or a sports injury.

Transport precedence is a way of determining how quickly a patient needs to be transported, usually based on injury/illness type and severity. In this study, none (n=0, 0%) of the patients required urgent transport. Pressure ulcer patients required priority and routine movement, 33.33% (n=5) and 66.67% (n=10), respectively. Of the non-PU patients, 20% (n=12) required priority transport and the vast majority flew in routine status (n=48, 80%).

In the military system, it is common for patients to require multiple patient transports to get from the point of injury to definitive care; however, in this study the majority of PU patients required only 1 AE transport (n=9, 60%) followed by 2 and greater than or equal to 3 movements at 20% (n=3) each. The non-PU patients were fairly evenly distributed between 1, 2, and greater than or equal to 3 AE transports at 36.67% (n=22), 36.67% (n=22), and 26.67% (n=16).

The first 10 documented diagnoses for both the PU and non-PU patients are listed in Table 2. Of note, is that the documented diagnoses are not necessarily prioritized; for instance, a patient may have what is considered an equally or more severe diagnosis that is not represented. The most frequently documented first diagnosis for PU (n=9, 60%) and non-PU patients (n=24, 40%) was fracture. The second most frequent diagnosis for PU patients was traumatic amputation (n=3, 20%) and for non-PU patients open wound and unspecified injury (n=9, 15%) were the second most frequent diagnosis.

Care Requirements

The care requirements included the degree of mobility (ambulatory versus litter) and the use of a backrest, cardiac monitor, pulse oximeter, suction, oxygen, or intravenous therapy. In this study, the preponderance of the PU patients was transported on a litter (laying) 93.33% (n=14) compared to ambulatory (seated) (6.67%, n=1). The non-PU patients were transported on a litter 63.33% (n=38) and ambulatory 36.67% (n=22) of the time (0% missingness). In addition, the use of litter backrest was only documented once for both PU (n=1, 6.67%) and non-PU patients (n=1, 1.67%). Of note, is that data for the use of a litter backrest were missing 92% of the time. The use of a cardiac monitor was also poorly documented (80% missingness) and of those that were documented, neither the PU nor the non-PU patients required a cardiac monitor (n=0, 0%). The use of a backrest or a cardiac monitor were the only care requirements that did not show statistical significance between the PU and non-PU patients (Table 2).

The use of in-flight pulse oximetry was documented 100% of the time for both PU and non-PU patients. Pressure ulcer patients were ordered pulse oximetry 66.67% (n=10) of the time compared to non-PU patients at 10% (n=6). Likewise, the use of suction had a 0% missingness. Pressure ulcer patients used suction therapy more frequently (n=4, 26.67%) than did non-PU patients (n=2, 3.33%). Due to the oxygen desaturation that occurs at altitude, it is not uncommon for patients to have oxygen ordered in-flight (PU n=10, 66.67%; non-PU n=11, 18.33%). In addition, some patients may have a “stand-by” oxygen order in the event of desaturation. In this case, 3 of 15 (20%) PU patients had “stand-by” oxygen ordered and compared to 6 of 60 (10%) non-PU patients. The final care requirement is intravenous (IV) therapy. The use of IV therapy was undocumented 45.3% of the time. Either an IV catheter or a saline lock was employed. For PU patients, IV catheters were more frequently used (n=9, 60%) than a saline lock (n=5, 33.33%). Non-PU patients tended to have saline locks more frequently (n=19, 31.67%) compared to IV catheters (n=8, 13.33%).

Systems Variables

As aligned in Aim #1b, the systems variables included flight duration, total AE transport time, aircraft type, flight type, and total patient load (Table 3). Flight time is the time that the patient was flying associated with the PU event. The Mean flight duration time for PU patients was 310.24 $\pm$ 161.30 minutes (Median = 411.00; Mode 450.00; Range = 56 - 456.00). The Mean flight duration for non-PU patients was 291.78 $\pm$ 174.86 minutes (Median = 325.50; Mode = 108; Range 35 – 960). There was no statistically significant difference between the Mean flight duration for PU and non-PU patients ($t(73) = .711$, $p > .05$). As stated earlier, in AE it is common for patients to be transported more than one time. Therefore, patients may have experienced additional cumulative flight time, which is assumed time of decreased mobility; in this case, defined as total AE transport time. Pressure ulcer patients experienced a Mean total transport time of 383.33 $\pm$ 91.90 minutes (Median = 411.00; Mode = 450.00; Range = 86 – 456). Non-PU patients had a total transport time of 388.87 $\pm$ 126.97 (Median = 413.00; Mode = 413.00; Range = 72 – 960). However, there was no statistically significant difference for total AE transport time between the PU and non-PU groups ($t(73) = .875$, $p > .05$).

