ASSESSING THE PREDICTIVE VALIDITY OF THE SALZBERG SCALE DURING ACUTE CARE AND INPATIENT REHABILITATION

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Pressure ulcers (PrU) are a leading secondary medical complication in the spinal cord injury (SCI) population. With over two hundred known risk factors, PrU prevention is extremely complex but can provide an astounding difference in a patient's recovery. Multiple risk assessment scales allow us to quantify risk across a broad range of populations, yet the literature provides little evidence that these tools are representative of PrU development in the SCI population. The Pressure Ulcer Assessment Scale for the Spinal Cord Injured (Salzberg Scale) is a risk assessment scale specific to the SCI population, composed of fifteen risk factors that divide PrU development risk into four categories. The objective of this thesis is to assess the predictive validity of the Salzberg Scale during acute care and inpatient rehabilitation following spinal cord injury.

Data was extracted from a primary study on PrU outcomes for newly injured traumatic SCI patients in acute care and inpatient rehabilitation. A secondary analysis assigned subjects a raw Salzberg Scale score based on collected medical information and Salzberg Scale component definitions. The Salzberg scores were used to compute sensitivities, specificities, and accuracy of the scale with newly defined risk cut-off scores for acute hospitalization and inpatient rehabilitation.

Sensitivity and specificity were calculated for the scale's ability to predict PrU ranging from two to 22 days after administration of the Salzberg Scale risk assessment tool. The use of

the scale in the acute care hospitalization to assess risk for PrU within 2-3 days showed the only strong predictive results with an area under the curve (AUC) of 0.8482 at the indicated cutoff score of 15. The sensitivity of 100.0% and a specificity of 75.0%, showed a more accurate prediction balance than the validation study conducted by Salzberg on a broader population sample. Overall, failure of the scale's predictive ability to predict a pressure ulcer over a longer time period suggests further studies must be completed in order for the scale be recommended for implementation in an inpatient rehabilitation setting.

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PREFACE

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1.0 INTRODUCTION

1.1 DISCUSSION OF PROBLEM

Pressure ulcers (PrU) are a leading secondary medical complication in the spinal cord injury (SCI) population.[51, 65] Pressure ulcer development has been known to interfere with the physical, psychological, and social aspects of well-being along with impacting overall quality of life.[48] With over 200 known risk factors and treatment costing about $1.3 billion annually, pressure ulcer prevention is extremely complex but can provide an astounding difference in a patient's recovery and save money for the patient and hospital system.[19]

More than thirty-eight scales allow us to quantify risk across a broad range of populations, yet the literature provides little evidence that these tools are representative of pressure ulcer development in the SCI population.[7, 19, 51] Unlike the most popular and well researched scales such as the Braden Scale, the Norton Scale and the Waterlow Scale, the Pressure Ulcer Assessment Scale for Spinal Cord Injured (referred to as Salzberg Scale or SCIPUS) is a risk assessment scale created specifically to identify risk of pressure ulcer development in the SCI population.

Proper identification of individuals with SCI at risk for PrU development and initiation of appropriate preventative practices is necessary to lower the PrU incidence and prevalence.[7] Evaluation of risk assessment scales and other general prevention measures have been flagged as

crucial by various health reviews in the United States. Healthy People 2010 lists reduction of pressure ulcer incidence as an a main objective for healthcare providers.[71] In addition, more research on preventative tools is urgent in accordance to the Deficit Reduction Act of 2005. As of 2008, hospitals are no longer to receive compensation or reimbursement for "care related conditions" such as pressure ulcers that occur during "incident hospitalization" as they were deemed a preventable condition.[32]

Overall, if risk assessment and prevention are not incorporated in healthcare practice, pressure ulcer development will continue to be a burden on the lives of those with SCI in various physical, psychological, as well as economical ways. Defining the risk cut off scores of the Salzberg Scale is essential in order to properly assess the already high-risk SCI population. Limited use of the Pressure Ulcer Assessment Scale for the Spinal Cord Injured suggests positive findings for the general SCI population, yet the tool has not been analyzed for the acute hospitalization and inpatient rehabilitation of new, traumatic SCI individuals. The objective is to evaluate the psychometric properties of the Salzberg scale in order to provide evidence predictive validity in new, traumatic SCI individuals.

1.2 OBJECTIVES AND SPECIFIC AIMS

The objective of this thesis was to assess the predictive validity of the Salzberg Scale during acute care and inpatient rehabilitation following spinal cord injury.

This retrospective secondary analysis covered three main aims. Each aim was accomplished using the Rehabilitation Engineering Research Center (RERC) on Spinal Cord

Injury clinical data collected on new, traumatic spinal cord injury subjects from acute care and inpatient rehabilitation settings. Collected from 2008 through 2012, the data set included detailed objective clinical tests including diagnoses and medical comorbidities, pain and depression scores, ambulatory and medication descriptions, as well as Braden Scale scores for each subject assessment date. Through data outcome compilation, raw Salzberg Scale scores were calculated and used for analysis of psychometric properties of the scale.

The initial aim verified the generalized statement that the Salzberg Scale predicts pressure ulcer formation in the SCI population. The descriptive analysis assessed the difference in scores between those with and without pressure ulcer formation. The second aim evaluated risk cut-off points within the RERC study population. New sensitivities and specificities were calculated in order to define potential "Risk Cut-Off Point" associated with new, traumatic SCI. Each population will have its own specific risk scores associated with specific characteristics of its population demographics and injury severity. This is the basis of newly calculated risk cut-off point establishment. Thirdly, the new sensitivities and specificities were used to evaluate the accuracy and power of the Salzberg Scale scoring using an ROC Curve.

1.3 ORGANIZATION OF THE THESIS

Six chapters follow the introduction. Chapter 2 is a review of the literature on pressure ulcer research focusing on risk factors for the development of pressure ulcers in the SCI and other populations. Chapter 3 is a review of PrU prevention techniques, specifically the use of validated risk assessment. Chapter 4 contains a description of the research design and methods

used in this study. Chapter 5 provides the results. Chapter 6 is a discussion of the results. Lastly, Chapter 7 summarizes the work, explains limitations, and gives future directions of the research.

2.0 REVIEW OF THE LITERATURE

2.1 PRESSURE ULCER DEVELOPMENT IN INDIVIDUALS WITH SPINAL CORD INJURY (SCI)

2.1.1 Definition

For this study, the definition of a pressure ulcer is defined by the National Pressure Ulcer Advisory Panel. Based on the 2012 revision, pressure ulceration is defined by the following: "A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated."[56] The majority of pressure ulcers are found below the waist, specifically the skin overlying the bony prominences such as sacrum, trochanters, ischium, and heels, but can be found anywhere on the body where pressure and compressive forces are maintained for a sufficient period of time.[9, 49, 76] PrU are also known as decubitus ulcers, pressure sores, and/or bed sores. [9]

2.1.2 Clinical Diagnosis and Staging

Staging of PrUs is completed after the clinical diagnosis and identification of PrU development. This can be completed though visual inspection and/or palpation.[37] Various systems have been developed for the classification of pressure ulcers. Consistently recognized by the Wound Ostomy and Continence Nurses Society (WOCN), the National Pressure Ulcer Advisory Panel (NPUAP) staging system is a favored set of guideline for pressure ulceration diagnosis. [2, 22] Created in 1989, the original NPUAP staging system was composed of a four-stage system similar to the earliest systems created by Guttmann in 1955.[13] Based on the growing popularity of the NPUAP Staging System, the European Pressure Ulcer Advisory Panel (EPUAP) also developed a similar system in 1998. The EPUAP Staging System was not adopted for diagnostic use in the United States since inter-observer reliability was low and there is still a need for clarity within the staging definitions.[1, 11]

Following the creation of the NPUAP Staging System, factors such as accuracy, consistency, and inter-rater reliability of the staging system were investigated. Of the four stages, nurses exhibited uncertainty differentiating between Stage II and Stage III pressure ulcers. Diagnostic inaccuracies led to the reevaluation of the NPUAP Staging System.[13] At the 2005 Consensus Conference, NPUAP acknowledged the idea that suspected deep tissue injury (sDTI) as well as unstageable categories were etiologies of pressure ulcer formation yet they could not be accurately described by the existing staging system.[14] Through solicitation of current facilities using NPUAP guidelines, the NPUAP presented a newly drafted scale for participants to comment on "the qualities of clarity, succinctness, accuracy, and discrimination for each definition."[13] Refinement of the updated staging system was solidified at the 2007 NPUAP Consensus Conference.[29] The most recent revision (2012) was adopted and is currently used

today. The current NPUAP staging definitions are represented in Table 1.[56] Today, the NPUAP and EPUAP have a unified recommendation and definition system that is referenced often.[35]

Table 1. 2012 NPUAP Staging System

Stage	2012 NPUAP Staging System Definitions
1	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicated "at risk persons" (a heralding sign of risk)
2	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.* This stage should not be used to describe skin tears, tape burns, incontinence associated with dermatitis, maceration or excoriation. *Bruising indicates deep tissue injury.
3	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscles are *not* exposed. Slough may be present but does not obscure the depth of tissue loss exposed. Slough may be present but does not obscure the depth of tissue loss. *May* include undermining and tunneling. The depth of a Category/Stage III pressure ulcer varies by anatomical location.
4	Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location.
Suspected Deep Tissue Injury (DTI)	Purple or maroon localized are of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or *shear*. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones.
Unstageable	Full thickness tissue loss in which the based of the ulcer is covered by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV.

2.1.3 Etiology

Though the exact etiology of pressure ulceration is not fully understood, researchers have hypothesized pressure ulcer origins through four pathophysiological pathways.[75] The first of the hypotheses is based on localized ischemia caused by capillary occlusion reasoned by pressure loading.[23, 27] Ischemia, the insufficient supply of blood to an organ, prevents oxygen, essential nutrients and metabolites from being carried to and away from cells. This, in turn, causes the buildup of various cell waste products leading to the degradation and death of localized cells.[53,60] Another explanation refers to reperfusion injury theory. Reperfusion injury is an injury that results from the accumulation of inflammatory substances in the body as blood is reintroduced to an area previously affected by ischemia.[38] The third hypothesis of pressure ulcer encompasses the impaired lymphatic function in the body which causes accumulation of metabolic waste products and enzymes exhibiting similar responses as ischemia in a previous hypothesis.[50]

Shear force may increase of PrU development.[43] Shear forces are parallel to the skin surface. It has the ability to damage blood vessels and compromise the blood supply leading to ischemia, necrosis, and cellular death.[49, 53] An example of shear force occurs when a person is in a hospital bed. When the back of the mattress is elevated, the weight of the upper body slides downward toward the bottom of the hospital bed. There is an opposing, parallel force that causes deformation. Though previously suggested that the frictional force may lead to the development of PrU, the 2009 International NPUAP-EPUAP Pressure Ulcer Prevention and Treatment Clinical Practice Guideline eliminated the frictional force as a factor. Despite friction resisting the shearing force, friction relates mainly to skin injuries that are not considered to be a PrU. Friction that causes shear strain in the tissue potentially leads to the increase in tissue breakdown,

which leads to PrU development. The sole force of friction cannot allow an injury to be categorized as a PrU.[6]

Overall, there are two popular theories describing the mechanisms of pressure ulcer development and progression. The first theory states that pressure ulcers form deep within the muscle tissue, close to the bone, and move outward toward the superficial layers of the skin. This is known as the deep tissue injury theory.[40] Deep tissue injury arises when the muscle layers adjacent to the bone endure sustained loading. They are not necessarily visible until the unrelieved, ischemic injury and local necrosis reach the outer layers of the skin.[49, 53, 61, 73] The second, and lesser popular model, is the top to bottom model. This model states that pressure ulcer formation begins from the superficial skin destruction at the dermis through forces such as friction, and the injury proceeds inward toward the deeper tissue.[15, 61]

2.1.4 Risk Factors

Due to the drastically altered physiology of a SCI patient immediately after injury, pressure ulcer formation is a leading health care problem.[41] Major factors associated with pressure ulcer development are level of activity, ambulation and level of mobility, incontinence, as well as severity of injury.[7, 10, 66] There are over 200 noted risk factors for pressure ulcer development in the SCI population.[19] The fifteen risk factors chosen by Salzberg will be discussed thoroughly in the third chapter of this thesis. These factors include level of activity, level of mobility, completeness of SCI, urinary incontinence or moisture, level of spasticity, age (years), tobacco usage, past or current pulmonary disease, past or current cardiac disease, glucose levels, past or current renal disease, impaired cognitive function, health care setting of pressure ulcer development, current albumin levels, and current hematocrit levels.[67] Each of these fifteen risk

factors designated in the Pressure Ulcer Risk Assessment Scale for the Spinal Cord Injured will be discussed in detail on later pages.

2.1.5 Incidence and Prevalence

PrU incidence and prevalence varies by population and healthcare setting. In 2005 Chen et al conducted a study noted in the review using secondary complication data from the National Spinal Cord Injury Database. Chen et al. identified that the risk of developing a PrU was consistent over the first ten years post-injury (prevalence rate of 11.5% to 14.3% for Stage II or higher PrU) while risk eventually increased 15 years post injury (prevalence rate of 21.0% Stage II or higher PrU).[20] Pagliaccci et al found that 26.9% of 684 people with newly, traumatic SCI admitted to one of 32 rehabilitation centers in Italy presented with one or more PrU as well.[54] It has been recommended that the development of innovative strategies for prevention of PrU is needed to lower the high incidence and prevalence of PrU.[22]

Incidence and prevalence of pressure ulcer development has been difficult to collect based on various pressure ulcer classification systems, inconsistent data collection and identification from multiple sources, as well as studies evaluating prospectively versus retrospectively.[31] According to data collected from the Model Spinal Cord Injury Systems (MSCIS) one third of individuals with SCI will develop at least one PrU in their initial acute or inpatient rehabilitation care. Thereafter, between 15%-33% of persons with SCI will develop pressure ulcers once in community settings.[41] With a range of 232,000 to 316,000 individuals with SCI in the United States, up to 85% will develop a pressure ulcer at some point during their life.[47, 62, 72] In addition, PrU-related complications cause up to 60,000 deaths a year, 7%-8% of these involving those with persons with SCI. [44]

2.1.6 Financial Impact

Though costs of treating pressure ulcers vary based on severity of the ulcer, each year, the United States spends more than $1.3 billion annually on treatment costs.[19, 43, 65] The highest estimation is upwards of $5 billion for treatment and management of pressure ulcers.[44, 52] In 2011, the cost of healthcare and living expenses of SCI patients ranged from $1,461,255 in the case of a minor injury all the way to the exorbitant $4,373,912 in the case of high level tetraplegia (C1-C4).[72] Out of these estimated healthcare and living expenses, 25% are attributed to treatment of pressure ulcers.[19]

Partial thickness pressure ulcers (Stage I or Stage II) are estimated to cost $125-$451 per incidence. For more severe pressure ulcers, full thickness pressure ulcers (Stage III and Stage IV and sDTI) cost an estimated $14,000-$25,000 per ulcer to treat.[58, 80] The cost of the pressure ulcer is higher with a more severe stage based on longer healing times and increased likelihood for complications.[46, 51] The magnitude of pressure ulcer development has been linked to increased hospital stays of approximately four days as well as prolonged nursing care time by nearly fifty percent.[30, 80] As noted, pressure ulcer development comes at a “tremendous personal and societal cost.”[45, 51] Implementation of preventative measures may decrease pressure ulcer incidence and in turn lower its financial impact.[12, 25, 26, 34, 51]

3.0 ASSESSMENT SCALES TO ASSESS PRESSURE ULCER RISK

3.1 SCALES FOR GENERAL POPULATION

3.1.1 The Braden Scale, Norton Scale, and Waterlow

Various risk assessment scales have been created in order to aid clinicians in the proper implementation of preventative measures for patients at risk for PrU development. Whether in a nursing home setting or a surgical unit, risk assessment scales have been made to be general or modified to a specific population at risk for developing PrU.[16, 59] It has been concluded that informal risk assessment such as skin integrity examination of a patient cannot take the place of a formal risk assessment.[7] Three of the most common PrU risk assessment scales are the Braden Scale, Norton Scale and the Waterlow Scale.

