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# Clinical Practice Guideline for Differentiating Risk Factors for Avoidable and Unavoidable Pressure Ulcers.

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# Walden University

College of Health Sciences

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Vivian Suárez Irizarry

has been found to be complete and satisfactory in all respects,  
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2018

Abstract

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Unavoidable Pressure Ulcers

by

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

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## Abstract

Pressure ulcers (PUs) present intrinsic risk factors that are not consistently identified by clinical assessments. The objective of this project was to develop a clinical practice guideline (CPG) to provide nurses with guidance in identifying and differentiating how intrinsic and extrinsic risk factors are associated with populations at risk for developing avoidable and unavoidable PUs. CPG development followed a systematic method to search the literature, organize findings, and assess the strength of the resulting evidence and its applicability to the CPG. Quality of the CPG was assessed by a panel of 8 health care professionals using the Appraisal of Guidelines for Research & Evaluation II instrument. Findings of the assessment indicated a high overall quality of the CPG; its immediate use was recommended and systematic evaluation was suggested to promote usage in a wider array of health care contexts. The quality domains with the highest scores were scope, purpose, applicability, editorial independence (all 100%), rigor of development (99.7%), and clarity of presentation (99.3%). The stakeholder involvement domain demonstrated the lowest--yet still robust--score (94.4%). The CPG can be used to emphasize appropriate and specific nursing competencies for making informed decisions when identifying and describing patients at risk for developing PUs. Further research and evaluation of the use of this CPG will be useful to demonstrate how CPGs can help to decrease the incidence of avoidable PUs. The potential for positive social change relative to the prevention of PUs is high. Decreased incidence of preventable PUs will eliminate unnecessary health care costs and improve overall health outcomes of patients at all levels of socioeconomic status.

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## Dedication

This study is dedicated to God of all promises. The God, who gave me the strength to continue even when difficulties were confronted: “I can do all this through him who gives me strength”. Philippians 4:13.

To my family, specially my husband Andrés Velázquez, who always believed in me. His unconditional support, love and patience became strength during this journey. Without Andres’s help, this goal could had not been achieved. My kids Angélica and Manuel, thanks for understanding and cooperating during the long process. Your love became my greatest motivation to accomplish this goal. To my parents for being part of whom I am and whom I want to be in life. Very special thanks, in memory of my mother, who always taught me to strive with faith and strength. You lived knowing that there are no limits for those you believe.

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## Section 1: Nature of the Project

### Introduction

General preventive measures for pressure ulcers (pressure injuries) begin with the identification of risk factors for, and the etiology of, preventable (avoidable) and not preventable (unavoidable) pressure ulcers (PUs). Nurses need to be more knowledgeable of the main characteristics of patients at risk for PUs. Knowledge gained allows to make a difference in an accurate prognosis and preventing possible PUs/PIs (Pressure Ulcer Prevention Toolkit: Joint Commission Resources, 2012). National and International discussion among wound care experts and providers has continued to whether all PUs/PIs are preventable (WOCN, 2009; Edsberg et al., 2014). Pressure ulcer incidence rates continue steady, representing the failure of known, preventative treatment and strategies in certain patients (Thomas, 2003). These findings raise the question whether all PUs are avoidable. Descriptions of avoidable versus unavoidable PUs for the hospital setting have not been implemented officially by regulatory organizations. On the other hand, the Centers for Medicare and Medicaid Services (CMS) has published a statement that “pressure ulcers should be prevented in residents of long-term care settings, except in the case of patients whose clinical condition validates that they were unavoidable” (CMS, 2004). The National Pressure Ulcer Advisory Panel (NPUAP) has agreed that not all PUs are preventable (2010).

