Defining Unstageable Pressure Ulcers as Full Thickness Wounds: Is this Definition Consistent with Clinical Outcomes?

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A dissertation

submitted in partial fulfillment of the requirements

for the degree of

Doctor of Philosophy

University of Washington

2015

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School of Nursing

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Abstract

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Hospital acquired pressure ulcers affect millions of patients in the U.S. annually. The incidence of hospital acquired pressure ulcers internationally is hard to gauge as there is no internationally accepted tracking process, nor does a pressure ulcer registry exist at this time. Pressure ulcers are associated with patient pain and suffering, decreased quality of life, increased morbidity and mortality, increased length of stay, and increased cost of care. Full thickness pressure ulcers (Stage III, IV, and unstageable) are considered events that should never happen in hospital settings by the National Quality Forum and are included in a list of serious occurrences alongside events such as wrong site surgery, patient death due to medication errors, and sexual abuse or assault of a patient. Given that there is consensus that not all hospital acquired pressure ulcers are avoidable and some life-saving interventions increase the risk of pressure ulcer

development, it may be argued that it is inappropriate to include pressure ulcers in this grouping. The designation of pressure ulcers as never events has spurred policy which prevents funding for care of these events by insurers and requires public reporting. Significant time and dollars are spent by facilities in the care of these ulcers, associated intensive review proceedings, and reporting of these ulcers.

Unstageable pressure ulcers, ulcers in which the wound base is obscured by slough or eschar, are defined as full thickness wounds and, as such, are included in the never events list. However, there is currently no literature to support this definition. Clinicians have difficulty in correctly identifying unstageable pressure ulcers and there are no existing histopathologic exams, lab studies, or other means to confirm unstageable pressure ulcers. Therefore, clinicians are forced to rely on their clinical expertise for diagnosis. Clinical observations on the healing trajectory of unstageable pressure ulcers shared in this dissertation indicate that these ulcers do not always heal consistently with full thickness wounds.

The two studies described in this dissertation attempt to address the healing trajectories of unstageable hospital acquired pressure ulcers. The purpose of these studies is to answer the question of whether unstageable pressure ulcers are appropriately defined as full thickness wounds, or if there are cases in which these ulcers are partial thickness, indicating less severity of tissue damage. Studies on unstageable pressure ulcers help increase understanding of these wounds and have the potential to improve patient care, outcomes, and current policy measures.

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GLOSSARY

Academic Medical Center (AMC): Hospitals that include or are closely affiliated with a medical school and provide complex medical services, medical education, and research.

Age: Age of the patient when pressure ulcer in study was first identified

Barber-surgeon: Medical providers in medieval Europe who cut hair, performed surgery, extracted teeth, and provided other forms of medical care. In the mid-1700s these two professions (barbers and surgeons) were officially separated.

Dermis: The layer of skin below the epidermis (the outer layer), which is composed of two layers; the papillary (superficial dermal structures) and reticular dermis (deep dermal structures).

Epidermis: The outer layer of the skin, which is composed of five layers; the stratum corneum, stratum lucidum, statum granulosum, stratum spinosum, and stratum basale.

Eschar: Non-viable tissue that is brown or black and may be hard, soft, or soggy.

Extrinsic factors: Factors that affect a patient from the external environment. (A partial list of examples includes pressure, shear, moisture, medical devices such as splints, and turning a patient.)

Full thickness wound: Wounds that extend into the deep dermal structures (hair follicles, sebaceous glands, and sweat glands) and beyond. Tissue destruction may include fat, muscle, tendon, bone, or other deep structures. These wounds heal through the development of granulation tissue (defined below) and contraction.

Healing trajectory: Tissue characteristics found at wound base at confirmation of unstageable pressure ulcer and the evolution of the wound base over time as documented in the medical record.

Granulation tissue: Pink or red, moist, granular appearing tissue that is primarily composed of connective tissue and new blood vessels. Deep structures such as those found in the reticular dermis, fat and muscle do not regenerate; therefore, granulation tissue is generated by the body to fill wounds with full thickness tissue loss.

Hospital acquired pressure ulcer (HAPU): A pressure ulcer that develops while a patient is admitted to a hospital.

Intrinsic factors: Factors that affect a patient through their own physiology or condition. (A partial list of examples includes: chronic diseases, poor nutrition, cognitive impairment, and aging.)

Papillary dermis: The top layer of the dermis containing connective tissue and blood vessels which provides nutrients to the epidermis and helps control skin temperature.

Partial thickness wound: A wound that does not extend into the reticular dermis. Partial thickness wounds heal by regeneration, meaning the same tissue (epidermis and papillary dermis) is generated to heal or close the wound.

Pressure ulcer (PU): Localized areas of injury to skin and/or underlying tissue caused by pressure or pressure and shear together.

Pressure ulcer site: The anatomical location of the pressure ulcer. In this study, one patient may have more than one pressure ulcer site. (For example, a patient may have a wound on their sacrum and their heel.)

Reticular dermis: The lower layer of the dermis, located under the papillary dermis and above the subcutaneous tissue. Blood vessels, connective tissue, hair follicles, sebaceous and sweat glands are all found here.

Slough: Soft, moist non-viable tissue that can be white, yellow, tan or green.

University HealthSystem Consortium (UHC): A national health care network of not-for-profit and academic medical centers, serving more than 5,200 health systems members and their affiliates, dedicated to leading health care innovation, creating knowledge and fostering collaboration to help members.

Unstageable pressure ulcer: Considered full thickness wounds that cannot be staged due to the presence of slough or eschar, which obscures the true wound base.

ACKNOWLEDGEMENTS

The studies completed for this dissertation were funded in part by Achievement Rewards for College Scientists, Becky and Jack Benaroya ARCS Endowment, Seattle Chapter ARCS, Seattle, WA; Warren G. Magnuson Scholarship, University of Washington, Seattle, WA; and the Valerie Weiss Memorial Scholarship, King County Nurses Association, Seattle, WA.

I have had the great fortune of working with JoAnne D. Whitney, Margaret W. Baker, and Jeanne R. Lowe as my supervisory committee. My appreciation for this exceptional group of researchers is beyond words. My committee acted as superior mentors as they helped me navigate the world of research science. The patience, understanding, and wisdom exhibited by these women over the last several years will not be forgotten and will continue to act as a reminder of the type of researcher and person that I aspire to be.

When asked what my experience in the doctoral program at the University of Washington's School of Nursing has been like, the first thing that always comes to mind is, "You don't know what you don't know." These last five years have opened my mind to concepts and understandings that were previously unknown to me and which not only make me a better researcher, clinician, and scientist, but also improve my understanding of the world around me and make me a better consumer of research. My doctoral studies made it possible for me to know the right questions to ask and view existing research with a critical eye accompanied by gratitude for all the work that has been done and the knowledge that there is much more to do. The field of research is a lifelong, never-ending, and active art and science; one that I am grateful to have entered. I feel great responsibility for ensuring that my work is sound, rigorous, and meaningful. The gratitude I have for my studies is enormous.

My beloved, Quinn; our two dogs, Mae Belle and Peeps; our kitten, Lefty; and our 21 year old cat who passed away last year, Chyna, all loved me no matter how stressed or overwhelmed I was each day, brought me happiness and a comfort in knowing that they were there for me. Their love was and is what gets me through each day, no matter the stressors around me.

My family and friends who were patient and supportive throughout the last five years were essential in this journey; they believed in me and boosted my spirits along the way. Special recognition to my brother, Callius, and my sister, Lianna, who were consistently reminding me that I could do it. I can't thank them enough for being there for me and cheering me on.

My undergraduate professors; Verna Harms, Marylou Sena, and Pamela Detrick; each of whom inspired me in unique ways through their examples of what it meant to be professionals with integrity and heart.

The professional mentors and role models that I have had the honor of working with throughout my career in healthcare; Kathy Colagrassi, Connie Mackenroth, Paula Minton-Foltz, and Abdelhak Abdou. These individuals provided me with tools, skills, faith, humor, and open-heartedness that I needed to grow professionally.

My colleagues, past and present, at Harborview Medical Center; Shirley Taylor, Nancy Unger, Mark Goetcheus, and Holly Vance. These exceptional clinicians made the studies contained in this dissertation possible due to their excellent patient care and documentation. Nancy Unger also provided important data abstraction necessary for the inter-rater reliability question in the second study. Abdelhak Abdou, for his statistical wisdom and guidance on both studies in this dissertation and his management of the clinical wound data base. Mr. Abdou's

insight was essential to the completion of this dissertation and I will always be grateful for his contributions. Sergio Villanueva for his co- management of the clinical wound data base.

The patients that I have been honored to work with throughout my career are the reason for my thirst for knowledge in wound care and the greatest driving factor in my studies. They are the reasons that I chose to pursue a doctoral degree and my greatest happiness would be to improve their lives in some small way.

I am ever thankful for the many research scientists in wound care who set the foundations for this fascinating and clinically meaningful field.

DEDICATION

For my father and mother, a scientist and an artist, who each bestowed in me a love of learning and a desire for continual growth. Though both have passed away, their spirits have never been far from me and have been essential in my personal journey. And for Quinn, for whom no explanation is needed.

CHAPTER 1.

INTRODUCTION

Pressure ulcers (PUs) are localized areas of injury to skin and/or underlying tissue caused by pressure or pressure and shear together. There are six categories of PUs defined by the National Pressure Ulcer Advisory Panel (NPUAP).[1]

Pressure Ulcer Categories

* Stage I PUs are areas of non-blanching redness to intact skin.
* Stage II PUs have partial thickness tissue loss and may appear as a serous filled blister.
* Stage III PUs are full thickness wounds which may extend into subcutaneous fat, but do not extend into muscle, tendon, and bone.
* Stage IV PUs are full thickness wounds and extend down to muscle, tendon, or bone.
* Suspected Deep Tissue Injuries are areas of deep purple or maroon tissue or a blood filled blister.
* Unstageable PUs are considered full thickness wounds that cannot be staged due to the presence of slough or eschar, which obscures the true wound base.[1]

Photographic examples of PU stages are included as Appendix A.

History of Pressure Ulcers

The problem of PUs has likely been present since the dawn of humankind to one extent or another, with historical evidence of PUs in Egyptian mummies dating back as far as five thousand years.[2] Pressure ulcers, their causes, and cures were important enough to Ambrose Paré, notable sixteenth century barber-surgeon, to discuss in his autobiography.[3] More than three hundred years after Paré's autobiography, in 1877, well respected French neurologist, Jean Marie Charcot, discussed the causes (though different from what is known today), progression, and presentation of PUs in *Lectures on Diseases of the Nervous System*.[4] And in more recent history, the use of plaster-of-Paris splints is noted to have increased the incidence of PUs in WWII.[5]

The NPUAP, founded in 1987, is an internationally recognized not- for-profit organization dedicated to PU prevention and treatment.[6] The current PU staging system was developed by the NPUAP and is used around the world. Recommendations and guidelines created by this organization influence public policy and patient care. Unstageable PUs, which will be discussed throughout this dissertation, were first recognized by the NPUAP by name in 2007. However, these ulcers have been recognized and discussed by clinicians for many years before they were officially a part of the staging system. Charcot described unstageable PUs in his 1877 publication in which he includes a description of eschar covering the wound base of PUs and provides accompanying plates which are consistent with what we find today in the presentation of unstageable PUs.[4] These plates are included as Appendix B.

Magnitude of Problem

Pressure Ulcers are a common finding in hospitalized patients. A 2009 study shows the incidence rate of hospital acquired pressure ulcers (HAPU) to be 5%.[7] However, incidence rates do vary by study and can range from 0.4% to 38%.[8] These incidence rates translate into acute care facilities in the United States (US) treating an estimated 2.5 million nosocomial PUs yearly and have significant costs associated with treatment.[9,10] The Centers for Medicare and Medicaid Services (CMS) rate the average cost of treating a full thickness PU at $43,180.[11]Annual estimates for PU care in the US have been as high as 11 billion dollars.[11] Costs may be considerably higher than this; however, as this is based on 2007 CMS data.