Evaluation of aircraft type was considered related to PU development, such that 60% (n=9) of PU patients flew on a C-17 aircraft compared to 53.33% (n=32) for non-PU patients. Pressure ulcer patients flew on C-130 and KC-135 20% (n=3) of the time. Non-PU patients flew on C-17s, C-130s, and KC-135s 53.33% (n=32), 15% (n=9), and 31.67% (n=19) respectively. In addition, flight type (non-combat, combat, or humanitarian) was evaluated. PU patients flew most frequently on non-combat missions (n=10, 66.67%) and combat missions (n=5, 33.33%). Non-PU patients flew on non-combat missions 75% (n=45) and on combat missions 25% (n=15). Neither PU nor non-PU patients (n=0, 0%) were flown on humanitarian missions. Finally, the Mean total patient load on flights associated with the PU event was 18.33 $\pm$ 13.68 and for non-PU patients was 15.22 $\pm$ 9.67 (Table 3). There was no statistical difference in the total patient load for PU versus non-PU patients ($t(73) = .310$, $p > .05$).

TABLE 3. *Non-critical aeromedical evacuation (AE) trauma patient systems variables.*

Systems Variables				
	Ulcer (n=15)	**No Ulcer (n=60)**	***P* Value**	**% Missingness**
Flight Characteristics n(%)				
Flight Duration (Mean, SD, minutes)	310.27(161.30)	291.78(174.86)	.711	0.00
Total Transport Time (Mean, SD, minutes)	383.33(91.90)	388.87(126.96)	.875	0.00
Aircraft Type			.728	0.00
C-17	9(60.00)	32(53.33)		
C-130	3(20.00)	9(15.00)		
KC-135	3(20.00)	19(31.67)		
Flight Type			.526	0.00
Non-Combat	10(66.67)	45(75.00)		
Combat	5(33.33)	15(25.00)		
Humanitarian	0(0.00)	0(0.00)		
Total Patient Load (Mean, SD, number)	18.33(13.68)	15.22(9.67)	.310	

Interventions Variables

As shown in Table 4 (Aim #1c), the Mean number of AE crewmembers per mission per patient was 4.51 ± 2.74 (Median = 5.00; Mode = 1.00; Range = 1.00-9.00) for PU patients and 3.92 ± 2.67 (Median = 4.67; Mode = 1.00; Range = 1.00-7.00) for non-PU patients; however, in both cases, there were multiple modes and the lowest one is represented. As it relates to the number of AE crew, there was no statistical significance ($t(73) = .448$, $p > .05$). There was 0% missingness based on the AER data.

TABLE 4. *Non-critical aeromedical evacuation (AE) trauma patient intervention variables.*

Intervention Variables				
	Ulcer (n=15)	**No Ulcer (n=60)**	***P* Value**	**% Missingness**
AE Crew Characteristics n(%)				
Number of AE Crew Members (Mean, SD, number)	4.51(2.75)	3.92(2.67)	.448	0.00

Pressure Ulcer Incidence (Rate)

To address Aim #1d, "What is the pressure ulcer incidence rate?" the following results are reported. The AHRQ (2014) states that PU rates are calculated as the number of PUs per 1000 patient discharges times 100. In the AE environment, all patients that get on a flight get off the flight so the number of admissions and discharges is the same. Also, since patients tend to be transported more than one time, the number of patient movement requests for the time period will be used as the denominator to calculate the PU incidence rate. This calculation took into consideration the number of patients discharged (n=73,377), including each patient having more than one discharge and the number of patients who developed a PU (n=15) during the study time period (2008 to 2012). That being said the PU incidence rate was < 1% (.02).