The NPUAP stated that there are clinical situations in which the development of PUs may be unavoidable (NPAUP, 2010). In February 2014, a national expert consensus conference was convened by the NPUAP to investigate the issue of

avoidable/unavoidable hospital-acquired PUs (HAPUs) using an organ system framework and considering the complexities of no modifiable intrinsic and extrinsic risk factors. An extensive literature review was conducted to analyze and synthesize the state of the science in the area of unavoidable PU development. An interactive consensus was reached among participants of other organizations and audience members. The group determined that unavoidable PUs do occur (Edsberg et al; 2014). Findings of this conference became the foundation for the NPUAP's Pressure Ulcer Registry, the first database of its type to allow clinicians to input cases of PUs in an effort to provide statistically significant, rigorous analysis of the variables associated with the development of unavoidable PUs. Unanimously, participants voted that not all PUs are avoidable because the patients' health status may prevent pressure relief, and perfusion cannot be improved (Black et al; 2011).

The NPUAP has conducted the 2 international consensus conferences on PU avoidability-unavoidability. The first conference in 2010 established consensus on the existence of some selected situations where PU development can be considered unavoidable. Based on an extensive review of the scientific literature on pressure ulcer risk factors and PU development, this 2014 conference established consensus on some risk factors that, in some selected situations, have been shown to increase the likelihood of the development of an unavoidable pressure ulcer. The effort from these pioneering conferences continues to define additional conditions associated with the development of an unavoidable PU. Using the CMS's definitions, the NPUAP defined unavoidable PUs as those PUs that develop even though the provider (a) evaluated the individual's clinical

condition and pressure ulcer risk factors; (b) defined and implemented interventions consistent with individual needs, goals, and recognized standards of practice; (c) monitored and evaluated the impact of the interventions; and (d) revised the approaches as appropriate (NPUAP, 2010; Black et al., 2011). Although this definition is applicable and useful, it is conceptual rather than operational and does not provide practical application (Pittman et al., 2016).

The Wound, Ostomy and Continence Nurses (WOCN) Society also issued a position statement on avoidable versus unavoidable PUs, stating that the pressure ulcer process is complex, multifactorial, and cannot always be halted (WOCN, 2009). The WOCN Society recommended further research to examine the implications of modifiable and unmodifiable risk factors in pressure ulcer development and the implications for clinical practice (2017). Recognizing the clinical complexities and high incidence of comorbidities frequently faced in today's clinical setting, it is realistic to say that not all PUs can be defined as avoidable or preventable (Schmitt et al., 2017).

### **Problem Statement**

Each year, more than 2.5 million people in the United States develop PUs (CMS, 2009). These skin lesions bring adverse outcomes in patients that may include pain, risk of developing an associated serious infection, and increased health care utilization and costs [citation needed]. The cost of care may surpass \$70,000 and treatment in the U.S. is estimated at \$11 billion annually. A 5-year study, which included older patients admitted to hospital in Ontario, Canada, determined the adjusted net cost to be \$44,000 and \$90,000 for a hospital-acquired pressure ulcer (HAPU) at Stage 2 and 4, respectively

(Chan et al. 2013). The population at risk of PUs is expected to grow given the increase of an aging population and the incidence of impaired mobility and chronic conditions, such as diabetes and obesity (Bennett et al., 2004; Sullivan & Schoelles, 2013). The successful preventive measures cannot be applied if individuals are not correctly classified as being at risk. Risk-screening tools are inadequate if they: (a) are not related to the population being screened, (b) do not accurately describe for significant risk factors, (c) are not used consistently, or 4) are scored erroneously (Thomas, 2001; Papanikolaou, Lyne, & Anthony, 2007).

The most controversial aspect of PUs is that of avoidability. It is recognized that PUs etiology is a complex process that involves multiple, often non-modifiable, intrinsic risk factors, which are not fully identified by pressure ulcer risk assessment scales (Berlowitz & Brienza, 2007; Edsberg et al., 2014; Lyder, 2003; Registered Nurses Association of Ontario [RNAO], 2011). More than 100 risk factors associated with pressure ulcer development have been identified (Anderson et al., 2015). The quantity and diversity of risk factors challenge the clinician to choose and apply applicable preventive interventions in a timely fashion. The process is not fully understood, but it seems rational that the greater the number of risk factors present, the greater challenge it will be to prevent the development and/or deterioration of PUs (Lyder et al., 2012).