The first risk assessment scale created to evaluate PrU development risk was the Norton Scale in 1962.[70] Developed for the geriatric population, it is composed of five items: physical condition, mental state, activity, mobility, and incontinence. Each item is rated from 1 (very bad) to 4 (very good) with a maximum score of 20 points.[57] Scrutinized for its validity, patients with a cutoff score of fifteen or sixteen points or higher are considered at risk for pressure ulcer development.[30] Newer scales have been modeled off of the Norton Scale by redefining risk factors as described by recent research studies.[26]

The second scale created and modeled after the Norton scale is the Waterlow Scale. Known to be more accurate at predicting pressure ulcers in orthopedic patients as compared to Braden Scale and Norton, the Waterlow Scale consists of eight items: build/weight for height, visual assessment of the skin in the area at risk, sex and age, continence, mobility, appetite, medications, and special risk factors. Unique to the scale is its weighted risk factors that vary in score distribution depending on the risk indicator contribution to PrU development.[30, 57] Receiving a score of 16 or above, defined cutoff point for at-risk patients in clinical studies predicts PrU development. This means that patients are considered at higher risk when there is an increase in the sum of the eight categories. The scale has patient risk broken down into categories of at risk, high risk, and very high risk.[3, 78]

The third and most popular scale is the Braden Scale. Created it 1987, it has been concluded to be the best risk assessment scale due to its extensive reliability and validity testing to date.[55, 69] Composed of six subscales, the Braden Scale incorporates sensory perception, activity, mobility, moisture, nutrition, and friction/shear. Each subcategory is rated from 1 to 4 points with friction/shear rated only from 1 to 3 points. Unlike other scales, a score lower than 16-18 points subjects a patient to be at higher risk for PrU development. Since its introduction, various cut-off scores have been recommended based on the specific population of patients. Studies validating the use of this scale have had sensitivities ranging from 79% to 100% over a variety of treatment settings.[43] The Braden scale has multiple strengths. Whether it be its high utility in clinical or research settings, existing validity and reliability evidence, or inclusion of the latest indicative factors of PrU risk, the Braden Scale has had consistent implementation since its creation.[39]

Between these three scales, it is very difficult to compare the predictive validity as many validation studies, characteristic research methods, and outcome measures are evaluated in each study.[8] In some studies, the Waterlow and Braden are represented as having the best sensitivities whereas the Norton Scale has the best specificity. [8, 57] Contrasting these studies, there are articles which state that the Braden Scale results has superior predictive validity based on prospective versus retrospective studies. [24] Overall, all risk assessment instruments identified more patients at risk of PrU development over clinical judgment alone.[8]

3.1.2 Validity for SCI Patients

Though the Norton Scale, Waterlow Scale, and Braden Scale have been validated for use in hospital settings and nursing homes, they lack application and validation of specific populations such as the SCI population.[51] The predictive value of existing risk assessment tools are imprecise for the SCI population as they were originally designed for the general medical population.[33] WB Mortenson et al. completed a systematic review of risk assessment scales for pressure ulcer development using the SCI population.[51] Of the seven scales incorporated into the review, the Norton Scale, Waterlow Scale, and Braden Scale were evaluated.

Based on previous studies regarding reliability, validity, administrator burden and respondent burden, each of these three scales had poor to adequate predictive validities with the spinal cord injury population. Being that the spinal cord injury population is initially at high risk for PrU development, it is crucial that a risk assessment scale identify the specific risk of this population.[36] As stated so precisely in an analysis describing usability of surveys on various population, "[G]eneralizability Theory indicates that [previous] results cannot be applied to

individuals with SCI, which undermines confidence in these scales to reproduce stable results over time with this population."[21] This means that there were such a small subpopulation of SCI subjects included in the various studies assessing the three scales, that the overall predictive validity could not be attributed to the SCI subpopulation's contribution.

Lack of content validity causes institutions to assume the scale's application to the population. Given that the Braden Scale and Waterlow performed similarly and closest to adequate scoring based on psychometric property evaluation, these scales are the best tools that are currently available despite benefitting from additional testing within the SCI population.[51] Included in the systematic review was the Salzberg Scale. This was the only scale made specifically for the risk assessment of the SCI population. Despite its higher sensitivity (74.7%) and specificity (56.6%) scores, it could not be deemed the best assessment tool since has not been validated. Mortenson et al. advised that the Salzberg Scale undergo further psychometric testing in order for recommendation. Lastly, more prospective studies that allow head-to-head comparison of these risk assessment scales would represent a stronger method to evaluate concurrent and construct validity for proper direct recommendation of a SCI specific risk assessment tool.[28, 51]

3.2 SCALE FOR SCI POPULATION

3.2.1 Development of Scales

With over 250,000 individuals with SCI in the United States, currently no method exists to accurately identify which of these individuals will have a higher risk for developing pressure ulcers.[67] This idea sparked the curiosity of colleagues Dr. Andrew Salzberg and Daniel Byrne. Developing a research interest in the early 1990s, Salzberg and Byrne set out to perform a systematic review of literature regarding the many risk factors associated with pressure ulcer development for people with SCI. [19, 52, 65] the Norton Scale, the Gosnell Scale, and the Braden Scale were addressed specifically for their lack of content validity in the systematic review.[19] In addition to these three scales, other papers have cited that the Waterlow Scale also lacked content and concurrent validity.[55, 79]

Certain criticism pertaining to these scales revolve around their vaguely defined risk factors, lack of weighting of risk factor for emphasis, and better prediction based on medical practitioner intuition.[64, 77] In addition, inadequate number of individuals with SCI in sample sizes and various confounding variables make justifying the results of formerly created scales to the SCI population difficult. The results of the systematic review led to a reduction of the 200 known risk factors to a succinct list of fifteen. These fifteen tailored risk factors to the SCI population were incorporated in the Pressure Ulcer Risk Assessment for the Spinal Cord Injured.

3.2.2 Pressure Ulcer Risk Assessment for the Spinal Cord Injured

The first study on the Pressure Ulcer Risk Assessment for the Spinal Cord Injured, commonly referred to as the Salzberg Scale was published in 1996.[67] Salzberg and Byrne et al included the previously established fifteen risk factors that correlate to pressure ulcer development in the SCI population. Stated in their original study, these fifteen factors were included based on four main criteria. The fifteen risk factors must have some form of statistical association with pressure ulcer development in the SCI population. In addition, each risk factor included in the scale had a plausible biological mechanism, literature support as well as relate to the improved prediction of pressure ulcer development.[67] The fifteen risk factors included in the study were level of activity, degree of mobility, completeness of SCI, urinary incontinence, diagnosis of autonomic dysreflexia, age, comorbidities such as those pertaining to cardiac, pulmonary, and renal pathophysiology, level of cognition, diagnosis of diabetes, history of cigarette smoking, residency, and diagnosis of hypoalbuminemia and anemia.

Each risk factor is weighted differently ranging from a value of 0, 1, 2, 3, or 4 points based on their significance and relevance to pressure ulcer development. Those with the largest score determination are level of activity, level of mobility, age, history of tobacco use, existing pulmonary disease, and location of residence. These all have a possibility of contributing two or more points to the total score at the time of assessment. To determine which score should have been assigned to the subject or patient, Salzberg provided an objective, easily defined list of operational definitions. Each category must be filled out to create a total score. Total scores range from 0 to 25 points. The lower the compiled score, the lower the level of risk a person will have for pressure ulcer development.

3.2.3 Risk Category Breakdown

In the process of developing the Salzberg Scale, Salzberg and colleagues established four categories to define the amount of risk. The four categories can be seen in Table 2 below.

Table 2 Salzberg Scale Risk Categories

Risk Category	Point Value/Range
LOW	0-2
MODERATE	3-5
HIGH	6-8
VERY HIGH	9-25

These categories were based on initial sensitivity and specificity analysis of 219 subjects. Their data indicated that patients with a score greater than 6 had the 'highest balance of sensitivity and specificity, demonstrated by the intersection of the sensitivity and specificity lines.'[67] As recommended by Salzberg, Braden, as well as W.B. Mortenson, each specific setting should test baseline risk categories on the population they study or treat. This way, the scale is personalized and specific for the appropriate settings use. It is essential that the tool be tested on the intended population prior to implementation.

3.2.4 Previous Use of Scale

The Salzberg Scale has been used in a limited amount of studies.[34, 51, 67, 68] Its usage varies from its preliminary psychometric testing to additional medical record support in larger interventional studies.[10] Use of this scale is found in trace studies due to its lack of validity and popularity as a promising measurement tool. In 2007, W.B. Mortenson et al. composed a systematic review of risk assessment scales for pressure ulcer development in individuals with SCI.[51] Information on

the Salzberg Scale as well as six other risk assessment scales was evaluated based on published results of each scales reliability, validity, respondent burden, and administrative burden. Of all tools, the Salzberg Scale had the most items to assess with its unique categories of autonomic dysreflexia and living setting. It was identified that the Salzberg Scale had the best sensitivity and specificity of all measures tested during acute care hospitalization as well. It also had the highest construct validity. What diminishes the scale's high sensitivity and construct validity is its only application in retrospective studies and limited published results.[51]

Despite the Salzberg Scale being customized for the assessment of individuals with SCI, there is still the criticism of minimal reliability data and general population use in other studies than its founding study. It has yet to be recommended until further psychometric evaluation is completed.[33] Additionally, the predictive value of the Salzberg Scale in various settings (e.g., community or hospital) requires investigation as well.

4.0 RESEARCH DESIGN AND METHODS

Data collection was made possible by the Rehabilitation Engineering Research Center on Spinal Cord Injury (RERC-SCI). The RERC-SCI assists persons with SCI through research and development of technologies that can be incorporated into the improvement of rehabilitation and reintegration of persons into society. Made up of developmental and research projects, the clinical core of this particular study was designed to enroll new, traumatic SCI patients for the collection of demographic information, medical information, pressure ulcer outcomes, and urine and blood samples during the acute, inpatient, and outpatient stages of rehabilitation. For a complete listing of variables collected, see Table 3.

Informed consent reviewed and approved by the University of Pittsburgh Institutional Review Board (IRB) was obtained for both the RERC-SCI study and amended for the retrospective secondary analysis. Patients enrolled were charted at the University of Pittsburgh Medical Center (UPMC) facilities and after discharge. The Clinical Core of RERC-SCI collaborated with UPMC and the UPMC Model System on SCI to recruit, screen, and enroll subjects with new, traumatic SCI. All personnel in the Clinical Core team were qualified to collect data and perform proposed responsibilities. Data was taken from each enrolled patient three times a week during acute care hospitalization, once a week during inpatient rehabilitation, and annually after discharge in outpatient care. Outpatient follow-up consisted of six months, twelve months, and yearly time points until the conclusion of the study. All evaluations

continued thru the termination of the study. The RERC-SCI was funded by the National Institute on Disability Rehabilitation Research grant, #H133E070024.

Table 3. Data Collected for RERC-SCI

Variables Categories	Variable Specifics
Demographics	Admission Date, Consent Date, Date of Injury, Age, Sex, Marital Status, Ethnicity, Height, Weight, Past Medical History (PMH) of Smoking
Injury	Cause of Injury; Level of Injury: Cervical, thoracic, Lumbar, Sacral, Coccyx, Other; Bilateral vs. left and right; Complete vs. Incomplete; American Spinal Injury Classification (ASIA) score, Lower Extremity Score Injury Severity Score (ISS)
Medical Information	Alcohol Use, Tobacco Use, Musculoskeletal Pain, PHQ Depression Scale, Medical Comorbidities (cardiovascular, hematopoietic, respiratory, ENT, gastrointestinal, rheumatologic, musculoskeletal, neurologic, endometric/metabolic, immunological, psychiatric, malignancy, substance abuse, UTI, integumentary), Number of Pressure Ulcers, Braden Risk Score, Bladder and Bowel Management, Medications (NSAIDs, Steroids, Antibiotics, and Others), Ambulation Status
Pressure Ulcer	Size, Shape, Severity (based on NPUAP Staging System), Progression of the PU

4.1 RESEARCH DESIGN

This study was a retrospective secondary analysis of the data collected by the clinical core of RERC-SCI. Using the existing database information, specific variables pertaining to the Salzberg Scale were extracted to evaluate the psychometric properties of the scale. The extracted variables were the fifteen risk factors that composed the Salzberg Scale, demographic information of included subjects, and assessment dates for time point analysis in both acute care hospitalization and inpatient rehabilitation. The extracted variables were recorded at each subject assessment

The extracted data were then put into a separate database for lucid analysis of the particular psychometric properties of the scale. The psychometric properties evaluated were sensitivity, specificity, Receiver Operating Curve (ROC) Curve, and other predictive validity measures. These properties are explained in further detail in 4.4 DATA ANALYSES. Table 4 conveys the extracted variables used to organize the secondary analysis data.

Table 4. Secondary Analysis Data Extracted

Secondary Analysis Variables Categories	Secondary Analysis Variable Specifics
Demographics	Admission Date, Consent Date, Date of Injury, Age, Sex, Marital Status, Ethnicity, Height, Weight, Past Medical History (PMH) of Smoking, Rehabilitation Stage, Assessment Date, Current Residence
Injury	Complete vs. Incomplete; American Spinal Injury Classification (ASIA) score,
Medical Information	Tobacco Use, Medical Comorbidities (cardiovascular, hematopoietic, respiratory, gastrointestinal, neurologic, immunological, psychiatric, integumentary), Number of Pressure Ulcers, Ambulation Status, Albumin Levels, Hematocrit Levels, Bladder and Bowl Management
Pressure Ulcer	Incidence Date

4.2 SUBJECT INCLUSION AND EXCLUSION CRITERIA

4.2.1 Primary Study Subject Inclusion and Exclusion Criteria

In the primary RERC on SCI study, subjects with new, traumatic SCI were recruited within 24-72 hours after admission to UPMC Neurotrauma Centers. Subjects were eligible to be in the study if they met the following criteria:

1) Received acute medical and/or surgical treatment at UPMC hospitals

2) Received acute rehabilitation at Institution of Rehabilitation Research (IRR) South Side or UPMC Mercy after the acute medical and/or surgical treatment
3) Are 18 years and older
4) New, acute traumatic SCI (e.g. motor vehicle accident, fall, sports injury, gunshot wound)

Subjects were to be automatically excluded from the study if they had any of the following:

1) Pre-existing diseases that would affect the inflammatory response to SCI (e.g. autoimmune or demyelinating diseases)
2) Previous SCI or other neurological dieses that affect the motor or sensory function of the subject

In the RERC on SCI study, 104 subjects were enrolled from 2008 through 2012. At the end of the study, 48 subjects were still enrolled in the study, 13 subjects were out of the study due to death or lost to follow-up, and the remaining 43 subjects withdrew themselves from the study for reasons such as lack of interest or dislike of blood draws.

