PRESSURE ULCER RISK FACTORS ASSOCIATED WITH LEVEL OF PARALYSIS IN PERSONS WITH SPINAL CORD INJURY: ANALYSIS OF THE NATIONAL SPINAL CORD INJURY DATABASE

by

DonnaLee Pollack

DISSERTATION

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Supervising Committee:

Marco Brotto, Research Advisor
Linda Cowan
Jessica Smith

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ABSTRACT

PRESSURE ULCER RISK FACTORS ASSOCIATED WITH LEVEL OF PARALYSIS IN PERSONS WITH SPINAL CORD INJURY: ANALYSIS OF THE NATIONAL SPINAL CORD INJURY DATABASE

DonnaLee Pollack

The University of Texas at Arlington, 2022

Research Advisor: Marco Brotto

The National Spinal Cord Injury Model Systems (SCIMS) were established in 1970 to provide and study comprehensive care for anyone with a traumatic spinal cord injury. A spinal cord injury (SCI) is defined as transient or permanent motor and/or sensory deficits as a result of an acute traumatic injury to the spinal cord. Twenty-nine federally funded Model System Centers have collected data from approximately 6% of new SCI cases in the United States since the founding of the National Spinal Cord Injury Database. The National Spinal Cord Injury Database (NSCID) was created in 1973 to store the collected data, and NSCID is the most extensive spinal cord injury database in the world. The purpose of this study was to determine the association between known pressure ulcer (PU) risk factors and presence of pressure ulcer, stratified by level of paralysis, in persons with traumatic injury SCI whose data are included in the NSCID. This study also determined the association between known PU risk factors and level of paralysis in the same population. Persons with paraplegia reported PU at a higher percentage than persons with tetraplegia, 30.9% vs. 27.7%, $p<.001$. There were 17 PU risk factors measured in this study,

and 77 subfactors. Paraplegics reported a greater percentage of PU than tetraplegics in 65 of these subfactors. paraplegics were 8% more likely to report PU than tetraplegics, *OR*=1.08, 95% CI (1.04, 1.13). There were 77 subfactors in this study, and 36 of those had significant OR, with paraplegics more likely to report PU than tetraplegics for 35 of the 36 significant findings. Paraplegics need to be informed of their higher risk for pressure ulcers. Identification of a biomarker would be the gold standard for early identification and prevention of pressure ulcers.

Keywords: pressure ulcer, spinal cord injury, risk factor, paraplegia, tetraplegia

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LIST OF ABBREVIATIONS

ASIA: American Spinal Injury Association

CHART: Craig Handicap Assessment and Reporting Technique

FIM: Functional Independence Measure

IRB: Institutional Review Board

NSCID: National Spinal Cord Injury Database

NSCISC: National Spinal Cord Injury Statistical Center

PU: Pressure Ulcer

SCI: Spinal Cord Injury

SCIMS: National Spinal Cord Injury Model Systems

TRPM: Theoretical Risk and Prevention Model

VA: Veterans Administration

VHA: Veterans Health Administration

CHAPTER ONE

INTRODUCTION

The National Spinal Cord Injury Model Systems (SCIMS) were established in 1970 to provide and study comprehensive care for anyone with a traumatic spinal cord injury. A spinal cord injury (SCI) is defined as transient or permanent motor and/or sensory deficits as a result of an acute traumatic injury to the spinal cord (National Spinal Cord Injury Statistical Center, 2020). Twenty-nine federally funded Model System Centers have collected data from approximately 6% of new SCI cases in the United States since the founding of the National Spinal Cord Injury Database (Chen et al., 2016; University of Alabama at Birmingham, 2020a). The National Spinal Cord Injury Database (NSCID) was created in 1973 to store the collected data, and NSCID is the most extensive spinal cord injury database in the world (Chen et al., 2016; University of Alabama at Birmingham, 2020a). The National Spinal Cord Injury Statistical Center (NSCISC) manages the NSCID and facilitates research (Chen et al., 2016).

The purpose of this study was to determine the association between known pressure ulcer (PU) risk factors and presence of pressure ulcer, stratified by level of paralysis, in persons with traumatic injury SCI whose data are included in the NSCID. This study also determined the association between known PU risk factors and level of paralysis in the same population. Data variables were selected and study results were interpreted using the framework from the Theoretical Risk and Prevention Model (Krause, 1996; Krause et al., 2013). This chapter will review the background and significance of PU in persons with SCI, theoretical framework, study purpose and research questions.

Background and Significance

Approximately 17,900 persons sustain some form of SCI per year in the U.S. (National Spinal Cord Injury Statistical Center, 2021). There are approximately 296,000 persons currently living with SCI, and over 42,000 are Veterans of the United States Armed Forces (National Spinal Cord Injury Statistical Center, 2020). More than half of these Veterans with SCI (27,000) Veterans receive their care through the U.S. Department of Veterans Affairs, specifically through the Veterans Health Administration (VHA) system of care (U.S. Department of Veterans Affairs, 2019). Pressure ulcers are a significant problem for the SCI population, with over 95% of adults with a SCI reporting at least one PU since onset of spinal injury, and pressure ulcers are the second leading cause of hospitalization among the SCI population (National Spinal Cord Injury Statistical Center, 2020). Pressure ulcers are defined as localized skin or tissue damage that results from pressure, and are difficult to heal due to the ischemic tissue damage (European Pressure Ulcer Advisory Panel; National Pressure Injury Advisory Panel; Pan Pacific Pressure Injury Alliance, 2019). Over 30% of SCI patients are hospitalized every year, and the PU prevalence rate among hospitalized SCI patients is 49.2% in comparison to the PU prevalence rate of 25.2% for hospitalized non-SCI patients (Scheel-Sailer et al., 2013).

The mortality rate without PU in all hospitalized patients is 1.8%, while the mortality rate with PU is 9.1% (Bauer et al., 2016). Pressure ulcers have increased the cost of patient care by as much as $28,000 per episode of hospitalization, with over 90% of patients needing surgical debridement (Bauer et al., 2016; Fuller et al., 2009). Moreover, PU are correlated with higher rates of death within 30 days of hospital discharge, which is a quality measure by the Centers for Medicare and Medicaid Services (Lyder et al., 2012).

A higher level of paralysis has been traditionally associated with higher pressure ulcer risk, however, two recent studies found a specific (lower) level of paralysis was associated with a higher pressure ulcer risk. Two main levels of paralysis reported in these studies are commonly defined as paraplegia, which means persons have a motor and/or sensory loss affecting the trunk and legs, and tetraplegia or quadriplegia, which means persons have a motor and/or sensory loss affecting the arms, trunk and legs. Tetraplegia (or quadriplegia) and paraplegia are primarily caused by traumatic injuries, such as motor vehicle accidents or falls, and are included in the NSCID. Hemiplegia is an injury that affects one side of the body and is most often caused by non-traumatic injuries such as a stroke. The NSCID does not include persons who have non-traumatic SCI, such as persons with hemiplegia or multiple sclerosis, therefore hemiplegia was not included in this study. Persons with paraplegia were twice as likely to develop a pressure ulcer as persons with quadriplegia in a secondary data analysis of the 2012 U.S. Minimum Data Set (Cowan et al., 2019). Lessing et al. (2020) also found that persons with a thoracic level injury (paraplegia) were twice as likely to develop PU compared to persons with a cervical level injury (quadriplegia) in a retrospective case control study in Tanzania.

The National Spinal Cord Injury Database (NSCID) collects data on a representative sample of SCI patients in the United States, including Veterans who receive initial care at a non-Veterans Health Administration (VHA) facility. The National Institute of Nursing Research promotes and supports large database nurse-led research to study chronic illnesses and their effect on patients and caregivers (National Institute of Nursing Research, 2022). Publications and presentations using NSCID data were reviewed with no publications nor presentations identified as reviewing the association of known PU risk factors and level of paralysis (National Spinal Cord Injury Statistical Center, 2019). Analysis of the NSCID data set contributes to the field of

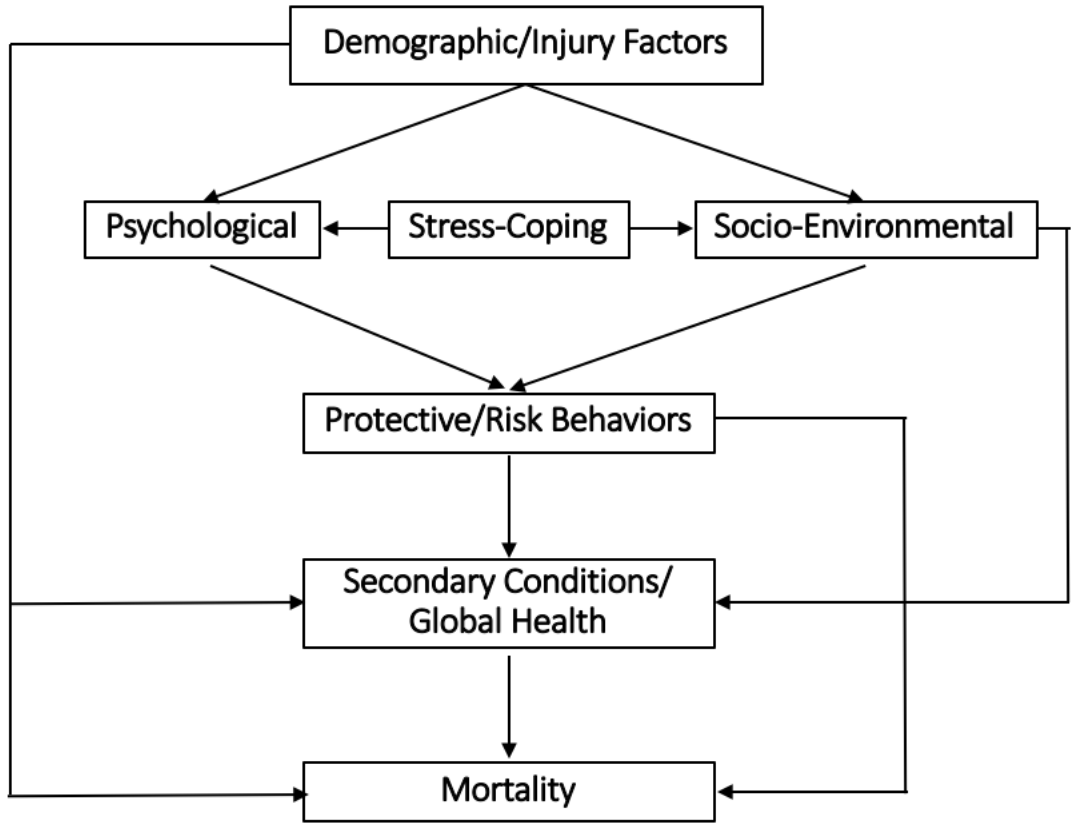
research by helping to define pressure ulcer risk factors, which will enable health care providers to target interventions appropriately.

Framework

The Theoretical Risk and Prevention Model (TRPM) was created in 1996, and updated in 2013, to classify risk and protective factors for mortality in persons with SCI (Krause, 1996; Krause et al., 2013). The TRPM was created by a research psychologist to prioritize interventions to prevent secondary health conditions in persons with SCI (Krause, 1996). Association, not causation, between variables was examined with this model. Secondary health conditions, such as PU, were recognized as resulting from SCI and as affecting mortality (Krause, 1996). Using the TRPM allows persons with SCI, health care providers and caregivers to focus resources on interventions that reduce secondary health conditions and thus reduce mortality (Krause, 1996; Krause et al., 2013).

Figure 1

Theoretical Risk and Prevention Model



Source: Krause 1996, Krause et al., 2013

The TRPM framework consist of 3 levels of risk factors: demographic/injury factors, psychological and socio-environmental factors, and protective/risk behaviors. The three levels of risk factors affect secondary conditions/global health and mortality. *Demographic/Injury factors* directly affect psychological and socio-environmental factors, secondary conditions/global health and mortality, and indirectly affects protective/risk behaviors. Demographic/Injury factors include but are not limited to age, gender, race and paralysis level. *Psychological factors* are directly affected by demographic/injury factors and stress/coping mechanisms; directly affect

protective/risk behaviors and indirectly affect secondary conditions/global health and mortality. Psychological factors include but are not limited to depression and anxiety. *Socio-Environmental factors* are directly affected by demographic/injury factors and stress/coping mechanisms and directly affect protective/risk behaviors, secondary conditions/global health and indirectly affects mortality. Socio-Environmental factors include but are not limited to income level, education level, Veteran status and marital status. *Protective/Risk Behaviors* are directly affected by psychological and socio-environmental factors, indirectly affected by demographic/injury factors, and directly affect secondary conditions/global health and mortality. Protective/risk behaviors include but are not limited to alcohol use, smoking, drug/medication use, exercise and healthy diet. *Secondary Conditions/Global Health* are directly affected by demographic/risk factors, socio-environmental factors and protective/risk factors, indirectly affected by psychological factors, and directly affects mortality. Secondary conditions/global health include but are not limited to pressure ulcers, sepsis and pneumonia. *Mortality* is directly affected by demographic/injury factors, protective/risk factors and secondary conditions/global health, and indirectly affected by psychological factors and socio-environmental factors.

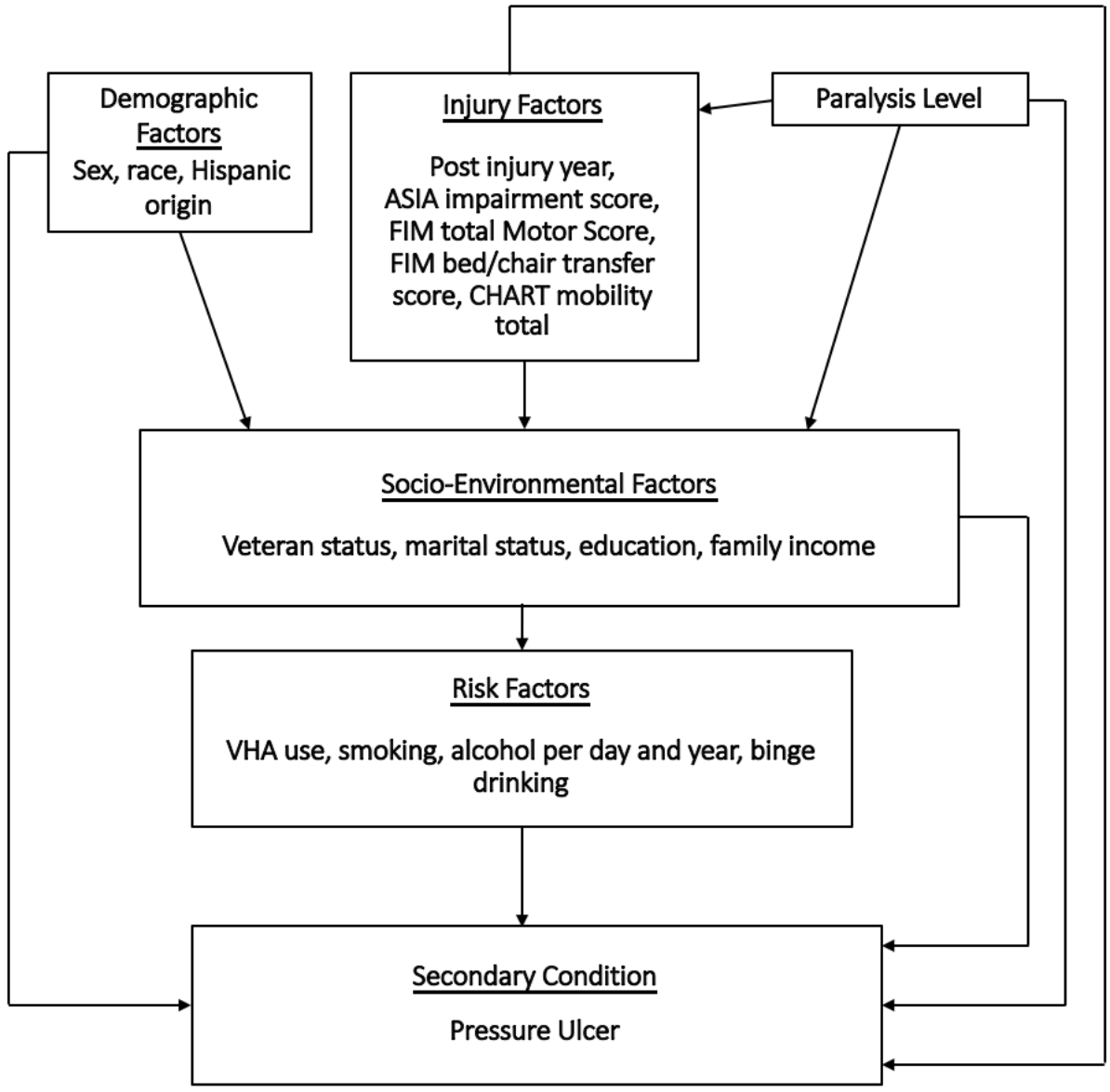
This model does not account for physiological factors such as time in seated or lying positions or repositioning schedules, nor does the model address as yet unidentified biological factors related to physiological biomarkers or epigenetics. The TRPM was an appropriate choice of model for this study because the primary study variables, level of injury and pressure ulcer status, were addressed, and in addition, the selected database did not have information available on repositioning nor on lab values.