There is a need to expand the knowledge for determining avoidable versus unavoidable PUs and validate best practices to reduce the incidence of avoidable PUs (WOCN, 2009). Expert recommend the following: endorse the basic components of accurate and appropriate assessment and documentation for pressure ulcer prevention and

management (i.e., skin assessment, description of skin integrity, identification of extrinsic and intrinsic risk factors for pressure ulcer development, including hemodynamics and comorbidities); and determine the role of validated instruments, computer-based algorithms, digital technology, ultrasound, and other modalities for assessment and documentation (Alvey, Hennen, & Heard, 2012; NPUAP et al., 2014; Pittman et al., 2016).

The problem addressed in this project is the lack of an evidence-based clinical guideline that help nurses identify, describe, and document the modifiable and non-modifiable risk factors associated with the development of avoidable (preventable) versus unavoidable (non-preventable) PUs. New models and best practices are crucial to help determine which PUs are unavoidable (Anderson et al., 2015; Levin et al.; 2009). Assessing at-risk patients requires a decision process, including understanding numerous characteristics of a patient's status (Choi et al., 2014). PUs are considered to be an avoidable injury and continue to be a key quality indicator (National Patient Safety Agency [NPSA] 2010; NHS Improving Quality, 2014); as the goal to prevent PUs remains essential, the number of PUs classified as preventable remains uncertain. CMS advises that nurses consider all risk factors independent of the scores obtained on any validated pressure ulcer prediction scales, because not all factors are found on any one tool. The WOCN Society supports further research and quality improvement proposals to expand the science and understanding in differentiating avoidable and unavoidable PUs, identifying etiological factors and conditions associated with unavoidable PUs, and validating best practices for preventing PUs (WOCN, 2017).

## **Purpose Statement**

The purpose of this project was to develop a clinical practice guideline (CPG) that would help nurses identify, describe, and document factors that influence the development of preventable (avoidable) and non-preventable (unavoidable) PUs. This CPG is expected to help differentiate between modifiable (extrinsic) and unmodifiable (intrinsic) risks factors associated with the development of preventable (avoidable) and non-preventable (unavoidable) PUs. The integration of evidence-based data will provide guidance to target high-risk populations pondering individualized unmodifiable (intrinsic) and modifiable (extrinsic) risk factors in order to reliably implement prevention strategies for all patients deemed at risk. The CPG components of an avoidable and unavoidable pressure ulcer will be considered in light of the state of the science and NPUAP consensus statements.

## **Study Objectives**

The objectives for this study were as follows:

1. To give nurses guidance and to help them become competent in the identification, description, and documentation of modifiable and unmodifiable risk factors associated with PU development.
2. To give nurses guidance and to help them become competent to differentiate in high-risk populations the factors that influence the development of avoidable (preventable) and unavoidable (non-preventable) PUs.
3. To provide consistency and appropriate nursing documentation in circumstances where a pressure ulcer has been identified as unavoidable.

4. To give nurses guidance and structure that support their decision process and knowledge they need to implement timely and appropriate prevention plans.

### **Practice-Focused Questions**

1. What modifiable (extrinsic) and non-modifiable (intrinsic) risk factors are associated with pressure ulcer development?
2. What modifiable (extrinsic) and non-modifiable risk factors (intrinsic) influence the development of avoidable versus unavoidable pressure ulcer development?
3. Does the clinical practice guideline meet the validation criteria according to the expert panel review?
4. Does the clinical practice guideline support the application of current evidence-based practice?

### **Nature of the Project**

This project sought to describe the development of a CPG to improve nursing practice that integrated evidence-based and empirical data to describe modifiable (extrinsic) and non-modifiable (intrinsic) risk factors in a patient's unique profile that are associated with the development of avoidable or unavoidable pressure ulcers. The CPG will incorporate the results of a literature review, combining expert consensus and scientific data to support the identification and description of modifiable and nonmodifiable PUs risk factors related to the development of avoidable versus unavoidable PUs. The CPG will be designed to appropriate identify and describe risk factors that help define avoidable/unavoidable PUs based on the WOCN and the



NPUAP's conceptual definition and consensus. The clinical practice guidance criteria will follow a systemic review to define the inclusion and exclusion criteria of the modifiable and non-modifiable risk factors related to avoidable/unavoidable PUs, and then grade the strength of evidence.