Pain and suffering are well-documented finding in patients with PUs.[12-17] Fox describes pain, drainage, loss of independence, emotional problems (such as anger and depression), worry regarding if the wound will heal, relationships with significant others, body image, and social isolation as common themes found in patients with PUs.[14]

Mortality has been associated with PU development in hospital settings. [18-20] However, the data do not support that people die from PUs. [19, 20] Instead, it has been noted that in critically and chronically ill patients, the development of full thickness PUs is a comorbid pathologic process. [19]

Bry et al. found that the majority of patients with HAPUs required extended hospital stays prior to the development of these ulcers due to their illnesses. [18] A recent study using data from the University HealthSystem Consortium (UHC), which included data from 210 academic medical centers, found that the average length of stay (LOS) for patients with HAPUs was 20 days longer than patients who did not have HAPUs. [21] Another study, using data from California

hospitals, found similar results with a mean LOS for patients with HAPUs stage II or greater of 24.9 days and those without PUs with a mean of 4.8 days.[22]

All of the above mentioned factors; incidence rates, patient pain and suffering, mortality, increased LOS, and associated costs; have been driving factors for regulatory bodies to develop policies with the intention of decreasing PU development in healthcare settings. These changes in PU public policy have significantly changed how clinicians view PUs and the quality of PU care.[23]

What We Know About Unstageable Pressure Ulcers

Unstageable PUs are defined by the NPUAP as full thickness PUs in which the wound base is covered with slough or eschar; these ulcers cannot be staged until the slough or eschar is "debrided" or removed from the wound base.[1] Slough is soft, moist avascular tissue that can be white, yellow, tan or green while eschar is avascular tissue that is brown or black and may be hard, soft, or soggy. [1] (Figures 1&2)

Defining unstageable PUs as full thickness wounds is not supported by literature. Research on the healing trajectory of Unstageable PUs, which would provide information regarding the quality of the tissue at the wound base, and thus elucidate the depth of the ulcer, is not currently available.

Importance of Further Research on the Healing Trajectory of Unstageable Pressure Ulcers

Pressure ulcers are recognized and considered indicators for the level of quality in healthcare.[24] Considering this, it is important to appreciate the stigma attached to full thickness PUs, which are often associated with negligence and widely seen as never events (events that should never occur in healthcare settings). This is in spite of the knowledge that in the treatment of hospitalized patients there are times when actions are required that increase PU risk, but are

necessary to advance other life-saving care.[10] Although it is clearly not the intention of the organizations, the fact that full thickness PUs are considered serious reportable events by the National Quality Forum (NQF)[25] and that PUs overall are considered nursing quality indicators by the Agency for Healthcare Research and Quality, NQF, and the American Nurses Association may play a role in promoting this stigma.[26] A more accurate understanding of Unstageable PUs and their evolution may help decrease stigma and increase understanding.

The Department of Health and Human Services, The Centers for Medicare and Medicaid Services (CMS), and state Departments of Health (DOH) have all implemented public policy measures around the occurrence, reporting, and payment for HAPUs. Many of these measures are specific to full thickness PUs.

If research provides evidence that not all Unstageable PUs are full thickness wounds, this information has the potential to influence NQF recommendations and requirements around public policy. Such changes in recommendations could save hospitals considerable time and cost involved in the intensive review and reporting process. This savings of important and limited healthcare dollars could allow for these funds to be redirected to essential patient care.

Reliability of Pressure Ulcer Staging

Correct identification and staging of PUs is important in order to accurately judge the scope of the problem.[27] However, literature shows wide variability in the ability of nurses and physicians to correctly identify and stage PUs. While multiple studies find low to moderate reliability in identification and staging,[28-34] there are other studies finding high reliability.[27, 35-37] Both nurses and physicians demonstrate a particular challenge in identifying Unstageable PUs.[28, 29, 34]

Harborview Medical Center

The two studies described in this dissertation were conducted at Harborview Medical Center (HMC). Harborview began as a six bed county hospital in 1877 and is currently a 425 bed level one trauma/burn center and county hospital. Harborview's mission includes serving people who: are incarcerated in King County Jail, have mental health conditions, have sexually transmitted diseases, have substance use disorders, are indigent, are non-English speaking and poor, need trauma care, need burn care, need specialized emergency care, are victims of domestic violence and sexual assault. The facility provided 168 million dollars in charity care in fiscal year 2014.[38]

Harborview has long shown a commitment to PU prevention and care through education of staff and providers; use of specialty surfaces, devices, and dressings; involvement in local and national PU committees; and research.

In 2007 HMC implemented a new electronic medical record (EMR), Cerner ®, which assists staff in appropriate wound documentation through prompts and reference text which defines wound specific terminology. The first line of the admission charting addresses PUs, presence of PUs is included in the EMR template for nursing documentation of frequently charted assessments, and there are specific wound documentation fields. Within the wound documentation fields, definitions of PUs and wound characteristics are embedded and accessible by clicking on the text (e.g. clicking on "pressure ulcer" opens up a window with definitions of PU stages). A PU documentation example with reference text to assist staff with documentation and understanding is located in Appendix C.

Two Studies Assessing the Healing Trajectory of Unstageable Pressure Ulcers

The author's experience as a Certified Wound Care Nurse at HMC involves direct care for patients with wounds as well as assisting with intensive reviews, root cause analyses, and action plans for reportable events to the DOH. Since the 2007 NPUAP definition of unstageable PUs was created, defining these wounds as full thickness, both the author and her colleagues at HMC found that many of the patients they provided care for with unstageable PUs did not heal consistently with wounds that were full thickness. This clinical observation elicited questions regarding the definition of these ulcers.

An initial study was conducted by the author in 2013 in which a retrospective review was completed for all patients with unstageable HAPUs at HMC over a 3 year and 4 month period. That study provided valuable information regarding the healing trajectory of unstageable PUs, however, statistical significance regarding healing consistent with full thickness injury was not reached due to the sample size. This initial study was the foundation and inspiration for a second study involving 6 years and 7 months of data. The outcomes of these studies are shared in this dissertation.

CHAPTER 2.

DEFINING UNSTAGEABLE PRESSURE ULCERS AS FULL THICKNESS WOUNDS: ARE THESE WOUNDS BEING MISCLASSIFIED?

Abstract

Purpose: The purpose of this research is to study the evolution of unstageable pressure ulcers (PUs) over time through evaluation of wound characteristics to determine if their healing trajectory is consistent with full or partial thickness wounds.

Subjects and Settings: Patients with hospital acquired (HA), unstageable PUs were evaluated. Subjects were cared for at a level one trauma/burn center and safety net hospital in the Pacific Northwest between November 2007 and March 2011.

Methods: This study employed a retrospective design to collect data. One hundred ninety four unstageable PUs were examined. The sources of data were the electronic medical record and a clinical PU data base. The PU data base is managed by certified wound care nurses and includes data on all verified hospital acquired pressure ulcers (HAPU) since 2007. Unit of analysis was individual PU site.

Results: Of the initial 194 unstageable PUs identified, 120 were excluded due to lack of data needed to address research questions. Out of the 74 unstageable PUs that remained in the study, approximately a third (33.8%) were found to follow a healing trajectory consistent with partial thickness wounds.

Conclusion: The findings of this study indicate that although many unstageable PUs demonstrate healing trajectories consistent with full thickness wounds, others follow a wound healing trajectory consistent with partial thickness wounds. Additional research is indicated and opening

a discussion regarding the possible revision of the current definition for unstageable PUs is recommended.

KEY WORDS: Unstageable, Pressure Ulcer, Slough, Eschar

Introduction

Pressure Ulcers (PU) are defined as localized areas of injury to skin and/or underlying tissue caused by pressure or pressure in combination with shear. The National Pressure Ulcer Advisory Panel (NPUAP) defines 6 categories of PUs.[1] While these categories are commonly referred to as stages, they are not stepwise in progression nor do they have a hierarchical designation. For example, a Stage I does not necessarily progress to a stage IV, nor does a stage IV heal to a Stage I. Nevertheless, Stage III, IV, unstageable PUs, and suspected deep tissue injuries are considered more severe than Stage I and Stage II PUs. Unstageable PUs are defined as full thickness ulcers with a wound base that is covered with slough or eschar; these ulcers cannot be further categorized until the slough or eschar is removed from the wound base.[1] Slough is soft, moist avascular tissue that can be white, yellow, tan or green and eschar is avascular tissue that is brown or black and may be hard, soft, or soggy. [1](Figures 1 and 2)

If all unstageable PUs are full thickness wounds, clinicians should expect to find deep structures such as granulation tissue, fat, muscle, tendon, ligament, bone, or cartilage at the wound base prior to closure. Granulation tissue is pink or red, moist, granular appearing tissue that is primarily composed of connective tissue and new blood vessels.[1] The body generates granulation tissue to fill full thickness wounds because fat, muscle, and other deep structures do not regenerate and must be replaced with granulation tissue. If deep structures or granulation tissue are not present at the wound base, it is plausible that not all unstageable PUs are full

thickness wounds. If unstageable PUs demonstrate a healing trajectory consistent with partial thickness wounds; the clinician would anticipate finding regenerating papillary dermis and epidermis rather than granulation tissue. Systematic evaluation of observations and documentation of the healing process of unstageable PUs is a first step towards better understanding if these ulcers are always full thickness. (Box 1)

PubMed and CINAHL were used to search for English language articles using the following key words: "unstageable pressure ulcer", "unstageable pressure ulcer healing", "pressure ulcer healing", "pressure ulcer", "slough", and "eschar." Studies were identified that described incidence, prevalence, demographics, treatment, inter-rater reliability of staging, and assessment.[10, 28-30, 35, 39-49] However, no studies describing the healing trajectory of unstageable PUs were identified, indicating a significant gap in our knowledge, even though the need for studying the evolution of PU stages has been argued for nearly 2 decades.[24] If there are no studies describing healing trajectories, we argue that we cannot be certain we are correctly classifying all unstageable PUs as full thickness wounds. Within the context of this study, healing trajectory is operationally defined as tissue characteristics found at wound base at confirmation of unstageable PU and the evolution of the wound base over time as documented in the medical record.

Clinical Significance

Data gained from this study has the potential to aid our understanding of the course of healing for unstageable PUs. The Department of Health and Human Services' final rule on provider preventable conditions lists hospital acquired pressure ulcers (HAPUs) as a condition for which Medicare payment to hospitals may be reduced and that cannot be assigned to a higher diagnosis-related group, thus will not obtain a higher reimbursement.[11] Safety net hospitals,

which are facilities that provide care to uninsured, those on Medicaid, and other vulnerable populations, are already financially vulnerable institutions and may be adversely affected by policies reducing payments for HAPUs.[50] Improved understanding of the evolution of unstageable PUs has the potential to influence such public policy. This is especially relevant to this study since unstageable PUs have recently been added to reportable events through the Department of Health (DOH) in Washington and multiple other states, alongside Stage III and IV ulcers due to recommendations from the NQF suggesting that they are full thickness wounds.[25] The reporting process was implemented to make facilities aware of serious system issues that require alterations and assist in improving patient care and outcomes while decreasing healthcare costs.[51,52] However, it is important to note that the reporting process takes a considerable amount of time and resources for hospitals to participate in. The use of punitive policies, such as public reporting and reduced payments do not take into consideration the complexity of care and if the PU was avoidable or not. Such punitive policies tend to create blame and shame on facilities rather than recognizing system errors, which are not fixed with punitive measures.[52]

The purpose of this study was to describe the evolution of healing in unstageable HAPUs and to determine whether existing assumptions that these are full thickness wounds is consistent with what is observed in clinical practice. The aims of this study were to 1) Describe selected characteristics of patients with unstageable PUs that either healed or did not heal and 2) Identify the healing trajectories of unstageable PUs and if these healing trajectories are consistent with full or partial thickness wounds.

Methods

This study was conducted using retrospective record review. Data sources were electronic medical record (EMR) chart review and PU data base review. Certified Wound Care Nurses (CWCNs) at Harborview Medical Center have managed a PU data base that includes information on all recognized HAPU since 2007.

Data gathered included admission date, date the PU was first identified, weekly follow up, date of closure, and date of discharge. Also collected was data about PU staging, anatomical location, size (length, width, depth, and any undermining or tunneling); wound base tissue type(s), drainage type and amount, odor, periwound (skin around the wound) skin assessment, and patient perception of pain. As part of a structured note, CWCNs included information on wound characteristics with each assessment. These assessments were completed approximately weekly on patients with HAPUs and; therefore, the data for each HAPU in this study was reviewed over the time that the wound was followed by a CWCN. Additional data was abstracted from the EMR and included patient demographics, admitting diagnosis, comorbid conditions, vasopressor use, and spinal cord injury.

Characteristics indicating full thickness wound healing included presence of granulation tissue, fat, muscle or other deep structures within the wound base prior to wound closure. Characteristics indicating partial thickness wound healing included regeneration of superficial dermis and/or epidermis in the absence of granulation tissue or deep structures at wound base. (Box 1)

Study procedures were reviewed and approved by the University of Washington Human Subjects Division and the Harborview Medical Center Institutional Review Board.