Risk Factors for Pressure Ulcer Development

The Aim #2 research question was "What relationships exist between the client characteristics, systems characteristics, and interventions variables on PU development (outcomes)?" All of the PU (n=15) and non-PU (n=60) patients were included in the regression analysis. Constrained variables with missing data of greater than or equal to 50% were not included in the model (Mechanism of injury [80%], backrest [92%], cardiac monitor, [80%], oxygen [60%]) in order to minimize bias. In addition, prior to running the analysis, some categorical variables were changed to dummy or indictor variables to mitigate the effect of n < 5 (Field, 2013) (Backrest, cardiac monitor, pulse oximetry, suction, oxygen, IV therapy) based on the results of the cross tabulation analyses.

A binomial Firth conditional logistic regression (Allen, 2012; Ma, Blackwell, Boehnke, & Scott, 2013; Wang, 2014; Williams, 2019) was conducted in the face of PUs as a rare event (n=15; incidence rate < 1%) to determine the effects of the independent client, systems, and intervention variables on the development of PUs in non-critical AE trauma patients (Table 5). The regression showed statistical significance in two of the 12 variables that were used in the model, namely the use of IV therapy ($p = .04$) and pulse oximetry ($p = .010$) (Table 5).

TABLE 5. *Firth conditional logistic regression in predicting pressure ulcer development.*

Variable	B	OR (95% CI)		*p*
Age	-0.002	.998	(.879, 1.100)	.950
Flight Duration (Minutes)	-0.001	.999	(.986, 1.007)	.690
Total Mission Time (Minutes)	0.0005	1.000	(.991, 1.013)	.869
Number of AE Crew	0.06	1.078	(.687,1.977)	.611
Total Patient Load	-0.01	.990	(.892, 1.091)	.758
Injury Type	-0.02	.963	(.084, 34.122)	.958
Intravenous Therapy	**1.06**	**4.680**	**(.874, 379.427)**	**.040**
Flight Type	.30	1.823	(.121, 172.184)	.538
Pulse Oximetry	**-1.04**	**.125**	**(<.001, .474)**	**.010**
Suction	-0.03	.944	(.069, 87.856)	.960
Transport Precedence	0.29	1.772	(.270, 57.033)	.471
Mobility Classification	0.10	1.215	(.035, 28.421)	.822

Chapter Summary

In Chapter 4, the patients with and without PUs were described using descriptive statistics. The PU incidence rate was reported and the risk factors for development of PUs in this AE patient population were identified. The next chapter will discuss the study findings in the context of the sample characteristics, AE system, and the extant literature.

CHAPTER 5: DISCUSSION

Chapter 5 provides a discussion of the study findings, putting them into context within the Quality Health Outcomes Model (QHOM), general nursing practice, and the military enroute care environment. Topics for discussion include the QHOM, risk factors for PU development, study strengths and limitations, and implications for healthcare clinicians and military leadership. Finally, recommendations for future research and closing remarks are provided.

Quality Health Outcomes Model

Initially, the Quality Health Outcomes Model (QHOM) was chosen as a theoretical framework because it was systems based, the main constructs (Client, System, Interventions, and Outcomes) would fit within the AE construct, and the bi-directional nature of the relationships seemed to reflect the complexity of the AE system. However, upon application of the QHOM model, several key considerations became evident.

First, the primary model limitation as identified in Chapter 2 was that there was no direct relationship between nursing interventions and the dependent variable (PU development) (Figure 1). Nursing interventions were mediated by either client characteristics or systems characteristics. Regardless, I considered the relationship and conducted the associated analyses, which did not reveal statistical significance.

Next, while the bi-directional nature of the relationships between the constructs was preferred, upon application the bi-directional relationships were not necessarily logical. For instance, while patient demographics (client characteristics) may logically affect patient outcomes (PU development), it is not logical that PU development would affect patient age. The same considerations were represented between the bi-directional relationships of the other constructs. Therefore, the QHOM was not necessarily the best fitting model for this study.

Risk Factors for Pressure Ulcer Development

The discussion regarding the risk factors for PU development are presented within the QHOM framework, namely client, systems, and interventions variables on the outcome, PU development. Of note, is that all of the data queried from the AER for this study were dependent upon the global personnel who entered the pre-flight data into the patient movement request (PMR) system, the US Transcom Regulating Command and Control Evacuation System (TRAC2ES). Data were input by a variety of transitory people frequently in the deployed environment with a variety of skill sets and training. Administration clerks, nurses, and physicians entered data into the PMR and due to the fluid and austere military operational circumstances may have had little time to enter only the most important information into the system to ensure safe in-flight care.