Application of framework to study

The TRPM was used to guide variable selection for the study and to interpret study results (Krause, 1996). The model was modified to divide demographic and injury levels, and level of paralysis was listed as a separate variable on the same level as demographic and injury factors. Demographic factors in this study were sex, race and Hispanic origin. Injury factors in this study were post injury year, ASIA impairment score, Functional Independence Measure (FIM) bed/chair transfer score, and Craig Handicap Assessment and Reporting Technique (CHART) mobility total. Socio-Environmental factors in this study were Veteran status, marital status, highest formal education level completed and family income level. Risk behaviors in this study were use of Veteran's services, smoking, and alcohol use. Alcohol use was broken down into use of alcohol in past year, number of drinks per day and the frequency of binge drinking. Secondary condition/global health in this study were the presence or absence of pressure ulcer. Psychological factors, stress/coping and mortality were not included to allow the study to focus on the specific, identified pressure ulcer risk factors. The modified TRPM with study variables is shown in Figure 2.

Figure 2

Proposed Modified Theoretical Risk and Prevention Model with Study Variables



Source: Krause 1996, Krause et al., 2013

Propositions

1. Characteristics of persons with SCI and PU may differ from persons with SCI and without PU.

2. Known risk factors for PU may differ depending on level of paralysis.

Hypothesis

1. The null hypothesis is persons with paraplegia and persons with tetraplegia will report the same frequency of pressure ulcers.

2. The alternative hypothesis is persons with paraplegia will report pressure ulcers at a higher frequency than persons with tetraplegia.

Purpose

The purpose of this study was to determine the association of known PU risk factors and presence of PU, stratified by level of paralysis, in persons with traumatic injury SCI by analyzing data from persons in the 2011-2016 cohort of the NSCID. This study also determined the association between known PU risk factors and level of paralysis in persons with traumatic injury SCI by analyzing data from persons in the 2011-2016 cohort of the NSCID.

Research Questions

1. What is the association between known PU risk factors and presence of pressure ulcer, stratified by level of paralysis, in persons with traumatic injury SCI whose data is maintained in the NSCID?

2. What is the association between known PU risk factors and level of paralysis in persons with traumatic injury SCI whose data is maintained in the NSCID?

Model Assumptions

1. The association between each set of risk factors and development of secondary conditions/mortality is in addition to the effects of demographics and injury level.

2. Risk factors do not equally impact development of secondary conditions and/or mortality.

3. There is a causal relationship between risk factors and development of secondary conditions and/or mortality.

Summary

This chapter reviewed the background and significance of PU in persons with traumatic injury SCI, theoretical framework, study purpose and research questions.

CHAPTER TWO

CRITICAL REVIEW OF RELEVANT LITERATURE

This chapter provides a critical review of the relevant literature related to PU risk factors in persons with SCI. Data sources and search strategy will be described. The literature review will be presented according to the Theoretical Risk and Prevention Model (Krause, 1996; Krause et al., 2013). Demographic factors, injury factors, socio-environmental factors, and risk behaviors will be discussed.

Data Sources and Search Strategy

CINAHL, MEDLINE and Cochrane databases were searched using the terms spinal cord injury, SCI, paraplegic, quadriplegic or tetraplegia; pressure ulcers, bed sores, pressure sores or pressure injury; risk factors, contributing factors, predisposing factors, predictor or cause; protective factors; time; and national spinal cord injury database. Suggest search terms, Boolean/phrase, and apply equivalent subjects were enabled. Subheadings checked were spinal cord injuries, pressure ulcer, spinal cord injury nursing, spinal injuries and time factors. Time frame was August 2001 - August 2021, and restrictions were English language, abstract available and peer review. Database searches yielded 517 records, and automated duplication review removed 154 records. Abstracts were reviewed for the resulting 363 records, with 313 excluded for not meeting criteria of research on factors affecting pressure ulcer development in persons with spinal cord injuries. Full articles for 50 studies were requested, obtained and reviewed. Of the 50 full studies reviewed, 19 were excluded for not studying PU risk factors in persons with SCI, one was excluded as a poster presentation duplicate of a research study, and three systemic reviews or meta-analyses were excluded. The final number of studies reviewed for this literature review was 27.

Demographic Factors

Pressure ulcer development in SCI patients has been studied by various researchers, with associations identified by demographic factors. Demographic factors include but are not limited to sex, race and ethnicity.

Sex of the person with SCI was not conclusively found to be associated with PU development. Since 2015, over 75% of new SCI cases in the United States are males, which could confound PU risk association analysis (National Spinal Cord Injury Statistical Center, 2020). Males were more likely to develop PU than females $\chi^2(1, N = 37) = 5.90$, $p < .05$ in a preliminary retrospective mail and telephone survey of persons with SCI who were 6 - 17 years post-injury and selected from the SCI Model Systems database (Jones et al., 2005). Males were also associated with PU development, $OR = 1.35$ (Coefficient = 0.26, s.e. = 0.06, $p < .01$) in an Iranian cross sectional observational study ($n = 7489$) of low socioeconomic status SCI outpatients (Eslami et al., 2012). Males were not associated with PU development in a secondary data analysis of 104 persons with SCI in U.S. inpatient and outpatient settings (Brienza et al., 2018). No significant association was found between males or females and PU development in an Iranian cross sectional study of 580 patients, age 18-55 years, with SCI more than 6 months (Sadeghi Fazel et al., 2018).

Race and ethnicity associations with PU development are varied, with African Americans and non-Hispanics identified as most likely to develop PU in persons with SCI. Race and ethnicity as a potential risk factor may be mediated by other factors such as socioeconomic status when determining pressure ulcer risk factors. African Americans with SCI were initially found to be more likely to develop PU by Saunders et al. (2010) in a cohort study ($n = 1466$) in a rehabilitation hospital in the southeastern U.S., but this association was not a factor when

socioeconomic status was controlled for using household income and education level. African Americans were over one and one half times more likely to develop pressure ulcers, *OR* = 1.7, 95% CI (1.4, 2.0) in a cohort study of nine Model SCI System centers of persons with SCI (*n* = 3361) living in community settings (Chen et al., 2005). African Americans were also 3 times more likely to develop recurrent PU, *OR* 3.38, 95% CI (1.109, 10.327) in a convenience sample of 64 persons with SCI at six VHA SCI Centers (Guihan et al., 2008). Race was not a significant factor in a secondary data analysis of a prospective cohort study of SCI patients (*n*=104) from inpatient and outpatient settings (Brienza et al., 2018). Non-Hispanic ethnicity was associated with a ten-fold increase in PU development, *OR* 10.30, 95% CI (3.46, 30.65) in a cross sectional study of 350 SCI patients in a U.S. hospital (Li et al., 2016).

Injury Factors

Post injury year as a risk factor. One study reported post injury year >30 compared to post injury year 1 was significantly associated with PU in Veterans with SCI (*n* = 2574, *IRR* = 1.27, *p*<.0001). This secondary data analysis of a cross sectional survey used questions adapted from the Center for Disease Control and Prevention's Behavioral Risk Factor Surveillance System (Smith et al., 2008).

Level of paralysis, or category of neurological impairment as a risk factor. Level of paralysis is not a consistently identified as a PU risk factor in the literature. Levels of paralysis are paraplegia, meaning persons have a motor and/or sensory loss affecting the trunk and legs, and tetraplegia or quadriplegia, meaning persons have a motor and/or sensory loss affecting the arms, trunk and legs. Cowan et al. (2019) conducted a secondary data analysis of the 2012 U.S. Minimum Data Set (*n* = 51,664) and discovered that persons with paraplegia were twice as likely to develop PU as persons with quadriplegia, *OR* = 2.03, 95% CI (1.76, 2.35). Persons with a

thoracic level injury (paraplegia) were twice as likely to develop PU compared to persons with a cervical level injury (tetraplegia), *OR* = 2.16, 95% CI (1.05, 4.49) in a retrospective case control study in Tanzania (*n* = 267) conducted at a specialized orthopedic and neurosurgical hospital (Lessing et al., 2020). However, level of paralysis was not significant in a secondary data analysis from a smaller prospective cohort study of 104 patients in hospital and outpatient settings (Brienza et al., 2018). Additionally, there was no significant association between level of paralysis and PU development in a cross-sectional study of Iranian outpatient clinic patients (*n* = 580) age 18 – 55 years with SCI greater than 6 months duration (Sadeghi Fazel et al., 2018). Paralysis level as a pressure ulcer risk factor may affect other pressure ulcer risk factors. For example, a person with paraplegia could independently sit in a wheelchair for long periods without repositioning or participate in other risky health behaviors such as drinking alcohol or smoking cigarettes as opposed to a person with tetraplegia who would be dependent on a caregiver to reposition them or provide alcoholic drinks and cigarettes, if desired. Furthermore, a person with tetraplegia may need care in a skilled nursing facility where caregivers follow a standard of care that includes pressure ulcer prevention through frequent repositioning, as opposed to person with paraplegia who could potentially live independently, but who would then be solely responsible for pressure ulcer prevention.

Completeness of injury as a risk factor. In contrast to the inconsistent findings regarding paralysis level, completeness of injury was consistently listed in the literature as a risk factor for PU development. Completeness of injury is measured by the American Spinal Injury Association (ASIA) in levels A, B, C and D. ASIA A is a complete injury, meaning no sensory or motor function below the level of injury. ASIA B, C and D are incomplete injuries. ASIA B means the person has sensory function below the neurological level of injury but not motor

function. ASIA C denotes minimal motor function below the level of injury, with over half of key muscles below the level of injury with minimal muscle function. ASIA D means the person has some motor function with at least half of key muscles below the level of injury able to perform active movements against gravity.

Gould et al. (2014) conducted a cross sectional retrospective survey (n = 120) of U.S. Veterans with SCI at an outpatient VHA clinic and found that persons with ASIA A were four times more likely to develop PU than persons with an incomplete injury, *OR* = 4.02, 95% CI (1.74, 9.27). ASIA A was also found to associated with PU in a secondary data analysis from a prospective cohort study of U.S. patients in acute care and outpatient settings (n = 104), with persons with ASIA A injury 4.5 times more likely to develop PU than persons with ASIA B, 95 % CI (1, 20.65), and 4.6 times more likely to develop PU than persons with ASIA C, 95% CI (1.3, 16.63) (Brienza et al., 2018). Persons with ASIA C were less likely to develop PU than persons with ASIA A, *OR* = 0.25, 95 % CI (0.07,0 .90) and persons with ASIA D were less likely to develop PU than persons with ASIA A, *OR* 0.28, 95 % CI (0.10, 0.82) in a study of SCI inpatients (n = 185) in Switzerland (Scheel-Sailer et al., 2013).

Complete injuries were also more likely to correlate with PU in non-U.S. settings. Researchers in Norway conducted a national, retrospective cross sectional study (n = 1012) of new SCI patients in a hospital setting, with persons with ASIA D less likely to develop PU compared to persons with ASIA A, *OR* = 0.1, 95% CI (0.1, 0.2), and persons with ASIA C were less likely to develop PU compared to ASIA A, *OR* = 0.3, 95% CI (0.2, 0.5) (Irgens et al., 2020). Persons with complete motor injuries, or ASIA A, were 3.51 times more likely to develop PU in a prospective, population based cohort study (n =141) in a South African hospital 95% CI (1.22, 10.04) (Joseph & Nilsson Wikmar, 2016). Nigerian researchers persons found that persons with

ASIA A had a higher percentage of pressure ulcers than persons with ASIA B, C or D, 73% vs. 33%, *p*=0.016, in a prospective study of 105 SCI patients at a regional trauma and rehabilitation center (Idowu et al., 2011). A retrospective, case control study was conducted in an orthopedic and neurosurgery hospital in Tanzania (n=267), and persons with ASIA A were 8 times more likely to develop PU, *OR* = 8.33, 95% CI (3.34, 24.61) (Lessing et al., 2020). Persons with a complete SCI injury, or ASIA A, were more than twice as likely to develop PU than persons with incomplete injuries at eight inpatient SCI rehabilitation centers in the Netherlands, *n* = 193, *OR* = 2.3, 95% CI (1.1, 4.9) (Verschueren et al., 2011).

Mobility as a risk factor. A lower level of mobility is correlated with a higher risk of developing PU. DiVita et al. (2015) conducted a retrospective cohort study, from the Uniform Data System for Medical Rehabilitation, of persons in an inpatient medical rehabilitation setting and found that wheelchair use was 3.5 times more likely associated with PU development than walking in persons with SCI, *OR* = 3.59, 95% CI (2.74, 4.68), however, mobility status beyond walking or wheelchair use was not available. Mobility can also be measured using the Functional Independence Measure (FIM) Tool. The FIM has 13 categories related to motor function with each category scoring from one to seven, with a lower score indicating lower motor function. A prospective observational cohort study at an urban rehabilitation SCI center (*n* =159) was conducted by DeJong et al. (2014), who found that admission FIM transfer scores less than 3.5 was associated with PU development (β = 1.39, Wald = 4.2196, *p* = .04). Delparte et al. (2021) found that a FIM bed/chair transfer sub score < 4 predicted PU development (sensitivity =97%, AUC=74%, FN=0.49%) when developing a pressure injury risk screening instrument for persons with SCI using a retrospective chart review at an inpatient SCI rehabilitation center (*n* = 807). In a retrospective cohort study of 754 persons at an inpatient SCI rehabilitation center in Canada,

Flett et al. (2019) looked at SCI pressure ulcer scale, the Braden scale for predicting PU and FIM components for items that would predict PU risk, and persons with FIM bed/chair transfer score ≤ 1 were two and half times more likely to develop PU (LR 2.62, AUC=0.77, sensitivity = 0.83, negative predictive value = 0.95). Verschueren et al. (2011) found that Dutch SCI rehabilitation patients (n = 193) with a higher transfer score on the FIM were less likely to develop PU than persons with a lower FIM transfer score, OR = 0.88, 95% CI (0.82, 0.95).

Socio-Environmental Factors and Pressure Injury Risk

Socio-environmental factors include partner status, education level, and family income level. There is an inconclusive link between **partner status**, defined as being married, cohabitating or being in an intimate relationship, and PU status. A secondary data analysis of a prospective, self-report mail survey of U.S. persons with SCI living in the community (n = 165) was conducted by Kroll et al. (2007), who found that persons who were married or cohabitating were less likely to report PU presence OR = 0.329, 95% CI (0.135, 0.802), which could indicate partners functioning as unpaid caregivers. Marital status was not found to be significantly associated with PU status in a secondary data analysis of a prospective cohort study of persons with SCI (n = 104) in U.S. hospital and outpatient settings (Brienza et al., 2018). Persons with SCI who also lacked an intimate partner were more likely to develop PU in a cross sectional observational study of persons (n = 7489) with low socioeconomic status in Iran, OR = 1.28, (Coefficient = 0.25, s.e. = 0.07) (Eslami et al., 2012). Socioeconomic status, including the ability to access healthcare, could be a confounding factor in analysis of partner status as a pressure ulcer risk factor.