Subjects and Setting

All patients eighteen and older admitted from November 2007 until March 2011 who developed an unstageable HAPU were deemed eligible for inclusion in this retrospective review. The study setting was Harborview Medical Center, a 413 bed level one trauma/burn center and safety net hospital in the Pacific Northwest. Harborview serves a diverse and medically complex patient population with a large service catchment including Washington, Wyoming, Alaska, Montana, and Idaho. Data were entered into a de-identified word spreadsheet by the primary investigator in consultation with a hospital based data analyst.

Data Analysis

The primary outcome of this study was percent of unstageable PUs that healed consistent with partial thickness wounds and percent that healed consistent with full thickness wounds. Data analysis focused on descriptive analysis of the variables and a comparative analysis between the full thickness and partial thickness groups on selected variables. Fisher's exact test was used to test for and compare associations of categorical variables between the two groups (unstageable PUs that were more consistent with full thickness wounds and those that were more consistent with partial thickness) and Student's T-test and the Mann-Whitney test were performed to compare differences between full thickness and partial thickness for continuous variables.

Results

Subjects were in-patients at a level 1 trauma/burn center and safety net hospital with confirmed unstageable HAPUs during their in-patient stay.

One hundred ninety four unstageable PUs were reviewed for possible inclusion in the study. One hundred twenty were excluded due to insufficient data being present to answer the research questions. Reasons for exclusion included eschar or slough obscuring the wound base (patient discharging or expiring before slough/eschar was debrided from wound base), wound improperly categorized/not an unstageable PU (2 mucosal PUs, 1 moisture associated skin damage, 1 necrotizing fasciitis, 1 Suspected Deep Tissue Injury, 1 scab, 1 burn), and missing data. (Figure 3)

Aim 1) Describe selected characteristics of patients with unstageable PUs that either healed or did not heal. Seventy four unstageable PUs were included in the final analysis. These PU were categorized by location; the most frequent was the sacrum/coccyx, followed by the buttocks. (Table 1) Fisher's test found no statistically significant difference in healing trajectories between males and females, p= .078. The Likelihood ratio of 7.25 was not statistically significant in relation to outcomes and ethnicity, p = .12. (Table 2) The mean age of patients whose unstageable PUs healed consistently with full thickness wounds was 39.8 years versus a mean age of 45.7 years among those whose PU healing trajectory was consistent with a partial thickness wounds, with no statistical difference (t=-1.44, p=.15). (Table 3)

The average time from admission to presentation of unstageable HAPU was 18.9 ± 11.0 days (mean ± SD) for those that evolved into full thickness wounds and 15.8 ± 11.0 days for those that evolved into partial thickness wounds, this was not statistically significant, (t=1.14, p = .26).

Aim 2) Identify the healing trajectory (identify tissue characteristics and final outcome of the wound) of unstageable PUs at a level 1 trauma center and assess if the healing trajectories of unstageable PUs in this study are consistent with full or partial thickness wounds. Analysis

showed 33.8% (n=25) of unstageable PUs healed consistently with a partial thickness wound. Of these 25 (33.8%) had an initial presentation of eschar at the wound base, 48 (64.9%) had a presentation of slough, and 1 (1.4%) had an initial presentation with both slough and eschar. Thirty two percent (n=8) of wounds presenting with eschar healed consistently with the trajectory of a partial thickness wound and 68% (n=17) healed consistently with a full thickness wound. Of wounds presenting with slough, 35.4% (n=17) healed consistently with partial thickness wounds and 64.6% (n=31) healed consistently with full thickness wounds. One PU presented with both eschar and slough at initial evaluation; its healing trajectory was consistent with a full thickness wound. (Figure 4)

Discussion

Findings suggest that not all PUs identified clinically as unstageable have healing trajectories consistent with full thickness wounds. With 33.8% of unstageable PUs in this study healing consistently with partial thickness wounds, the current definition of unstageable PUs as full thickness comes into question.

Further research on this subject and revision of the current definition of unstageable PUs has the potential to both improve our understanding of these wounds and open discussion regarding the appropriateness of these ulcers being reportable events.

Given policy regarding reporting of unstageable PUs, patient and public perception of care provided to those with HAPUs, and patient outcomes; the current definition of unstageable PUs should be closely reviewed and revised if appropriate.

Limitations

As a retrospective study, we were limited to asking questions that were answerable through the existing EMR and data base. There was also a risk that certain desired information was missing from or incorrectly input into these sources with limited to no options for crosschecking or ensuring validity of documentation.

Another limitation owes to the fact that this study was conducted at a level 1 trauma center, burn center, and safety net hospital and that the results from this study may not be generalizable to other health care settings. Future studies in more diverse settings and with broader patient populations are needed to increase generalizability of these findings.

In the clinical setting, PUs are staged according to clinical manifestations rather than histopathologic findings.[37] Accurate identification of wound characteristics and PU stage are complex skills that require knowledge and experience to master. [24] This observation is consistent with results from multiple studies that report difficulties encountered when nurses and physicians are asked to stage PU including unstageable ulcers.[28,29,49] Buckley et al. observed that sutures and dried blood may be mistaken for eschar while bone, tendon, callous, and the staining from topical iodine may be mistaken for slough. [34] The authors of this study have observed that scabs and crust can also be mistaken for eschar, while surgical mesh and the residue from honey dressings can be mistaken for slough. Considering how often these other findings are present at the wound base, the likelihood of misclassification may be significant. Given the difficulties in accurately identifying slough and eschar, it is possible that some PUs in this study were incorrectly classified as unstageable. Additional research on definitive characteristics of unstageable PUs is needed in order for clinicians to accurately diagnose them from other wounds.

Conclusions

The purpose of this study was to examine the healing evolution of unstageable PUs to learn if the current definition of unstageable PUs is accurate. Results indicate that 33.8% of unstageable HAPUs involved in this study demonstrated a healing trajectory consistent with partial thickness wounds. These results suggest that the current definition of unstageable PUs as full thickness wounds may not be accurate. Further research on this topic is necessary in order to increase our understanding of unstageable PUs and how best to define and identify them.

Figure 2-1: Slough

Figure 2-2: Eschar

Box 2-1: Definitions of partial and full thickness healing trajectories

Tissue found at wound base indicating partial thickness wound.	Tissue found at wound base indicating full thickness wound.
Papillary dermis	Granulation tissue
Reticular dermis (not extending into)	Fat
Epidermis	Muscle
	Tendon
	Ligament
	Bone
	Cartilage
	Reticular dermis (extending into)

Table 2-1: Unstageable PUs by anatomical location (Frequency (%))

Location	Full Thickness	Partial Thickness	Subgroup Total
Buttock	12 (24.5)	6 (24)	18 (24.3)
Face/Neck	1 (2)	3 (12)	4(5.4)
Lower Extremity	5(10.2)	4(16)	9(12.2)
Occiput	9(18.4)	3(12)	12(16.2)
Sacrum/Coccyx	18(36.7)	5(20)	23(31.1)
Trunk	2(4.1)	0	2(2.7)
Upper Extremity	2(4.3)	4(16)	6(8.5)
Sample Total	49(100)	25(100)	74(100)

Table 2-2: Patient demographics

Variables	Full Thickness	Partial Thickness	Subgroup Total
Gender			
Female	23 (46.9)*	6 (24)	29 (39.2)
Male	26 (53.1)	19 (76)	42 (59.2)
Sample Total	49 (100)	25 (100)	74 (100)
			p =.078
Ethnicity			
Asian/Pacific Islander	2 (4.1)	0	2 (2.7)
Black/African American	6 (12.2)	1 (4.0)	7 (9.5)
Caucasian	35 (71.4)	20 (80)	55(74.3)
Hispanic/Latino	3 (6.1)	4 (16)	7 (9.5)
Native American	3 (6.1)	0	3 (4.1)
Sample Total	49 (100)	25 (100)	74 (100)
			p = .123

* = Frequency (%)

Table 2-3: Patient age demographics

	Full Thickness	Partial Thickness
Age *Mean (95% CI)*	39.8 (34.91, 44.68)	45.7 (39.08, 52.36)
Minimum	18	20
Maximum	75	75

Figure 2-3: Exclusion Factors

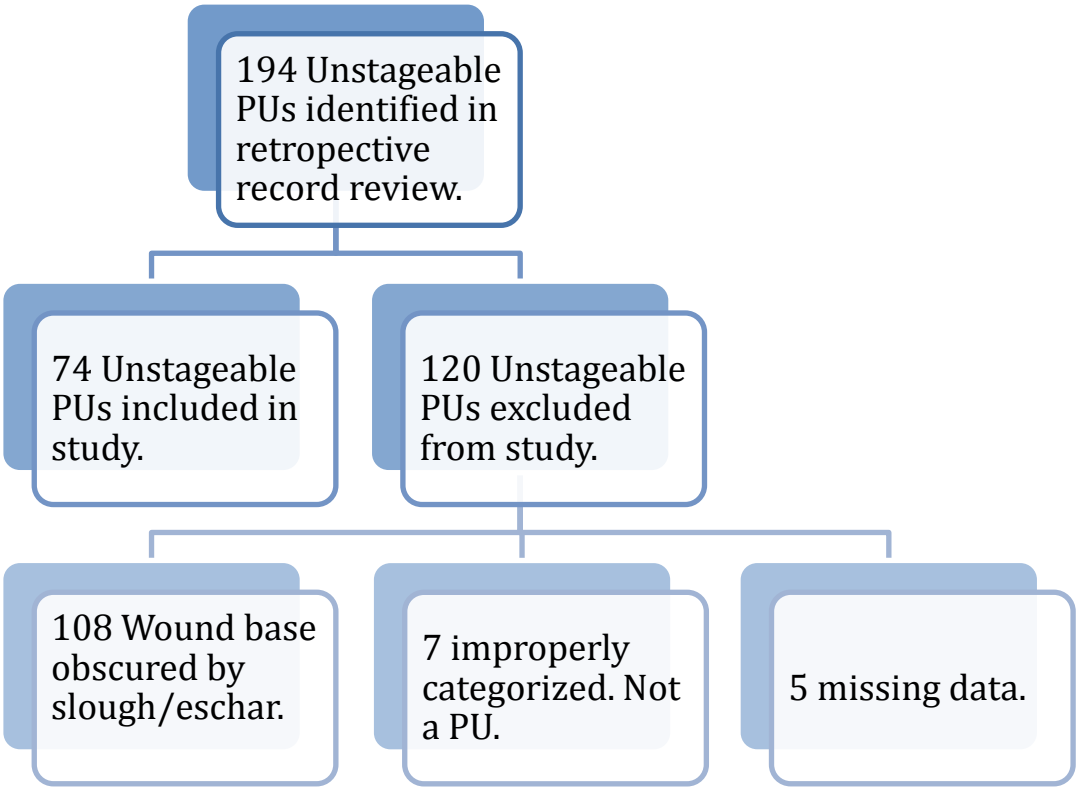
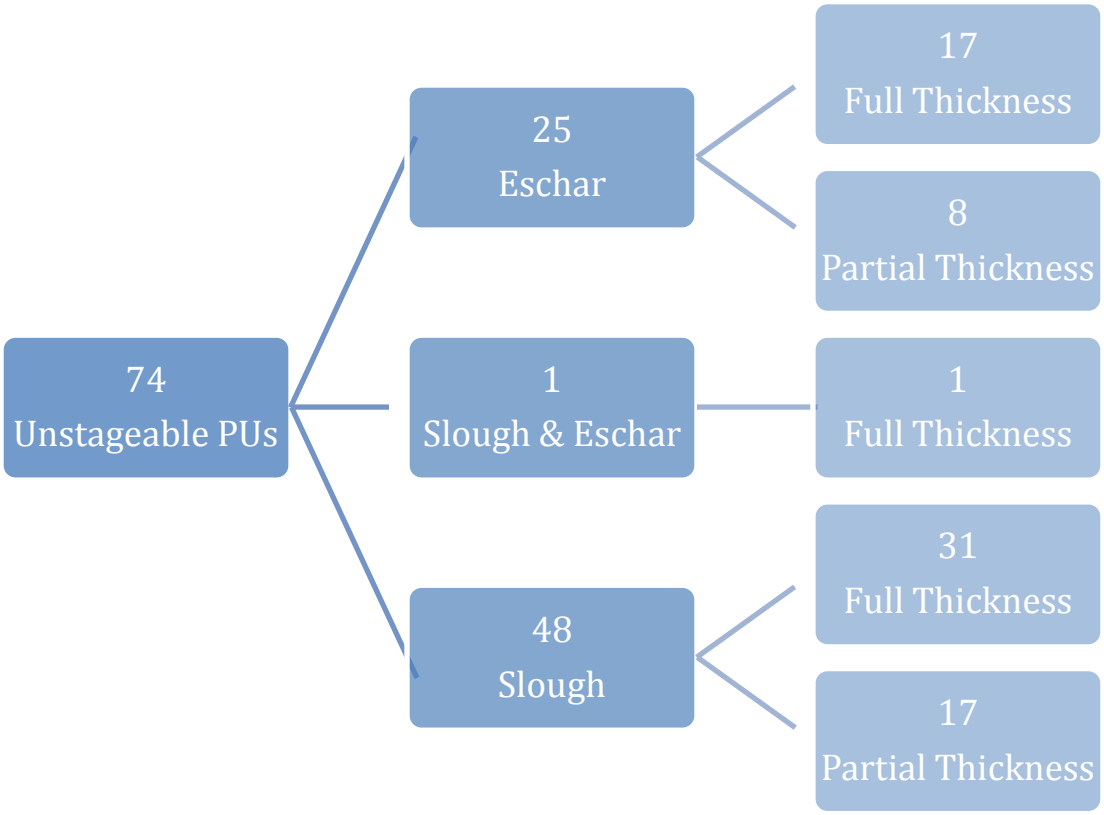


Figure 2-4: Outcomes of unstageable PUs based on initial tissue presentation



CHAPTER 3.