Client Variables

Demographics

Specifically age and gender were not found to be predictors of PU development and were consistent with the type of military patients flown in AE who are younger, male, and generally healthy pre-trauma compared to civilian in-patient populations (Callcut, Johannigman, Kadon, Hanseman, & Robinson, 2011).

Diagnoses

Variables were not determined to be risk factors for PU development, which is surprising because this sample were all patients with trauma diagnoses and trauma patients are known to be at risk for PU development due to soft tissue injuries with changes in vascularity and tissue perfusion (Table 5). Diagnoses variables demonstrated intermittent excessive missingness, which can be explained in some cases and not in others (Table 2). For instance, as expected, injury type was 100% populated because the difference between battle injury (BI) versus disease non-battle injury (DNBI) is a distinction that categorizes military patients for consideration of the Purple Heart medal for injury in combat. The mechanism of injury (MOI) was sparsely populated (80% missingness) in that 100% of the PU patients had MOI data and none of the non-PU patients had MOI documented for unknown reasons. As stated previously, an a priori decision was made to remove variables from the regression model with >50% missingness, of which MOI was one. Since the vast majority of PU patients incurred battle injuries (n=11, 73.33%), it is understandable that the majority of the MOI for these patients was combat related (explosive n=10, 66.67%; bullet/GSW/firearm n=2, 13.33%).

The documented primary diagnoses are corroborated based on the injury type (BI versus DNBI) and the MOI as most PU (n=9; 60%) and non-PU patients (n=24; 40%) experienced open or closed fractures. Of note is that patients could have multiple diagnoses and the first diagnosis listed is not necessarily the most severe. Considering that the patients were not critical or seriously ill, it is understandable that the majority of the patients were flown in “routine” status (PU n=10, 66.67%; non-PU n=48, 80%). Despite the fact that 60% (n=9) of the PU patients were only transported one time. Logic would dictate that the more times a patient flew, the higher the risk of PU development due to presumed immobility; however, based on the Fisher’s exact test (p = .266) this was not the case as the number of movements was not significantly different between PU and non-PU patients (Table 2).

Care Requirements

Tables 2 and 5 presented an interesting dichotomy of information. The thought was that litter patients and the number and type of care requirements would be surrogates for immobility; that the more care requirements that were employed, the less mobile the patient would be, placing them at increased risk for PU development. The degree of immobility proved true to some degree as 93.33% (n=14) of PU patients were transported on litter. The overall hypothesis that the care requirements inhibited mobility and therefore put patients at increased risk for PU development was not proved as the use of IV therapy (OR= 4.680, p=.04) was the only care requirement that was identified as a risk factor for PU development; however, its use would likely decrease patient mobility in-flight.

Unfortunately, three care requirements, backrest, cardiac monitor, and oxygen use were not sufficiently documented (>50% missingness) to be included in the model. Most surprising of these was the poor oxygen use documentation because desaturation in the hypobaric environment is a primary consideration for all patients (Johannigman et al., 2015). Interestingly, the use of pulse oximetry was 100% documented and was statistically significant (OR= .125, $p = .01$) as being a factor that is less likely for PU development. Notably, 10 of 15 (67%) of the PU patients had pulse oximetry ordered and nine of them (90%) also had oxygen ordered. One possible explanation is that with the increased risk of hypoxia at altitude and the associated increased pulse oximetry patient monitoring, there is a positive effect on PU prevention; however, additional investigation will be required to say definitively.

It is not unusual for the use of suction to be documented 100% of the time because it is an AE standard of care to have suction ordered as needed for patients at risk for seizure (Secretary of the Air Force, 2017). Of note, is that the only patient care equipment that is available in-flight is that equipment ordered for individual patient use and emergency equipment, which is typically reserved for in-flight emergency care. As stated previously, the use of IV therapy was the only care requirement identified as a risk factor.