Education level reached by the person with spinal cord injury has been inconclusively correlated with PU, however, higher **family income** has been correlated with PU prevention. The

inconsistency between education level and family income as pressure ulcer risk factors may be due to the education level measured at individual level and income measured at family level. Chen et al. (2005) conducted a cohort study at nine Model SCI System Centers of persons living in the community (n=3361) and found persons without a high school diploma more likely to have a PU, *OR* = 1.3, 95% CI (1.1, 1.5). A cohort study was conducted at a U.S. rehabilitation hospital (n=1466) and researchers found SCI injured persons without a high school diploma twice as likely to develop PU as persons with a bachelor's or higher degree, *OR* = 2.06, 95% CI (1.25-3.41) (Saunders et al., 2010). Education level was not significantly associated with PU in a secondary data analysis by Brienza et al. (2018) of persons with SCI in U.S. acute and outpatient settings (n=104), nor was educational level found significant in a cross sectional Iranian study of 580 persons with SCI at outpatient clinics (Sadeghi Fazel et al., 2018). Persons with SCI and with family income under $25,000 per year were almost twice as likely to develop PU as persons with SCI and with family income over $75,000 per year in a cohort study (n=1466) at a U.S. rehabilitation hospital, *OR* = 1.97, 95% CI (1.26, 3.09) (Saunders et al., 2010). Household income was found to be significantly associated with PU by Saunders et al. (2012) in a cross sectional study at a U.S. hospital (n=2549), with SCI injured persons with family income under $25,000 per year twice as likely to develop PU as SCI injured persons with family income over $75,000, OR = 2.03, 95% CI (1.42, 2.91).

Personal Behaviors which May Increase or Decrease PU Risk

Personal behaviors as risk factors may traditionally include smoking and alcohol use, while personal behaviors which may be considered to be protective include the use of VHA health care services. **Smoking** is a known risk factor for impaired wound healing (Sørensen, 2012) but has not been shown to consistently correlate with PU presence, which may be related

to inconsistency in smoking measurements. Smoking is variously defined as current smoking, past smoking and cigarettes smoked per lifetime. Current smoking was not significantly associated with PU development in several smaller studies. One cross sectional retrospective study of 120 patients at a VHA SCI outpatient clinic (Gould et al., 2014) found no significant association between smoking status and PU development. A retrospective chart review of Veterans at an outpatient VHA SCI clinic (n=87) conducted by Rabadi &Vincent (2011) showed no difference in PU development between current smokers and current non-smokers. Tobacco use was not significantly associated with PU in a cross sectional study (n=148) of persons with SCI and stage 3 or stage 4 PU at a VHA SCI center (Guihan & Bombardier, 2012). However, in larger studies, smoking status was associated with PU development. Li et al. (2016) conducted a cross sectional study at a U.S. hospital (n=350), and persons with SCI and currently smoking were more than two and half times likely to develop PU than non-smokers, *OR* = 2.69, 95% CI (1.00, 7.27). Persons who smoked at least one pack per day were almost three times more likely to develop PU than non-smokers in a cross sectional study of 1050 participants in the SCI Model Systems Registry, *OR* = 2.82, 95% CI (1.45, 5.47) (Saunders & Krause, 2010). Persons who smoked more than 100 cigarettes in their lifetime were three times as likely to develop PU as persons who never smoked in a U.S. mail survey of 826 persons with SCI at least 5 years duration, *OR* = 3.00, 95% CI (1.52, 5.94) (Krause & Broderick, 2004). Sadeghi Fazel et al. (2018) conducted a cross sectional study of 580 persons age 18-55 years with SCI more than 6 months and found no significant association between current smoking and PU presence.

Alcohol use has not been shown to be associated with PU development, but binge alcohol use has been noted as a factor. Tate et al. (2004) conducted a retrospective cross sectional study of 16 SCI Model Systems centers (n=3041) and found that alcohol use (not defined as excessive

or binge alcohol use) was not associated with PU. Alcohol use was not associated with PU in a cross sectional study (n=148) of persons with SCI and stage 3 or stage 4 pressure ulcer at six VHA SCI centers (Guihan & Bombardier, 2012). However, persons with SCI who consumed over 30 alcohol drinks per month, or binge drinking, were 5 times as likely to develop PU in a cross sectional study (n=350) at a U.S. hospital, *OR* = 5.26, 95% CI (1.24, 22.26) (Li et al., 2016).

One study noted that Veterans with SCI who received health care at a non-VHA setting instead of/in addition to **VHA health care** (*n* = 2574) were more likely to develop PU as reported by Center for Disease Control and Prevention's Behavioral Risk Factor Surveillance System, (*IRR* = 1.13, *P*=.024) (Smith et al., 2008). The VHA offers the largest system of SCI care in the United States with care offered at specialized SCI centers, outpatient SCI clinics and home care (U.S. Department of Veterans Affairs, 2019). Veterans receiving coordinated care at VHA specialized SCI centers may be more likely to receive continuity of care rather than non-specialized care at non-VHA settings, or Veterans receiving care at both VHA and non-VHA settings may not receive consistent, coordinated care, which could affect PU prevention strategies.

Summary

This chapter provided a critical review of the relevant literature related to PU risk factors in persons with SCI. Data sources and search strategy were described. Demographic factors, injury factors, socio-environmental factors and protective/risk factors were discussed.

Conflicting studies were found regarding PU risk factors in persons with SCI. No studies were found in which researchers identified the association of known PU risk factors and level of

paralysis using data from the National Spinal Cord Injury Database (National Spinal Cord Injury Statistical Center, 2019).

CHAPTER THREE

METHODS AND PROCEDURES

The research design, setting and sample are discussed in this chapter. Conceptual and operational definitions of study variables are defined, and statistical tests and ethical considerations are detailed.

Research Design

The purpose of this study was to determine the association of known PU risk factors and presence of PU, stratified by level of paralysis, in persons with traumatic injury SCI by analyzing data from persons in the 2011-2016 cohort of the NSCID. This study also determined the association between known PU risk factors and level of paralysis in persons with traumatic injury SCI by analyzing data from persons in the 2011-2016 cohort of the NSCID. A secondary data analysis of the longitudinal National Spinal Cord Injury Statistical Center (NSCISC) 2011-2016 data set was conducted (Chen, 2016a). The independent study variables included paralysis level and completeness of injury, demographic factors, socioeconomic status including Veteran status, and risk behaviors. The outcome variable was presence of PU over the past 12 months.

The NSCISC manages collected data from the National Spinal Cord Injury Model Systems (SCIMS) and facilitates research (Chen et al., 2016). Over 30 rehabilitation centers across the United States have participated in the NSCID (Chen et al., 2016). Form 1 information is collected during the initial hospitalization, and Form 2 collects follow on information at specific yearly intervals (National Spinal Cord Injury Statistical Center, 2020).

Secondary data analysis allowed review and analysis of longitudinal data collected at multiple SCI rehabilitation centers across the United States. Performing a secondary data analysis requires determining the objectives of the study being analyzed, because the source data

collection objectives may conflict with the secondary data analysis objectives (MacInnes, 2016). Objectives for the NSCID include (1) studying the longitudinal course of SCI, (2) identifying and evaluating trends related to initial SCI and follow on complications, (3) identifying and evaluating trends in health care delivery, (4) creating treatment outcome standards, and (5) facilitating collaborative research (National Spinal Cord Injury Statistical Center, 2015).

Sample

The NSCID is a convenience sample of traumatically injured SCI patients receiving care from 29 SCI Model Centers in the United States (Chen et al., 2016; University of Alabama at Birmingham, 2020b). Ketchum et al. completed a review in 2018 and determined that these data from NSCID are representative of the United States traumatically injured SCI population (Ketchum et al., 2018). Data collected up to 2016, along with supporting documents, are designated for public use. There are over 32,000 persons enrolled on Form 1, the initial data collection form, and over 26,000 follow up records on Form 2, with the longest follow up at 40 years post injury (Chen et al., 2016; University of Alabama at Birmingham, 2020b).

Inclusion and exclusion criteria have been set by the NSCISC and are listed below.

Inclusion Criteria

1. For this study SCI is defined as transient or permanent motor and/or sensory deficits as a result of an acute traumatic injury to the spinal cord as a result of trauma. This includes medical/surgical complications and radiation damage.

2. Transient or permanent motor and/or sensory deficits as a result of the spinal cord injury.

3. Receive care at SCIMS center within one year of SCI.

4. Minimum one week stay at SCIMS center.

5. Complete acute rehabilitation program before discharge from SCIMS center.

6. Informed consent and HIPAA forms signed.

Exclusion Criteria

1. Participant has been treated at another SCIMS center for the traumatic injury resulting in SCI.

2. Participant has completed rehabilitation for the traumatic injury at another facility.

Power Analysis

Power analysis was performed using G*Power 3.1 (Faul et al., 2007). Input parameters were z-tests, logistic regression, A priori, two tailed test, binomial, Pr(Y=1|X=1) H0 at 0.3, with alpha set at 0.05, power at 80%, and effect size set at 1.5 (small) based on previous studies on PU prevalence in persons with spinal cord injury (Brienza et al., 2010; Brienza et al., 2018; DiVita et al., 2015; Gould et al., 2014). The results were 242 for total sample size.

Setting

The 2011-2016 data set for SCIMS includes data from 14 model systems, 5 follow up centers and 10 former centers (National Spinal Cord Injury Statistical Center, 2016). Active model systems included in the data base are located in Birmingham, Alabama; Rancho, California; Englewood, Colorado; Miami, Florida; Atlanta, Georgia; Chicago, Illinois; Louisville, Kentucky; two centers in Boston, Massachusetts; Ann Arbor, Michigan; West Orange, New Jersey; Philadelphia, Pennsylvania; Pittsburgh, Pennsylvania and Seattle, Washington (National Spinal Cord Injury Statistical Center, 2016). Follow up centers are former Model System Centers and submit follow up data (National Spinal Cord Injury Statistical Center, 2016). Follow up centers are located in San Jose, California; New York City, New York; Houston, Texas; Columbia, Missouri; and Fishersville, Virginia (National Spinal Cord Injury

Statistical Center, 2016). Data from former centers that no longer participate in the Model System are included, and these centers are located in Phoenix, Arizona; New Orleans, Louisiana; Detroit, Michigan; New York City, New York; Rochester, New York; Cleveland, Ohio; Richmond, Virginia; Milwaukee, Wisconsin; and Washington D.C. (National Spinal Cord Injury Statistical Center, 2016).

Measurement

The NSCISC collects information on each participant on five forms: Personal Data, Record Status, Registry, Form I and Form II. The Personal Data form holds personal identifiers such as name, address and date of birth. Identifying information from the Personal Data form is not available in the public datasets. The Record Status Form includes information regarding patient current status, vital status source, and date and cause of death, if applicable. Identifying information from the Record Status Form is not available in the public datasets. The Registry form includes information regarding injury at admission and discharge from the SCIMS center, and identifying information is not available in the public datasets. Form 1 has 417 variables and is used for data collection during the initial hospitalization, and Form 2 has 276 variables and is used for data collection at subsequent interviews. Copies of data collection forms can be found at the NSCISC website (National Spinal Cord Injury Statistical Center, 2022). Data on Form I and Form II are gathered through medical exams, medical record reviews and personal interviews (National Spinal Cord Injury Statistical Center, 2018). Three standardized measurement tools are used during data collection in addition to NSCISC specific questions: the American Spinal Cord Injury Association (ASIA) Impairment scale, the Functional Independence Measure (FIM) and the Craig Handicap Assessment and Reporting Technique (CHART).

The majority of the data points on Form I and Form 2 are from the ASIA Impairment Scale, which is the standard measurement tool for neurological classification of spinal cord injury. The ASIA scale is an extensive and thorough assessment of the motor and sensory function of each dermatome of the individual, using light touch and sharp/dull discrimination for sensory testing, and a range of motor movements for the motor function (American Spinal Injury Association, 2019). The measurement tool is established as reliable, with a correlation coefficient 0.9 and higher (Chen et al., 2016). The validity is established through negative and positive predictive probability of >91%, meaning that the ASIA results accurately predict the functionality of the person with SCI (Chen et al., 2016). The ASIA scale is a complex tool to learn and use, and the Primary Investigator of this secondary data analysis has completed the 6 hour training course in the use of this tool to aid in understanding the challenges of data collection in this study (Appendix A).

The FIM is a tool developed by the American Congress for Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation to assess disability effect on mobility, self-care, communication and cognitive function (Kidd et al., 1995). There are 13 motor elements that measure mobility and self-care, and five cognitive elements that measure communication and cognition (Kidd et al., 1995). Kidd et al. (1995) compared the FIM to the established Barthel Index (BI) to determine validity. For validity, the kappa statistic for admission was .92 (95% CI: .77, 1.0), for discharge the kappa statistic was .88 (95% CI: .66, 1.0) and for change the kappa statistic was .78 (95% CI: .49, 1.0) (Kidd et al., 1995). Inter-rater reliability for the total score of the FIM was high with intraclass correlation coefficient at 0.83, and internal consistency was also high with a Cronbach's alpha of 0.94 (Brosseau & Wolfson, 1994).

The CHART was developed according to the World Health Organization (WHO) model of disablement (Whiteneck et al., 1992). The WHO model of disablement has three main components: impairment, disability and handicap (Whiteneck et al., 1992). Impairment refers to the loss of anatomic function of the human body, disability refers to the limitations for the human body to perform activities due to the impairment, and handicap refers to the limitations for the individual human to participate in society due to the impairment (Whiteneck et al., 1992). Handicap is divided into six dimensions: physical independence, cognitive independence, mobility, occupation, social integration and economic self-sufficiency (Whiteneck et al., 1992). The four dimensions used in the NSCID are physical independence, mobility, occupation and social integration. CHART was tested for reliability and validity in the SCI population, and reliability was found excellent for test-retest over 1 week (ICC $\geq$.75), adequate to excellent for test-retest over 2 weeks(ICC .40-.74 - ICC $\geq$.75), and excellent total score reliability and all item reliability (ICC $\geq$.75), except adequate reliability for physical independence for 21-25 day test-retest (ICC .40-.74) (Raad & Moore, 2013). Validity was adequate to excellent between the Community Integration Questionnaire and the CHART (r .31-59 adequate, $r \geq 0.6$ excellent).

Variables

The independent variables of identified PU risk factors were divided into demographic factors, injury factors, socio-environmental factors and risk behaviors, according to the Theoretical Risk and Prevention Model (Krause, 1996; Krause et al., 2013). The operational definitions of the variables are from the Data Dictionary for the National Spinal Cord Injury Database 2011-2016 (Spinal Cord Injury Model System, 2015) and are defined below and in Table 1.