4.2.2 Secondary Study Subject Inclusion and Exclusion Criteria

For the current analysis, 51 subjects of the original 104 subjects were included for this study. Subjects were eligible to participate in the current study if they met the following criteria:

1) Did not voluntarily withdraw from RERC-SCI study
2) Contain all information required for the Salzberg Scale component extraction and other analysis data (e.g., Braden Scale, ASIA score, ambulation status)

Subjects who were categorized as “withdrawn” were not allowed to be used in the study as past medical records could not be accessed to extract certain information to complete the

Salzberg Scale assessment. Inaccessibility to data extraction was due to restrictions of the IRB. The items that needed to be extracted were albumin levels and hematocrit levels for each assessment date in order to have all variables of the Salzberg Scale accounted for in a score compilation. Subjects needed to have either albumin or total protein levels listed for the exact assessment date. Hematocrit levels also needed to be listed for the exact assessment date to maintain consistency and accurate data extraction. These values were not recorded for in the original database of the study. Access to this information could only be obtained through already consented patients or those who had passed away or had been lost to follow-up based on IRB specifications.

4.3 DATA COLLECTION

Data extraction from the original RERC-SCI study was a crucial component to the success of the compilation of Salzberg Scale scores. Two databases were used for the extraction of the data. The first was the original database used to hold the primary RERC-SCI study. This held the majority of the sought after variables. Categorical titles of information held in this database can be referred to in Table 3. The second database of information was the computerized medical records pertaining to each subject. Albumin and/or total protein levels and hematocrit levels for each included subject were found in these records. A secondary analysis spreadsheet was used to organize and input data specific to the current study for statistical analysis. This spreadsheet held categories for each risk factor of the Salzberg Scale, assessment dates and phase specifications (acute hospitalization or inpatient rehabilitation), ASIA scores, and demographic information. Exact categorical topics in the secondary analysis spreadsheet can be referred to in Table 4.

To begin data extraction for the secondary analysis database, operational definitions of the Salzberg Scale factors were first studied in detail in order to look for exact variables in the original database and computerized medical records of subjects. Operational definitions ranged from International Classification of Disease (ICD) definitions, quantitative measurements, to objective observational details. The objective observational details pertained to three of the fifteen risk factors. The three factors were level of activity, mobility, and urine incontinence or constantly moist. These factors were coded based on the expert opinion of the two nurses who assessed each subject in acute hospital and inpatient rehabilitation settings. Each of the nurses reviewed extensive medical record notation and assessment notes of each subject pertaining to the three risk factors. In order to eliminate bias or skewed coding of the three risk factors, the nurses of the primary study were given practice evaluations or scorings to compare the assessments. Out of 48 variables from 12 subjects, the nurses overlapped with identical scoring 45 times (94%) showing strong consistency and similar coding methodology.

Within this population, the limiting factor or variable to determine if the subject would be included was albumin or total protein measurement availability. This was the first risk factor that was assessed to minimize obsolete data collection. For each qualified subject, albumin levels were taken from the medical records. This narrowed our search to 51 subjects that allowed calculation of complete Salzberg Scale scores.

Based on the operational definition as well as measured value, a coded value was assigned based on the Salzberg Scale. This process was repeated for all fifteen risk factors for each assessment date. The only varying step was from where the data were taken in the second step of the process (See Figure 1 Data Collection Process for flowchart of data collection process).

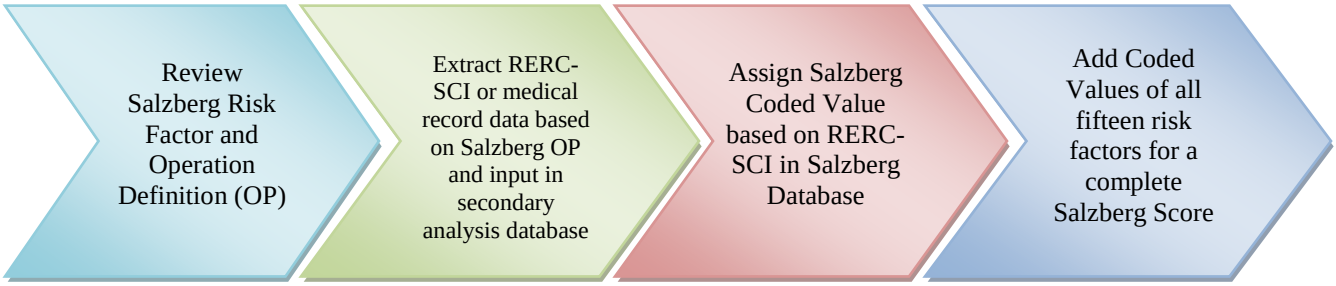

Figure 1 Data Collection Process

Whether data were extracted from the RERC-SCI primary database of computerized medical records, variables were based on exact Salzberg operational definitions. Once each variable had been collected, all variables are summed together for a compiled Salzberg Scale Score. This was the number that was used in statistical analysis.

Although each subject had complete Salzberg Scale scores for individual assessment dates, many subjects had missing data for Salzberg Scale score calculations over a large range of visits. A forward-carrying imputation method was initially attempted to account for each subject's missing scores. Based on large scale missing data of multiple subjects, an imputation method could not be used, as there would be too great of an assumption factor made when analyzing the dataset. Alternatively, a methodology evaluating the short term and long term use of the Salzberg Scale was established to eliminate possibility of skewed data.

The available data was analyzed two ways to assess the predictive validity of the scale for this study population (see Figure 2). The first analysis looked at the short-term risk assessment. This grouping of the data, also known as *next visit prediction group*, would only include subjects who had a Salzberg Scale score followed by a study follow up for assessment of pressure ulcer development. When the subjects were scored in acute hospitalization, then the subject's pressure ulcer assessment would range two to three days after the initial Salzberg Scale score compilation, as subjects were assessed three times a week as part of the primary study protocol. If the subject were scored in inpatient rehabilitation, then the subject's pressure ulcer assessment would be five to seven days after the initial Salzberg Score compilation as subjects were assessed one time per week.

This subject group captures the predictive validity of the Salzberg Scale when administered in a short-term, frequent method. Isolation of a direct time point for pressure ulcer formation could be highly correlated to a specific range of Salzberg Scores, as the obtained score of the initial visit would likely estimate the development of the PrU upon the following visit. Although only 28 subjects were included in this group, 55 pairings were gathered from these subjects. Two subjects were included in both the acute and inpatient settings whereas the other subjects were in either acute hospitalization on inpatient rehabilitation settings. Individual subjects contributed a range of one to six observation pairings to the 55 pairings used in statistical analysis as long as the assessment pairings fit the next visit prediction group criteria. (See Table 5)

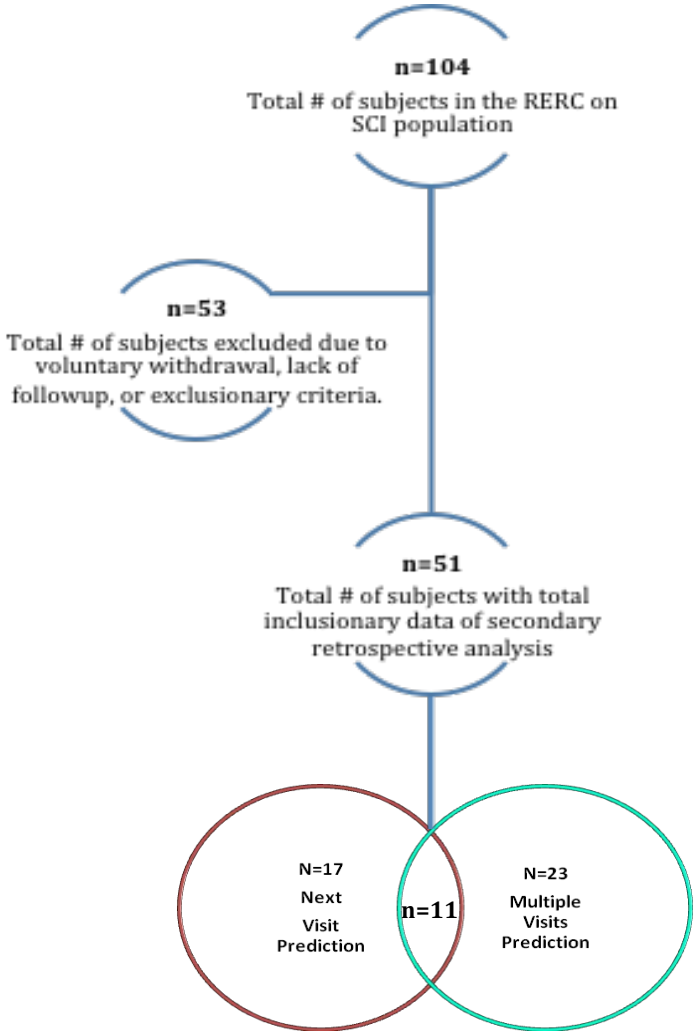

Figure 2 Subject Selection Flow Chart

Table 5 Number of Observation Pairing Contributed Per Subject in Next Visit Prediction Group

Number of Observations Pairings Contributed	Number of Subjects in Acute	Number of Subjects in Inpatient
1	13	6
2	0	2
3	3	3
4	2	0
5	0	0
6	0	1

The second analysis, known as the *multiple visits prediction group*, gauged the predictive validity of the scale over a longer period of time in each setting. There is not a consistent number on how many times a risk assessment tool should be administered. Results of the Salzberg Scale's predictive validity over long-term use with less frequent scorings would show whether frequent or less frequent administration of the scale should be implicated in a clinical setting. After the first assessment and compilation of the Salzberg Scale score for each time point of the subject in the multiple visits prediction group, PrU development was checked on the third assessment after the first observation. Assessment groupings were chosen if there was a beginning score and a following score assessed on the third assessment after the observation. If an assessment were missed between the first and third assessment, the grouping was still inclusive as the first and third assessment were complete.

Three assessment dates between visits was determined as the greatest distance eligible for predictive value before other confounding variables may interfere with the relationship between the predictive qualities of the scale and PrU development. For subject in acute hospitalization, the time ranging in between three assessment dates was five to seven days since the initial

assessment. For subjects in inpatient hospitalization, the time ranging in between the three assessment dates was 18 to 22 days since the initial assessment. Although only 34 subjects were included in this group 77 pairings were gathered from all of the subjects. Three subjects were n both the acute and inpatient group. Subjects contributed a range of one to seven observation pairings for each patient that contributed to the total 77 pairings used in the statistical analysis. (See Table 6) As long as each subject's assessment availability in the RERC-SCI data had the criteria of the assessment grouping, multiple time points could be included for analysis.

Table 6 Number of Observation Pairing Contributed Per Subject in Multiple Visits Prediction Group

Number of Observations Pairings Contributed	Number of Subjects in Acute	Number of Subjects in Inpatient
1	14	6
2	3	3
3	2	3
4	3	1
5	0	0
6	0	0
7	1	1

In addition, each subject group was evaluated based on the stage of rehabilitation in which their assessment occurred. Three analyses were performed based upon the stage of care. The first section contained all of the observation pairings from acute care rehabilitation and inpatient rehabilitation, also known as the total group. The second and third analyses of evaluation solely examined acute care rehabilitation and inpatient rehabilitation, respectively. Through the combined phase, or total stage approach, general score trends were evaluated. The

individual stages of treatment were evaluated to show if the scale has a greater predictive validity in acute hospitalization over inpatient rehabilitation or vice versa.

4.4 DATA ANALYSES

Exploratory and explanatory approaches were used to assess the data in order to evaluate the psychometric properties of the Salzberg Scale. An exploratory approach assesses qualitative trends in Salzberg Scale scores of included subjects with or without pressure ulcer development through box plots. A more in depth analysis occurs in the explanatory approach, which utilizes objective outcomes. In order to validate a scale, the scale's results were tested for certain psychometric properties: sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). These calculations are further analyzed to assess the power of the prediction tool through the use of the Receiver Operating Characteristic (ROC) Curve.

4.4.1 Box Plots

Box plots are important for initial data analysis. When comparing data from two or more groups, they allow interpreters to see distributions of data and a summary of data. Box plot figures have similar characteristics. Whiskers on either end of x-axis categories represent the range or categorical spread of Salzberg Scores. The shaded rectangle between the whiskers represents the scores between the first and third quartile of scores. The diamond within the shaded rectangular space represents the average score and the horizontal line represents the median score of the population. Box plots assessed differences between the total group, acute care hospitalization

group, and inpatient rehabilitation group trends. An illustration of a generic box plot is shown in Figure 3.

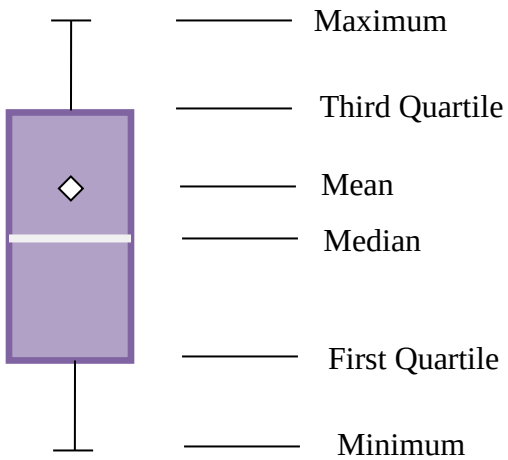

Figure 3 Generic Box Plot Characteristics

4.4.2 Sensitivity and Specificity

Sensitivity is defined as "the probability that a test will be positive for persons who actually have" pressure ulcer development.[43] This is the fraction of subjects who have developed new pressure ulcers and are above a certain score on the Salzberg Scale predicted for risk. On the other hand, specificity is "the probability that a test will be negative for subjects who do not have" pressure ulcer development.[43] Ideally, risk assessment tools should have a 100% sensitivity and 100% specificity rate. In real-world clinical use, this level of precision is not achievable. The accepted or reasonable predictive validity sensitivity and specificity rates are 75% or higher.[17, 43] Determining calculation of the sensitivity and specificity takes place initially in a grid as seen in Table 7.