To determine the content and criterion validity the Appraisal of Guidelines for Research & Evaluation II (AGREE II) instrument was used. This instrument assesses the methodological rigor and transparency in which a guideline is developed. A multidisciplinary group of eight healthcare experts from academic and specialty areas were used, including two nurses educator/researcher (PhD), one nursing educator (MSN), one quality improvement nurse (RN), one physician (MD), one wound care specialist (certified nurses) and two nurse practitioner [FNP-BC]). The panel of experts were asked to rate the content for relevance, clarity, comprehensiveness, and appropriateness using a content validity survey. The use of domain scores made it possible to discuss whether the guideline should be recommended for use. The expert panel was e-mailed an informed consent prior to participating in the CPG revision. Experts were asked to review the CPG and return an evaluation and feedback within 2 weeks using a secure e-mail system. Results were integrated into a secured data base for analysis. IBM SPSS Statistics 21 software was used to perform descriptive statistics and to evaluate the results. The approval I Walden's Institutional Review Board was obtained prior to collecting data.

## Significance

A better understanding of the relationship between modifiable and nonmodifiable causative risk factors and the development of PUs can improve ability to identify patients at high risk and thus enable better targeting of resources in clinical practice (Coleman, 2013). Appropriate identification and mitigation of risk factors can prevent or reduce the formation of PUs. In some instances, PUs are unavoidable because the magnitude and severity of risk are unmodifiable, or preventive measures are either contraindicated or inadequate due to the severity of risk (NPUAP, 2010). The scientific literature on PU risk factors and PU development identifies some risk factors and some circumstances in which the likelihood of an unavoidable PU could increase (Edsberg et al., 2014). Improving the process to capture the extrinsic and intrinsic factors is vital in order to improve the identification of patients who may develop unavoidable PUs. The WOCN Society (2017) position statement on avoidable versus unavoidable PUs recommended further research to evaluate which comorbidities and intrinsic factors are related to PU development to determine the clinical implications in the nursing practice. Additionally, it recommended that clinical documentation must include contraindications to preventive care in order to demonstrate rationale to determine unavoidable PU development (WOCN, 2017).

Over the last 16 years, the NPUAP has published various educational materials, white papers, and position statements on extensive collection of topics related to PU, but despite educational efforts from multiple organizations, the current research does not adopt the multiple medical and clinical situations that may affect a patient's risk and

vulnerability for developing unavoidable PUs (NPUAP et al., 2014). It is time to integrate evidence-based knowledge that supports the nursing decision process to describe patient's risk profile specifying modifiable and unmodifiable causes (Edsberg et al., 2014). From the perspective of real life practice, the literature shows gaps and limitations that affect clinical and organizational outcomes mostly due to lack of documentation obtained from the initial patient's risk assessment and the need to properly describe patients at risk of developing unavoidable PUs. PU prevention involves a variety of aspects in the nursing process; and the content of nurses' reasoning when identifying the individualized patient's risk factors is the first step in guiding the development of an accurate and measurable preventive care planning for nursing.

Evidence-based practices are centered on critical appraisals of effectiveness of care and the application of scientific data. The process of clinical decision making begins with the identification and description of risk factors that may be modifiable and unmodifiable. It is necessary that healthcare staff can identify the major characteristics, factors, and circumstances that influence the development of avoidable and unavoidable PUs. Further, it allows to make an accurate identification and documentation by implementing an evidence-based system to help define avoidable/unavoidable PUs. The identification of modifiable and unmodifiable risks factors will result in a best decision making when implementing clinical interventions. The NPUAP consensus statements (2014) understand that risk factors, monitoring, interventions, goals, and standards of practice are applied with the objective of preventing PU development consistent with a holistic goal of care (NPUAP National Consensus, 2014).