Table 1
Study Variables

Variable	Conceptual Definition	Operational Definition	Level of Measurement
Dependent Variable			
Pressure ulcer	Secondary Condition	Open Pressure Ulcer Grade 2-4	Nominal
Independent Variables			
Demographic Risk Factors			
Sex	Demographic Factor	Gender by male, female, or other/transgender	Nominal
Race	Demographic Factor	Race by Caucasian, African American or Black, Native American, Eskimo or Aleutian, Asian or Pacific Islander, Other or Multiracial	Nominal
Hispanic Origin	Demographic Factor	Hispanic origin by Hispanic or Latino origin or not of Hispanic origin	Nominal
Injury Risk Factors			
Post injury year	Demographic Factor	Year 1, then in 5 year increments up to year 40	Ordinal
Level of paralysis or category of neurological impairment	Level of Paralysis	From medical examination, utilizing International Standards for Neurological Classification of Spinal Cord Injury, Revised 2011	Nominal
ASIA Impairment	Injury Factor	From medical examination, utilizing International Standards for Neurological Classification of Spinal Cord Injury, Revised 2011	Nominal

FIM Total Motor Score	Injury Factors	Functional Independence Measure: Total of 13 motor items, score 13-91	Ordinal
FIM Bed/chair transfer	Injury Factors	Functional Independence Measure: Mobility, Transfers, Bed, Chair, Wheelchair, score 1-7	Ordinal
CHART Mobility total	Injury Factor	Auto calculated total using CHART number of hours out bed/day, number of days out of the house/week, nights away from home in last year	Ordinal
Socio-Environmental Factors			
Veteran	Socio-Environmental Factor	Active Duty Veteran of United States military	Nominal
Marital Status	Socio-environmental Factors	By never married, married, separated, divorced, widowed, other, living with significant other	Nominal
Highest Formal Education Level Completed	Socio-Environmental Factors	By 8th grade or less, through 11th grade, Associate, Bachelor, Master or Doctorate degree earned	Ordinal
Family Income Level	Socio-Environmental Factors	In US dollar amount per year, grouped	Ordinal
Risk Behaviors			
Utilization of Veterans Services	Protective/Risk Factor	Received health care services at VHA medical system since last survey review	Nominal
Smoking	Protective/Risk Factors	Tobacco cigarette smoking, does not include cigars or smokeless tobacco	Nominal

Alcohol: How often have you had a drink in the past year	Protective/Risk Factors	Alcohol use in past year	Nominal
Alcohol: How many on a typical day	Protective/Risk Factors	Number of alcohol drinks per day	Nominal
Alcohol: How often 6+ drinks	Protective/Risk Factors	How often 6+ alcohol drinks per day	Nominal

The dependent variable PU is noted on Form II and was obtained through interview. Patients were asked to report a "pressure sore with open or broken skin" in the past 12 months. Variables were coded as no, yes, declined/participant doesn't know, or unknown. Interviewers were not required to review participant medical records, however, if the medical record indicated PU in the past 12 months the interviewer coded "yes" for pressure ulcer. Coding for all variables is detailed in Table 2.

Table 2
Variable Coding

Variable	Codes	Level of Measurement	Statistical Tests
Dependent Variable			
Pressure ulcer	0=No 1=Yes 7=Declined/Participant doesn't know 9=Unknown Blank (only if category of Care =5)	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Independent Variables			
Demographic Risk Factors			
Sex	1=Male 2=Female 3=Other, Transgender 9=Unknown	Nominal	Descriptive: Frequencies, Percentages

			Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Race	1=Caucasian 2=African American or Black 3=Native American, Eskimo, Aleutian 4=Asian or Pacific Islander 5=Some Other Race, Multiracial 7=Declined 9=Unknown	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Hispanic Origin	0=Not of Hispanic origin 1=Hispanic or Latino origin 7=Declined 9=Unknown	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Injury Risk Factors			
Post injury year	1-40 Valid post-injury anniversary year, grouped in 5 year increments: 1, 5, 10, 15, 20, 25, 30, 35, 40	Interval	Descriptive: Mode, Median, Range, Frequencies, Percentages Difference between variables: Mann Whitney U Association among variables: Odds Ratio
Level of paralysis or category of neurological impairment	1=Paraplegia, incomplete 2=Paraplegia, complete	Nominal	Descriptive: Frequencies, Percentages

	3=Paraplegia, minimal deficit 4=Tetraplegia, incomplete 5=Tetraplegia, complete 6=Tetraplegia, minimal deficit 7=Normal neurologic 8=Normal neurologic, minimal neurologic deficit 9=Unknown Blank=Category of care = 5		Difference between variables: Pearson Chi square Association among variables: Odds Ratio
ASIA Impairment	A: Complete Injury, no sensory or motor function in sacral segments S4-S5 B: Incomplete, sensory but not motor function below neuro level C: Incomplete, motor function below neuro level and more than half of key muscles have muscle grade less than 3 D: Incomplete, motor function below neuro level and at least half of key muscles below neuro level have muscle grade 3 or greater E: Normal, sensory and motor functions are normal U: Unknown Blank: Category of Care =5	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
FIM Motor Total	Functional Independence Measure: Total of 13	Interval	Descriptive: Frequencies, Percentages Mode, Median, Range,

	motor items, each score 1-7, total 13-91 1: Total assistance 2: Maximal assistance 3: Moderate assistance 4: Minimal contact assistance 5: Supervision or setup 6: Modified independence 7: Complete independence		Difference between variables: Mann Whitney U Association among variables: Odds Ratio
FIM Bed/chair transfer	Functional Independence Measure: Mobility, Transfers, Bed, Chair, Wheelchair, score 1-7 1: Total assistance 2: Max50imal assistance 3: Moderate assistance 4: Minimal contact assistance 5: Supervision or setup 6: Modified independence 7: Complete independence	Interval	Descriptive: Frequencies, Percentages Mode, Median, Range, Difference between variables: Mann Whitney U Association among variables: Odds Ratio
CHART Mobility total	Auto calculated total using CHART number of hours out bed/day, number of days out of the house/week, nights away from home in last year 0-100 valid range 999: unknown 100: no handicap to mobility	Interval	Descriptive: Frequencies, Percentages Mode, Median, Range, Difference between variables: Mann Whitney U Association among variables: Odds Ratio
Socio-Environmental Risk Factors			
Veteran	0=No 1=Yes 0=Unknown	Nominal	Descriptive: Frequencies, Percentages

			Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Marital Status	1=Never married 2=Married 3=Divorced 4=Separated 5=Widowed 6=Other, unclassified 7=Living with significant other, Partner, unmarried couple 9=Unknown	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Highest Formal Education Level Completed	1=8th grade or less 2=9th through 11th grade 3=High school diploma or GED 4=Associate Degree 5=Bachelor's Degree 6=Master's Degree 7=Doctorate (Ph.D., M.D., law degrees, etc.) 8=Other, unclassified (3 yr. nursing degree, special education) 9=Unknown	Ordinal	Descriptive: Frequencies, Percentages Difference between variables: Mann Whitney U Association among variables: Odds Ratio
Family Income Level	1<$25,000 2= $25,000-$49,999 3=$50,000-$74,999 4=$75,000 or more 6=Participant doesn't know 7=Declined 9=Unknown, interview not done	Interval	Descriptive: Frequencies, Percentages Mode, Median, Range, Difference between variables: Mann Whitney U Association among variables: Odds Ratio

Risk Behaviors			
Utilization of Veterans Health Services	0=No services, but participant is a Veteran 1=Yes 8=N/A, not a Veteran 9=Unknown, interview not done Blank (only if category of care =5)	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Smoking	0=Not at all 1=Some days 2=Everyday 7=Declined/Participant doesn't know 9=Unknown, less than 16 years old, interview not done Blank (category of care =5)	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Pearson Chi square Association among variables: Odds Ratio
Alcohol: How often have you had a drink in the past year	Alcohol use in past year 0: Never 1: once a month or less 2: 2-4 times per month 3: 2-3 times a week 4: 4 or more times a week 7: Declined, doesn't know 9: Unknown Blank: category of care =5	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Mann Whitney U Association among variables: Odds Ratio
Alcohol: How many on a typical day	Number of alcohol drinks per day: 0: None 1: 1 or 2 2: 3 or 4 3: 5 or 6 4: 7-9 5: 10 or more	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Mann Whitney U Association among variables: Odds Ratio

	7: Declined, doesn't know 9: Unknown Blank: category of care =5		
Alcohol: How often 6+ drinks	How often 6+ alcohol drinks per day 0: never 1: less than monthly 2: Monthly 3: Weekly 4: Daily or almost daily 7: Declined, doesn't know 9: Unknown Blank: category of care =5	Nominal	Descriptive: Frequencies, Percentages Difference between variables: Mann Whitney U Association among variables: Odds Ratio

Note: Category 5 indicates loss to follow up.

Pressure ulcer

Pressure ulcer was documented on Form II and was obtained through interview. Categories were no, yes, declined/doesn't know, unknown and blank.

Demographic risk factors

Demographic risk factors were sex, racial or ethnic group and Hispanic origin. ***Sex*** was noted on the registry, Form I and Form II and was obtained through interview. The categories were male, female, other or transgender, and unknown. ***Race*** was noted on the registry, Form I and Form II and was obtained through interview. The categories were Caucasian, African American or Black, Native American, Eskimo, Aleutian; Asian or Pacific Islander, Some other Race, Multiracial; declined and unknown. ***Hispanic Origin*** was noted on the registry, Form I and Form II and was obtained through interview. The categories were not of Hispanic origin, Hispanic or Latino origin, declined and unknown.

Injury risk factors

Injury risk factors were post injury year, level of paralysis, ASIA impairment score, Functional Independence Measure (FIM) bed/chair transfer score, and Craig Handicap Assessment and Reporting Technique (CHART).

Post injury year was documented on Form II and was calculated from date of injury. Form II was collected in post injury years 1, 5, 10, 15, 20, 25, 30, 35, 40, and each individual was identified as belonging to one of these injury year groups. Date of injury was not included in data release to the public.

Paralysis level, or category of neurological impairment was documented on Form I. The designation was determined by a physical examination by a medical provider that had been trained in the American Spinal Cord Injury Association (ASIA) International Standards for Neurological Classification of Spinal Cord Injury. Neurological impairment was defined in the NSCID as paraplegia, tetraplegia or normal neurologic. Paraplegia and tetraplegia were further distinguished as incomplete, complete or minimal deficit. Paraplegia was loss of motor and/or sensory function at the thoracic, lumbar or sacral level of the spinal cord, and resulted in malfunction or total lack of function of the trunk and legs, depending on the level of injury. Tetraplegia was loss of motor and/or sensory function in the cervical level of the spinal cord and resulted in malfunction or total lack of function of the arms, trunk and legs, depending on the level of injury. A complete injury means there was a complete lack of sensory or motor function at the lowest sacral segment, and an incomplete injury means there was partial sensory and/or motor function below the neurological level of injury. Minimal deficit was defined as no significant loss of function or sensation as a result of minimal damage to the spinal cord. Normal neurologic was included to capture the <1% of persons who have recovered from their SCI

injury, which meant that the initial loss of motor and/or sensory function was due to spinal shock, not permanent damage to the spinal cord. Variables were coded as paraplegia, incomplete; paraplegia, complete; paraplegia, minimal deficit; tetraplegia, incomplete; tetraplegia, complete; tetraplegia, minimal deficit; normal neurologic, and unknown. For data analysis, paraplegia complete and incomplete were combined to one paraplegia variable, tetraplegia complete and tetraplegia incomplete were combined to one tetraplegia variable, and minimal deficits and normal neurologic were removed from the data analysis.

ASIA impairment was documented on Form I and carried over to Form II. The designation was determined by a physical examination by a medical provider that had been trained in the American Spinal Cord Injury Association (ASIA) International Standards for Neurological Classification of Spinal Cord Injury. Categories ranged from normal to complete injury and were coded by letters A-E, with multiple categories labeled incomplete. Category A was Complete injury, which indicated no sensory or motor function in sacral spine S4-S5. Category B Incomplete indicated sensory function below the neurological level of injury but not motor function. Category C Incomplete indicated motor function below the neurological level of injury, with over half of key muscles below the level of injury with a grade 0-2, indicating minimal muscle function. Incomplete D indicated motor function below the neurological level of injury with at least half of key muscles below the level of injury with a muscle grade 3+, indicating the ability to perform active movements against gravity and greater. For data analysis, Complete injury variables were combined, Incomplete injury variables were combined, and normal, unknown and complete recovery were removed from the data analysis.

FIM Motor total was noted on Form I and Form II and was obtained through interview. The variable was auto calculated from the scores of 13 FIM Motor items. Each score was from 1

to 7, and FIM Motor Total score range was from 13-91. Lower scores indicated more assistance needed with motor items, and a score of 91 indicated complete independence in motor items. For data analysis, variables were grouped as follows: Group 1 = 13 - 32, Group 2 = 33 - 52, Group 3 = 53 - 72 and Group 4 = 73 - 91.

FIM Bed/chair transfer was noted on Form I and Form II and was obtained through interview. The score range was from 1 – 7, with a score of 1 indicating total assistance needed, and a score of 7 indicating complete independence in transfers from bed, chair and wheelchair.

CHART mobility total was auto-calculated by NSCISC using the results from CHART number hours out of bed/day, number of hours out of house/week and nights away from home last year. The range was from 0 – 100, with 100 indicating complete mobility in current environment. CHART variables were obtained through interview and recorded, on Form I and Form II. For data analysis, variables were grouped as follows: Group 1 = 0 – 25, Group 2 = 26 – 50, Group 3 = 51 – 75 and Group 4 = 76 – 100.

Socio-environmental risk factors

Socio-environmental risk factors were Veteran status, marital status, highest formal education level completed and family income level.

Veteran status was obtained through interview and was noted on Form I and Form II. The interviewer asked the question “Are you a Veteran of the U.S. Military Forces?” Veteran was defined as someone who has served on active duty in the U.S. Military Forces but did not include reservists unless the reservist was activated to active duty, which is consistent with Veterans Affairs definition of Veteran. Variables were coded as no, yes and unknown.

Marital status was obtained through interview and was noted on Form I and Form II. The categories were never married, married, divorced, separated, widowed, other, living with significant other, partner, unmarried couple and unknown.

Highest formal education level completed was obtained through interview and was noted on Form I and Form II. The interviewer recorded the highest level of education completed at the time of interview and ranged from 8th grade or less to doctoral level. Trade and technical schools were not included in this variable. The data dictionary also provided a conversion chart for education levels completed in Mexico.

Family income level was obtained through interview and was noted on Form I and Form II. The range of income levels was from under $25,000 to over $75,000. Income for all family members over the age of 15 and living in the household was included in the total.

Risk Behaviors

Risk behaviors were utilization of VHA services, smoking, and alcohol use. Alcohol use was broken down into use of alcohol in past year, number of drinks per day and the frequency of binge drinking.

Utilization of VHA services was obtained through interview and was noted on Form I and Form II. Participants were asked if VHA services had been utilized since last NSCISC interview. All types of VHA services qualified including pharmacy, SCI center and prosthetics. Responses were coded for services received or not received for Veterans, or not applicable for non-Veterans.

Smoking was obtained through interview and was noted on Form I and Form II. The range was from smoking not at all to smoking every day. The variable related only to cigarette smoking and did not include other tobacco use such as cigars or smokeless tobacco.

Alcohol: how often have you had a drink in the past year was obtained through interview and was noted on Form I and Form II. The range was from never drinking to 4 or more times per week over the past 12 months. One drink was standardized to 12 ounces of beer, 1.5 ounces of hard liquor or 5 ounces of wine.

Alcohol: how many drinks on a typical day was obtained through interview and was noted on Form I and Form II. The range was from none to 10 or more drinks on a typical day of drinking alcohol over the past 12 months. One drink was standardized to 12 ounces of beer, 1.5 ounces of hard liquor or 5 ounces of wine.

Alcohol: how often 6+ drinks was obtained through interview and was noted on Form I and Form II. The range was from never to daily or almost daily over the past 12 months. One drink was standardized to 12 ounces of beer, 1.5 ounces of hard liquor or 5 ounces of wine.

Data Collection

Data collection was through physical exam, personal interview and record review at initial hospitalization and at defined intervals after initial injury, with the intervals occurring one year after initial injury and at 5 year intervals thereafter (National Spinal Cord Injury Statistical Center, 2015). Initial interviews were performed in person, with additional data gathered from record review and physical exam (National Spinal Cord Injury Statistical Center, 2015). Subsequent interviews were in person, over the phone or by mail (National Spinal Cord Injury Statistical Center, 2015). There are several personnel designated to work on the NSCID, including Project Director, Database Coordinator/Collector, Liaison Nurse, Data Entry Clerk and Data Analyst (National Spinal Cord Injury Statistical Center, 2015). Center directors and database directors review the variables every 2-3 years, and when changes are made, the entire

system of data collection is updated to include the databases, data dictionary, and updated training for the persons interviewing (National Spinal Cord Injury Statistical Center, 2015).