Table 7 Summary of Sensitivity and Specificity Calculation

	PrU Development	No PrU Development
Above Cut-off Score (At risk)	a	b
Below Cut-off Score (Not at risk)	c	d

In order to interpret Table 7, it is important to understand what each of the variables means. Data can be grouped under four different actualities, or outcomes. These are known as true positive, true negative, false positive and false negative results. True positive is the proportion of people who developed a pressure ulcer and were classified as at risk by the Salzberg Scale; true negative is the proportion of people who did not develop a pressure ulcer and were classified as not at risk by the Salzberg Scale. A false positive is the proportion of people who did not develop a pressure ulcer and were classified as at risk by the Salzberg Scale; a false negative is the proportion of people who develop a pressure ulcer and were classified as not at risk by the Salzberg Scale. Possible results of the data can be figuratively seen on Table 8.

Table 8 Clinical Results Organizer for Sensitivity and Specificity

		Actual Clinical Result	
Salzberg Scale Classification		**Develops Pressure Ulcer**	**Does Not Develop Pressure Ulcer**
	At risk	True Positive (TP)	False Positive (FP)
	Not at risk	True Negative (TN)	False Negative (FN)

Sensitivity and specificity are presented as in the form of percentages. Each can be calculated by using the values from Table 7 and entering them into Equation 1 and Equation 2. Sensitivity and Specificity were taken for each Salzberg Scale score collected in both the next visit prediction group and the multiple visits prediction group.

Equation 1 Sensitivity Calculation

$$Sensitivity = \frac{a}{(a+c)}$$

Equation 2 Specificity Calculation

$$Specificity = \frac{b}{(b+d)}$$

4.4.3 Predictive Values

In addition to sensitivity and specificity tests, Positive Predictive Values (PPV) and Negative Predictive Values (NPV) are also reported to determine the predictive validity of measurement tools. Accuracy of PPV and NPV are useful when interpreting predictive value of individual assessments because the PPV and NPV account for incidence of new pressure ulcer development as well as the number of cases screened in the data set.[18] The definition of PPV for this study is the probability that a subject who scored above the determined cut-off score will actually develop a pressure ulcer; the NPV for this study is the probability that a subject who scored below the determined cut-off score will not develop new a pressure ulcer. Calculation of PPV and NPV also utilize the variables seen in Table 7 in Equation 3 and Equation 4. Both PPV and NPV were calculated for each Salzberg Scale score collected for the next visit prediction group and the multiple visits prediction group.

Equation 3 Positive Predictive Value

$$PPV = \frac{a}{(a+b)}$$

Equation 4 Negative Predictive Value

$$NPV = \frac{d}{(c+d)}$$

For a summary of accuracy terms, see Table 9.

Table 9 Summary of Predictive Validity Terminology

Term	Definition
Sensitivity	The probably that a test will be positive for persons who actually have pressure ulcer development
Specificity	The probability that a test will be negative for subjects who do not have pressure ulcer development
Positive Predictive Value (PPV)	The probability that a subject who scored above the determined cut-off score will actually develop a pressure ulcer
Negative Predictive Value (NPV)	The probability that a subject who scored below the determined cut-off score will not develop new a pressure ulcer
True Positive (TP)	The proportion of people who developed a pressure ulcer and were classified as at risk by the Salzberg Scale
True Negative (TN)	The proportion of people who did not develop a pressure ulcer and were classified as not at risk by the Salzberg Scale
False Positive (FP)	The proportion of people who did not develop a pressure ulcer and were classified as not at risk by the Salzberg Scale
False Negative (FN)	The proportion of people who develop a pressure ulcer and were classified as not at risk by the Salzberg Scale

4.4.4 ROC Curve

A ROC Curve is the ideal choice of analysis when the variable of interest is continuous. An ROC curve allows a researcher to test threshold of the sensitivity or TP rate versus the specificity change over the Salzberg Scale. If the test threshold is high, there will be few FP. Graphically, the closer the ROC curve is to the diagonal, the lower the threshold and less useful the test is at discriminating between the TP and FP populations.[39] The steeper the ROC curve, the better the test. To characterize the distance of the ROC curve to the diagonal on the graph, area under the ROC curve (AUC) measures the strength of the research tool quantitatively. Essentially, the

AUC is a measure of probability of how likely the test will reveal a TP. The closer the AUC is to 0.5, the worse the test's performance. The closer the AUC is to 1.0, the stronger the predictability of the test.[74] An ROC curve can be constructed to measure the strength of the Salzberg Scale's prognostic validity after the evaluation of the study's sensitivity and specificity.

5.0 RESULTS

The results section is presented as three distinct portions. The beginning portion states the demographics for each subject sample population, next visit prediction and multiple visit prediction. The second part of the results shows the exploratory analysis for both the next visit prediction group as well as the multiple visit prediction group. The third portion of the results section contains two subcategories specific to the sample population being discussed. The first explanatory results will discuss the next visit predictions group. The second explanatory subsection will discuss the multiple visits description group.

Table 10 Demographics of Next Visit Prediction Populations

	Acute and Inpatient Combined (Total) **(n=28)**	Acute Care Hospitalization **(n=18)**	Inpatient Rehabilitation **(n=12)**
Age (Mean ± SD)	40.4 ±16.7	36.3 ± 14.9	43.5 ± 18.6
Gender			
Female	8 (28.5%)	3 (16.7%)	5 (41.7%)
Male	20 (71.5%)	15 (83.3%)	7 (58.3%
Marital Status			
Single	12 (42.8%)	6 (33.3%)	5 (41.7%)
Married	11 (39.2%)	8 (44.4%)	4 (33.3%)
Divorced	4 (14.3%)	3 (16.7%)	3 (25.0%)
Widowed	1 (3.7%)	1 (5.6%)	0 (0.0%)
Education			
High School	18 (64.3%)	13 (72.2%)	7 (58.3%)
Tech/2 Yr Degree	6 (21.4%)	4 (22.2%)	2 (16.7%)
4 yr. College	2 (7.1%)	0	2 (16.7%)
Post Graduate	1 (3.6%)	0	1 (8.3%)
Missing	1 (3.6%)	1 (5.6%)	0 (0.0%)
Cause of Injury			
Fall	9 (32.1%)	4 (22.2%)	6 (50.0%)
Gun Shot Wound:	2 (7.1%)	1 (5.6%)	1 (8.3%)
Motor Vehicle Accident	13 (46.4%)	10 (55.5%)	5 (41.7%)
Violence	4 (14.4%)	3 (17.3%)	0 (0.0%)
ASIA Score			
A	13 (46.4%)	11 (61.2%)	5 (41.7%)
B	3 (10.8%)	1 (5.6%)	2 (16.7%)
C	6 (21.4%)	3 (16.6%)	3 (24.9%)
D	5 (21.4%)	3 (16.6%)	2 (16.7%)
Ethnicity			
African American	5 (17.8%)	3 (16.6%)	2 (16.7%)
Caucasian	23 (82.2%)	15 (83.4%)	10 (83.3%)

Table 11 Demographics of Multiple Visits Prediction Populations

	Acute and Inpatient Combined (Total) **(n=34)**	Acute Care Hospitalization **(n=23)**	Inpatient Rehabilitation **(n=14)**
Age (Mean ± SD)	41.0 ± 17.1	38.8 ± 15.9	42.9 ± 18.1
Gender			
Female	10 (29.4%)	6 (26.0%)	5 (35.7%)
Male	24 (70.6%)	17 (74.0%)	9 (64.3%)
Marital Status			
Single	13 (38.2%)	10 (43.4%)	5 (35.7%)
Married	15 (44.1%)	9 (39.1%)	6 (42.9%)
Divorced	4 (11.7%)	2 (8.8%)	3 (21.4%)
Widowed	2 (6.0%)	2 (8.7%)	0 (0.0%)
Education			
High School	24 (70.6%)	18 (78.2%)	8 (57.4%)
Tech/2 Yr Degree	6 (17.6%)	4 (17.5%)	2 (14.2%)
4 yr. College	2 (5.9%)	0 (0.0%)	2 (14.2%)
Post Graduate	0 (0.0%)	0 (0.0%)	1 (7.1%)
Missing	2 (5.9%)	1 (4.3%)	1 (7.1%)
Cause of Injury			
Fall	13 (38.2%)	6 (26.0%)	7 (50.0%)
Gun Shot Wound:	2 (5.9%)	1 (4.3%)	1 (7.1%)
Motor Vehicle Accident	15 (44.1%)	12 (52.2%)	6 (42.9.0%)
Violence	4 (11.8%)	4 (17.5%)	0 (0.0%)
ASIA Score			
A	16 (47.0%)	14 (60.8%)	6 (42.9%)
B	3 (8.8%)	2 (8.8%)	2 (14.2%)
C	10 (29.4%)	5 (21.6%)	4 (28.6%)
D	5 (14.8%)	2 (8.8%)	2 (14.3%)
Ethnicity			
African American	6 (17.6%)	5 (21.8%)	2 (14.2%)
Caucasian	28 (82.4%)	18 (78.2%)	12 (85.6%)

Table 12 Observation Pairings of the Next Visit Prediction Group

	Acute and Inpatient Combined (Total)	Acute Care Hospitalization	Inpatient Rehabilitation
Number of Observation pairings with PrU Development	5 (9.0%)	2 (6.8%)	3 (11.5%)
Number of Observation Pairings without PrU Development	50 (91.0%)	27 (93.2%)	23 (88.5%)

Table 13 Observation Pairings of the Multiple Visits Prediction Group

	Acute and Inpatient Combined (Total)	Acute Care Hospitalization	Inpatient Rehabilitation
Number of Observation Pairings with PrU Development	9 (11.7%)	3 (6.7%)	6 (18.8%)
Number of Observation Pairings without PrU Development	68 (88.3%)	42 (92.7%)	26 (81.2%)

5.1 DESCIPTIVE STATISTICS

In the exploratory analysis, general predictive performance of the Salzberg Scale was analyzed for each subject group, next visit and multiple visits prediction group. Salzberg Scale scores for each group were evaluated for the three stages of care; combined acute hospitalization and inpatient rehabilitation (total group), acute hospitalization only, and inpatient rehabilitation only. The Salzberg Scale score of the first visit was used to create box plots for each of the three stages for each group.

5.1.1 Exploratory Analysis of Next Visit Predictions Groups

The first three box plots represent the exploratory analysis of the next visit prediction group. Shown in Figure 4, subjects in the total group which did not include the development of a PrU (0) versus those that did include development of a PrU (1) had slightly different scores. Combined, the sample population of the next visit prediction group totaled 28 subjects sharing 55 usable observation pairings for analysis. Comparisons of the mean Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are shown in the Table 14 below. Five out of 55 observation pairings involved the development of a PrU between the two treatment settings.

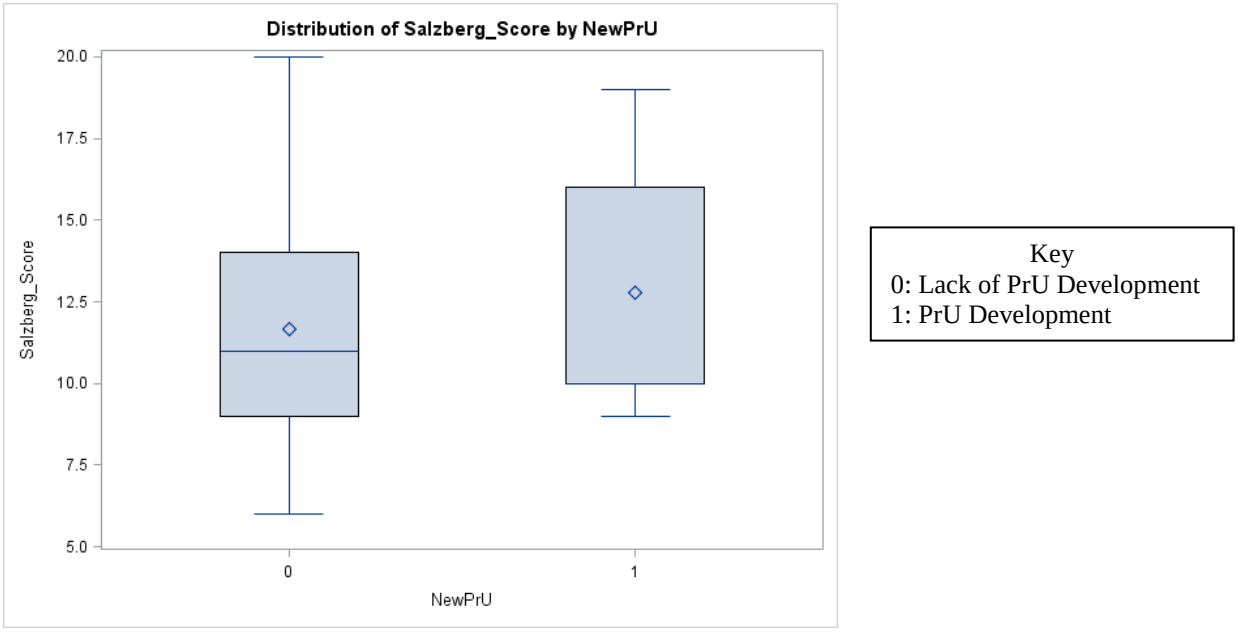

Figure 4 Total Population Exploratory Comparison of Next Visit Prediction Group

Table 14 Total Population Box Plot Results of Next Visit Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	11.68	12.8
Maximum Salzberg Scale score	20	19
Minimum Salzberg Scale score	6	9
Median Salzberg Scale score	11	10

The second state, or acute care hospitalization, is shown in Figure 5. Comparisons of the mean of Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are noted in Table 15. Out of the 28 subjects, 18 observation pairings had assessments scores available to analyze. Three observation pairings out of the 29 developed PrU. Lack of PrU Development is denoted by 0 on the boxplot while development of PrU is denoted as 1.