Systems and Interventions Variables

Flight and AE Crew Characteristics

Flight and AE Crew characteristics were not shown to impact the risk of PU development (Tables 3, 4, & 5). The flight duration and total transport time were similar for both PU and non-PU patients, which is consistent considering the patients were matched based on plus or minus one year of the PU (traumatic injury) and the frequency that they were transported was also not significantly different between both groups (Table 2). Due to the nature of the conflict in Iraq and Afghanistan during the study period (2008-2012), flights would have been similar in nature to the stated matching period. The Fisher's exact text (p =.728) did not show a statistical difference regarding aircraft type between PU or non-PU patients.

The final consideration was related to nurse staffing. According to Alderden et al. (2011), low nurse staffing is a predictor of PU development. Pressure ulcer patients had both higher in-flight patient loads (18.33 $\pm$ 13.8) and more AE crew (4.5 $\pm$ 2.75) compared to non-PU patients whose in-flight patient loads were 15.22 $\pm$ 9.67 and AE crew (3.92 $\pm$ 2.67) respectively; however, there was no statistical difference between the PU patients and the non-PU patients for either the total patient load or the number of AE crew (Tables 3 & 4). Therefore, in this case, it is not unexpected that neither total patient load nor the number of AE crewmembers was identified as a risk factor for PU development.

Pressure Ulcer Incidence (Rate)

Noteworthy, is the extremely low PU incidence rate (<1%), which is remarkable considering the austere patient care environment (low barometric pressure, combat operations, in-flight limited resources, and decreased mobility). When the results of this study and the PU study by Dukes et al. (2014) (critically ill/injured PU incidence rate 5%) are combined, the overall picture of PU development in the AE system is positive. Remembering that the PU incidence is a Nurse Sensitive Quality Indicator (NDSQI), a 0% PU incidence is the goal; however, such low rates for non-critical trauma patients (<1%) and critically ill/injured patients (5%) suggests high quality nursing care in-flight.

Strengths and Limitations

The principal strength of this study was the use of large DOD data sources. Large DOD data sources support data collection on diverse patient populations to answer a wide variety of research questions. Of the two study data sources (AER & DODTR), the use of the DODTR has been well documented. However, this is the first study to employ the use of the AER and the first study to consider the quality of care in non-critical AE patients. Pressure ulcers as a complication (outcome) was obtained from the DODTR, which has trauma diagnosis as an inclusion criterion. The AER was robust enough to match patients who had flown in the AE system, had a documented trauma diagnosis, and had flown within plus or minus one year of the complication date.

While there are benefits to using large datasets such as the AER and DODTR in research, there are also considerations that must be recognized and addressed as much as possible. Common disadvantages to using large healthcare data sets are sampling bias, measurement reliability, and limited, inaccurate, and missing data, which pose research validity problems (Carmines & Zeller, 1979; Loke, & Mattishent, 2017; Talbert, & Sole, 2013). Loke and Mattishent (2017, p. 2) state of large healthcare datasets, “The comprehensiveness and accuracy of the recorded clinical data may not be sufficient to allow evaluation of all potentially relevant variables.” For example, as described previously the use of pressure reducing litter mattresses has been shown to be a PU mitigation strategy (Bridges, 2005; Bridges et al., 2003; Kosiak, 1961); however, there are no reliable data in the AER or DODTR to be able to capture litter mattress use as a risk factor for PU development in this study. In addition, several variables had to be removed from the regression model due to excessive missing data (mechanism of injury, back rest, cardiac monitor, & oxygen use).

A strength and a limitation of this study was the low PU incidence. A PU rate of <1% during the study period (2008-2012) speaks volumes to the outstanding care that is provided in-flight, especially considering the austere care environment; however, the small sample size created its own challenges for the study, namely accommodating statistical analysis of rare events.

Implications for Healthcare Clinicians and Military Leadership

This study provides several implications for healthcare clinicians and military leadership. The most important implication is that based on measuring PUs as a NSQI, care in the air is good. While assigning attribution to in-flight care is difficult, it is not impossible using clearly defined and measurable criteria, which need to be standardized based on the outcome, the evidence in the extant literature, and within the AE context.