A main concern with a study at various centers over a long period of time is consistency. The NSCID certifies their data collectors, with face to face meetings, site visits, and teleconferences with each center, in addition to providing a data dictionary and manual of procedures (National Spinal Cord Injury Statistical Center, 2015). The database has converted to a web based data management system, and quality assurance checks are performed every 6 months (Chen et al., 2016).

Ethical Considerations

Signed informed consent is required to be obtained at each individual SCI Model Center, and the consent form is individual to each SCI Model Center (National Spinal Cord Injury Statistical Center, 2015). The informed consent must include Certificate of Confidentiality language designated by the National Institute of Neurological Disorders and Stroke (U.S Department of Health & Human Services, 2019). The initial consent must be signed and submitted to the NSCID, and subsequent follow up interviews are permitted with verbal informed consent (National Spinal Cord Injury Statistical Center, 2015). In addition, a signed Health Insurance Portability and Accountability Act form must also be submitted with the informed consent (National Spinal Cord Injury Statistical Center, 2015).

Specific procedures and terminology are used to obtain consent per the NSCISC Standard Operating Procedures and Policies. Recruitment includes multiple visits to establish a relationship with the participants, collaboration with and introduction by the SCI physician, leaving printed material for review by patient and family before asking for consent, and involving the patient's family in the consent process (National Spinal Cord Injury Statistical

Center, 2015) Incentives provided are small items such as a pen, calendar or squeeze ball (National Spinal Cord Injury Statistical Center, 2015).

Data were de-identified prior to public release (Chen, 2016b). Names and unique identifiers such as injury location have been removed and dates were compressed to year only (Chen, 2016b). Researchers requesting de-identified data are required to attest that no attempt to identify participants will be made (University of Alabama at Birmingham, 2020b).

The Institutional Review Board (IRB) at the University of Texas at Arlington was contacted and verified that secondary data analysis of this open source de-identified data set did not require IRB approval (Appendix B).

Data Analysis

Data were obtained through public use data available on the NSCID website (National Spinal Cord Injury Statistical Center, 2015). The NSCID is a longitudinal data base with 113,360 observations from 32,159 participants. Data on each participant are gathered prior to discharge from the Model System Center and follow up interviews are performed at one year after discharge and then at five year intervals. Only the most recent interview was selected if the participant had two interviews in the 2011-2016 timeframe. This study focused on the cross sectional 2011-2016 database to allow analyses to include variables added in 2011: PU, tobacco use and family income. The number of participants in the initial sample of the 2011-2016 database was 12,048. Criteria for inclusion in the sample for this data analysis are information available in the dataset for the following variables: level of paralysis, ASIA level, and pressure ulcer. Participants without recorded information for these variables were removed from the dataset, with 463 removed for no level of paralysis noted, 94 removed for lack of ASIA level noted, and 821 were removed for lack of PU information. Due to confidentiality concerns, two

additional participants with significant identifying characteristics were removed to avoid the possibility of unintentional identification. The remaining dataset was 10,668 participants. Data were cleaned by removing unknown, declined and blank values from data analysis. Data were analyzed using International Business Machines Statistical Package for the Social Sciences 25 (IBM Corp., 2015).

Delimitations

This research study was limited to the NSCISC 2011-2016 data set to eliminate errors related to comparing data sets with differing reporting requirements. Risk factors and data selection were limited to decrease errors related to multiple analyses.

Chapter Summary

The research design, setting and sample were discussed in this chapter. Conceptual and operational definitions of study variables were defined, and statistical tests and ethical considerations were detailed.

CHAPTER FOUR

FINDINGS

This chapter will present the findings of the secondary data analysis of the National Spinal Cord Injury Database. Number, percentage, Chi square and Mann Whitney U are presented to define descriptive statistics. Number, percentage and Odds Ratios are presented to determine the association between known PU risk factors and presence of PU, stratified by level of paralysis; and the association between known PU risk factors and level of paralysis in persons with traumatic injury SCI.

Results: Descriptive

Descriptive statistics of the data set, grouped into persons with and without PU according to PU risk factors, are shown in Table 3 and described here. In the overall sample, 29.3% of persons with SCI in the 2011-2016 sample reported a PU in the past 12 months.

Demographic Risk Factors

Demographic risk factors in the data set are sex, race, and ethnicity. Within the risk factor group of **sex**, males had a greater percentage of PU than females, 30.1% vs. 26.2%, with the difference being significant, $\chi 2(1) = 12.60$, $p < .001$. For **race**, the group that encompassed Native Americans, Eskimos and Aleutians had the highest percentage of PU, 38.4%, and Asians or Pacific Islanders had the lowest percentage of PU, 24.1%. Differences among factors in the race group were significant, $\chi 2(4) = 57.41$, $p < .001$. For **ethnicity**, non-Hispanics had a significantly higher percentage of PU than Hispanics, 29.9% vs 24.1%, $\chi 2(1) = 14.98$, $p < .001$.

Injury Risk Factors

Injury risk factors in the data set are post injury year, level of paralysis, ASIA level, FIM motor total score, FIM bed/chair assist score, and CHART score. Differences among year groups

in the **post injury year** factor were significant, U = 10802821, Z = -6.811, p < .001. Post injury year 40 reported the highest percentage of PU, 37.1%, and post injury year 1 reported the lowest percentage, 24.9%. **Level of paralysis** was divided into two groups, paraplegia and tetraplegia, and persons with paraplegia were significantly more likely to report PU than persons with tetraplegia, 30.9% vs. 27.7%, $\chi 2(1) = 13.35$, p < .001. **ASIA impairment** levels were grouped into complete and incomplete, and persons with ASIA complete impairment were significantly more likely to report PU than persons with an incomplete injury, 42.4% vs. 18.0%, $\chi 2(1) = 763.63$, p < .001. FIM motor total score was divided into 4 groups, with a lower score indicating a lower level of functional independence. Differences between the 4 groups was significant, U = 7887847.5, Z = -26.889, p < .001. Persons in the lowest scoring group, 13-32, reported the highest level of PU at 47.7%, and persons in the highest scoring group, 73-91, reported the lowest level at 19.7%. **FIM bed to chair transfer** consists of 7 groups ranging from total assistance to complete independence, and differences between the groups was significant, U = 7113406, Z = -25.392, p < .001. The total assistance group reported the highest percentage of PU at 49.7%, and the complete independence group reported the lowest percentage at 16.9%. The **CHART** mobility factor was grouped into 4 groups, with lower scores indicating lower level of mobility. The lowest scoring group, 0-25, reported the highest percentage of PU at 61.6%, and the highest scoring group, 76-100, reported the lowest percentage at 20.9%. Differences among groups in the CHART factor was significant, U = 8243163, Z = -24.811, p < .001.

Socio-Environmental Risk Factors

Socio-Environmental risk factors in the data set are Veteran status, marital status, education level and family income. Non-Veterans were significantly more likely to have PU than **Veterans,** 27.9% vs. 21.7%, $\chi 2(1) = 8.07$, p = .005. Differences among groups for **marital**

status was significant, $\chi 2(5) = 91.32$, $p < .001$. Persons who were divorced reported the highest percentage of PU at 33.8%, and persons who were married had the lowest at 23.9%. For **education level,** persons who had a 9th through 11th grade education reported the highest percentage of PU at 36.6%, and persons with a doctorate level degree reported the lowest percentage of PU at 24.1%. Differences among groups was significant, U = 10570853, Z = -5.745 $p < .001$, with the "other" group excluded during Mann Whitney U test due to inability to appropriately place the "other" group in order with the group variables. For **family income**, persons with family income less than $25,000 per year reported the highest percentage of PU at 35.1%, and persons with family income of $75,000 or more reported the lowest percentage of PU at 21.8%. Differences among groups was significant at U = 8013029.5, Z = -11.738, $p < .001$.

Risk Behaviors

Risk behaviors are Veteran utilization of VHA services, smoking, and alcohol use by day and year and binge alcohol drinking. **Veterans who utilized VHA services** reported the highest percentage of PU at 31.6%, Veterans who did not utilize VHA services reported the lowest percentage of PU at 24.2%, and persons who were not Veterans reported a PU percentage of 29.5%. Differences among groups were significant, $\chi 2(2) = 10.85$, $p = .004$. For **smoking**, persons who did not smoke at all reported the lowest percentage of PU at 28.0%, and persons who smoked some days reported the highest percentage at 34.7%, $\chi 2(2) = 29.81$, $p < .001$. For **alcohol intake per year**, differences among groups was significant, U = 10029135, Z = -10.229, $p < .001$. Persons who drank alcohol 2-3 times per week over the past year reported the lowest percentage of PU at 21.6%, and persons who never drank over the past year reported the highest percentage of PU at 33.6%. For **alcohol intake per day**, persons who recorded no daily intake of alcohol reported the highest percentage of PU at 33.4%, and persons who drank 7 to 9 alcoholic

drinks daily reported the lowest percentage of PU at 22.2%. Differences among groups was significant at $U = 10388030.5$, $Z = -7.62$, $p < .001$. For **binge alcohol intake**, or alcohol intake of 6+ drinks per day, persons who never engaged in binge drinking reported the highest percentage of pressure ulcers at 30.1%, and persons who engaged in monthly binge drinking reported the lowest percentage at 23.1%. Differences among groups was significant at $U = 10916161.5$, $Z = -5.174$, $p < .001$.

Table 3

Comparing Pressure Ulcer Risk Factors in Persons with Spinal Cord Injury

	Pressure Ulcer=Yes		Pressure Ulcer=No		
	n	% by row	n	% by row	Test of differences[a]
Demographic Risk Factors					
Sex					
Male	2526	30.1%	5875	69.9%	$\chi 2(1) = 12.60$, $p < .001$
Female	595	26.2%	1672	73.8%	
Race					
Caucasian	2156	27.8%	5592	72.2%	
African American or Black	743	35.8%	1332	64.2%	
Native American, Eskimo, Aleutian	28	38.4%	45	61.6%	$\chi 2(4) = 57.41$, $p < .001$
Asian or Pacific Islander	42	24.1%	132	75.9%	
Some Other Race, Multiracial	59	25.2%	175	74.8%	
Ethnicity					
Not Hispanic	2850	29.9%	6694	70.1%	$\chi 2(1) = 14.98$, $p < .001$
Hispanic or Latino	247	24.1%	779	75.9%	
Injury Risk Factors					
Post Injury Year					
1	598	24.9%	1804	75.1%	
5	516	28.1%	1323	71.9%	
10	442	29.3%	1064	70.7%	$U = 10802821$, $Z = -6.81$, $p < .001$
15	290	27.5%	764	72.5%	
20	317	32.3%	664	67.7%	
25	251	33.0%	510	67.0%	

30	325	32.6%	671	67.4%	
35	287	32.9%	586	67.1%	
40	95	37.1%	161	62.9%	
Level of Paralysis					
Paraplegia	1569	30.9%	3501	69.1%	$\chi 2(1) = 13.35, p < .001$
Tetraplegia	1552	27.7%	4046	72.3%	
ASIA Impairment					
Complete Injury	2093	42.4%	2848	57.6%	$\chi 2(1) = 763.63, p < .001$
Incomplete Injury	1028	18.0%	4699	82.0%	
FIM Motor Total (Grouped)					
13-32	846	47.7%	926	52.3%	$U = 7887847.5$, $Z = -26.89$, $p < .001$
33-52	415	36.9%	709	63.1%	
53-72	522	37.9%	855	62.1%	
73-91	1112	19.7%	4545	80.3%	
FIM Bed to Chair Transfer					
Total assistance	1030	49.7%	1041	50.3%	$U = 7113406$, $Z = -25.39$, $p < .001$
Maximal assistance	94	33.0%	191	67.0%	
Moderate assistance	78	29.3%	188	70.7%	
Minimal assistance	100	33.3%	200	66.7%	
Supervision or setup	116	36.4%	203	63.6%	
Mod. independence	892	27.9%	2307	72.1%	
Independent	600	16.9%	2941	83.1%	
CHART Mobility Total (Grouped)					
0-25	376	61.6%	234	38.4%	$U = 8243163$, $Z = -24.81$, $p < .001$
26-50	621	44.2%	783	55.8%	
51-75	782	33.6%	1548	66.4%	

76-100	1285	20.9%	4866	79.1%	
Socio-Environmental Risk Factors					
Veteran Status					
No	1584	27.9%	4097	72.1%	$\chi 2(1) = 8.07$, p = .005
Yes	100	21.7%	360	78.3%	
Marital Status					
Never married	1264	32.2%	2662	67.8%	
Married	918	23.9%	2921	76.1%	
Divorced	682	33.8%	1335	66.2%	$\chi 2(5) = 91.32$, p < .001
Separated	75	31.9%	160	68.1%	
Widowed	87	28.2%	221	71.8%	
Living with significant other	86	27.0%	232	73.0%	
Education Level					
8th grade or less	60	27.4%	159	72.6%	
9th through 11th grade	342	36.6%	593	63.4%	
High school diploma or GED	1528	29.8%	3598	70.2%	
Associate Degree	352	29.7%	834	70.3%	$U = 10570853$, $Z = -5.75$, $p < .001$[b]
Bachelor's Degree	514	26.2%	1446	73.8%	
Master's Degree	188	24.5%	578	75.5%	
Doctorate (Ph.D., M.D., law degrees, etc.)	68	24.1%	214	75.9%	
Other, unclassified (3 yr. nursing degree, etc.) [b]	59	33.5%	117	66.5%	
Family Income Level					
<$25,000	1467	35.1%	2713	64.9%	
$25,000-$49,999	568	27.1%	1527	72.9%	$U = 8013029.5$, $Z = -11.74$, $p < .001$
$50,000-$74,999	306	24.7%	931	75.3%	
$75,000 or more	438	21.8%	1569	78.2%	

Risk Behaviors					
Utilization of VHA Services					
No services, but participant is a Veteran	183	24.2%	572	75.8%	
Yes	165	31.6%	357	68.4%	$\chi 2(2) = 10.85$, p = .004
N/A, not a Veteran	2760	29.5%	6596	70.5%	
Smoking					
Not at all	2362	28.0%	6084	72.0%	
Some days	222	34.7%	418	65.3%	$\chi 2(2) = 29.81$, p < .001
Everyday	518	33.6%	1025	66.4%	
Alcohol intake per year					
Never	1501	33.6%	2966	66.4%	
Once a month or less	751	29.9%	1759	70.1%	$U = 10029135$, $Z = -10.23$, $p < .001$
2-4 times/month	407	23.4%	1329	76.6%	
2-3 times/week	224	21.6%	814	78.4%	
4 or more/week	178	23.4%	583	76.6%	
Alcohol intake per day					
None	1539	33.4%	3071	66.6%	
1 or 2	1050	25.7%	3028	74.3%	
3 or 4	310	24.5%	955	75.5%	$U = 10388030.5$, $Z = -7.62$, $p < .001$
5 or 6	122	31.7%	263	68.3%	
7 to 9	22	22.2%	77	77.8%	
+10 or more	18	29.5%	43	70.5%	

Binge alcohol intake/6+ per day					
Never	2660	30.1%	6165	69.9%	
Less than monthly	244	23.7%	787	76.3%	U = 10916161.5,
Monthly	85	23.1%	283	76.9%	Z = -5.17,
Weekly	55	25.9%	157	74.1%	p < .001
Daily or almost daily	15	23.4%	49	76.6%	

Note. [a]Chi squared test of independence was run for nominal variables, Mann Whitney U test was run for ordinal variables
[b]For Education, the Mann Whitney U test was run when excluding the "Other, unclassified"
group

Results: Association

The association between known PU risk factors and presence of PU, stratified by level of paralysis, and the association between known PU risk factors and level of paralysis are shown in Table 4 and described here. Odds Ratios are also displayed in graph format in Appendix C.