DEFINING UNSTAGEABLE PRESSURE ULCERS AS FULL THICKNESS WOUNDS: IS THIS DEFINITION CONSISTENT WITH CLINICAL OUTCOMES?

Abstract

Purpose: The purpose of this research was to study the evolution of hospital acquired wounds that are consistent with the current definition of unstageable pressure ulcers (PU), determine if their healing trajectory was consistent with partial and/or full thickness wounds, and discuss any characteristics of the patients or their wounds that may be associated with or predictive of healing trajectory.

Subjects and Settings: Patients who acquired wounds that are consistent with the current definition of unstageable PUs during their in-patient stay from November 1, 2007 through June 30, 2014. The setting was a level one trauma/burn center and safety net hospital in the Pacific Northwest.

Methods: Using a retrospective record review, approximately 252 unstageable PUs were analyzed. Sources of data were the electronic medical record and a clinical wound data base. The data base has been managed by certified wound care nurses and data analysts since its inception in 2007 to present. Unit of analysis was PU, not patient. Statistical analysis was completed using SPSS version 22.

Results: Of the initial 252 wounds initially identified, 132 were excluded due to lack of data needed to address research questions. Out of the 120 wounds that remained in the study, 54.2% were found to follow a healing trajectory consistent with partial thickness wounds. Vasopressor use, spinal cord injury, larger wound size, and higher BMIs were positively associated with full

thickness healing trajectories. Unstageable PUs on the sacrum/coccyx/buttocks and those positive for odor and exudate were more likely to heal consistently with full thickness wounds. Those located on the lower extremity were more likely to heal consistently with partial thickness wounds.

Conclusion: The findings of this study were consistent with author's previous exploratory study and indicate that, while some unstageable PUs demonstrate healing trajectories consistent with full thickness wounds, others follow a wound healing trajectory consistent with partial thickness wounds. Additional research is indicated and opening a discussion regarding the possible revision of the current definition for unstageable PUs is recommended.

KEY WORDS: Unstageable, Pressure Ulcer, Slough, Eschar, Pressure Sore, Decubitus

Introduction

Pressure ulcers (PU) are widely viewed as indicators of quality in healthcare.[24] With this in mind, it is important to appreciate the stigma attached to full thickness PUs, which are often associated with negligence and widely seen as events that should never occur in healthcare settings if appropriate care is provided. However, there are times in which necessary, life-saving interventions for hospitalized patients increases the risk of PU development.[10] The National Quality Forum (NQF) describes full thickness PUs as serious reportable events, [25] this combined with PUs being considered nursing quality indicators by the Agency for Healthcare Research and Quality, NQF, and the American Nurses Association, may promote this stigma.[26] Research dedicated to improving our understanding of Unstageable PUs and their evolution may help decrease stigma, improve care, and increase understanding of these wounds.

There are 6 recognized categories of PUs by the National Pressure Ulcer Advisory Panel (NPUAP). These categories range from partial to full thickness pressure injuries with stage I & II categorized as partial thickness and stages III, IV, and unstageable PUs categorized as full thickness wounds. Suspected deep tissue injury is a category which may or may not evolve into a full thickness wound.[1] Unstageable PUs are ulcers that have eschar or slough obscuring the wound base and, until the slough or eschar is debrided, cannot be otherwise staged.[1] Slough is white, yellow, tan or green non-viable tissue and eschar is hard, soft, or soggy black or brown non-viable tissue.[1]

Clinicians often have difficulties in appropriately staging PUs. [28,29,49] Slough and eschar, the clinical manifestations of unstageable PUs, can be challenging to identify and confused with other structures that are often present in the base of wounds. Bone, tendon, callous, staining from topical iodine,[34] surgical mesh, the residue from honey dressings,[53] coagulum, and adherent fibrinous exudate may be mistaken for slough. Sutures, dry blood,[34] scabs, and crusts[53] may be mistaken for eschar. As there are currently no bedside tools to differentiate between the different types of tissues that may present similarly to slough or eschar, there are times when clinicians may not have the experience or tools necessary for definitive diagnosis of tissue at the wound base. For this reason, certified wound care nurses (CWCN) at the facility described in this study, when faced with tissue at the wound base that they were not convinced was eschar or slough, began the practice of documenting that they were not confident of the type of tissue at the wound base, but that slough or eschar were in the differential. The CWCNs then followed the wounds until the tissue at the wound base clearly presented as slough or eschar or the wound base was able to be visualized and thus staged or otherwise diagnosed.

An initial exploratory study was completed by this author in 2013 in which 74 unstageable HAPUs were analyzed. The results of that study indicated that approximately one-third of the unstageable PUs that were a part of the study healed consistently with partial thickness wounds, unlike the current definition of unstageable PUs, in which they are described as full thickness wounds. This finding is novel, has clinical value, and the potential to impact current stigma, policy, and clinical practice. Importantly, the findings of the study suggested that not all unstageable PUs are full thickness wounds. This indicated a need for further studies on the topic and warranted a discussion regarding the appropriateness of the current definition of unstageable PUs. However, there were limitations to the initial study and the findings led to considerations and a need for further investigation. The current study addressed several factors not included in the initial study. These factors were chosen after a review of literature in PubMed on variables associated with the development of HAPUs. No limitations were placed on year of publication. Only articles in English were included. Key words/terms included the following: pressure ulcer risk factors, pressure ulcer associated factors, unstageable pressure ulcer risk factors, unstageable pressure ulcer associated factors. This literature review was completed to assess what additional clinical factors should be considered for the study. Table 1 includes the variables associated with development of HAPUs from this literature review. It was not possible to combine variables under broader headings as concepts were not defined in the majority of studies reviewed.[18, 48, 54-75]

The primary purpose of this study was to describe the evolution of healing in unstageable HAPUs over time to determine if their healing trajectory, as observed in clinical practice, was consistent with the definition that unstageable PUs are full thickness wounds in all cases. The secondary purpose was to determine if there are any variables that may be associated with the

healing trajectories of these wounds. The specific aims of the study were to: 1) Identify the healing trajectory of unstageable HAPUs and assess if they are consistent with partial or full thickness wounds, 2) Describe and compare selected characteristics of patients and characteristics of their unstageable PUs during hospitalization, and 3) Determine if any patient characteristics or their unstageable PU characteristics are associated with or can predict the outcome of the ulcer healing consistently with a partial or full thickness wound.

Methods

This study was completed through retrospective record review and included all documented HA wounds consistent with the current definition of unstageable PUs. Sources of data included the electronic medical record (EMR) and wound data base. The wound data base is managed by CWCNs and documents all identified HAPUs from November 2007 to present.

Data gathered in this study included multiple variables from the initial exploratory study such as admission date, date HAPU first identified, weekly follow up, date of closure/healing, and date of discharge, initial and subsequent PU staging, anatomical location, size (length, width, depth), presence of undermining or tunneling, wound base tissue type(s), presence of and characteristics of exudate, odor, periwound skin, patient perception of pain, patient demographics, admitting diagnosis, comorbidities, vasopressor use, and spinal cord injury. Additional variables that were collected included timing of vasopressors (prior to confirmation of unstageable PU), Braden scores, BMI, surgery documented prior to confirmation of unstageable PU, and length of time in surgery. Data on wound characteristics is gathered approximately weekly for HAPUs by CWCNs and entered into the wound data base. Each HAPU in this study

was reviewed over the time that the wound was followed in the wound data base. It is through these data points that wound healing was assessed.

Full thickness wounds were defined by the following wound base characteristics: granulation tissue, fat, muscle, tendon, ligament, bone, and cartilage. Partial thickness wounds were defined by the following wound base characteristics: superficial dermal structures and epidermis.

Data were abstracted from the EMR and wound data base by the author and a hospital based data analyst, de-identified, and entered into and electronic spreadsheet before being transferred into SPSS version 22 for analysis. An inter-rater reliability study was conducted by a CWCN on the hospital based wound care team using a sample of 10% of the final population analyzed.

This study was reviewed and approved by the University of Washington Human Subjects Division and the Harborview Medical Center Institutional Review Board.

Subjects and Setting

Patients admitted from the dates of November 1, 2007 through June 30, 2014 who were eighteen years and older and developed unstageable HAPUs were eligible for inclusion. The setting was Harborview Medical Center, a 425 bed level one trauma/burn center and safety net hospital in the Pacific Northwest. Harborview serves a medically complex and diverse patient population for a geographical area encompassing approximately a quarter of the land mass of the U.S. including Washington, Wyoming, Alaska, Montana, and Idaho.

Data Analysis

The primary outcomes of this study were (Aim 1) percent of unstageable PUs that healed consistently with full thickness wounds and percent that healed consistently with partial thickness wounds. Descriptive analysis was used to determine frequency of unstageable PUs that healed consistently with partial or full thickness wounds.

Secondary outcomes were (Aims 2 and 3) to 1) describe and compare selected characteristics of patients and the characteristics of unstageable PUs during hospitalization and 2) determine if selected characteristics of ulcers or characteristics of patients may predict the outcome of ulcers healing consistently with partial or full thickness wounds. To describe and compare the characteristics of patients and ulcers descriptive analysis was used. The average and standard deviations of the continuous variables, as well as the range, were given in the description of the variables. If the variable did not follow a Gaussian or normal distribution, the median was used as the measure of central tendency. The distribution of relative frequency was given for categorical variables. Chi-square was used to analyze the relationship between categorical level variables and outcome of healing consistently with full or partial thickness wounds. To determine if characteristics of ulcers and patients predicted the outcome of ulcers healing consistently with partial or full thickness wounds, a stratified risk analysis was conducted. Significant relationships of variables with healing outcome were tested. Based on that analysis, variables that were likely to have a predictive relationship were determined. The outcomes of the correlational analysis were used to develop a regression model to test if there are variables that will predict the outcome of ulcers healing consistently with full or partial thickness wounds. Multivariate regression was used to adjust potential confounders identified from the descriptive statistics.

Results

Two hundred fifty two unstageable PUs were reviewed for possible inclusion in this study. One hundred thirty two were excluded due to insufficient data to answer the research questions. Pressure ulcers were excluded due to eschar or slough obscuring the wound base (in cases where patients discharged or expired before the non-viable tissue was debrided from wound base), wound improperly categorized/not an unstageable PU, present on admission, and missing data. (Figure 1)

An inter-rater reliability analysis using the Kappa statistic was performed to determine consistency among raters. Kappa = 0.83 ($p<0.001$) denotes a high level of agreement.