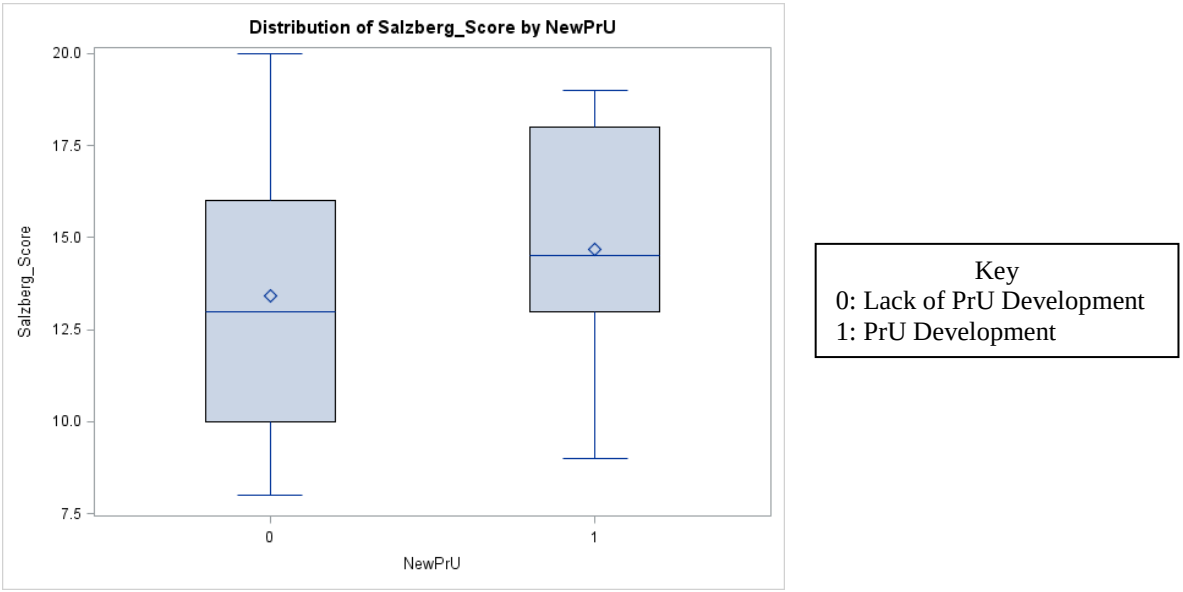

Figure 5 Acute Care Hospitalization Exploratory Comparison in Next Visit Prediction Group

Table 15 Acute Care Hospitalization Group Box Plot Results for Next Visit Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	13.0	17.5
Maximum Salzberg Scale score	20	19
Minimum Salzberg Scale score	8	16
Median Salzberg Scale score	13	17.5

The final state, or inpatient rehabilitation, is shown in Figure 6. Comparisons of the mean of Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are noted in Table 16. Out of the fifty-five observation pairings, 23 observation pairings' scores were available to analyze. Three observation pairings out of the 23 observation pairings involved the development of a PrU. Lack of PrU development is denoted by 0 on the boxplot while development of PrU is denoted as 1.

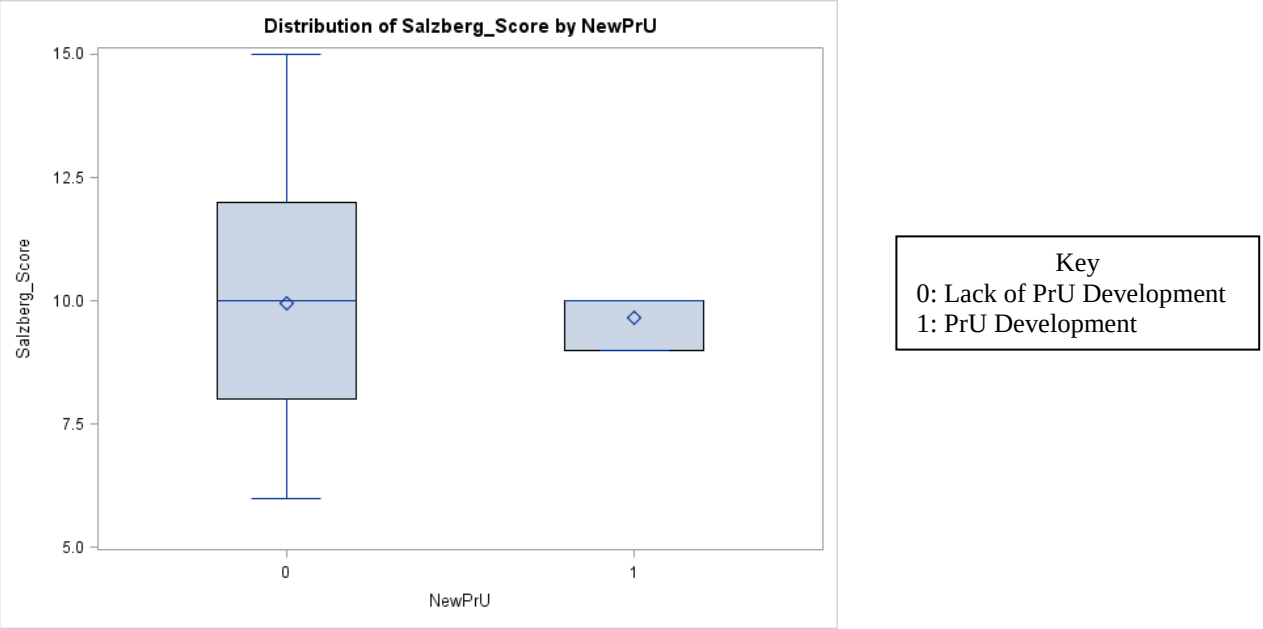

Figure 6 Inpatient Rehabilitation Exploratory Comparison for Next Visit Prediction Group

Table 16 Inpatient Hospitalization Box Plot Results for Next Visit Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	10.0	9.7
Maximum Salzberg Scale score	15	10
Minimum Salzberg Scale score	6	9
Median Salzberg Scale score	10	10

5.1.2 Exploratory Analysis of the Multiple Visits Prediction Groups

The second set of box plots represents the exploratory analysis of the multiple visits prediction group. The multiple visits prediction group analyzed a population of 34 subjects with a total of 77 observation pairings. The first state was the total population, regardless of what stage of

hospitalization they were assessed. Shown in Figure 7, subjects in the total group who did not develop PrU (0) versus those who did develop PrU (1) had slightly different ranges in score.

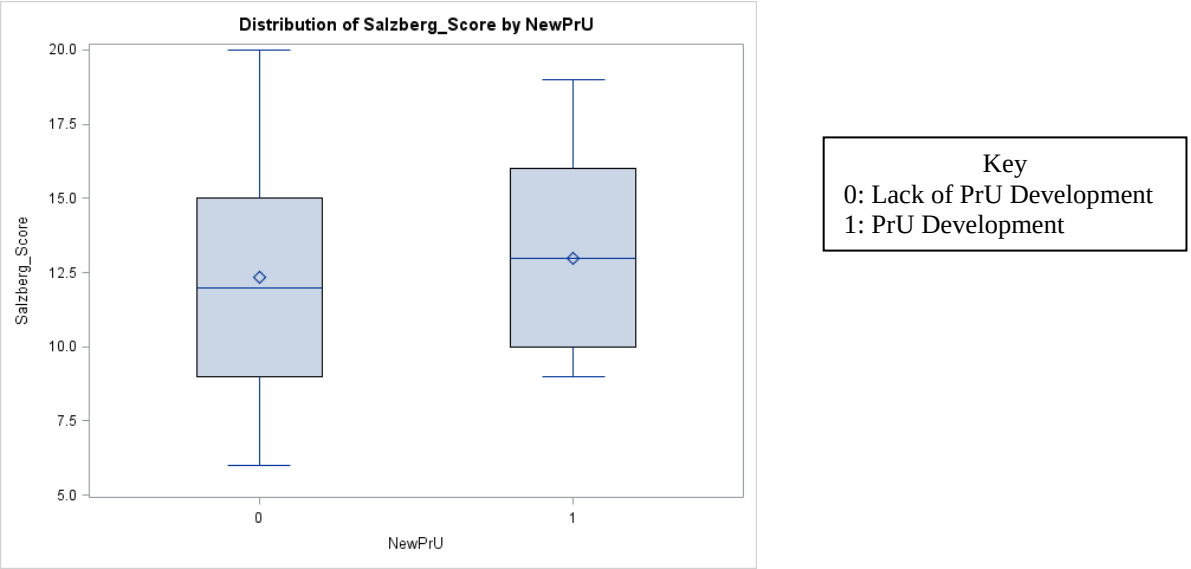

Figure 7 Total Population Exploratory Comparison for Multiple Visits Prediction Group

Comparisons of the mean Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are shown in the Table 17 below. Nine observation pairings out of the 77 observation pairings involved development of a PrU.

Table 17 Total Population Box Plot Results for Multiple Visits Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	12.4	13
Maximum Salzberg Scale score	20	19
Minimum Salzberg Scale score	6	9
Median Salzberg Scale score	12	13

The second state, or acute care hospitalization, is shown in Figure 8. Comparisons of the mean of Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are noted in Table 18. Out of the 77 observation pairings, 45 had assessments scores available to analyze. Three observation pairings out of the 45 involved the development of a PrU. Lack of PrU development is denoted by 0 on the boxplot while development of PrU is denoted as 1.

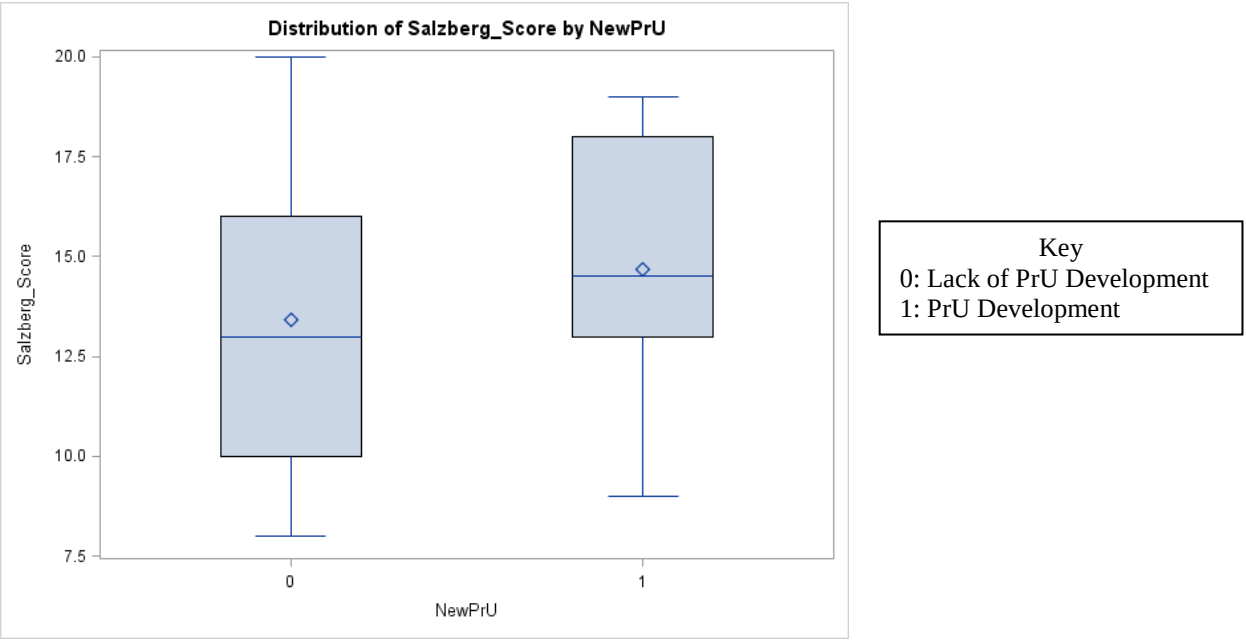

Figure 8 Acute Care Hospitalization Exploratory Comparison for Multiple Visits Prediction Group

Table 18 Acute Care Hospitalization Box Plot Results for Multiple Visits Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	13.4	14.7
Maximum Salzberg Scale score	20	19
Minimum Salzberg Scale score	8	9
Median Salzberg Scale score	13	14.5

The final state, or inpatient rehabilitation, is shown in Figure 9. Comparisons of the mean Salzberg Scale score, maximum Salzberg Scale score, minimum Salzberg Scale score, and median Salzberg Scale score are noted in Table 19. Out of the 77 observations, 32 observation pairings were available to analyze. Six observation pairings out of the 32 involved the development of a PrU. Lack of PrU development is denoted by 0 on the boxplot while development of PrU is denoted as 1.

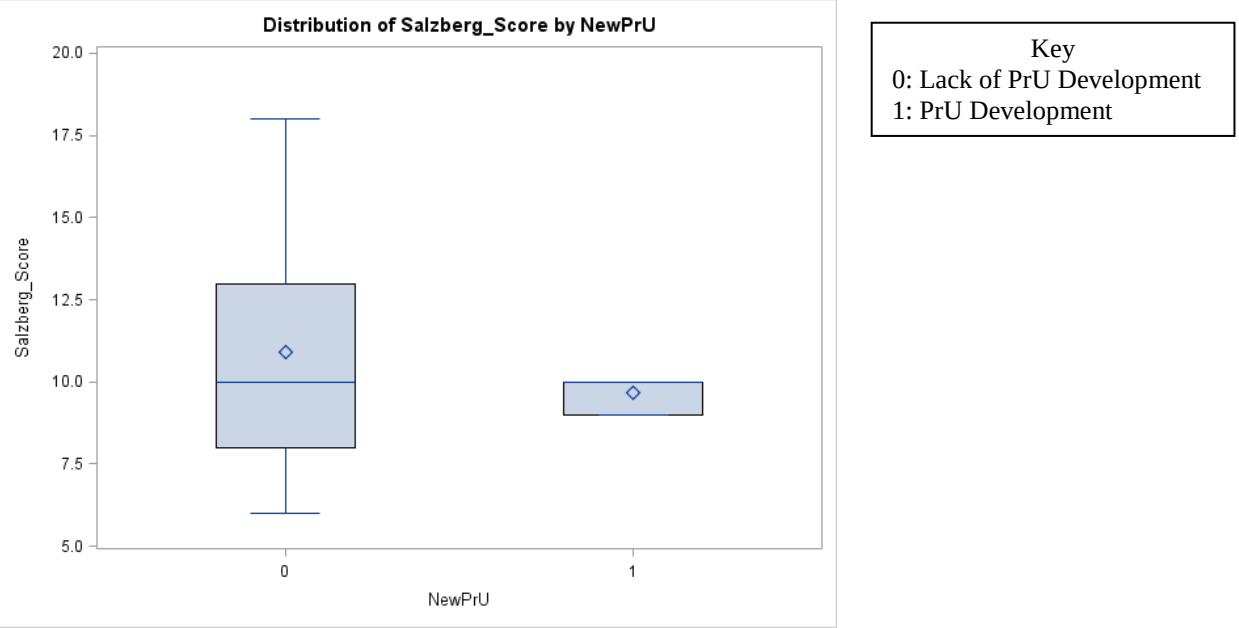

Figure 9 Inpatient Rehabilitation Exploratory Comparison for Multiple Visits Prediction Group

Table 19 Inpatient Rehabilitation Box Plot Results for Multiple Visits Prediction Group

	No PrU Development (0)	PrU Development (1)
Mean Salzberg Scale score	10.9	9.7
Maximum Salzberg Scale score	18	10
Minimum Salzberg Scale score	6	9
Median Salzberg Scale score	10	10

5.2 PSYCHOMETRIC PROPERTIES EVALUATION

5.2.1 Next Visit Prediction Group

5.2.1.1 Total Population

The explanatory data for this section are explained through four statistical analyses. The first statistical analysis shown in Table 20 is the basic calculation of sensitivity, specificity, and predictive values for the sample population data according to the Salzberg score received in the Total Group. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity as justified by Figure 10.