Secondly, the AER is an invaluable resource for the enroute care community to begin investigating AE patient outcomes and the provision of fixed wing care within the military en route care continuum. However, the demonstrated missing data illustrate the need for improved documentation, standardized definitions, and additional training of those entering data into the TRAC2ES database, which are the foundational data of the AER. In addition, it is recommended that in-flight documentation be revised to better represent in-flight nursing care, such as the documentation of the use of litter pads for PU prevention, the use of backrests, which may increase the risk of PUs due to increased friction and shear, patient position changes, and pre/post flight skin assessment when possible.

Finally, based on the study findings, the use of IV therapy was identified with increased risk of PU development. Therefore, clinicians need to be made aware of the associated risk to patients who have this care requirement and perform PU mitigation strategies to prevent PU development. In addition, the use of pulse oximetry is a PU sparing factor that is also an important finding for clinicians.

Recommendations for Future Research

This study represents the first patient outcomes-based research for non-critical AE patients. It is the first study in a needed program of research, which can affect thousands of military members and civilians globally, including 150,000 patients as currently represented in the AER from 2001-2018. Improved patient documentation and additional data abstraction is needed to capture in-flight patient care, pre-/in-/post-flight complications, and the biomedical effects of flight, including repeated exposures. In addition, with the advances in technology, it is recommended that registries, such as the AER and other DOD data repositories be expanded to interface with the patient's medical record in order facilitate documentation of the continuum of care and expeditious research and quality improvement in the face of the unique military and in-flight care environments.

It is promising that there is some enroute care outcomes-based research on the horizon. Another study for which I am the principal investigator is conducting the first comprehensive analysis of the AER data in order to create patient and flight profiles in a variety of operational contexts, such as non-combat, combat, and disaster/humanitarian response. The goal is to incorporate the data into existing joint military medical modeling, for which AE is currently unrepresented. Next, the study will evaluate AECM workload based on a variety of measures such as, self-evaluation of workload burden and the number of steps and amount of activity versus inactivity during an AE mission, among others. Finally, observation of specific pain related tasks will be performed in-flight as a patient outcomes measure.

Conclusion

These two studies represent the beginning of a long line of needed research associated with the AE system and enroute care in general. The AER is an outstanding resource to serve as the basis of future research and quality improvement. Continued data abstraction is needed to make the AER a more robust patient outcomes related data source that cannot be accomplished without improved pre-/in-/post-flight patient documentation. The QHOM adequately framed this study as a means to conduct the first outcomes-based evaluation of non-critical AE patients. As PUs are a NSQI, a PU incidence rate of <1% illustrates the outstanding quality of care that is being conducted in-flight. Identification of the risk factors that lead to PU development and prevention can help mitigate future PU development on the quest to zero PUs.

APPENDIX A:

DEPARTMENT OF THE AIRFORCE – AIR FORCE RESEARCH LABORATORY INSTITUTIONAL REVIEW BOARD APPROVAL LETTER AND EXEMPT REVIEWER CHECKLIST

DEPARTMENT OF THE AIR FORCE
AIR FORCE RESEARCH LABORATORY
WRIGHT-PATTERSON AIR FORCE BASE OHIO 45433

MEMORANDUM FOR 711 HPW/USAFSAM/FHE (DARCY MORTIMER)

FROM: 711 HPW/IR

SUBJECT: IRB Approval for the Use of Human Volunteers in Research

1. Protocol title: Risk Factors for Pressure Ulcer Development in Non-Critical Aeromedical Evacuation Trauma Patients

2. Protocol number: FWR20190008H

3. Protocol version: v1.00

4. Risk: Minimal

5. Approval date: 20 November 2018

6. Expiration date: 19 November 2019
   Your renewal submission date is ***one month prior*** to your expiration date. The renewal is due 19 October 2019

7. 32 CFR 219.110(b)(5)

8. The study objective is to explore the characteristics of non-critical aeromedical evacuation trauma patients and identify the risk factors for pressure ulcer development using existing data from the Aeromedical Evacuation Registry (AER) and the DoD Trauma Registry (DODTR).

9. A HIPAA waiver of authorization and a waiver of informed consent were granted for this protocol.

10. All inquiries and correspondence concerning this protocol should include the protocol number and name of the primary investigator. Please contact the 711 HPW/IR office using the organizational mailbox at AFRL.IR.ProtocolManagement@us.af.mil or calling 937-904-8094 [DSN 674].