Aim 1) Identify the healing trajectory of unstageable HAPUs and assess if they are consistent with partial or full thickness wounds. One hundred and twenty wounds consistent with the definition of unstageable PUs were included in the final analysis. Results showed 54.2% (n=65) of wounds included in this analysis healed consistently with partial thickness wounds and 45.8% (n=55) healed consistently with full thickness wounds (p=.94). Of the 120 PUs studied, 78 initially presented with slough at the wound base. Of these 78, 45 healed consistently with partial thickness wounds and 33 healed consistently with full thickness wounds. Thirty five PUs initially presented with eschar. Nineteen wounds presenting with eschar healed consistently with partial thickness wounds and 16 healed consistently with full thickness wounds. Seven PUs initially presented with both slough and eschar at the base, 1 of these healed consistently with a partial thickness wound and 6 healed consistently with full thickness wounds. (Figure 2)

Aim 2) Describe and compare selected characteristics of patients and characteristics of their unstageable PUs during hospitalization. Females accounted for 29.2% (n=35) of the study

population and males for 70.8% (n= 85). Patient demographics are described in table 2. Pressure ulcers were categorized by location, the most common being "sacrum/coccyx/buttock" followed by "head/neck/occiput". Unstageable HAPUs found on the Sacrum/Coccyx/Buttocks were more likely to heal consistently with full thickness wounds than Unstageable HAPUs found on other anatomical locations (p=.001) and those found on the lower extremities were more likely to heal consistently with partial thickness wounds (p=.029). (Table 3) Evaluation of admission diagnoses indicated trauma as the most common diagnosis followed by burns. (Figure 3) Categorical patient characteristics including spinal cord injury, obesity, vasopressor use prior to PU development, presence of comorbidities, and diabetes were analyzed using descriptive statistics. The unstageable PUs of patients who experienced vasopressor use prior to PU development were more likely to have these PUs heal consistently with full thickness wounds (p=<.001). One hundred percent (6.7% of overall study population) of patients diagnosed with obesity healed consistently with full thickness wounds (p=.001). Continuous patient characteristics included days from admission to confirmed development of PU, length of stay (LOS), BMI, time spent in surgery prior to PU development (minutes), and Braden score. Pressure ulcers in this study healing consistently with full thickness wounds had an average BMI of 34.8 ± 2.3 while those healing consistently with partial thickness wounds had an average BMI of 28.6 ± 0.9 (p=.008). Categorical and continuous variable findings are documented in Table 4.

Wound characteristics were gathered from the first documented visit by a CWCN. Categorical wound characteristics including wound edges, tunneling, undermining, odor, pain, status of periwound skin, exudate, and tissue at wound base and the continuous variable of size in cm^2 were analyzed using descriptive statistics. Unstageable PUs positive for odor (p=.043),

those positive for wound exudate (p=.020), and larger wounds were more likely to heal consistently with full thickness wounds 27±5.3 vs 3.24±.69 (p=<.001). (Table 5)

Aim 3) Determine if any patient characteristics or their unstageable PU characteristics are associated with or can predict the outcome of the ulcer healing consistently with a partial or full thickness wound. A logistic regression model was used to test the following predictor variables: vasopressor use prior to development of PU, spinal cord injury, PU size, and BMI. These variables were chosen to limit collinearity of associated variables. Full thickness outcome was entered as the dependent variable. Significance was found in the final model with p=<.0001 (-2 log likelihood = 105.63, χ^2 [8, N = 120] = 59.895, p < .001) and produced a Nagelkerke R^2 of .53. The regression results also indicated that inclusion of the variables resulted in 82.5% of cases being correctly classified; up from 54.2% when the constant was included in the equation.

Odds ratio review indicated that the odds of an unstageable PU healing consistently with a full thickness wound increased 11-fold when vasopressors were given prior to development of PU. The odds for patients with spinal cord injuries to have an unstageable PU heal consistently with a full thickness wound was 2-fold. Increasing PU size was associated with an increased likelihood of full thickness trajectory. For patients with larger wounds at initial confirmation, for each unit increase PUs were 1.1 times more likely to be full thickness than for those of smaller size. For each unit increase in BMI kg/m^2 the odds of healing as a full thickness wound increase from 1 to 1.02. (Table 6)

Discussion

Findings in this study are consistent with the author's initial exploratory study in which not all unstageable PUs healed consistently with full thickness wounds. In the current study,

54.2% of unstageable PUs healed consistently with partial thickness wounds. Given these outcomes, the current definition of unstageable PUs does not appear to address the variation of healing that can occur in these ulcers.

There is significant stigma attached to the development of PUs in hospital settings and full thickness PUs are widely regarded as events that should never happen in hospitals. This is despite the fact that there are many lifesaving interventions that increase the likelihood of PU development,[10] there is consensus from the NPUAP indicating that not all PUs are avoidable,[81] and multiple intrinsic and extrinsic risk factors have been identified in which the development of a PU is considered unavoidable.[82]

Recognizing limitations in the current definition and updating accordingly has the potential to assist in greater understanding of these wounds and making positive changes in public understanding and policy related measures.

The most common admission diagnoses of trauma (47.5%) followed by burns (18.3%) in this study are not surprising considering the study was completed at a level 1 trauma/burn center. No significant relationship was found between diagnosis and healing outcome of full or partial thickness.

Unstageable PUs of larger size in surface area (Mean = 27 cm^2), positive for odor, positive for exudate, and patients with higher BMIs (Mean = 34.8 kg/m^2) had statistically significant associations with the outcome of healing consistently with full thickness wounds. Those found on the sacrum/coccyx/buttocks were more likely to heal consistently with full thickness wounds and those found on the lower extremities were more likely to heal consistently with partial thickness wounds. Multivariate analysis findings identified strong relationships between vasopressor administration prior to ulcer development and spinal cord injury in

unstageable PUs that healed consistently with full thickness wounds. These findings may be useful in helping identify patients at high risk so that more aggressive interventions may be employed to assist in PU prevention and care in these populations.

Although several studies have found an association between higher BMIs and PU development,[56, 67, 76-80] the association with more severe PU outcome has not previously been reported to the author's knowledge. This association between higher BMIs and full thickness outcomes adds to the growing understanding regarding obesity as an important clinical parameter in health status and in healthcare delivery.

Obesity was found to be statistically significant in this study with p=.001; however, only 8 patients (6.7% of overall study population) had this diagnosis included in their medical record. The BMIs included in this study suggest a higher diagnosis of obesity in this population than documented. The inclusion of all patient diagnoses in hospital EMRs may be limited due to constraints on the number of lines available in the EMR for new diagnoses[21] and this may have been a factor in the findings of this study related to obesity.

Limitations

Consistent with limitations inherent to retrospective design, study questions were limited to what was answerable through the existing EMR and wound data base. Information contained within may have been incorrect at times with minimal options for crosschecking the data to ensure validity. Although the inter-rater reliability test performed in this study assisted with confirmation of results abstracted from the sources of data, it does not ensure the validity of the information contained in those sources.

A large number of patients were excluded from the study due to discharge from facility prior to debridement of slough or eschar at wound base. The large geographic area served by

HMC and the number of unaffiliated follow up clinics in which patients are seen, made it impossible to follow the outcomes of these patients outside of the hospital setting. The large number of cases that were excluded may have influenced the study results.

Due to the setting, a level 1 trauma/burn center and safety net hospital, the results of this study may not be widely generalizable. Similar studies in a variety of healthcare settings would be beneficial in identifying if outcomes are consistent and may increase generalizability.

There are also limitations related to correct identification of tissue at the wound base as described earlier in this paper.[34,53] Additionally, clinicians may have challenges correctly diagnosing a PU from other wounds that develop slough and/or eschar such as traumatic wounds, burns, lower extremity arterial insufficiency wounds, skin failure, and soft tissue necrosis secondary to buttock claudication from hypogastric embolization. Given the multiple challenges in identification and diagnosis, there is the possibility that some of the wounds contained in this study were misidentified, as is true of any data set containing information on unstageable PUs.

Patient care would benefit from additional research including larger studies in diverse settings to improve generalizability, prospective studies, histological studies on biopsies of slough and eschar to assess for any factors that may be specific to PUs, and new developments in technology to assist clinicians in accurate diagnosis of PUs.

Conclusions

The purposes of this study were to increase understanding of unstageable PUs through investigation of their healing trajectory, to describe and compare wound and patient characteristics, and determine if any characteristics were associated with or can predict the healing trajectory of unstageable PUs. The outcomes of this study were consistent with the first

exploratory study completed by this author on the topic and indicate that not all unstageable PUs heal consistently with full thickness wounds. This second study further helps to decrease the gap in knowledge around and addresses the question of whether the current definition of unstageable PUs is accurate. The topic would benefit greatly from additional research including prospective studies on the healing trajectory of unstageable PUs in different healthcare environments and longer term follow-up of healing outcomes.

Table 3-1. Literature review results of factors associated with HAPU development

Factors	Factors Cont.
Activity [61, 73, 75]	Infection [59]
Age [21, 22, 58, 59, 61, 63, 64, 68-70]	Length of stay [21, 22, 59, 61, 67, 70, 71-74]
Anemia [18, 74]	Level of consciousness [73]
Bed bound [71]	Male gender [69]
Being black [55]	Malnutrition [18, 55, 64, 69, 71]
BMI (underweight and overweight) [56, 60, 67, 76-80]	Mobility [18, 61, 70, 72]
Cancer [67]	Moisture [61]
Case mix index [21]	More days in bed [57]
Cardiovascular disease [67, 70]	More days without nutrition [57]
Cognitive impairment/altered mental status [18, 71, 72]	More diagnoses listed [22]
Cooperation (level of) [73]	Need for extra nursing care [75]
COPD [67]	Norepinephrine [70, 74]
Corticosteroids [67]	Nursing home residence prior to admit [69]
C-reactive protein [73]	Nutrition consult for actual or potential imbalance [75]
Creatinine >3 mg/dL [68]	Organ failure [18]
Decreased serum albumin [18, 72]	Patients treated in intensive care units [54-57]
Diabetes Mellitus [58, 67, 68]	Recent hospitalization [69]
Difficulty turning in bed [69]	Risk assessment scales (Braden & Norton) [48, 58-64]
Dry skin [69]	Sensory perception [62, 75]
Edema [75]	Severity of illness [56, 71, 74]
Emergency dept. stay > 2hrs prior to admit [66]	Sickness at admission score [55]
Friction & shear [61, 70, 75]	Spinal cord injury [68]
General anesthesia [55]	Surgery during hospital stay [21, 22, 55, 59, 64]
Hospitalization for fracture [64]	Two or more co-morbidities [55]
Impairment in activities of daily living [55]	Use of intraoperative blood products [65]
Incontinence [18, 60, 61, 69, 71, 72, 74]	Use of wheelchair during hospitalization [75]
Indwelling catheter [75]	