Table 20 Tests of Salzberg Scale Cutoff Points in the Total Group

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
6	100	4	9.4	100
7	100	6	9.6	100
8	100	20	11.1	100
9	80	32	10.5	94.1
10	**40**	**46**	**6.9**	**88.5**
11	40	56	8.3	90.3
12	40	60	9.1	90.9
13	40	72	12.5	92.3
14	40	80	16.7	93.0
15	40	86	22.2	93.5
16	20	88	14.3	91.7
17	20	90	16.7	91.8
18	20	96	33.3	92.3
19	0	96	0	90.6
20	0	100	0	90.1

Sensitivity versus specificity is plotted against one another for each of the specific cutoff scores in Figure 10. The red line is representative of specificity while the blue line is representative of sensitivity. We see here that the intersection, or best balance between sensitivity and specificity for the total population, is located at a cut-off score of ten points. Noticeably seen in Table 20, PPV (%) values are extremely low in comparison to the higher NPV (%) values by an average difference of 53%.

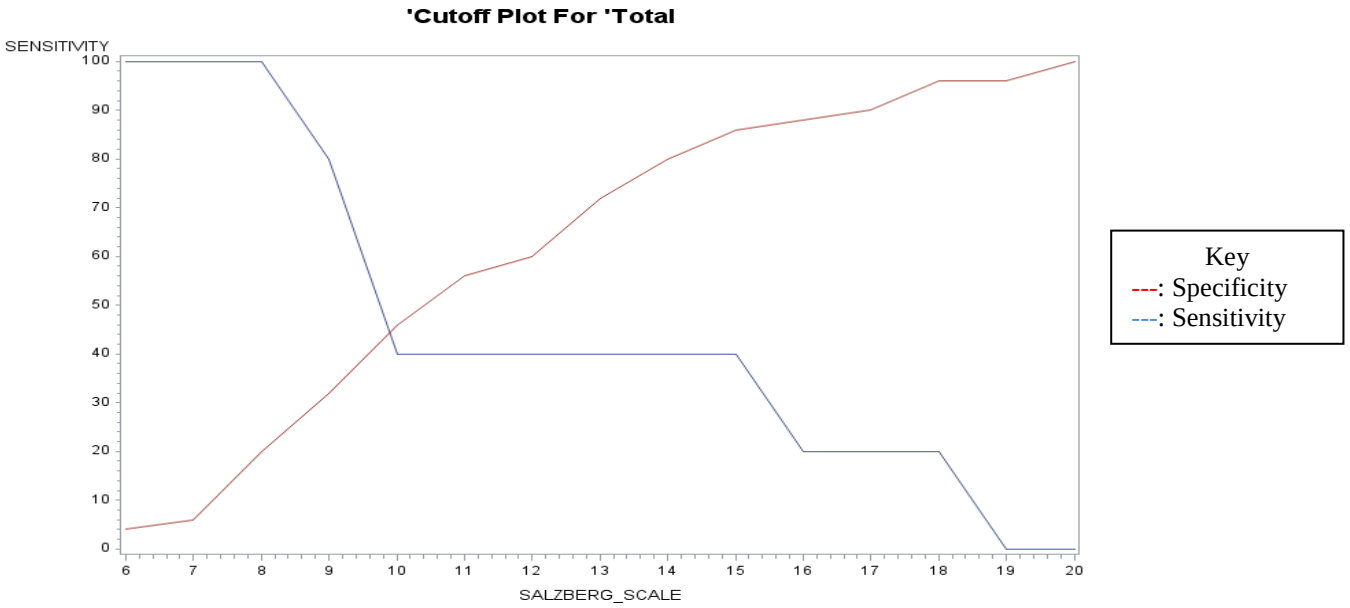

Figure 10 Cut off Plot for Total Population

Figure 11 represents the ROC curve for the total group based on the proposed cutoff score of ten from Figure 10. The AUC was calculated as for 0.5740. This analysis implies that the Salzberg Scale is a weak predictor of pressure ulcer development using ten as the discriminating cutoff score in acute rehabilitation. The closer the AUC is to 0.5, the more likely results are to result chance. The closer the AUC is to 1, the more likely the results are related to a specific characteristic, or cutoff.

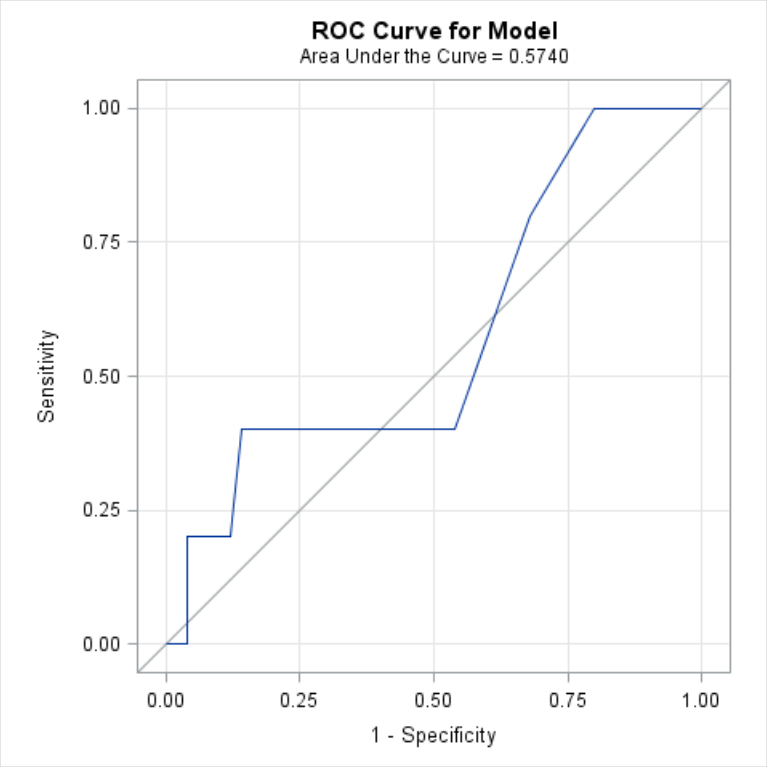

Figure 11 ROC of Salzberg Scale for Total

5.2.1.2 Acute Hospitalization Only

The second statistical analysis set shown in Table 21 explains is the basic calculation of sensitivity, specificity, and predictive values for the sample population data according to the Salzberg score received for the observations in acute care hospitalization only. The table shows a consistently high sensitivity for more scores beneath fifteen and high specificity scores above fifteen points. There is also a trend of extremely low NPV values of 3.1 or smaller. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity.

Table 21 Statistical Calculation Table for Data Set in Acute Phase

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
8	100	3.6	6.9	1.0
9	100	21.4	8.3	1.3
10	100	32.1	9.5	1.47
11	100	42.9	11.1	1.75
12	100	46.4	11.8	1.9
13	100	60.7	15.4	2.5
14	100	67.9	18.1	3.1
15	100	75	22.2	4
16	50	78.6	14.3	2.3
17	50	82.1	16.7	2.8
18	50	92.9	33.3	7.0
19	0.0	92.9	0.0	0.0
20	0.0	100	0.0	0.0

Figure 12 shows that the ideal cutoff point between high risk and very high risk categories is at a Salzberg Scale score of 15. The originally proposed cutoff score between high and very high risk proposed through the original Salzberg study was 9. This is a six point increase from the originally proposed cutoff score which discriminated between high and very high risk groups.

Figure 13 represents the ROC curve for the total group based on the proposed cutoff score of 15 from Figure 12. The AUC was calculated for 0.8482. This analysis implies that the Salzberg Scale is a strong predictor of PrU development using 15 as the discriminating cutoff score between high and very high risk groups in acute hospitalization. The closer to 0.5, the more likely results are likely to be of chance. The closer the AUC is to 1, the more likely the results are related to a specific characteristic, or cutoff.

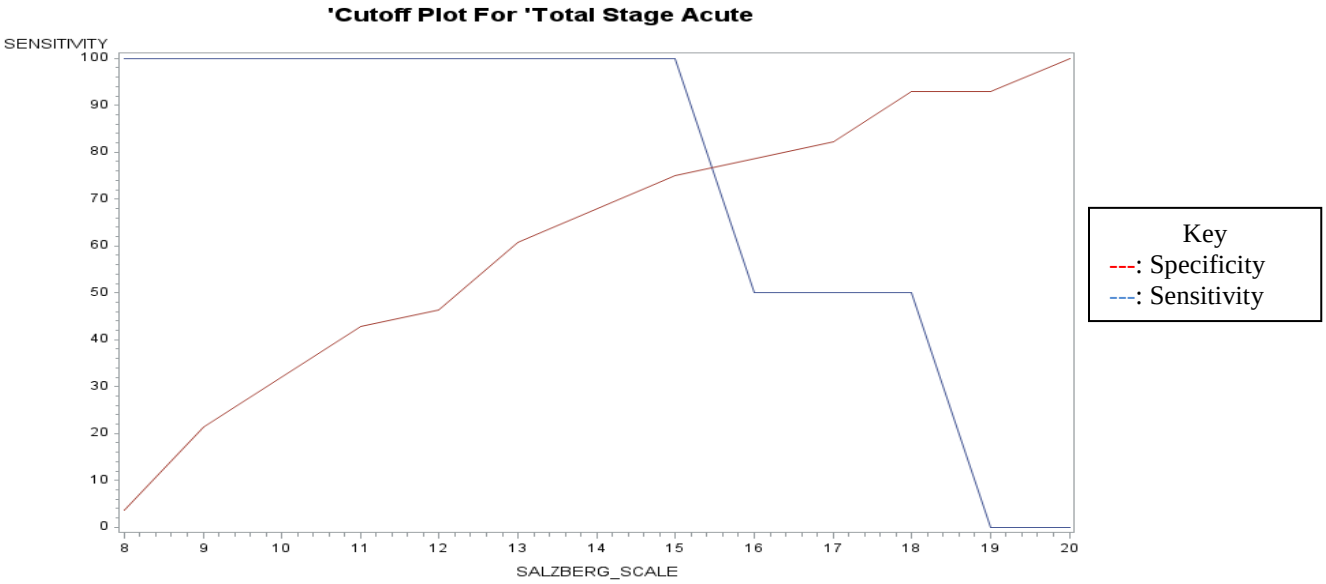

Figure 12 Cut off Plot for Acute Hospitalization

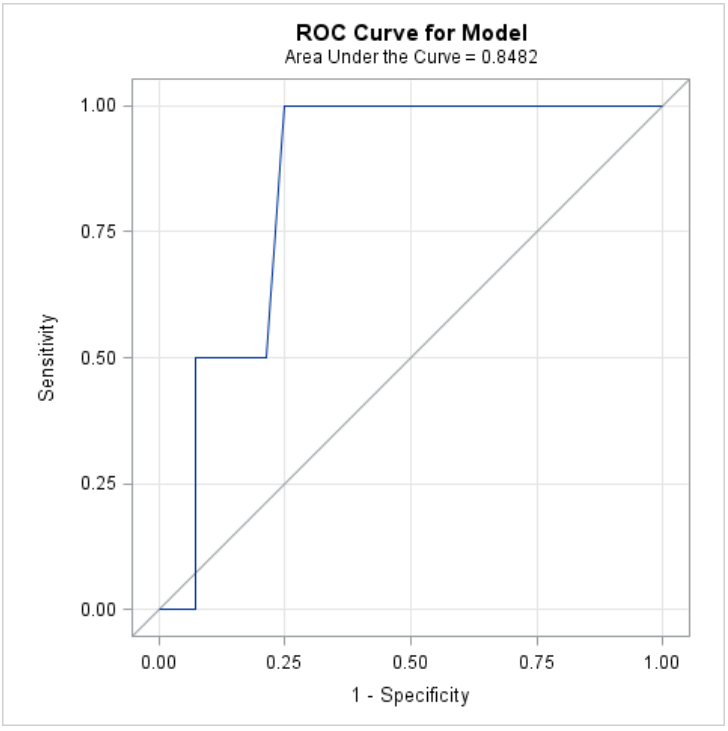

Figure 13 ROC Curve of Salzberg Scale for Acute Phase

5.2.1.3 Inpatient Rehabilitation Only

Lastly, the third statistical analysis set shown in Table 22 explains the basic outcomes of sensitivity, specificity, and predictive values for the sample population data according to the Salzberg score received in the inpatient rehabilitation group only. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity. Based on the best balance between a sensitivity of 66.7% and a specificity of 45.5%, a score of nine is considered the ideal cutoff score within the inpatient observations. The balance is evident in the intersection in Figure 17 at a score just above nine.

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Table 22 Statistical Calculation Table for the Data Set in Inpatient Phase

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
6	100	9.1	13.0	0
7	100	13.6	13.6	0
8	100	40.9	18.8	0
9	**66.7**	**45.5**	**14.3**	**0.7**
10	0	63.6	0	1.6
11	0	72.7	0	1.4
12	0	77.3	0	1.3
13	0	86.3	0	1.2
14	0	95.5	0	1.0
15	0	100	0	1

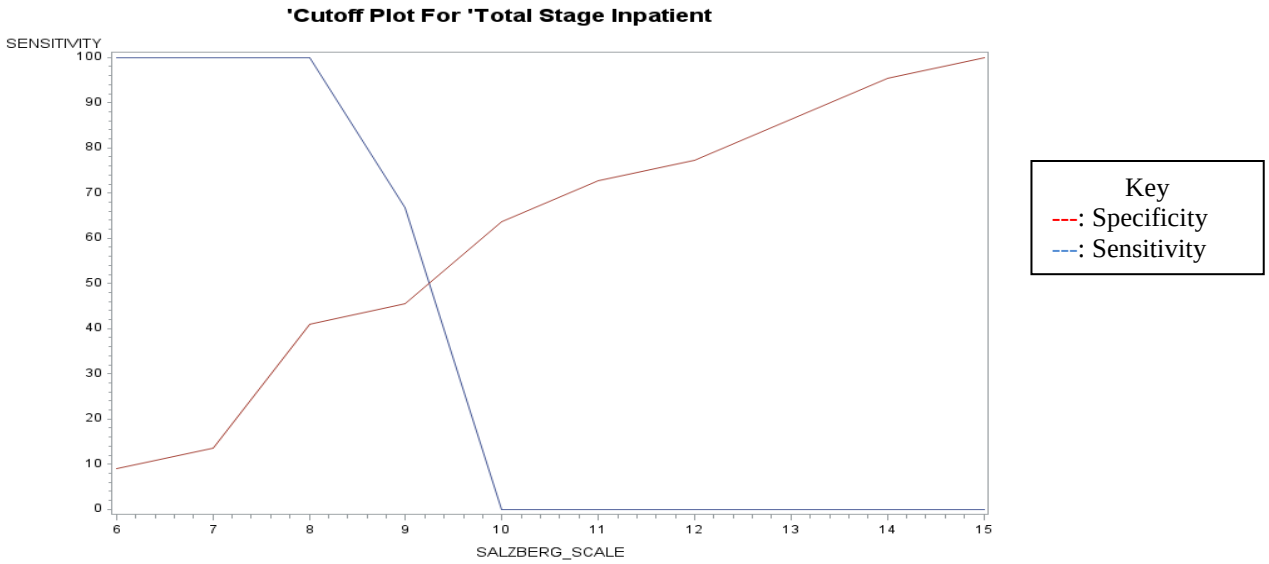

Figure 14 Cut off Plot for Inpatient Rehabilitation

Based on the extremely low to nonexistent sensitivity within these scores, the ROC curve showed an AUC of 0.4924 indicating the Salzberg Scale to be completely left to chance as a source of prediction. (See Figure 14 and Figure 15)

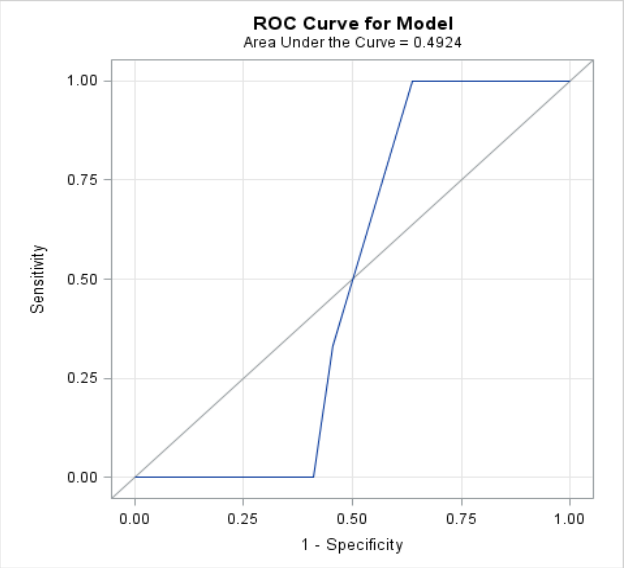

Figure 15 ROC of Salzberg Scale for Inpatient Rehabilitation

5.2.2 Multiple Visits Prediction Group

5.2.2.1 Total Population

As for the Multiple Visits Prediction Group, the same statistical analysis measures were considered. The total group set of analyses were attempted first. Table 23 shows their results in regards to sensitivity, specificity, PPV, and NPV values for each of the scores represented in the population. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity.