## Summary

Identification of the patient's risk remains fundamental in the strategies of a PU-prevention program. The identification of patient's risks is more than defining a numerical score; it entails identifying those risk factors that contribute to the score and reducing the discrepancies by the applicability of the intensity and effectiveness of the strategies for the PU prevention (Kelechi, Arndt, & Dove, 2013). There are many factors and there is much complexity in the etiology, prevention, and management of PUs. The study of PU prevention is considered to be somewhat new, and that understanding is still evolving. It is well known that the etiology of PUs is a complex process in which multiple, often non-modifiable, intrinsic risk factors are associated, and which cannot entirely be measured by PU risk assessment tools (Berlowitz & Brienza, 2007; Edsberg et al., 2014; Lyder, 2003; RNAO, 2011). Currently, despite the great educational efforts from numerous entities, robust, scientific evidence that supports the identification of modifiable and unmodifiable patient risk factors is missing (NPUAP et al., 2014). Current investigations do not address the medical, multifactorial circumstances that may affect a patient's risk and vulnerability for developing PUs (WOCN, 2009).

For many years, multiple organizations developed and updated best practice guidelines or CPGs for the prevention and treatment of PUs. In 2003, the WOCN Society published a CPG for the prevention and management of PUs; it was updated in 2010 and 2016 (WOCN, 2017). The objective of the CPG is to provide up-to-date, evidence-based recommendations to guide and support WOC nurses and other healthcare providers in the preventive care and management of patients with complex needs who have PUs or are at

risk for PUs. In 2008, the WOCN Society published a guideline (updated in 2016) to help evaluate and document PUs in a variety of clinical settings (<http://www.wocn.org/page/PUEvaluationCRG>). But there were no evidence-based recommendations to guide in the identification and documentation of modifiable and unmodifiable PU risk factors.

The development of this CPG will add to the body of knowledge about factors that potentially contribute to the development of avoidable and unavoidable PUs by integrating patient characteristics and circumstances related to patient's health status. Identifying the etiological factors and conditions associated to an avoidable and unavoidable pressure ulcer is necessary to ascertain the truth of best practices in pressure ulcers prevention. New screening methods as the use of a CPG will support nurses' decision making and improve accurate interventions to high-risk populations. It is evident the need of a systematical approach that support nurses and other healthcare providers to associate and define the development of avoidable/unavoidable PU. Section 2 will evaluate evidence of the complexity of PUs etiology and the need to differentiate intrinsic and extrinsic risk factors associated to the development of avoidable and unavoidable pressure ulcers.

## Section 2: Background and Context

### Introduction

PU/PIs represent a significant problem in the healthcare settings. The development of PU/PIs is considered the second most common reason for patients' hospital readmissions. The costs vary from \$20,000 to \$70,000 per wound (Ducker, 2004). Accordingly, the costs related treating PU/PIs complications during a single hospital stay transcend \$200,000 per patient when PU/PI isn't recognized on admission and complications progress from the PU/PI acquired (Brem, Maggi, Nierman, et al; 2010). CMS established that the average costs per hospital stay for a patient with a Stage 3 or Stage 4 PU/PI is \$43,180 (Courtney, Ruppman & Coopers, 2006). The CMS also concur that 257,412 beneficiaries that are admitted to hospitals develop Stage 3 and Stage 4 PU/PI, for a total CMS reimbursement to hospitals of over \$11 billion (CMS, 2009).

In 2007, a randomized retrospective study analyzed 51,842 Medicare beneficiaries' medical records from hospital discharges database for a 2-year period. The study showed that 5.8% of the patients had been admitted with PUs and 4.5% developed at least one new PU during hospitalization. Patients who developed HAPUs had a longer length of stay (4.8 versus 11.2), were more likely to die during the hospital stay (3.3% versus 11.2%), were more susceptible to die within 30 days of discharge (4.4% versus 15.3%) and were more probable to be readmitted within 30 days (17.6% versus 22.6%) when compared with those patients who did not develop a HAPU (Moore, 2013).