Figure 3-1. Exclusion factors

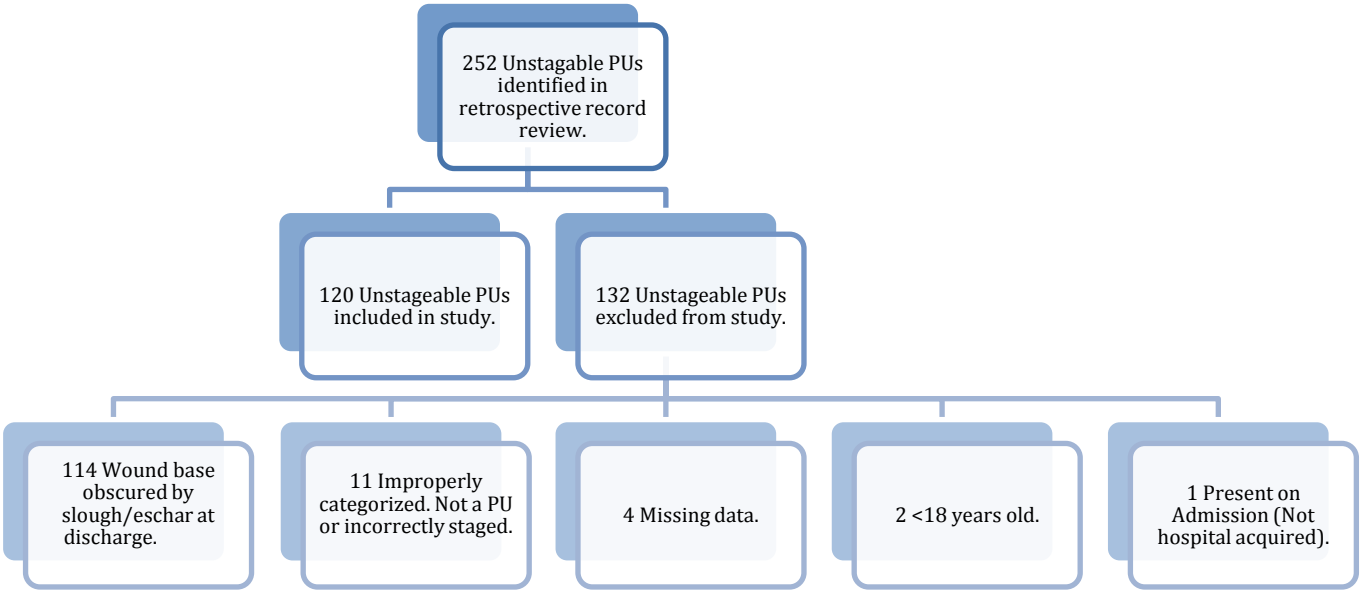


Figure 3-2. Outcomes of unstageable PUs based on initial tissue presentation

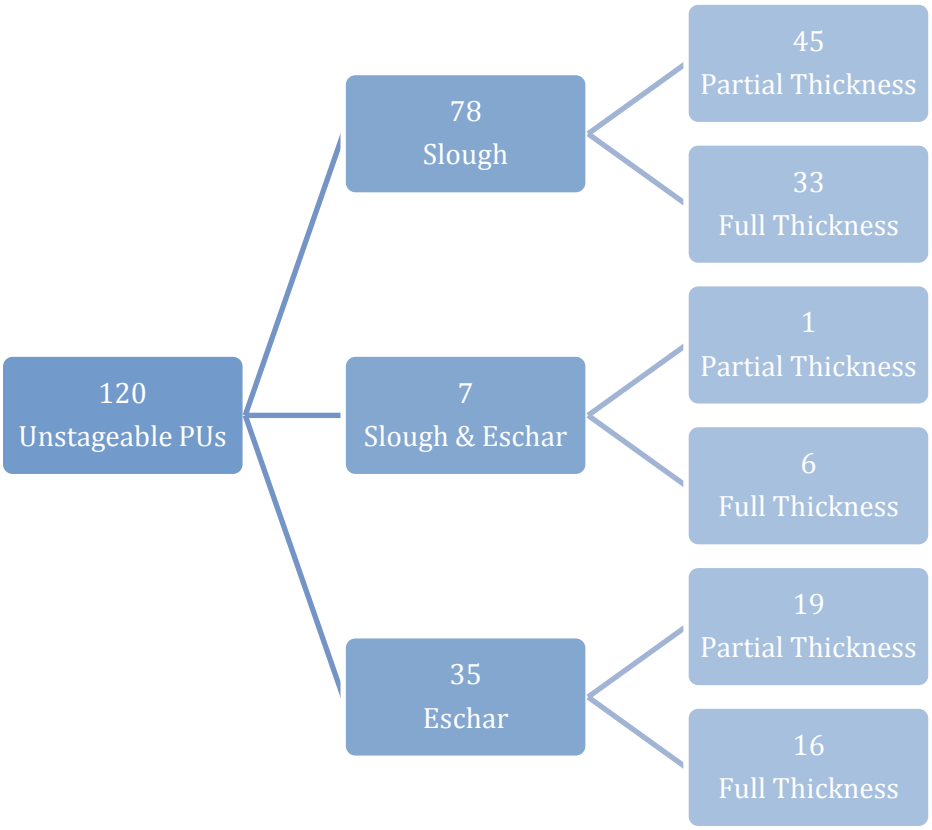


Table 3-2. Patient demographics by full thickness (FT) and partial thickness (PT) PUs

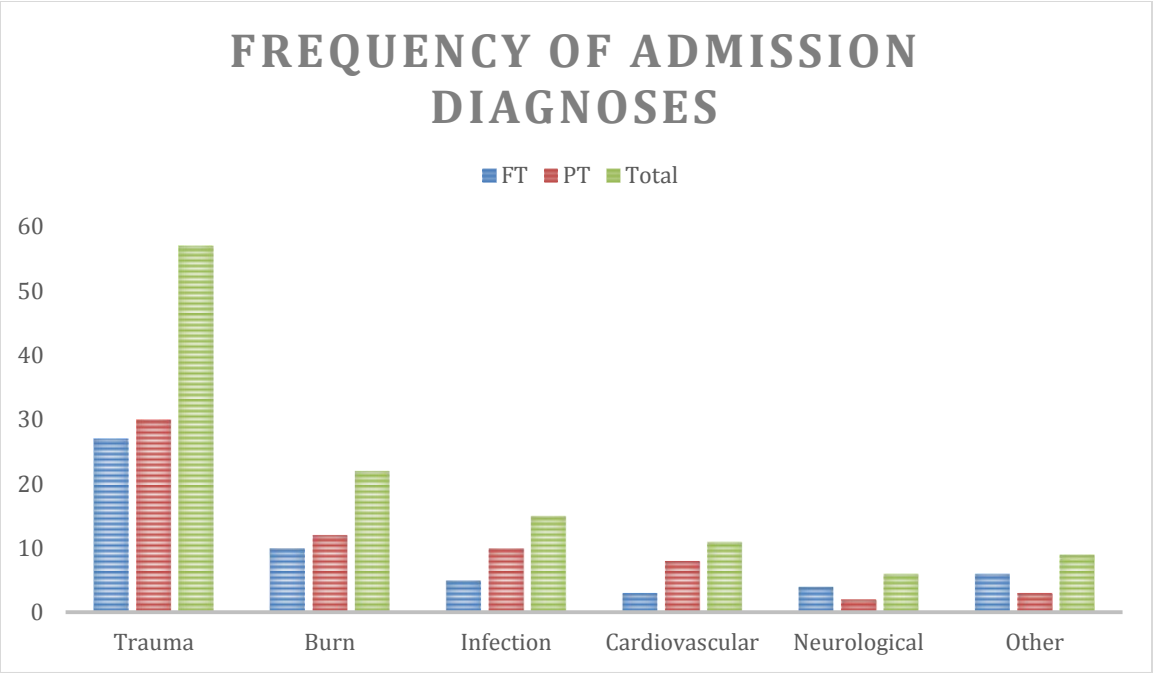
Variable	**FT (N=55)**	**PT (N=65)**
Age, Mean & Standard Error	41.6 ±2.5	49.6±2.4
Gender, male % (N)	67.3 (37)	73.8 (48)
Gender, female % (N)	32.7 (18)	26.2 (17)
Race, Caucasian % (N)	72.7 (40)	81.5 (53)
Race, not Caucasian % (N) Asian, African American, Hispanic, Native American	27.3 (15)	18.5 (12)

Table 3-3. Anatomical location of PUs by full thickness (FT) and partial thickness (PT)

Location	**FT**	**PT**	**Subgroup Total**
Sacrum/Coccyx/Buttock *N, (%), P-value*	35(63.6)	21(32.3)	56(46.7) p=<.001
Head/Neck/Occiput *N, (%), P-value*	9(16.4)	16(24.6)	25(20.8) p=.367
Lower Extremity *N, (%), P-value*	3(5.5)	13(20)	16(13.3) p=.029
Trunk *N, (%), P-value*	4(7.3)	7(10.8)	11(9.2) p=.546
Upper Extremity *N, (%), P-value*	4(7.3)	7(10.8)	11(9.2) p=.546
Genito-urinary *N, (%), P-value*	0(0)	1(1.5)	1(0.8) p=1.000
Sample Total	55(100)	65(100)	120 (100)

Figure 3-3. Admission diagnoses and healing trajectory:

Full thickness (FT), Partial thickness (PT)



*****Other category includes: ankylosing spondylitis, adult respiratory distress syndrome, HIV cerebral edema, hyperparathyroidism (x3), perforated bowel, respiratory distress, and status epilepticus.

Table 3-4. Patient characteristics by full thickness (FT) and partial thickness (PT) PUs

Variable	**FT (N=55)**	**PT (N=65)**	**Total & P-value**
Spinal Cord Injury %, (N), P-value	30.9(17)	23.1(15)	26.7(32) p=.409
Diabetes %, (N), P-value	14.5(8)	7.7(5)	10.8(13) p=.253
Obesity %, (N), P-value	14.5 (8)	0(0)	6.7(8) p=.001
Vasopressor prior to confirmed development of PU %, (N), P-value	96.4(53)	56.9(37)	75(90) p=<.001
Presence of 1 or more comorbidities %, (N), P-value	56.4(31)	49.2(32)	52.5(63) p=.468
Days from admit to confirmed development of PU Mean, Standard Error (SE), P-value	28.6±3.8	33.2±4.8	p=.529
Length of stay, Mean, SE, P-value	81.6±10.9	86.6±16.8	p=.435
BMI, Mean, SE, P-value	34.8±2.3	28.6±0.9	p=.008
Time spent in surgery prior to PU development, Mean, SE, P-value	385±45.4	358.7±49.6	p=.395
Braden Score Mean, SE, P-value	10.8±.3	11.06±.3	p=.581

Table 3-5. Wound characteristics by full thickness (FT) and partial thickness (PT) PUs*

Variable		**FT (N=55)**	**PT (N=65)**	**Total & P-value**
Wound edges not attached %(N)		2(1)	0(0)	1(1) p=.485
Tunneling present%(N)		2(1)	0(0)	0.9(1) p=.481
Undermining present%(N)		0(0)	0(0)	0(0)
Odor present%(N)		8.2(4)	0(0)	3.8(4) p=.043
Pain present%(N)		12.2(5)	14.3(7)	13.3(12) p=1
Impaired periwound skin%(N)		47.3(26)	32.3(21)	39.2(47) p=.128
Exudate present%(N)		75.5(40)	54.1(33)	64(73) p=.02
Wound base % (N)	*Wound base eschar % (N)*	29.1(16)	29.2(19)	29.2(35)
(P-value= .087)	*Wound base slough %(N)*	60(33)	69.2(45)	65(78)
	Wound base mixed slough & eschar %(N)	10.9(6)	1.5(1)	5.8(7)
Size (cm2) Mean,(SE), P-value		27 ±5.3	3.24±.69	p=<.001

*****Wound characteristics from initial visit.

Table 3-6. Logistic regression analysis

Variable		**B**	**S.E.**	**Exp(B)**	**95% C.I. for EXP(B)**	
					Lower	**Upper**
Step 1[a]	*VP(1)*	2.434**	.787	11.406	2.439	53.328
	SCI(1)	.684	.519	1.981	.717	5.476
	Size	-.146***	.046	.864	.789	.945
	BMI	-.014	.029	.986	.932	1.042
	Constant	.701	.932	2.016		

a. Variable(s) entered on step 1: Vasopressor (VP), Spinal Cord Injury (SCI), Size, BMI

b. *$p < .05$. **$p < .01$. ***$p < .001$.

CHAPTER 4.

CONCLUSION

The exact numbers of patients who develop hospital acquired pressure ulcers (HAPU) is difficult to gauge as rates vary by study. However, it is known that pressure ulcers (PU) affect millions of hospitalized patients and are the cause of significant burdens related to patient outcomes, pain and suffering, and healthcare costs, as described in chapter 1. Given the enormity of the problem, it is understandable why the National Quality Forum Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services, and state Departments of Health have all attempted to improve the current situation through policy, public reporting, and financial incentives.

Decreasing Rates

There is evidence that the CMS non-payment policy for full thickness HAPUs has spurred hospitals to implement interventions which have significantly decreased the rates of these wounds. Padula et al., in a study of over 10,000 HAPUs, found a drop in incidence rates from 11.8 cases per 1,000 inpatients in 2008 to 0.8 cases per 1,000 inpatients in 2012.[21] Literature identifies simplification and standardization of PU specific interventions and documentation/best practices, involvement of multidisciplinary teams and leadership, designated skin champions, staff education, use of specialty beds and support surfaces, use of risk assessment tools, and sustained audit and feedback for promoting accountability and recognizing successes as factors that may lead to decreases in PU rates.[83, 84, 85]

There are factors outside of the quality improvement interventions mentioned above that may also be involved in the decrease of HAPU rates. Increased attention to skin assessment and

documentation on admission leading to more accurate present on admission documentation may lead to a decrease in the documentation of HAPUs, but not an actual decrease in rate of occurrence.[7] A Department of Veterans' Affairs study indicated that PUs are often left out of the medical record with approximately 50% of stage IV PUs missing in discharge diagnoses.[86] Gaming of diagnosis codes (when HAPUs are omitted from discharge data to avoid reporting or to inappropriately mark them as present on admission), poor documentation, and complex rules around documentation and coding of HAPUs are additional concerns related to the drop in HAPU rates.[22]

Unavoidable Pressure Ulcers

Despite a decrease in rates, PUs remain a common outcome for hospitalized patients. The fact that some PUs occur in the setting of appropriate preventive interventions and scrupulous patient care is recognized by the National Pressure Ulcer Advisory Panel (NPUAP).[81, 82] There are times when the very interventions employed to save the life of a patient put them at risk for development of a PU. Sick patients are more likely to suffer from PUs,[87] and yet this is the very population that hospitals are designed to care for and are penalized for when these ulcers occur. The majority of HAPUs, however, are preventable and all possible measures should be taken to prevent their occurrence. It is when all preventive measures are employed and HAPUs still occur that the question of unavoidability comes into play.

Unstageable Pressure Ulcers

The current definition of unstageable PUs as full thickness wounds is widely accepted, but not consistent with clinical outcomes in all cases as evidenced in the two studies that

comprise this dissertation. The differences between partial and full thickness PUs are important to consider.