Research Question 1 was: What is the association between known PU risk factors and presence of PU, stratified by level of paralysis, in persons with traumatic SCI whose data is maintained by the NSCID? Pressure ulcer risk factors were compared by percentage for paraplegia and tetraplegia paralysis levels. Looking at persons with paraplegia with persons with tetraplegia overall, persons with paraplegia reported PU at a higher percentage than persons with tetraplegia, 30.9% vs. 27.7%, $p<.001$. There were 17 PU risk factors measured in this study, and 77 subfactors. Paraplegics reported a greater percentage of PU than tetraplegics in 65 of these subfactors.

Research Question 2 was: What is the association between known PU risk factors and level of paralysis in persons with a traumatic SCI whose data is maintained by the NSCID? Odds ratios for PU were determined for each risk subfactor, with OR >1 indicating higher odds for paraplegics to report PU, and OR <1 indicating higher odds for tetraplegics to report PU. Looking at persons with paraplegia and persons with tetraplegia overall, paraplegics were 8% more likely to report PU than tetraplegics, *OR*=1.08, 95% CI (1.04, 1.13). There were 77 subfactors in this study, and 36 of those had significant OR, with paraplegics more likely to report PU than tetraplegics for 35 of the 36 significant findings.

Demographic Risk Factors

Sex, race and ethnicity are the demographic risk factors. For **sex**, males with paraplegia reported a higher percentage of PU than males with tetraplegia, 31.9% vs. 28.5%, and the

difference was significant, *OR* = 1.17, 95% CI (1.07, 1.29). Females with paraplegia reported a higher percentage of PU than females with tetraplegia, at 27.8% vs 24.6%, but the difference was not significant. For **race**, the Native American, Eskimo and Aleutian paraplegia group reported the highest percentage of PU, 46.3%, vs 28.1% in the tetraplegia group, however, the difference was not significant. African Americans with paraplegia were one-third more likely to report PU than African Americans with tetraplegia, *OR* = 1.36, 95% CI (1.14, 1.63). Caucasians with paraplegia were more likely to report PU than Caucasians with tetraplegia, *OR* = 1.13, 95% CI (1.03, 1.25). For **ethnicity**, non-Hispanics with paraplegia were over 20% more likely to report a PU than non-Hispanics with tetraplegia, *OR* = 1.22, 95% CI (1.12, 1.33). Hispanics with tetraplegia reported a higher percentage of PU than Hispanics with paraplegia, 26.4% vs. 21.9%, but the difference was not significant.

Injury Risk Factors

Post injury year data collection starts at year one, with the next data collection at year five, and continues up to year 40 at five year intervals. Post injury year 5 was the only year group with significant findings, with paraplegics over 40% more likely to report PU than tetraplegics, *OR* = 1.43, 95% CI (1.17, 1.76). Of the remaining year groups, paraplegics reported a greater percentage of PU than tetraplegics in post injury year groups 1, 10, 20, 25, 30, 35 and 40.

Complete **ASIA impairment** level was the only risk factor in the entire data set that was significant for tetraplegia over paraplegia for PU, *OR* = 0.80, 95% CI (0.72, 0.90). Persons with tetraplegia and incomplete injury were more likely to report PU than persons with paraplegia and incomplete injury, 18.2% vs 17.5%, but the difference was not significant. Each group in the **FIM motor total** score risk factor was significant for persons with paraplegia reporting more PU than persons with tetraplegia, ranging from almost twice as likely to over three times as likely

(Group 1 FIM total 13-32 *OR* = 1.85, 95% CI [1.09, 3.13], Group 4 FIM total 73-91 *OR* = 3.37, 95% CI [2.86, 3.99]). Similarly, six out of seven groups in the **FIM bed to chair transfer** risk factor were significant for persons with paraplegic reporting more PU than persons with tetraplegia, ranging from almost twice as likely to over three times as likely (Supervision or set up *OR* = 1.83, 95% CI [1.16, 2.91], Complete independence *OR* = 3.54, 95% CI [2.84, 4.41]). Half of the groups in the **CHART** factor group were significant for paraplegics reporting more PU than tetraplegics (Group 2, 26-50 *OR* = 1.32, 95% CI [1.06, 1.64], Group 4, 76-100 *OR* = 1.42, 95% CI [1.25, 1.61]). The two remaining groups reported higher percentages in the paraplegic group, but the differences were not significant.

Socio/Environmental Factors

Veterans with paraplegia were more likely to report PU as compared to Veterans with tetraplegia, 24.2% vs. 20.5%, but the difference was not significant. Non-Veterans with paraplegia were almost 25% more likely to report PU, *OR* = 1.24, 95% CI (1.11, 1.39). Half of the groups in the **marital status** factor group were significant for PU in paraplegics over tetraplegics. The never married group was significant, *OR* = 1.16, 95% CI (1.01, 1.32); the married group was significant *OR* = 1.20, 95% CI (1.03, 1.39), and the widowed group had the highest odds ratio of paraplegics vs. tetraplegics, *OR* = 1.71, 95% CI (1.04, 2.82).

Of the eight levels in the **education** factor, only two had significant findings. In the 9th through 11th grade group, paraplegics were over 40% more likely to report PU than tetraplegics, *OR* = 1.41, 95% CI (1.08, 1.84). High school graduates (or GED equivalent) reported a higher level of PU, *OR* = 1.14, 95% CI (1.01, 1.29). For **family income**, persons with paraplegia and family income less than $25,000 per year were significantly more likely to report PU than persons with tetraplegia, *OR* = 1.16, 95% CI (1.03, 1.32).

Risk Behaviors

Paraplegic **Veterans who utilized VHA services** were almost twice as likely to report a PU than tetraplegic Veterans, *OR* = 1.93, 95% CI (1.33, 2.80). Paraplegic Veterans who did not utilize VHA services were more likely to report PU than tetraplegic Veterans who did not utilize VHA services, 26.4% vs. 22.4%, but the difference was not significant. For **smoking**, persons with paraplegia who smoked some days were over 1 ½ times to report PU than persons with tetraplegia, *OR* = 1.64, 95% CI (1.18, 2.29); and persons with paraplegia who smoked everyday were almost twice as likely to report PU than persons with tetraplegia *OR* = 1.88, 95% CI (1.51, 2.34).

For **alcohol intake per year**, three groups had significant values. Paraplegics who never consumed alcohol were more likely than tetraplegics to report PU, *OR* = 1.13, 95% CI (1.00, 1.28). Paraplegics who consumed alcohol once a month or less were more likely to report PU, *OR* = 1.21, 95% CI (1.02, 1.44); and paraplegics who consumed alcohol 2-4 times per month were also more likely to report PU, *OR* = 1.45, 95% CI (1.16, 1.81). For **alcohol intake per day**, persons with paraplegia who reported no daily alcohol intake were 13% more likely to report PU than persons with tetraplegia, *OR* = 1.13, 95% CI (1.00, 1.28); and persons with paraplegia who reported 1 or 2 daily drinks were 15% more likely to report PU than persons with tetraplegia, *OR* = 1.15, 95% CI (1.00, 1.33). Persons with paraplegia who reported alcohol intake of 3 or 4 daily drinks were over 1 ½ times more likely to report PU than persons with tetraplegia, *OR* = 1.52, 95% CI (1.17, 1.97).

For **binge alcohol intake**, paraplegics who reported no binge alcohol intake were more likely to report PU as compared to tetraplegics who reported no binge alcohol intake, *OR* = 1.18, 95% CI (1.08, 1.30).

Table 4

Odds Ratios of Pressure Ulcer Risk Factors by Level of Paralysis in Persons with Spinal Cord Injury

	Pressure Ulcer = Yes		Pressure Ulcer = Yes
	Paraplegia % (n) by row	Tetraplegia % (n) by row	Odds Ratio Paraplegia vs Tetraplegia, by row OR (95% CI)
Demographic Risk Factors			
Sex			
Male	31.9% (1251)	28.5% (1275)	1.17* (1.07, 1.29)
Female	27.8% (318)	24.6% (277)	1.18 (0.98, 1.42)
Race			
Caucasian	29.2% (1040)	26.7% (1116)	1.13* (1.03, 1.25)
African American	39.3% (410)	32.3% (333)	1.36* (1.14, 1.63)
Native American, Eskimo, Aleutian	46.3% (19)	28.1% (9)	2.21 (0.82, 5.91)
Asian or Pacific Islander	25.7% (19)	23.0% (23)	1.16 (0.58, 2.33)
Other, Multiracial	24.1% (32)	26.7% (27)	0.87 (0.48, 1.57)
Ethnicity			
Not Hispanic	32.0% (1439)	27.9% (1411)	1.22* (1.12, 1.33)
Hispanic	21.9% (117)	26.4% (130)	0.78 (0.59, 1.04)
Injury Risk Factors			
Post Injury Year			
1	26.5% (270)	23.7% (328)	1.17 (0.97, 1.40)
5	32.1% (263)	24.8% (253)	1.43* (1.17, 1.76)

10	31.4% (216)	27.6% (226)	1.20 (0.96, 1.50)
15	26.7% (151)	28.4% (139)	0.92 (0.70, 1.20)
20	33.4% (174)	31.1% (143)	1.11 (0.85, 1.45)
25	34.7% (144)	30.9% (107)	1.19 (0.88, 1.61)
30	33.3% (160)	32.0% (165)	1.06 (0.82, 1.39)
35	33.0% (146)	32.8% (141)	1.01 (0.76, 1.34)
40	36.9% (45)	37.3% (50)	0.98 (0.59, 1.63)
ASIA Impairment			
Complete Injury	40.3% (1206)	45.6% (887)	0.80* (0.72, 0.90)
Incomplete Injury	17.5% (363)	18.2% (665)	0.95 (0.83, 1.10)
FIM Motor Total (Grouped)			
13-32	62.3% (38)	47.2% (808)	1.85* (1.09, 3.13)
33-52	48.9% (138)	32.9% (277)	1.96* (1.49, 2.57)
53-72	46.7% (354)	27.1% (168)	2.35* (1.87, 2.95)
73-91	25.6% (921)	9.3% (191)	3.37* (2.86, 3.99)
FIM Bed to Chair Transfer			
Total assistance	63.4% (118)	48.4% (912)	1.85* (1.36, 2.53)
Max assistance	50.8% (30)	28.3% (64)	2.62* (1.46, 4.71)
Mod. assistance	38.2% (34)	24.9% (44)	1.87* (1.08, 3.23)
Min. assistance	38.2% (42)	30.5% (58)	1.41 (0.86, 2.30)
Supervision	43.7% (66)	29.8% (50)	1.83* (1.16, 2.91)
Mod. independence	34.0% (680)	17.7% (212)	2.39* (2.01, 2.85)
Independent	23.0% (490)	7.8% (110)	3.54* (2.84, 4.41)

CHART Mobility Total (Grouped)			
0-25	65.8% (156)	59.0% (220)	1.34 (0.96, 1.88)
26-50	48.3% (273)	41.5% (348)	1.32* (1.06, 1.64)
51-75	35.0% (364)	32.4% (418)	1.13 (0.95, 1.34)
76-100	23.7% (747)	17.9% (538)	1.42* (1.25, 1.61)
Socio-Environmental Risk Factors			
Veteran Status			
No	30.3% (781)	25.9% (803)	1.24* (1.11, 1.39)
Yes	24.2% (36)	20.6% (64)	1.23 (0.77, 1.96)
Marital Status			
Never married	33.9% (631)	30.7% (633)	1.16* (1.01, 1.32)
Married	25.6% (475)	22.3% (443)	1.20* (1.03, 1.39)
Divorced	35.7% (322)	32.3% (360)	1.17 (0.97, 1.41)
Separated	34.4% (42)	29.2% (33)	1.27 (0.73, 2.21)
Widowed	34.0% (49)	23.2% (38)	1.71* (1.04, 2.82)
Living with significant other, Partner	26.2% (44)	28.0% (42)	0.91 (0.56, 1.50)
Education Level			
8th grade or less	26.9% (28)	27.8% (32)	0.96 (0.53, 1.73)
9th - 11th grade	40.5% (190)	32.6% (152)	1.41* (1.08, 1.84)
High school diploma or GED	31.2% (792)	28.4% (736)	1.14* (1.01, 1.29)
Associate Degree	31.8% (184)	27.7% (168)	1.22 (0.95, 1.56)
Bachelor’s degree	26.4% (227)	26.1% (287)	1.01 (0.83, 1.24)
Master’s degree	27.7% (89)	22.2% (99)	1.34 (0.96, 1.87)

Doctorate (Ph.D., M.D., law degrees, etc.)	24.0% (23)	24.2% (45)	0.99 (0.56, 1.76)
Other, (3 yr. nursing degree, etc.)	33.0% (31)	34.1% (28)	0.95 (0.51, 1.78)
Family Income Level			
<$25,000	36.8% (766)	33.4% (701)	1.16* (1.03, 1.32)
$25,000-$49,999	28.6% (287)	25.7% (281)	1.16 (0.96, 1.41)
$50,000-$74,999	26.4% (156)	23.2% (150)	1.19 (0.92, 1.54)
$75,000 or more	22.8% (205)	21.1% (233)	1.10 (0.89, 1.37)
Risk Behaviors			
Utilization of VHA Services			
No services, but participant is a Veteran	26.4% (92)	22.4% (91)	1.25 (0.89, 1.74)
Yes	39.6% (91)	25.3% (74)	1.93* (1.33, 2.80)
N/A, not a Veteran	30.8% (1379)	28.3% (1381)	1.13* (1.03, 1.24)
Smoking			
Not at all	28.1% (1073)	27.9% (1289)	1.01 (0.92, 1.11)
Some days	39.7% (140)	28.6% (82)	1.64* (1.18, 2.29)
Everyday	39.5% (346)	25.8% (172)	1.88* (1.51, 2.34)
Alcohol intake per year			
Never	35.0% (726)	32.4% (775)	1.13* (1.00, 1.28)
Once a month or less	32.0% (395)	27.9% (356)	1.21* (1.02, 1.44)
2-4 times/month	26.8% (231)	20.2% (176)	1.45* (1.16, 1.81)
2-3 times/week	22.0% (110)	21.2% (114)	1.05 (0.78, 1.42)
4 or more times/week	23.6% (78)	23.3% (100)	1.02 (0.73, 1.43)
Alcohol intake per day			

None	34.9% (746)	32.1% (793)	1.13* (1.00, 1.28)
1 or 2	27.2% (521)	24.5% (529)	1.15* (1.00, 1.33)
3 or 4	28.2% (183)	20.6% (127)	1.52* (1.17, 1.97)
5 or 6	33.5% (67)	29.7% (55)	1.19 (0.77, 1.83)
7 to 9	27.5% (14)	16.7% (8)	1.89 (0.71, 5.03)
+10 or more	29.4% (10)	29.6% (8)	0.99 (0.33, 3.00)
Binge alcohol intake/ 6+ per day			
Never	32.0% (1323)	28.5% (1337)	1.18* (1.08, 1.30)
Less than monthly	24.2% (125)	23.1% (119)	1.06 (0.80, 1.42)
Monthly	26.8% (55)	18.4% (30)	1.63 (0.98, 2.69)
Weekly	29.0% (31)	22.9% (24)	1.38 (0.74, 2.55)
Daily or almost daily	13.3% (4)	32.4% (11)	0.32 (0.09, 1.15)

*denotes significant findings $p<.05$

Chapter Summary

This chapter presented the findings of the secondary data analysis of the National Spinal Cord Injury Database. Number, percentage, Chi square and Mann Whitney U were presented to define descriptive statistics. Number, percentage and Odds Ratios were presented to determine the association between known PU risk factors and presence of PU, stratified by level of paralysis; and the association between known PU risk factors and level of paralysis in persons with traumatic injury SCI.

CHAPTER FIVE

DISCUSSION

Interpretation of results are discussed in this chapter. Study limitations, implications for nursing practice and recommendations for future nursing research are included.