Rhonda Allen, MAS, CIP for:
KIM E. LONDON, JD, MPH
Chair, AFRL IRB

1st Indorsement to HPW/USAFSAM/FHE (DARCY MORTIMER). Approval for Use of Humans in Research, Expedited Review, FWR20190008H.

This protocol has been reviewed and approved by the AFRL IRB. I concur with the recommendation of the IRB and approve this research.

Mark A Koeniger 20 NOV 2018

MARK A. KOENIGER
Brigadier General, USAF, MC, CFS
Commander
711th Human Performance Wing

AFRL THE AIR FORCE RESEARCH LABORATORY

Exempt Reviewer Checklist

For AFRL IRB Use Only			
PI Name:	Darcy Mortimer	**Protocol Number:**	FWR20190008E
Protocol Title:	Risk Factors for Pressure Ulcer Development in Non-Critical Aeromedical Evacuation Trauma Patients		

IRB Determination				
Does this submission meet an Exempt Criteria?				
☒ Yes	Which exempt category applies?	**32 CFR 219.104 (d) (4)**		
	Is a limited IRB Review required to determine adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of data?		☐ Yes	☒ No
	If **Yes**, IRB Member determined that:			
	☐ Sufficient measures were taken to protect privacy and confidentiality.			
	☐ Insufficient measures were taken to protect privacy and confidentiality.			
☐ No	☐	The human subject research does not meet any exempt criteria. Referred to IRB Chair for IRB review.		
	- OR -			
	☐	The research uses an In Vitro diagnostic device with specimens that are NOT individually identifiable. Referred to IRB Chair to determine compliance with applicable FDA regulations.		

IRB Member Submission Analysis
This project was originally approved under expedited category 5, but meets the criteria for exempt review and approval under exempt category 4; the criteria set forth in 45 CFR 164.501 is met and a HIPAA authorization waiver has been granted for this project. There is an adequate plan to protect the identifiers, destroy the identifiers and assurance that the identifiers will not be disclosed. This project has been modified to reflect that certain variables will be taken from the DoDTR as the variables are not available in the AER. This project is now being converted to exempt status as of 11 June 2019.

AFRL IRB Signature	
ALLEN.RHONDA.COLLEEN.1395901547 Digitally signed by ALLEN.RHONDA.COLLEEN.1395901547 Date: 2019.06.11 10:03:02 -04'00'	Click or tap to enter a date.
IRB Reviewer	**Date**
Note: To sign this form electronically, please save it as a PDF and follow these instructions.	

APPENDIX B:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	February 14, 2019
Principal Investigator:	Darcy Lee Mortimer
Protocol Number:	1901316577
Protocol Title:	Risk Factors for Pressure Ulcer Development in Non-Critical Aeromedical Evacuation Trauma Patients
Level of Review:	Administrative Review
Determination:	Approved
IRB of Record:	Air Force Research Laboratory (AFRL), Wright Patterson Air Force Base, OH
Investigator at Site:	Darcy Mortimer
IRB of Record Protocol Number:	19-84; FWR20190008H

Documents Reviewed Concurrently:

Data Collection Tools: *Table 1 List of Variables.docx*
HSPP Forms/Correspondence: *Advisor Confirmation Email.pdf*
HSPP Forms/Correspondence: *application_2-5_v2018_4 Mortimer PU Study 006Dec18.pdf*
HSPP Forms/Correspondence: *Confirmation for Scientific Review and Department Review.pdf*
HSPP Forms/Correspondence: *IRB IA_AFRL Mortimer.pdf*
HSPP Forms/Correspondence: *list_of_research_personnel_2-3_v2018(1)Mortimer New Ceded Application.pdf*
Other Approvals and Authorizations: *COI Certification Complete for 1901316577.msg*
Protocol: *FWR20190008H v1.00 Protocol FINAL 11.7.18.docx*
Regulatory Documentation: *FWR20190008H Approval Letter.pdf*
Regulatory Documentation: *FWR20190008H Waiver Approval.pdf*

Regulatory Determinations/Comments:

- Air Force Research Laboratory Designated IRB of Record: When an institution is designated IRB of record, the UA IRB will not review the project. The University of Arizona agrees that it will rely on the review, approval, and continuing oversight of the institution's IRB pursuant to the terms of the Institutional Review Board Authorization Agreement.

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