Partial thickness PUs heal by regeneration, a process in which the body generates the same tissues that are lost in development of the wound, epidermis and superficial dermal layers. These wounds generally heal more quickly and with fewer complications. Full thickness wounds heal by scar formation, where the body generates granulation tissue to fill the area of lost tissue. This scar tissue, in concert with wound contraction, work together to close the wound. Full thickness wounds often take a longer time to heal and surgical interventions are sometimes necessary to close full thickness wounds.

Daily costs vary significantly between partial and full thickness HAPUs, with partial thickness ulcers estimated in the range of hundreds of dollars[88] and full thickness, stage IV ulcers, estimated as high as $129,248.[89]

These differences are some of the reasons full thickness HAPUs have come under such scrutiny in recent years. In the current definition, unstageable PUs are considered full thickness and, as such, facilities are penalized for their occurrence as described in chapters 1 through 3. The extensive intensive review and reporting processes necessary to meet regulations for stage III, IV, and unstageable PUs is time consuming and costly in an environment of scarce healthcare resources. If unstageable PUs are not all full thickness wounds, it would be more appropriate to wait for these wounds to reveal themselves as full or partial thickness before the decision to include them with stage III and IV ulcers is made.

Definition

Formal recognition of unstageable PUs by the NPUAP in 2007 was a positive step in recognizing their unique presentation. However, with increasing research on the topic of unstageable PUs, it is time to revisit the current definition. Revising the current definition of unstageable PUs to be more consistent with the definition of suspected deep tissue injuries, in which it is recognized that these wounds may or may not evolve into full thickness tissue loss, is a recommendation that would address the variations seen in unstageable PU healing trajectories. Updating the definition of these PUs has the potential to impact PU care, stigma related to development of Unstageable HAPUs, and policy.

Future Studies

Unstageable PUs are the subject of intense scrutiny and yet there is very little published research on the topic. This dearth of information makes the topic rife for continued research as virtually every aspect of unstageable PUs would benefit from further study.

Similar research to what was conducted for this dissertation, on level of tissue damage, carried out in multi-site studies would enhance our understanding of these ulcers and their healing trajectories significantly, improve generalizability, and add needed attention to the question of whether the current definition of full thickness is appropriate.

Research on histopathological aspects of unstageable PUs, including biopsies of tissue that is consistent with slough and/or eschar, may increase our understanding of these wounds and has the potential to improve our ability to appropriately stage them. A better understanding of

slough and eschar may also assist clinicians in differentiating between PUs and other wounds that develop these necrotic tissues.

Twenty years ago, Maklebust argued the need to study the meaning of each stage of PU and their natural evolution in order to better understand these "nonhomogeneous" wounds.[24] Her call to action is just as relevant today and with growing stigma, costs, and policy measures related to PUs, it is urgent that we continue this pursuit. Most importantly, increasing our understanding of PUs will improve patient care, the patient experience, and related outcomes.

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APPENDIX A: PHOTOGRAPHIC EXAMPLES OF PRESSURE ULCER STAGES

Stage I: Non-blanching redness to intact skin. Blanching may not be visible in skin with dark pigmentation, but its color may be different from surrounding skin.

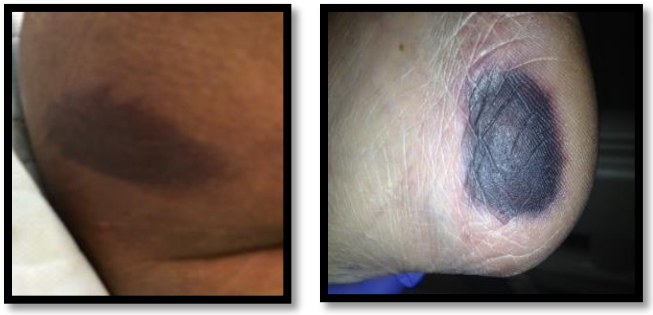
Stage II: Partial thickness tissue loss (does not extend all the way through the dermis). May present as shallow ulcer with red or pink wound bed, intact serum filled blister, or open blister.

Stage III: Full thickness PU in which subcutaneous fat may be seen in anatomical locations where it is present, but bone, tendon, and muscle are not visible.

APPENDIX A: PHOTOGRAPHIC EXAMPLES OF PRESSURE ULCER STAGES (Continued)

Stage IV: Full thickness PU that extends down to muscle, tendon or bone.

Suspected Deep Tissue Injury: Area of deep purple or maroon intact skin or a blood blister. May be challenging to identify in patients with dark skin.



Unstageable: Full thickness wound that cannot be staged due to the presence of slough or eschar, which obscures the true wound base.

- Definitions from: Prevention and treatment of pressure ulcers: clinical practice guideline. National Pressure Ulcer Advisory panel and European Pressure Ulcer Advisory Panel. 1025 Thomas Jefferson Street NW, Suite 500 East, Washington DC: 2009.

APPENDIX B: DEPICTIONS OF ESCHAROTIC PRESSURE ULCERS FROM CHARCOT'S 1877 PUBLICATION

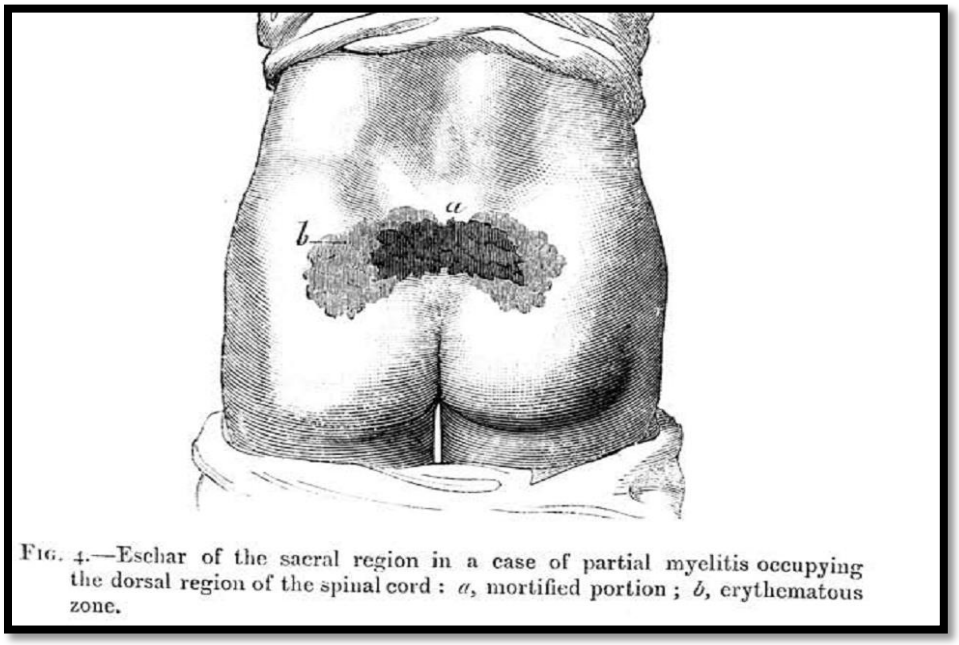


FIG. 4.—Eschar of the sacral region in a case of partial myelitis occupying the dorsal region of the spinal cord : *a*, mortified portion ; *b*, erythematous zone.

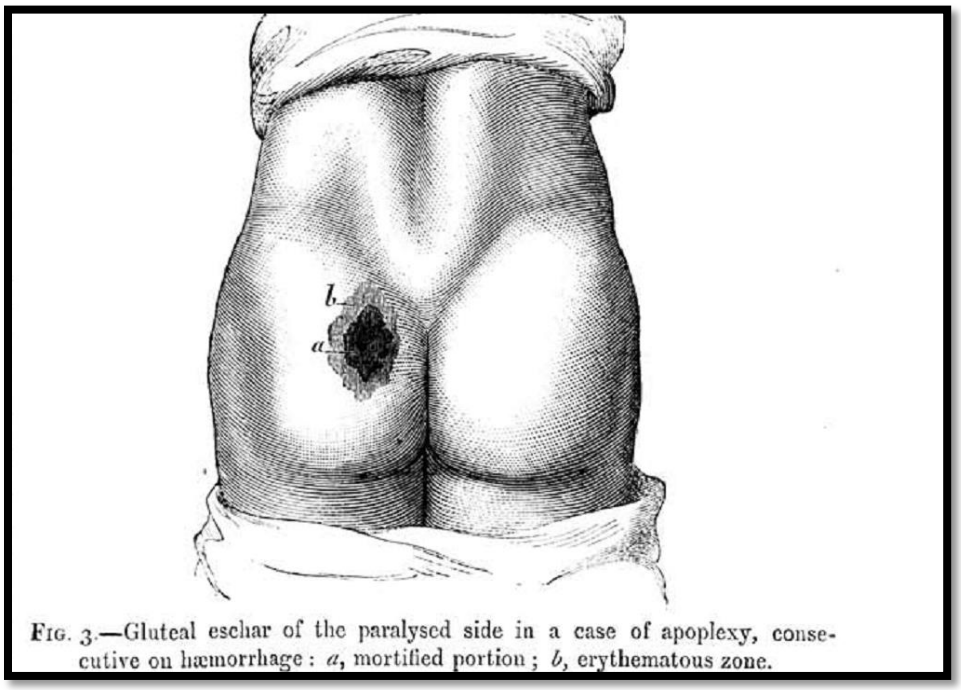
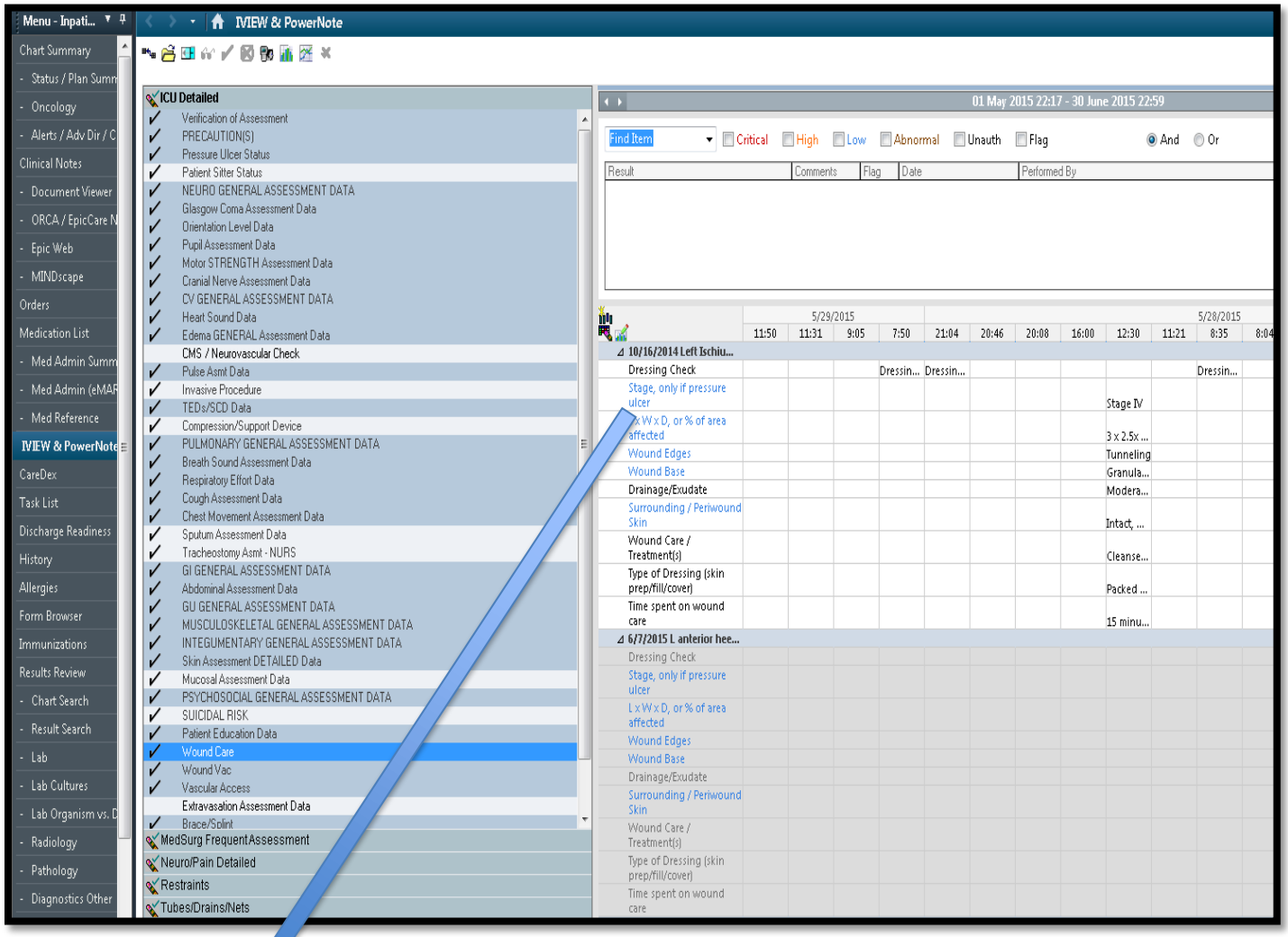
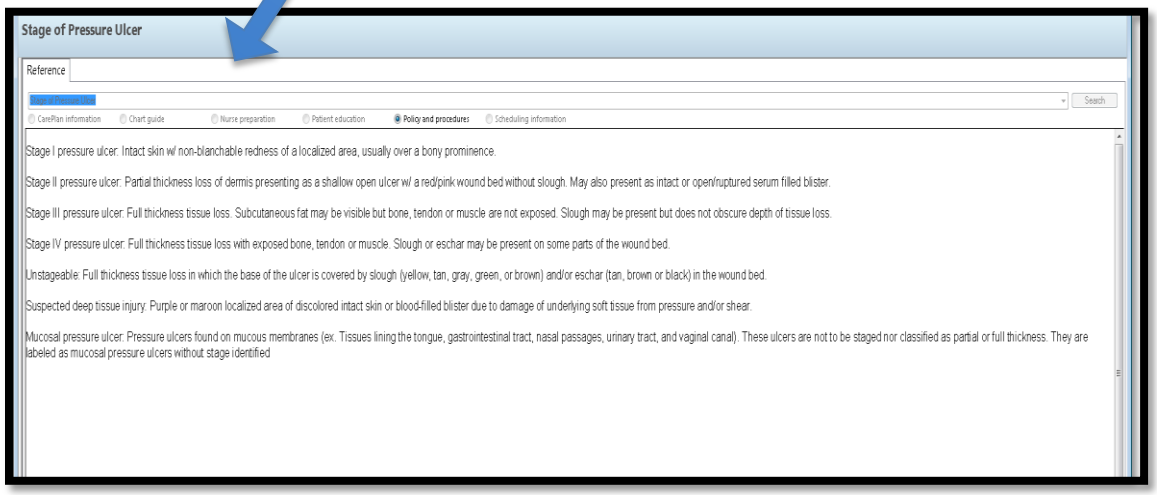