Table 23 Statistical Calculation Table for the Data Set in Total Group

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
6	100	2.9	12	100
7	100	4.4	12.2	100
8	100	14.7	13.4	100
9	77.8	26.5	12.3	90
10	55.6	38.2	10.6	86.7
11	55.6	47.1	12.2	88.9
12	55.6	51.5	13.1	90.0
13	33.3	61.8	10.3	87.5
14	33.3	70.6	13.0	88.9
15	33.3	80.9	18.8	90.2
16	22.2	85.3	16.7	89.2
17	22.2	86.8	18.2	89.3
18	11.1	97.1	33.3	89.2
19	0	97.1	0	0
20	0	100	0	0

The best balance seen is between sensitivity and specificity of 55.6% and 47.1 % respectively at a score of 11 points. The intersection can be seen in Figure 16. Despite its best balance, it is a very weak predictor of PrU development based on the ROC Curve in Figure 17. An AUC of 0.5458 does no correlate with strong predictive validity. The overall score of eleven is two points higher than Salzberg's original nine point cut off between the high and very high risk group.

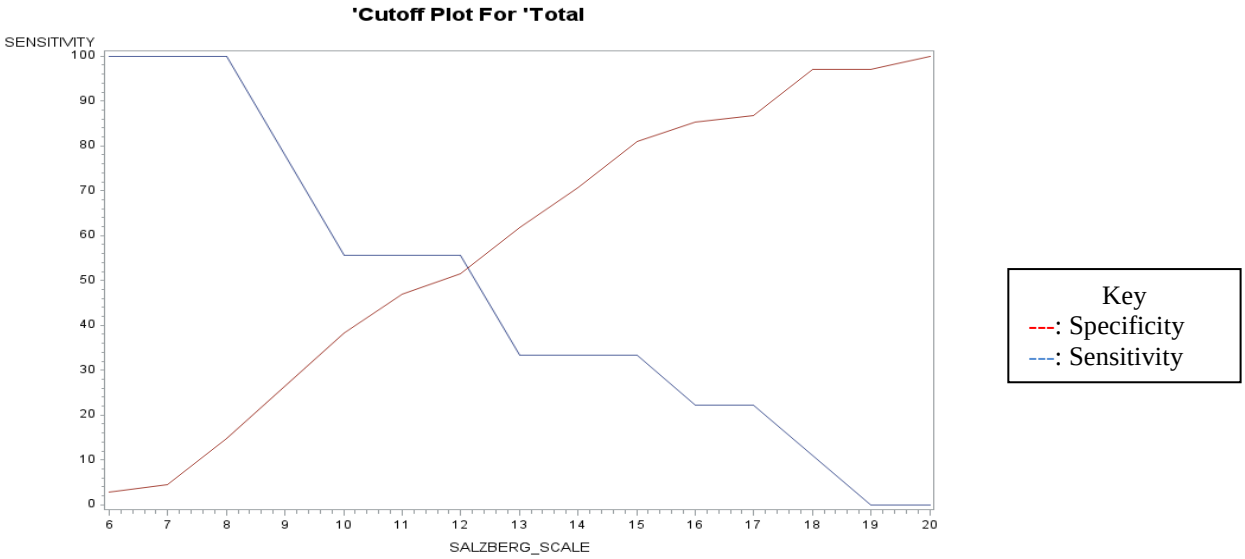

Figure 16 Sensitivity vs. Specificity of Total Group

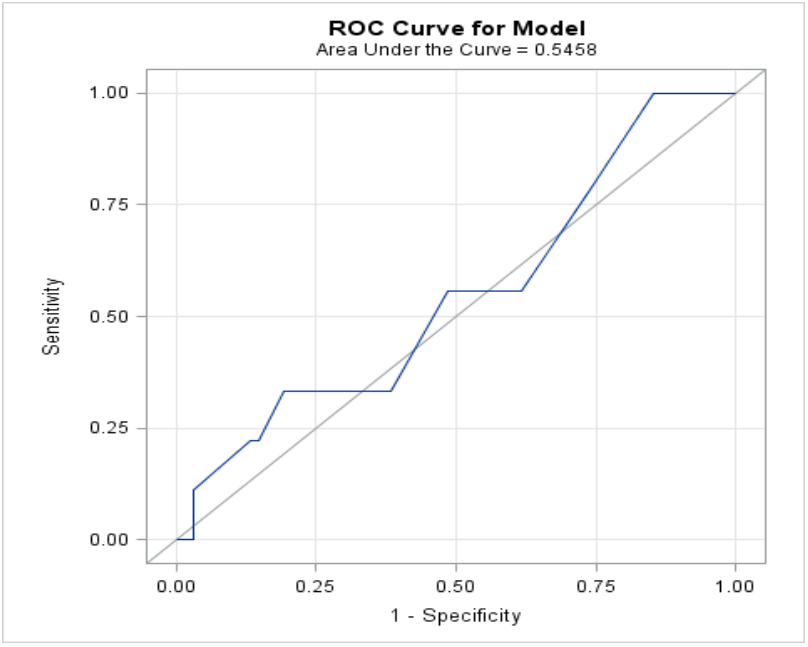

Figure 17 Total Group ROC Curve

5.2.2.2 Acute Hospitalization Only

Next, the overall statistical calculation set was taken for acute care hosiptalization for the multiple visits prediction method. Shown in Table 24 are the results of sensitivity, specificity, PPV, and NPV for each Salzberg Scale score represented in the acute care hospitalization population. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity.

Table 24 Statistical Calculation Table for Data Set in Acute Phase

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
8	100	2.6	13.6	100
9	83.3	17.9	13.5	87.5
10	83.3	28.2	15.1	91.7
11	83.3	35.9	16.7	93.3
12	83.3	41.0	17.9	94.1
13	50	51.3	13.6	86.9
14	50	61.5	16.7	88.9
15	50	71.8	21.4	90.3
16	33.3	76.9	18.2	88.2
17	33.3	79.5	20.0	88.6
18	16.7	94.9	33.3	88.1
19	0	94.9	0	86.0
20	0	100	0	86.7

Figure 18 shows that the ideal cutoff point between high risk and very high risk categories is at a rounded up Salzberg Scale score of 13. The originally proposed cutoff score between high and very high risk proposed through the original Salzberg study was nine. This is a noticeable four point increase from the originally proposed cutoff score. This particular group of data had the highest NPV scores showing its strong ability to decipher that the probability that a subject who scored below the determined cut-off score will not develop new a pressure ulcer.

The strength of identifying true negatives leads to a greater AUC of 0.5983 in the ROC Curve in Figure 19.

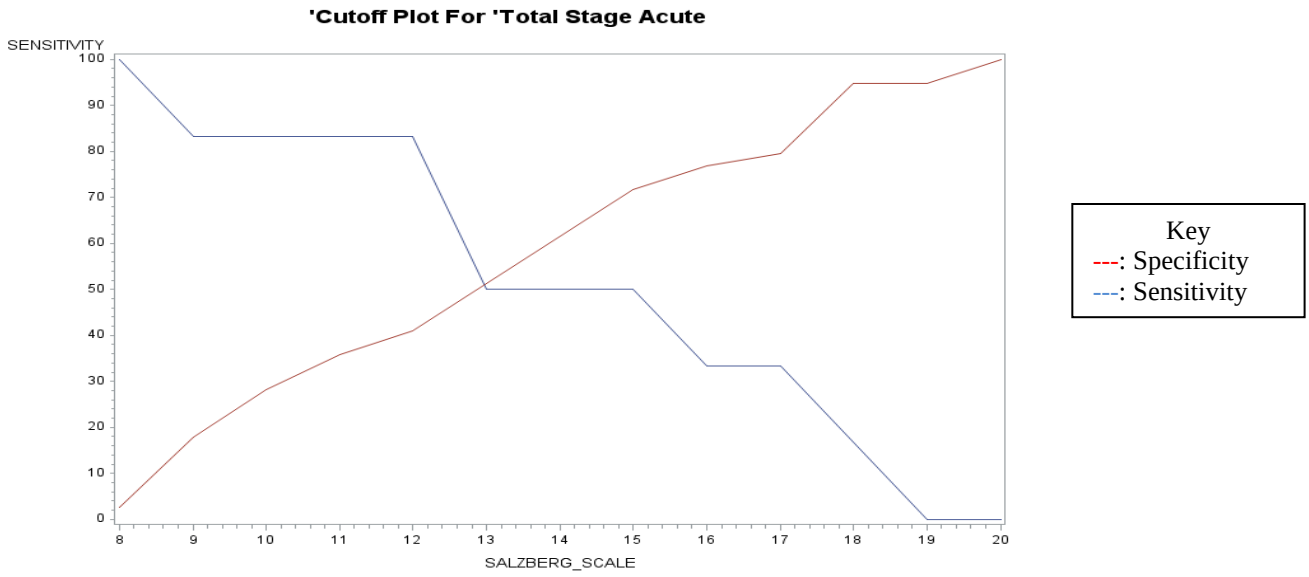

Figure 18 Sensitivity vs. Specificity of Acute Care Hospitalization Group

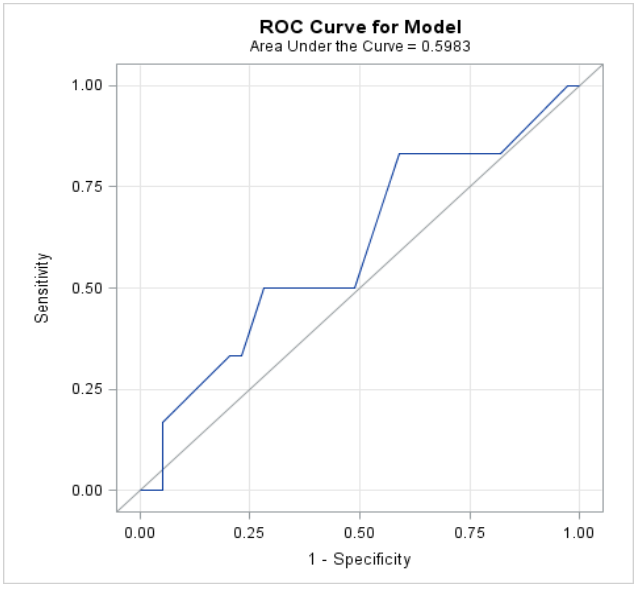

Figure 19 Acute Care Hospitalization Only ROC Curve

5.2.2.3 Inpatient Rehabilitation Only

Lastly, the psychometric properties of predictive validity were calculated for the inpatient rehabilitation group. General means of calculation are seen in Table 25. The inpatient only group suffered from terribly low PPV and sensitivities at any score above 10 points. Its stronger factor was determining the NPV on almost all occasions. The row highlighted in yellow represents that score with the balance of best sensitivity to specificity.

Table 25 Statistical Calculation Table for the Data Set in Inpatient Phase

Salzberg Scale Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
6	100	6.9	10	100
7	100	10.3	10.3	100
8	100	31.0	13.0	100
9	66.7	37.9	10	91.7
10	0	51.7	0	83.3
11	0	62.1	0	85.7
12	0	65.5	0	86.4
13	0	75.9	0	88
14	0	82.8	0	88.9
15	0	93	0	90
16	0	96.6	0	90.3
17	0	96.6	0	90.3
18	0	100	0	90.6

The best balance between scores is seen at nine points with a sensitivity score of 66.7% and a specificity score of 37.9%. In Figure 20, after intersection of the sensitivity and specificity, there is a deep plateau of the sensitivity, which represents poor identification of a higher score than nine leading to identification of PrU development. Reflected in Figure 21, the AUC

represents the predictability of PrU development for inpatient rehabilitation group. The AUC was calculated for 0.5862. This was slightly less than the acute rehabilitation group calculation. This analysis implies that the Salzberg Scale is an inaccurate predictor of pressure ulcer development using nine as the discriminating cutoff score between high and very high risk groups in inpatient rehabilitation.