Interpretation of Findings

This secondary analysis of a cross section of a longitudinal data base showed persons with paraplegia were more likely to report pressure ulcers than persons with tetraplegia. This study also showed that persons with paraplegia and certain pressure ulcer risk factors were more likely to report pressure ulcers than persons with tetraplegia, and in some cases this risk was up to three times greater for paraplegics.

Demographic Risk Factors

For **sex,** males with SCI were significantly more likely than females with SCI to report pressure ulcers ($\chi 2(1) = 12.60$, $p < .001$), and males with paraplegia were significantly more likely to report pressure ulcers than males with tetraplegia, *OR* = 1.17, 95% CI (1.07, 1.29). Although males were not consistently found more likely to report pressure ulcers in the literature review (Brienza et al., 2018; Eslami et al., 2012; Jones et al., 2005; Sadeghi Fazel et al., 2018), males comprise more than 75% of new SCI cases in the United States, which could potentially confound any pressure ulcer risk association analysis (National Spinal Cord Injury Statistical Center, 2020).

For **race**, the Native American, Eskimo and Aleutian group reported the highest percentage of pressure ulcers overall (38.4%), and the highest percentage of pressure ulcers in the paraplegia race group (46.3%, vs 28.1%). However, the finding was not significant, possibly due to the relatively small number of Native Americans, Eskimos and Aleutians in the study

sample (*n*=28), which is reflected in the wide Odds Ratio 95% Confidence Interval, *OR*=2.21, 95% CI (0.82, 5.91). However, this finding could be clinically significant, due to possible biologic factors such as genetic or lipid profiles, which have already been shown to affect cardiovascular and diabetes risk in Native Americans, for example (North et al., 2003). African Americans reported the next highest percentage of pressure ulcers at 35.8%, and this finding is supported by Chen et al. (2005) and Guihan et al. (2008), who found African Americans more likely to develop pressure ulcers than Caucasians. African Americans with paraplegia were significantly more likely to report pressure ulcers than African Americans with tetraplegia, *OR* = 1.36, 95% CI (1.14, 1.63). Overall, Caucasians accounted for 27.8% of pressure ulcers, but Caucasians with paraplegia were significantly more likely to report pressure ulcers than Caucasians with tetraplegia, *OR* = 1.13, 95% CI (1.03, 1.25), which supports the proposed association between paraplegia and presence of pressure ulcer.

In this study, for **ethnicity,** non-Hispanics were consistently more likely to report pressure ulcers than Hispanics. Non-Hispanics reported a significantly higher percentage of pressure ulcers than Hispanics, 29.9% vs 24.1%, $\chi 2(1) = 14.98$, $p < .001$, and these findings are supported by Li et al. (2016). Non-Hispanics with paraplegia were more likely to report a pressure ulcer than non-Hispanics with tetraplegia, *OR* = 1.22, 95% CI (1.12, 1.33), however, no explanation has been found for the difference between Hispanics and non-Hispanics.

Injury Risk Factors

Post injury year differences were significant, U = 10802821, Z = -6.811, $p < .001$. As expected, based on Smith et. al (2008) finding that post injury year group >30 was more likely to have pressure ulcers, the post injury year group 40 in this study reported the highest percentage of pressure ulcers, 37.1%, and post injury year group 1 reported the lowest percentage, 24.9%.

For paraplegia vs. tetraplegia, paraplegics were more likely to report pressure ulcers in post injury year groups 1, 5, 10, 20, 25, 30, and 35, but only findings for post injury year group 5 were significant, *OR* = 1.43, 95% CI (1.17, 1.76). A possible explanation for post injury year group variations could be survival rates for level of injury with and without PU.

Persons with an **ASIA impairment** complete injury level were significantly more likely to report pressure ulcers than persons with an incomplete injury, 42.4% vs. 18.0%, $\chi 2(1) = 763.63$, $p < .001$. This finding is supported by multiple researchers who found completeness of injury was a consistent factor for presence of pressure ulcer (Brienza et al., 2018; Gould et al.,2014; Irgens et al., 2020; Joseph & Nilsson Wikmar, 2016; Lessing et al., 2020; Scheel-Sailer et al., 2013; Verschueren et al., 2011). In contrast with the majority of factors in this study, complete ASIA impairment level was significant for tetraplegia over paraplegia for pressure ulcers, *OR* = 0.80, 95% CI (0.72, 0.90). Persons with tetraplegia and incomplete injury were more likely to report pressure ulcers than persons with paraplegia and incomplete injury, 18.2% vs 17.5%, but the difference was not significant. A possible interpretation of this finding is completeness of injury as a risk factor may be as significant as level of paralysis in pressure ulcer development.

Mobility was measured by FIM motor total score, FIM bed to chair transfer score, and CHART mobility score. For the **FIM Motor Total**, scores among groups were significant, U = 7887847.5, Z = -26.889, $p < .001$, with persons in the lowest mobility group reporting the highest level of pressure ulcers, and paraplegics were significantly more likely to report pressure ulcers than tetraplegics in all FIM motor total groups, (Group 1 FIM total 13-32 *OR* = 1.85, 95% CI [1.09, 3.13], Group 2 FIM total 33-52 *OR* = 1.96, 95% CI [1.49, 2.57], Group 3 FIM total 53-72 *OR* = 2.35, 95% CI [1.87, 2.95], Group 4 FIM total 73-91 *OR* = 3.37, 95% CI [2.86, 3.99]).

The **FIM to bed chair transfer** factor has 7 groups, and the group with the lowest mobility level reported the highest percentage of pressure ulcers, and the group with the highest mobility reported the lowest percentage of pressure ulcers, at 49.7% vs. 16.9%. Six out of these seven groups were significant for persons with paraplegia reporting more pressure ulcers than persons with tetraplegia.

CHART mobility measures the person's ability to navigate successfully in their environment, with a lower score indicating lower mobility. The lowest levels of reported pressure ulcers were found in the highest scoring group, and the highest levels of reported pressure ulcers were found in the lowest scoring group, 61.6% vs. 20.9%, $U = 8243163$, $Z = -24.811$, $p < .001$. All CHART mobility groups reported higher percentages of pressure ulcers for paraplegics vs. tetraplegics, but only two groups had significant findings (Group 2, 26-50 *OR* = 1.32, 95% CI [1.06, 1.64], Group 4, 76-100 *OR* = 1.42, 95% CI [1.25, 1.61]).

For mobility, this study showed that persons with higher mobility had lower likelihood of pressure ulcers prior to stratification by paralysis level, and these findings were supported by DeJong et al. (2014), Delparte et al. (2021), Flett et al. (2019) and Verschueren et al. (2011). However, when groups were divided by paralysis level, persons with higher mobility reported a higher percentage of pressure ulcers. While it may seem intuitive that higher mobility would mean a lower likelihood of pressure ulcers, this would be in contrast to the findings of this study that paraplegics are more likely to develop pressure ulcers than tetraplegics. A possible interpretation of these findings is higher mobility among SCI persons would mean more time spent sitting in a wheelchair, with fewer full body position changes, leading to more time in one position, which would translate to higher interface pressures, thus directly affecting development of pressure ulcers.

Socio-Environmental Risk Factors

For **Veteran** status, non-Veterans were more likely to report pressure ulcers than Veterans, 27.9% vs. 21.7%, $\chi2(1) = 8.07$, $p = .005$; and non-Veterans with paraplegia reported a higher percentage of pressure ulcers than non-Veterans with tetraplegia, *OR* = 1.24, 95% CI (1.11, 1.39). Veterans with paraplegia reported a non-significant higher percentage of pressure ulcers than Veterans with tetraplegia, 24.2% vs. 20.5%.

Overall, the findings from this study supported the findings of Eslami et al. (2012) and Kroll et al. (2007), that **partner status**, or being married, cohabitating or being in an intimate relationship, is protective against pressure ulcers in persons with spinal cord injury. Married persons reported the lowest percentage of pressure ulcers and divorced persons reported the highest, 23.9% vs. 33.8%, $\chi2(5) = 91.32$, $p < .001$. In contrast, when separated into paraplegics vs. tetraplegics, paraplegics were significantly more likely to report pressure ulcers if they never married, were currently married or were widowed. These findings could be related to the interplay between paraplegics being more independent and providing their own care, as compared to tetraplegics who would depend on paid caregivers and partners functioning as unpaid caregivers.

For **education level**, in this study, persons who had a high school diploma or less were more likely to report pressure ulcers, confirming findings by Chen et al. (2005) and (Saunders et al., 2010). Persons with an education level 9^{th} grade – 11^{th} grade reported the highest percentage of pressure ulcers at 36.6%, $U = 10570853$, $Z = -5.745$ $p < .001$. Paraplegics with 9-11^{th} grade education or with a high school diploma (or GED equivalent) were more likely to report pressure ulcers than tetraplegics with the same education level. Education level may be linked to pressure ulcer status through income level, as we know higher education affects income level (Tamborini

et al., 2015) and persons with lower income may not have the resources needed to provide effective pressure ulcer prevention care.

This study found that **family income** correlated with pressure ulcer status, which is consistent with previous studies (Saunders et al., 2010; Saunders et al., 2012). Persons with higher family income reported significantly lower pressure ulcer percentages, and persons with lower family income reported significantly higher pressure ulcer percentages, $U = 8013029.5$, $Z = -11.738$, $p < .001$. Paraplegics with lower family income were significantly more likely to report pressure ulcers than tetraplegics, *OR* = 1.16, 95% CI (1.03, 1.32).

Risk Behaviors

Paraplegic Veterans who utilized **VHA health care** services reported a higher percentage of pressure ulcers than tetraplegic Veterans who did not utilize VHA health care in this study, *OR* = 1.93, 95% CI (1.33, 2.80). This finding conflicts with Smith et al. (2008), who found that Veterans with traumatic injury SCI who received care at non-VHA settings were more likely to develop pressure ulcers than Veterans who only received VHA care. A possible explanation could be the way the study questions are phrased. Veterans were asked if they had received any VHA health services since the last NSCID interview, and Veterans were not specifically asked if they had received any wound care and/or SCI specialized care.

Overall, persons who did not **smoke** reported the lowest percentage of pressure ulcers, which supports the findings Li et al. (2016) and Saunders & Krause (2010). However, the highest percentage of pressure ulcers was reported in persons who smoked some days, not everyday, as would be expected if there was a true association between smoking and pressure ulcer status. For paraplegia vs. tetraplegia, persons with paraplegia who smoked some days or who smoked everyday were signficantly more likely to report pressure ulcers than persons with tetraplegia

who smoked the same amount (some days *OR* = 1.64, 95% CI [1.18, 2.29]); (everyday *OR* = 1.88, 95% CI [1.51, 2.34]).

Literature review reports inconsistent findings linking **alcohol intake** with pressure ulcer development, except for a link between binge alcohol and development of pressure ulcers. Overall, persons who reported no alcohol intake over the past year, no daily intake of alcohol and no binge drinking reported the highest percentage of pressure ulcers. Persons who reported the lowest percentage of pressure ulcers reported drinking alcohol 2-3 times per week, 7-9 drinks per day or monthly binge drinking, meaning at least one day of drinking 6+ alcoholic drinks. Paraplegics who never consumed alcohol per year, consumed alcohol once a month or less, 2-4 times per month were more likely to report pressure ulcers than tetraplegics. For daily alcohol intake, paraplegics who consumed no alcohol or who consumed 1-4 drinks daily were more likely to report pressure ulcers than tetraplegics. For binge alcohol intake, paraplegics who recorded no binge alcohol intake were more likely to report pressure ulcers than tetraplegics. The variation in findings related to alcohol and smoking could be due to access, meaning that a person who is tetraplegic would be dependent on a caregiver to provide a cigarette or alcoholic drink, and a person who is paraplegic would have a greater ability to smoke or drink alcohol at will.

Study Limitations

There are several study limitations. This is a secondary data analysis of a multi-center database that relies in part on self-reporting of variables, and findings may not be generalizable beyond the study sample due to variations in care outside the SCI model centers. The selected database does not include detailed information on pressure ulcer prevention practices such as

repositioning and support surface utilization. In addition, this is an associational study, therefore, causation cannot be established.

Conclusions

This secondary analysis of a cross section of a longitudinal data base showed persons with paraplegia were more likely to report pressure ulcers than persons with tetraplegia. Seventy-seven PU risk subfactors were examined in this study, and persons with paraplegia reported a higher percentage of pressure ulcers than persons with tetraplegia in sixty-five of the studied factors. Thirty-six of those findings were significant, with thirty-five of the thirty-six factors showing a greater association of paraplegia with reporting PU than tetraplegia. This study contributed to the field of study of pressure ulcer risk factors in persons with a spinal cord injury by confirming the novel findings of Cowan et. al (2019) who unexpectedly found persons with paraplegia at greater risk for pressure ulcer

Implications for Nursing Practice

There are multiple implications for nursing practice. Education for persons with spinal cord injury should emphasis the need for frequent repositioning, and persons with paraplegia should be informed of their greater risk for pressure ulcers. Any caregivers, both paid and unpaid, should be included in pressure ulcer prevention discussion. Smart technology, including smart phones and watches, could be utilized for automatic notifications for repositioning. Paraplegics should also be encouraged to have seat mapping with interface pressure measurements to create a custom seating support cushion.

Recommendations for Future Nursing Research

There are several recommendations for future nursing research. Study findings indicate a need for further exploration of the link between ASIA injury level and level of paralysis on

pressure ulcer development. Another avenue for research would be correlating the findings from this study with location of pressure ulcers for paraplegics and tetraplegics. Bone-muscle crosstalk, or the biochemical communication between muscle and bone, could play a role in PU development. Spinal cord injury leads to bone and muscle deterioration, which leads to osteoporosis and sarcopenia. Bone and muscles release hormones to communicate with each other, but the effect of spinal cord injury on this biochemical communication, and subsequent effect on PU development, is unknown. Currently, there are no biomarkers associated with pressure ulcer development, and the identification of a biomarker would be the gold standard for early identification and prevention of pressure ulcers.

Chapter Summary

Interpretation of results were discussed in this chapter. Study limitations, implications for nursing practice and recommendations for future nursing research were included.

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Appendix A

ASIA

AMERICAN SPINAL INJURY ASSOCIATION

InSTeP

International Standards Training E Program

CERTIFICATE OF COMPLETION

DonnaLee Pollack

has successfully completed InSTeP, the online training for the International Standards for the Classification of Spinal Cord Injury. This certificate is valid for 1 year from the date of issuance.

Patricia Duncan

Executive Director, ASIA

4/10/2020 9:49:45 PM

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Education (ACCME) through the joint providership of The Institute for Medical Studies and ASIA. The Institute for Medical Studies is accredited by the ACCME to provide continuing medical education for physicians.

The Institute for Medical Studies designates this live activity for a maximum of 6 AMA PRA Category 1 Credit(s)™.

Version: InSTeP: International Standards 2019

Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Appendix B

On Aug 3, 2021, at 07:23, Alvarez, Lisa <lisa.alvarez@uta.edu> wrote:

Hello Donnalee,

Thank you for reaching out. You do not need IRB approval to use this secondary data source - it is deidentified and public.

Let me know if you have any other questions.

Good luck with your dissertation,
Lisa

LISA ALVAREZ
IRB Specialist
Office of Regulatory Services
Lisa.Alvarez@uta.edu
Direct: 817-272-9329
Office: 817-272-3723
https://resources.uta.edu/research/regulatory-services/human-subjects/index.php
Chat with me on Teams or email regulatoryservices@uta.edu to request a virtual meeting or phone call!

UNIVERSITY OF TEXAS ARLINGTON

From: Pollack, Donnalee <donnalee.pollack@mavs.uta.edu>
Sent: Monday, August 2, 2021 7:24 PM
To: regulatoryservices <regulatoryservices@uta.edu>
Subject: Question re: secondary analysis of freely available de-identified data

Hello,

I am a PhD student in the College of Nursing and Health Innovation, and I would like to perform a secondary data analysis of the National Spinal Cord Injury Model Systems (SCIMS) Database. The data are de-identified and freely available.