FIG. 3.—Gluteal eschar of the paralysed side in a case of apoplexy, consecutive on hæmorrhage : *a*, mortified portion ; *b*, erythematous zone.

- Plates from: Charcot, JM. Disorders of nutrition consecutive on lesions of the spinal cord and brain. In: Lectures on the diseases of the nervous system, delivered at La Salpetriere. Vol. 1. London, UK: The New Syndenham Society, 1877.

APPENDIX C: HARBORVIEW MEDICAL CENTER ELECTRONIC MEDICAL RECORD PRESSURE ULCER DOCUMENTATION





CURRICULUM VITAE

NAME: Sunniva Zaratkiewicz

ADDRESS: Seattle, WA 98118

PROFESSIONAL LICENSE: Washington RN00155876 Exp. 11/10/2015

PROFESSIONAL CERTIFICATION: Certified Wound Care Nurse (CWCN)
#2005453434 Exp. 9/30/2017

PERSONAL STATEMENT:

I am passionate about the complex care of patients with wounds and have the great pleasure of working directly with patients, providers, and nurses in both in-patient and out-patient settings as a wound care specialist at Harborview Medical Center, a level 1 trauma and burn center. My work is driven by the desire to improve wound care and patient related outcomes through collaboration, direct care, and research.

ACADEMIC & PROFESSIONAL EDUCATION:

2010-2015	University of Washington, Seattle, Washington Doctorate of Philosophy in Nursing Science
2006	University of Washington, Seattle, Washington Wound Management Education Program
2001-2004	Seattle University, Seattle, Washington Bachelor of Science in Nursing
1993-1994	Brian Utting School of Massage, Seattle, Washington Therapeutic Massage

PROFESSIONAL & CLINICAL EXPERIENCE:

2012 -present	Program Manager, Wound, Ostomy, & Limb Preservation Services Harborview Medical Center, Seattle, Washington
Aug.-Nov. 2012	Subject Matter Expert, United States Attorney's Office – Western District of Washington, Seattle, Washington
2007- 2012	Skin & Wound Clinical Nurse Educator, Harborview Medical Center, Seattle, Washington
2006-2013	Certified Wound Care Nurse Preceptor, University of Washington Continuing Nursing Education Wound Management Education Program, Seattle, Washington
2004-2007	Staff/Charge Nurse, Harborview Medical Center, Seattle, Washington Medicine & Senior Care Unit

PUBLICATIONS:

Peer Reviewed Publications:

Zaratkiewicz, S; Whitney, J; Lowe, J; Taylor, S; O'Donnell, F; Minton-Foltz, P. Development & Implementation of a Hospital Acquired Pressure Ulcer Incidence Tracking System & Algorithm. November/December 2010, Journal for Healthcare Quality.

Alderden, J; Whitney, J; Taylor, S; **Zaratkiewicz, S**. Risk Profile Characteristics Associated With Outcomes of Hospital-Acquired Pressure Ulcers: A Retrospective Review. August 2011, Critical Care Nurse.

Zaratkiewicz, S; Teegardin, C; Whitney, J. Retrospective Review of the Reduction of Oral Pressure Ulcers in Mechanically Ventilated Patients: A Change in Practice. July-September 2012. Critical Care Nursing Quarterly.

Accepted In Press:

Zaratkiewicz, S; Whitney, J; Lowe; Baker, M. Defining Pressure Ulcers as Full Thickness Wounds: Are These Wounds Being Misclassified? November-December 2015. Journal of Wound, Ostomy, & Continence Nursing. In Press.

Professional Activities:

Harborview Medical Center:

Integrated Wound Oversight Council – Nursing Lead. 2015 to present

Hospital Acquired Pressure Ulcer Prevention Committee – Project Manager & Clinical Lead. 2007 to present

Hospital Acquired Pressure Ulcer Intensive Review Committee. 2007 to present

Patient Safety Committee. 2007 to present

Safe Patient Handling Committee. 2007 to present

Skin & Wound Assessment Team. 2005 to present

Product Evaluation and Safety Committee. 2007-1010 and 2012 to present

Regional:

Qualis Health Regional Pressure Ulcer Advisory Committee. 2007 to 2010

Seattle Wound & Ostomy Consortium. 2007 to present

National:

University HealthSystem Consortium's Imperatives for Quality Pressure Ulcer Focus Group -Subject Matter Expert. 2012 to 2013

University HealthSystem Consortium Pressure Ulcer Benchmarking Committee. 2008 to 2010

Novation Wound Management Council. 2012 to present – Vice Chair of Council. 2014 to present

Wound, Ostomy, & Continence Nursing Society Conference Planning Committee – Wound Track Co- Chair. 2015 to present

National & International Presentations:

World Union of Wound Healing Societies. June 2008. Toronto, Canada. Incidence Tracking of Hospital Acquired Pressure Ulcers (Poster).

University Health Consortium, Pressure Ulcer 2008 Benchmarking Project Knowledge Transfer Meeting. February 2009. Oak Brook, Illinois. Pressure Ulcer 2008 Benchmarking Project Findings & Conclusions (Speaker).

Washington Patient Safety Coalition. One Size Doesn't Fit All: Safe Care of the Very Large Patient Conference. April 2010. Portland, Oregon. Maintaining Skin Integrity Across Care Settings (Speaker).

American Society of Hand Therapists. March 2014. National Educational Webinar. Wound Care for the Hand Therapist (Speaker).

University HealthSystem Consortium. Supply Chain Council & Value Analysis Program Annual Meeting. March 2014. Seattle, WA. Pressure Ulcer Reduction Strategies (Speaker).

Regional Presentations & Classes:

Harborview Medical Center:

Wound Core I & II – Annual classes. 2007 to present.

Wound Care for Nurse Techs – Recurring Talk. 2007 to 2014.

Wound Care for Patient Care Services Orientation – Recurring Talk. 2007 to present.

Wound Care Basics for Rehab Physicians – Recurring Talk. 2007 to present.

Wound Care Basics for Medicine Residents – Recurring Talk. 2007 to present.

Fistula Workshop – Annual class. 2010 to 2013.

Wound Management Update, University of Washington Continuing Nursing Education. November 2008. "Never Events:" Systems & Strategies for Pressure Ulcers.

Seattle Nursing Research Workshop. January 2009. Hospital Approaches to Implementation of the 2008 Patient Safety Goals/Never Events: Pressure Ulcer Incidence Tracking.

University of Washington School of Nursing. June 2009. Topical Wound Management– **Sunniva Zaratkiewicz** & Shirley Taylor.

Update in Medical-Surgical Nursing, University of Washington Continuing Nursing Education. October 2009. Best Practices for Meeting National Patient Safety Goals: Incidence Tracking as a Pressure Ulcer Monitoring Strategy.

Washington State Academy of Physician Assistants 2009 Annual Fall Conference. October 2009. Wound Care Essentials Workshop – **Sunniva Zaratkiewicz** & Shirley Taylor.

University of Washington Division of Gerontology & Geriatric Medicine. November 2009. Wound Care Basics for Geriatric MDs.

University of Washington Doctor of Physical Therapy Program. June 2009, July 2010, July 2011, & July 2012. Wound Care Essentials.

Washington State Academy of Physician Assistants 22nd Annual Recertification Review Course. February, 2011. Wound Care Workshop – **Sunniva Zaratkiewicz** & Shirley Taylor.

Washington Patient Safety Coalition Patient Safety Teleconference Series. February 2011. Maintaining Skin Integrity Across Care Settings.

Northwest Center for Occupational Health & Safety - National Health Care Ergonomics Conference. June 2011. Care of the Bariatric Client from A to Z in the ED, Med/Surg, ICU, and OR, from Entry to Discharge.

University of Washington Wound Management Education Program. October 2011. Building an Effective Pressure Ulcer Prevention Program.

Harborview Medical Center Ambulatory Services General Medicine Conference. June 2012. Wound Care.

University of Washington School of Medicine, Family Medicine Residency Didactic. March 2013. Wound Care Basics.

University of Washington School of Medicine, Department of Orthopaedics and Sports Medicine – UW Hand Pitfalls and Complications, Course for Therapists. April 2013. Wound Care for the Therapist.

University of Washington Wound Care Update 2013 – Considerations for Diverse Populations. November, 2013. Palliative Wound Management: Changing Goals, Changing Strategies.

Western Institute of Nursing. April 2014. Seattle, WA. Advancing Pressure Ulcer Science: Risk Reduction and Assessment (Poster Symposium). JoAnne Whitney, Elizabeth Bridges, Jennifer Alderden, Lindsay Boyd, Deena Guran, & **Sunniva Zaratkiewicz**.

Apple Physical Therapy, April 2014. Tacoma, WA. Wound Care for Hand Therapists.

University of Washington Wound Care Update 2014 – Managing Wounds Across Care Settings. November, 2014. How Pressure Ulcers are a Lot Like the Greatest Hits of the 70's.

Harborview Medical Center, Physical Therapy All Staff Meeting, July 2015. Wound Care Essentials.

Community Activities:

Seven Star Women's Kung Fu. Martial Arts instructor & student. Seattle, Washington. 2005 to present

PROFESSIONAL & ACADEMIC MEMBERSHIP:

2004-present Sigma Theta Tau International Honor Society of Nursing

2006-present Wound, Ostomy, & Continence Nurses Society

2012-present Wound Healing Society

2013-present Association for the Advancement of Wound Care

2014-present Western Institute of Nursing

AWARDS & HONORS:

2004	Graduated Summa Cum Laude, Seattle University
2004	President's List, Seattle University
2004	Dean's List, Seattle University
2004	Sigma Theta Tau, Alpha Sigma Chapter Outstanding Senior Award
2009	Every Patient Every Time Award (In recognition of work in reducing the rate of, & patient suffering associated with, hospital acquired pressure ulcers.), Harborview Medical Center
2010-2013	Achievement Rewards for College Scientists (ARCS) Fellowship, University of Washington School of Nursing
2010-2013	Joseph C. & Edith A. Cole Endowed Nursing Scholarship, University of Washington School of Nursing
2010-2013	Joanne B. Sharma Scholarship, University of Washington School of Nursing
2013	Valerie Weiss Memorial Scholarship, King County Nurses Association
2013-2014	Magnuson Health Sciences Scholar, University of Washington