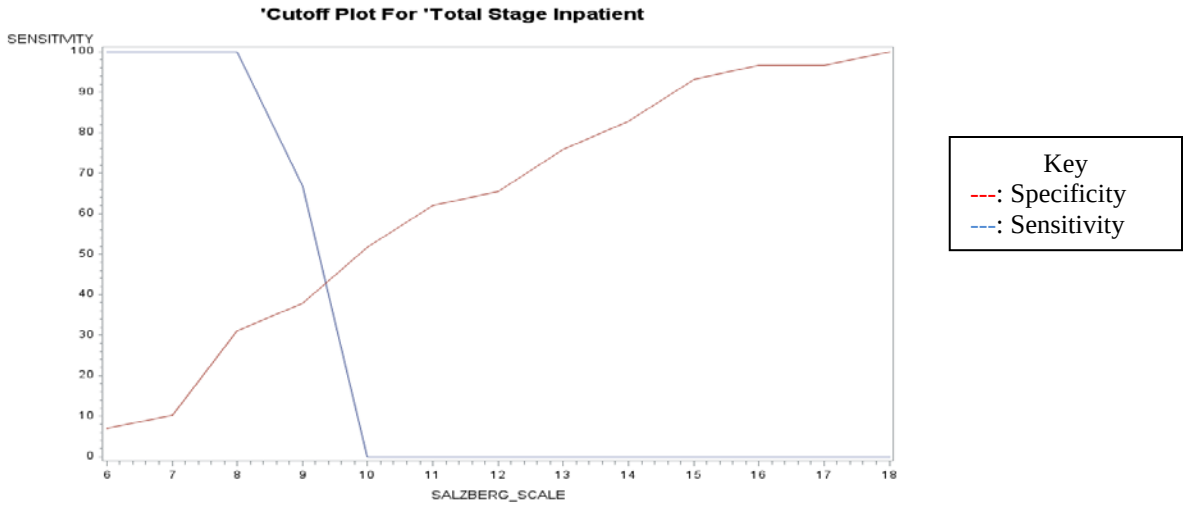

Figure 20 Sensitivity vs. Specificity of Inpatient Rehabilitation Group

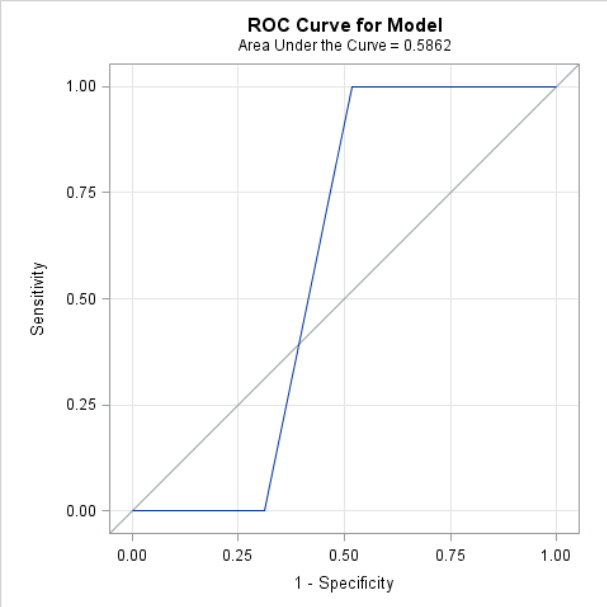

Figure 21 Inpatient Rehabilitation Group Only ROC Curve

6.0 DISCUSSION

The purpose of this study was to see evaluate the predictive validity the Salzberg Scale during acute care and inpatient rehabilitation following spinal cord injury by assessing of the scale's psychometric properties. The SCI QUERI Expert Panel on Pressure Ulcer Research Implementation suggested there is a need to develop weighted models of risk factors as clinical resources for critically ill or high risk populations.[36] The Salzberg scale weighs known PrU risk factors, but has not been evaluated for validity and/or reliability-since the reporting on its pilot study..[36, 51] The three aims of the study were composed to create risk cut-off scores for new, traumatic SCI using the Salzberg Scale in order to incorporate the psychometric testing needed to evaluate predictive validity.

The first aim was to verify the general statement that the Salzberg Scale has predictive risk capabilities. Based on the initial exploratory analysis, slightly higher average scores were seen for those who developed pressure ulcers alluding to possible predictive validity. When separating the population in to the next visits prediction and multiple visits prediction category, evidence of predictive validity no longer remained on the basis of average Salzberg Scale score being lower or similar to those who did not develop a PrU. With the purpose of seeing the scale's predictive properties in acute hospitalization and inpatient rehabilitation, the scale was tested for varying psychometric properties of time to PrU assessment 2-3 days after all the way through 22 days after assessment and stage of care including acute care hospitalization and inpatient

rehabilitation. Based on the exploratory analysis, the average score for a subject with pressure ulcer development was higher than those subjects that did not develop a pressure ulcer in the total and acute only settings. The biggest difference in average higher score was seen mainly in the acute hospitalization only. In contrast, there was lack of predictability based on the lower average Salzberg score in the inpatient rehabilitation. In regards to the first aim, this gave a weak initial impression that the scale had potential predictive ability as Salzberg believed that the higher the score of an assessment, the more likely the patient would be to develop a pressure ulcer.[67]

The second aim of the study was to identify an optimal risk cut-off score for developing a pressure ulcer in this extremely high-risk study population. This aim was completed by determining the best sensitivity versus specificity to find an optimal balance in scores based on the group and stage of care. This ultimately allowed for an opportunity to discuss risk categories for those in acute hospitalization and inpatient rehabilitation versus SCI individuals in a general sense as the pilot Salzberg Scale study addressed. In each group and sub-setting, an overall average cut-off score among the acute, traumatic injury group in similar methods to Salzberg's original study was identified. This aim identified PrU or lack of PrU development through risk score using a dichotomous method rather than four risk categories. Regardless of the score, Salzberg noted that there would always be "risk" for development of PrU as related to the four categories with the "low risk" being the minimal score. Rather than defining four categories of risk, the second aim was used to set a general standard score associated with risk in the new, traumatic SCI population.

The third and final aim was to use the newly calculated cut-off scores to evaluate the accuracy of the Salzberg scale for predictive capabilities and risk evaluation using ROC curve

analysis. When the psychometric properties were analyzed using the ROC curve, the results of the study suggested that the Salzberg Scale in actuality is a weak predictive assessment tool for PrU development based on the balanced cut-off scores. The results which ignore stage of care, or the total group, in both the next visit prediction group and multiple visit prediction group exhibited nearly identical outcomes of 0.5740 and 0.5458 respectively. AUC is indicative of a poor diagnostic test when the results are 0.50-.60.[74] This means that the Salzberg Scale score cannot distinguish risk over administration periods greater than 5-7 days for PrU development in this sample group. These results were also seen in the inpatient rehabilitation for next visit predictions group as well as the acute care and inpatient rehabilitation of the multiple visits prediction group. To reiterate, an AUC of 0.5 means that the likelihood of the assessment tool predicting PrU formation correctly is left to chance or toss-up. Elevated AUC represents discrimination of the assessment tool and its decimal is the percentage of randomly drawn pairs which are true.

One stage of care, the acute care hospitalization of the next visits prediction group showed good predictive validity with an AUC of 0.8482. Due to 100% sensitivity for subjects scoring 8-15 points, suggestion that all of these scores were correctly identified relates to the passing AUC in the ROC curve. The greatest balance of sensitivity and specificity for this phase of care, as seen in Figure 15, is at 15 points where the sensitivity was 100% and the specificity was 75%. Unlike the acute phase of the multiple visits prediction group, which had an AUC of 0.5983, we can see that reviewing results immediately after assessment, 2-3 days, is the more accurate way to predict PrU development in acute care hospitalization, possibly due to rapid changes in health level. A few weeks between assessments may weaken the association of

Salzberg Scale factors and their impact on risk as compared to other confounding variables such as implicated prevention techniques in the hospital and health improvement over time.

The multiple visits prediction group had a significant decrease of balance of sensitivity to specificity of 50% to 51.3%, which may be associated with a higher identification of true negatives as compared with the next visits predictions group in acute care hospitalization. The Salzberg Scale should have a high sensitivity so it is able to correctly identify as many individuals as possible positively (true positive). This also is the same standard needed to identify as many negative individuals when dealing with the concept of specificity. Being that it is highly difficult to achieve near perfection in sensitivity and specificity, a cut off level is based on a higher sensitivity, in the case of next visit prediction versus multiple visit predictions, as it is imperative not to miss the presence or risk of pressure ulcer development.[39] In Salzberg's original results, the balance of sensitivity and specificity had a higher specificity score in initial hospitalization of 84.2% as compared to sensitivity of 36.8% which is not favored.[51, 65, 68] Tailoring the Salzberg Scale to deliver a higher sensitivity is one aspect of the scale's properties that should be improved with refinement of risk evaluation in the new, traumatic SCI population.

Moving forward, it is noticeable that there are low PPV throughout next visit prediction group and multiple visit prediction group analyses. This can be attributed to the low incidence of pressure ulcer development in each category. The PPV will never be close to 100% even if the sensitivity and specificity are high such as in the next visit predictions group of acute care hospitalization.[39] When screening a population with very low incidence, it is inevitable that many people with positive test results will in fact be false positives or a Type II error.[5] In addition, low PPV may be associated with the effect of preventative measures used while subjects are being treated in the settings. For instance, subjects were not limited to prevention

techniques such as support surface technology, skin assessment or tissue integrity assessment, or pressure-relief turning schedules. These techniques would reduce the likelihood of PrU formation in an already high-risk population. In addition, the level of a patient's health improved during their stay in the hospital or inpatient facility, which led to decreased risk in development of pressure ulcers, thus decreasing the probability.[39] If PrU incidence in this sample population had in fact been higher, it is likely that the PPV would have been higher and the NPV would have been lower.[4] The incidence of PrU development in the RERC on SCI study was 42% as compared to an average of 32% incidence in the past year found by Saladin et. al and 43% incidence in the past year found by Krause et al.[42, 63] Being that the incidence of the study population had an incidence of 9% to 11.7%, the lower incidence isn't necessarily representative of the general population trends.

Another variation between Salzberg's preliminary results and this study's are differences in the population demographics. The two populations cannot be directly compared as populations are so different. Thus, the approach of dichotomous risk versus four categorical risk levels cannot be precisely equated. The difference in SCI patient may have impacted the cut-off scores greatly. Salzberg's sample population consisted of 219 patients who had endured injury for 17.2 ± 12.1 years.[67] On the other hand, the sample population of new, traumatic SCI patients had only endured injury for 35 ± 45 days. Drastic difference in human physiology impacts the secondary complications or risk factors that are accounted for in the scale. For instance, most patients in acute care hospitalization are bedridden due to intubation after initial traumatic spinal cord injury. This impacts the score by nearly seven points as their level of activity and mobility is nearly non-existent. As for the population of Salzberg, only two patients were confined to a bed and those temporarily hospitalized used mobility and activity data from a baseline state.[65] In

addition, the entire sample population of this study was in a hospital setting. This added two additional points to the entire population's total score, shifting the average score of the subjects to a higher cut-off. In Salzberg's population, the patients varied greatly with only 3% living in a nursing home or hospital at the time of the assessment.

After reviewing the various differences in populations, it can be seen that there are inconsistencies in the cut-off scores based on the elapsed time since injury of the patient. Salzberg's pilot study did not include a large group of newly, traumatic spinal cord injury patients which this study's entire sample population included. Salzberg recommended cut-off scores for a population specifically focused on outpatient care of 6-8 points for high risk, when newly, traumatic spinal cord injury have an average high risk score of 11 (range of 9-15 points). It is necessary for the subpopulations to be evaluated within the SCI population and tested for different levels of risk with the Salzberg Scale. The overall greater score suggests that patients in acute care hospitalization are automatically more susceptible to the development of PrU based on a higher point accumulation and need different weights on risk factors to differentiate from who is at risk and who is at extremely high risk of development.

Salzberg's Scale weighted risk factors must be modified to better accommodate the drastic changes between those patients in acute care hospitalization after traumatic spinal cord injury versus those who have endured long-term injury. In addition, the Salzberg Scale is not fit to measure the risk of the new, traumatic SCI population based on the results of the ROC curve unless it was short term administration of the scale (See Figure 14, Figure 18, Figure 20, Figure 22, Figure 24.) Left to chance, this scale is seen as unfit for subjects with newly, traumatic spinal cord injury unless specifically used in acute-care hospitalization every 2 to 3 days for reassessment. Potentially reevaluating the inpatient population using a 2-3 day administration

plan as opposed to a 5-7 day plan may result in better predictability of the scale. To confirm these results, another study using a cut off score of 15 points and newly, traumatic SCI patients in acute care hospitalization should be performed in addition to short-term administration in the five other population groups.

7.0 CONCLUSIONS, LIMITATIONS, FUTURE WORK

The results of the study suggest that the Salzberg Scale is unfit for subjects with newly, traumatic spinal cord injury unless specifically used in acute-care hospitalization every 2 to 3 days during medical assessments. However, these results were obtained using a small sample size and subjects limited to certain criteria that may vary from the general SCI population. This study presented various limitations. If this study were to be repeated, I would suggest using a prospective method along with patients in various medical settings outside of a direct hospital facility. I believe using a prospective method would be easier to set consistent follow-up dates for patient assessments and have a more accurate account of level of mobility, activity, and incontinence. In this study, the use of opinion from patient nurses through medical record analysis could have altered the precise coded values despite using expertise of the nurse to declare these values. In addition, short-term administration of the Salzberg Scale in the inpatient rehabilitation should be implemented in order to see the scale's applicability to other settings. Also, a prospective study would lend itself to a more accurate assessment of moisture control rather than relying on notes pertaining to catheterization changes and subjectivity of medical record interpretation.

In addition, I believe that it is important for the study to have albumin scores collected for every single assessment to avoid the use scattered scores and more than one observation from subjects accounted for in statistical analysis. Though the next visit prediction and multiple visit

prediction group calculations accounted for repeated subjects, this method may have impacted the results by not comparing identical population groups and varied subject demographics. Regarding my suggestion about patients living in various residential settings, the entire population worked with was in a hospital at the time of assessment. This automatically inflated the total score by one point. Being in a hospital setting, we were more likely to see patients who were intubated or sedated and had no capability of activity, which is the most heavily weighed component in the scale as well. This outcome led to inflated scores and potentially a higher cutoff score as seen in the results. Lastly, we only worked with patients directly after the traumatic injury, which is different from someone who suffers from traumatic injury but does not have the immediate secondary medical complications that also inflate the total score.

After recognizing these limitations, I believe that if corrected, the Salzberg Scale could show promising risk assessment of pressure ulcer development in the SCI population. With strong evidence of weak predictive validity based on ROC Curve results, I believe studies should use the higher cut off scores in both the acute and inpatient rehabilitation settings as well as the presented cut off score to see which scoring method and specify a scale for those of acute care hospitalization or new, traumatic injury versus outpatient care. Future studies should use the originally presented cutoff score from Salzberg's study with a control group and the newly identified cut off scores with the experimental group. The same group of patients could be used in both test groups for exact consistency and comparison.

Once the cut-off scores are solidified on the Salzberg Scale, I would like to see a head to head comparison of the Salzberg Scale predictive validity with the Braden Scale predictive validity in the same SCI population. WB Mortenson et al. recommended that the Braden Scale still be used based on the lack of psychometric testing of the Salzberg Scale. With the Salzberg

Scale pilot study and this study producing contradictory results and extreme cut off score difference, there is a need to see if changes made to the Salzberg scale hold up to the previous validation of the Braden Scale. This will provide the first study that presents which measurement tool is more accurate for risk identification using the same population. It will also answer many questions posed by those who speculate that a scale designed specifically for the SCI population will be a better indicator of risk than of a general assessment. Lastly, univariate analysis of the fifteen individual risk factors of the Salzberg Scale should be evaluated in order to determine if certain risk factors contribute more to the prediction of PrU development over others. Potential redistribution of coded values and elimination of risk factors may be identified if analysis is completed.

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