SCIMS Database website:
https://www.nscisc.uab.edu/Research/NSCISC_DatabasePublicUse

A screen shot from the database website is attached, and states:
"De-Identified Data are stripped of all HIPAA-defined identifiers, including names, geographic subdivisions smaller than a state, elements of dates (except year) related to an individual,

telephone numbers, fax numbers, email addresses, social security numbers, and medical record numbers."

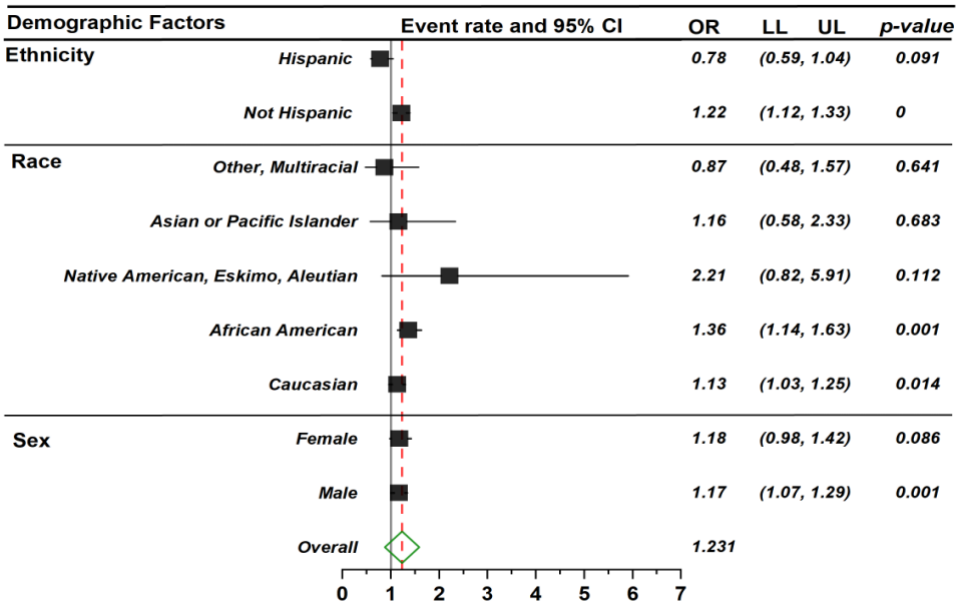
Do I need to obtain IRB approval from UTA prior to data analysis of the de-identified data for my PhD dissertation?

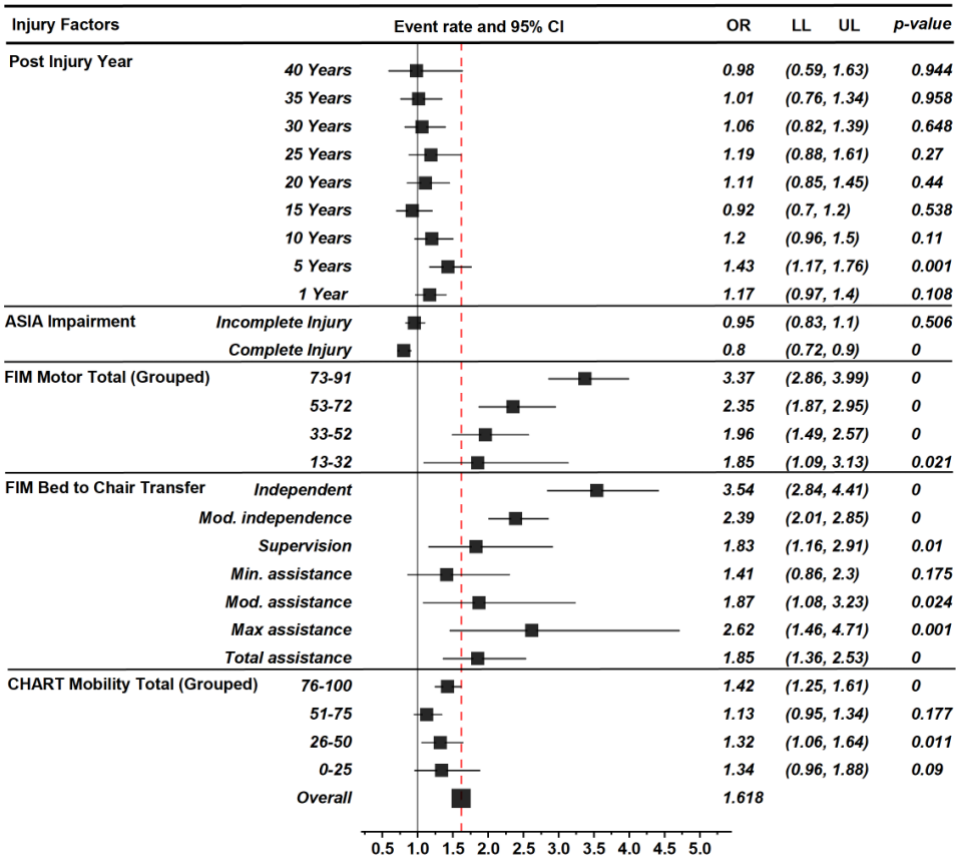
Thank you for your help,
DonnaLee

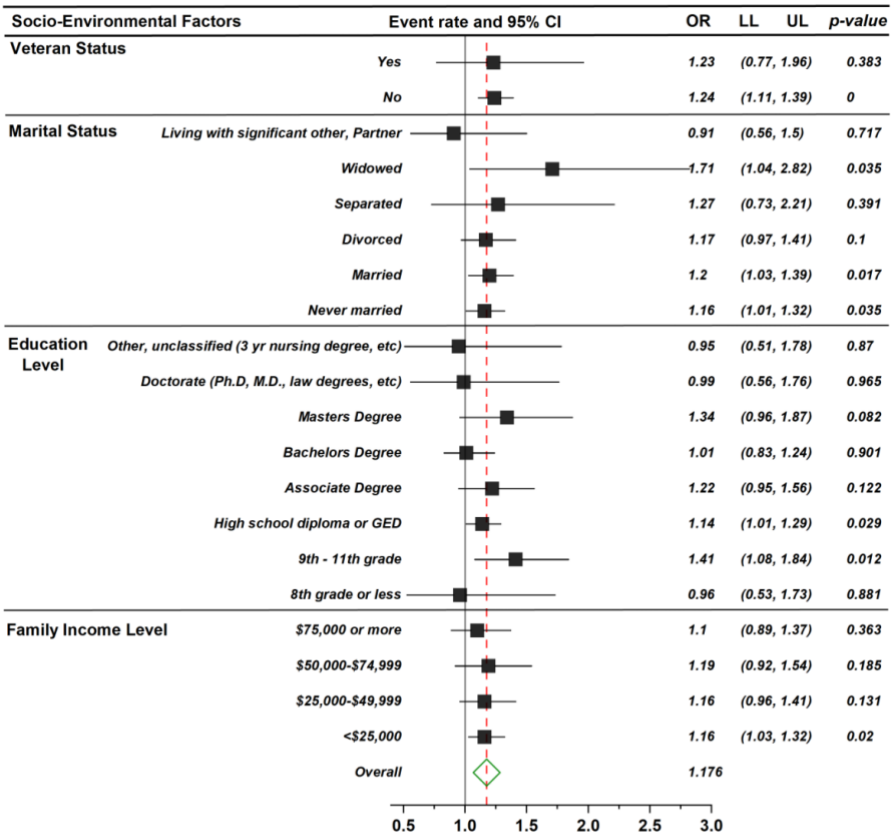
DonnaLee Pollack, RN, MSN, MPH, FNP-C, CWCN-AP
PhD Graduate Student
Jonas-Smith Trust Veterans Healthcare Scholar 2018-2020
College of Nursing and Health Innovation
Member, Brotto Lab
http://www.uta.edu/conhi/research/nrl/brotto-lab/index.php
Bone-Muscle Research Center
http://www.uta.edu/conhi/research/bmrc/index.php
University of Texas at Arlington

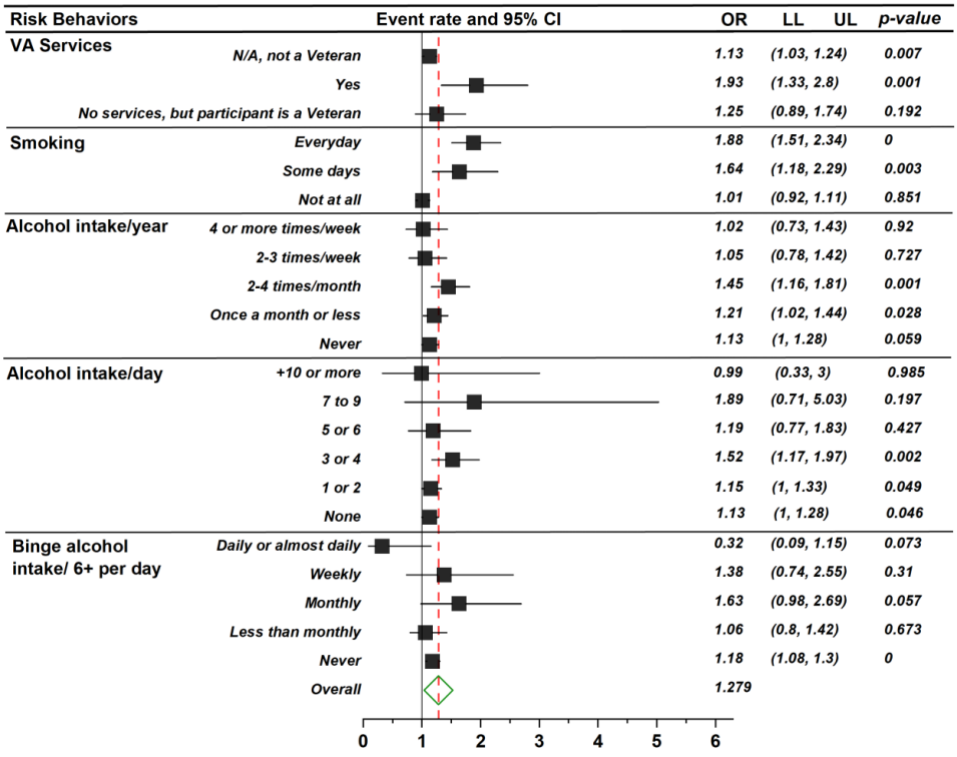
donnalee.pollack@mavs.uta.edu

Appendix C


Demographic Factors
Event rate and 95% CI
OR
LL
UL
p-value
Ethnicity
Hispanic
0.78
(0.59, 1.04)
0.091
Not Hispanic
1.22
(1.12, 1.33)
0
Race
Other, Multiracial
0.87
(0.48, 1.57)
0.641
Asian or Pacific Islander
1.16
(0.58, 2.33)
0.683
Native American, Eskimo, Aleutian
2.21
(0.82, 5.91)
0.112
African American
1.36
(1.14, 1.63)
0.001
Caucasian
1.13
(1.03, 1.25)
0.014
Sex
Female
1.18
(0.98, 1.42)
0.086
Male
1.17
(1.07, 1.29)
0.001
Overall
1.231
0
1
2
3
4
5
6
7


Injury Factors
Event rate and 95% CI
OR
LL
UL
p-value
Post Injury Year
40 Years 0.98 (0.59, 1.63) 0.944
35 Years 1.01 (0.76, 1.34) 0.958
30 Years 1.06 (0.82, 1.39) 0.648
25 Years 1.19 (0.88, 1.61) 0.27
20 Years 1.11 (0.85, 1.45) 0.44
15 Years 0.92 (0.7, 1.2) 0.538
10 Years 1.2 (0.96, 1.5) 0.11
5 Years 1.43 (1.17, 1.76) 0.001
1 Year 1.17 (0.97, 1.4) 0.108
ASIA Impairment
Incomplete Injury 0.95 (0.83, 1.1) 0.506
Complete Injury 0.8 (0.72, 0.9) 0
FIM Motor Total (Grouped)
73-91 3.37 (2.86, 3.99) 0
53-72 2.35 (1.87, 2.95) 0
33-52 1.96 (1.49, 2.57) 0
13-32 1.85 (1.09, 3.13) 0.021
FIM Bed to Chair Transfer
Independent 3.54 (2.84, 4.41) 0
Mod. independence 2.39 (2.01, 2.85) 0
Supervision 1.83 (1.16, 2.91) 0.01
Min. assistance 1.41 (0.86, 2.3) 0.175
Mod. assistance 1.87 (1.08, 3.23) 0.024
Max assistance 2.62 (1.46, 4.71) 0.001
Total assistance 1.85 (1.36, 2.53) 0
CHART Mobility Total (Grouped)
76-100 1.42 (1.25, 1.61) 0
51-75 1.13 (0.95, 1.34) 0.177
26-50 1.32 (1.06, 1.64) 0.011
0-25 1.34 (0.96, 1.88) 0.09
Overall 1.618
0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0


Socio-Environmental Factors
Event rate and 95% CI
OR
LL
UL
p-value
Veteran Status
Yes
1.23
(0.77, 1.96)
0.383
No
1.24
(1.11, 1.39)
0
Marital Status
Living with significant other, Partner
0.91
(0.56, 1.5)
0.717
Widowed
1.71
(1.04, 2.82)
0.035
Separated
1.27
(0.73, 2.21)
0.391
Divorced
1.17
(0.97, 1.41)
0.1
Married
1.2
(1.03, 1.39)
0.017
Never married
1.16
(1.01, 1.32)
0.035
Education Level
Other, unclassified (3 yr nursing degree, etc)
0.95
(0.51, 1.78)
0.87
Doctorate (Ph.D, M.D., law degrees, etc)
0.99
(0.56, 1.76)
0.965
Masters Degree
1.34
(0.96, 1.87)
0.082
Bachelors Degree
1.01
(0.83, 1.24)
0.901
Associate Degree
1.22
(0.95, 1.56)
0.122
High school diploma or GED
1.14
(1.01, 1.29)
0.029
9th - 11th grade
1.41
(1.08, 1.84)
0.012
8th grade or less
0.96
(0.53, 1.73)
0.881
Family Income Level
$75,000 or more
1.1
(0.89, 1.37)
0.363
$50,000-$74,999
1.19
(0.92, 1.54)
0.185
$25,000-$49,999
1.16
(0.96, 1.41)
0.131
<$25,000
1.16
(1.03, 1.32)
0.02
Overall
1.176
0.5
1.0
1.5
2.0
2.5
3.0


Risk Behaviors
Event rate and 95% CI
OR
LL
UL
p-value
VA Services
N/A, not a Veteran 1.13 (1.03, 1.24) 0.007
Yes 1.93 (1.33, 2.8) 0.001
No services, but participant is a Veteran 1.25 (0.89, 1.74) 0.192
Smoking
Everyday 1.88 (1.51, 2.34) 0
Some days 1.64 (1.18, 2.29) 0.003
Not at all 1.01 (0.92, 1.11) 0.851
Alcohol intake/year
4 or more times/week 1.02 (0.73, 1.43) 0.92
2-3 times/week 1.05 (0.78, 1.42) 0.727
2-4 times/month 1.45 (1.16, 1.81) 0.001
Once a month or less 1.21 (1.02, 1.44) 0.028
Never 1.13 (1, 1.28) 0.059
Alcohol intake/day
+10 or more 0.99 (0.33, 3) 0.985
7 to 9 1.89 (0.71, 5.03) 0.197
5 or 6 1.19 (0.77, 1.83) 0.427
3 or 4 1.52 (1.17, 1.97) 0.002
1 or 2 1.15 (1, 1.33) 0.049
None 1.13 (1, 1.28) 0.046
Binge alcohol intake/ 6+ per day
Daily or almost daily 0.32 (0.09, 1.15) 0.073
Weekly 1.38 (0.74, 2.55) 0.31
Monthly 1.63 (0.98, 2.69) 0.057
Less than monthly 1.06 (0.8, 1.42) 0.673
Never 1.18 (1.08, 1.3) 0
Overall 1.279
0
1
2
3
4
5
6