In 2012, the costs for PU/PI treatment were estimated in U.K. considering PU/PIs at different stagings. Stage 1 PU costs per patients were calculated at \$1, 912; for

Stage 2, the costs were estimated at \$8,255; for Stage 3 the number was \$14,240; and for Stage 4, it was \$22,222 (Dealey, Posnett & Walker, 2012). In a study by Brem et al. (2010), the costs associated with treatment and secondary complications were calculated using a retrospective chart analysis. An evaluation of patients with Stage 4 PU was conducted during 29 months of follow up. Of 19 patients, 11 were classified as HAPUs and 8 were classified as Community Acquired PUs (CAPUs). Secondary complications comprised pain, depression, local infection, osteomyelitis, anemia, sepsis, gas gangrene, necrotizing fasciitis, and death. The average cost for Stage 4 HAPUs was calculated at \$127,185 during one hospital stay and the average cost for Stage 4 CAPU was calculated at \$124,327. Healthcare providers must understand the clinical consequences of PUs in patients' lives and the organizational implications related to costs and quality of care. This understanding should include evaluating prevention initiatives in order to develop quality improvement practices and best practices (Joint Commission Resource, 2012).

In 2001, The NPUAP reported the incidence of PUs fluctuating from 0.4–38% for hospitalized patients; 2.2–23% for long-term care; and as high as 17% in home care (Bergstrom et al: 1992; Ayello, Frantz & Cuddigan, 2001). The cost of PUs must consider the cost of treatments, the costs to the patient and the family, and the costs to society which is affected by loss of time from work, as well as the potential cost of litigation and medical practice and more. CMS recommends that nurses consider all risk factors independent of the scores obtained on any validated PU prediction scale. The foundation for the implementation of reliable and effective prevention guidelines requires individualized description of risk factors that incorporate accurate management of

interventions (Joint Commission Resource, 2012). Most of the revised PU prevention guidelines available on the National Guideline website are still based on risk factors identified over 20 years ago and these may not have the same significance today (RNAO, 2005; American Medical Directors Association (AMDA), 2008). The development of a CPG that integrates current scientific data in defining factors associated with the development of avoidable versus unavoidable PUs will support nurses' decision making and improve accurate interventions to high-risk populations.

### **Concepts, Model or Theories**

The knowledge to action framework (KTAF; Graham et al., 2006) was chosen as the project's conceptual framework. It describes and facilitates the proposed change in practice. The KTAF and its application to the project will be described. The KTAF aims to help researchers interested with knowledge translation deliver sustainable, evidence-based interventions. The KTAF Knowledge to Action framework, established by Graham and colleagues (2000), makes it possible to systematically integrate new approaches to clinical practice. This framework builds on the structures from the assessment of planned-action theories that define in a systematic methodology interrelated concepts by which planned change occurs. The KTAF process is an iterative, dynamic, and complex process, related knowledge creation and the knowledge application (Graham et al., 2006).

The KTAF cycle details the sequence and steps involved in achieving the transfer of research knowledge into clinical practice consisting of two phases. The initial creation phases consist of synthesizing knowledge as part of producing new tools, such as clinical guidelines in response to an identified clinical problem. This step is to ensure that



knowledge is obtained from best available evidence before proceeding to the action phase, which include implementing and evaluating new knowledge in clinical practice (Graham et al., 2006). The action cycle includes seven phases: (a) identify the problem and relevant research; (b) adapt research to local context; (c) assess barriers to using the knowledge; (d) select, tailor and implement interventions; (e) monitor knowledge use; (f) evaluate outcomes; and (g) sustain knowledge use.

In KTA, process practice change consists of two concepts: knowledge creation and action. Inside KTA, knowledge is appreciated to be principally empirically derived (i.e., research based) but additionally incorporates other forms of knowing as experiential knowledge. The knowledge concept, denotes knowledge creation and comprises of the main types of knowledge or research, specifically, primary research, knowledge synthesis (e.g., meta-analysis), and knowledge tools and products (e.g., best-practice guidelines, decision-support tools; Graham et al. 2006).

(KTA by Graham et al. (2006) can also be used within broader frameworks as Outcomes-focused knowledge translation. The outcomes-focused knowledge translation was developed as a model to guide knowledge and it is also complementary to the KTA framework proposed by Graham et al. (2006). Outcomes-focused knowledge translation in this project we will utilize third-generation knowledge, that is, practice guidelines integrated in decision-support tools that deliver research evidence in response to patient outcomes data. Therefore, it will incorporate two major sources of knowledge for evidence-informed decision making: (i) patient outcomes data and (ii) research evidence

to differentiate risk factors associated with the development of avoidable versus unavoidable PUs.

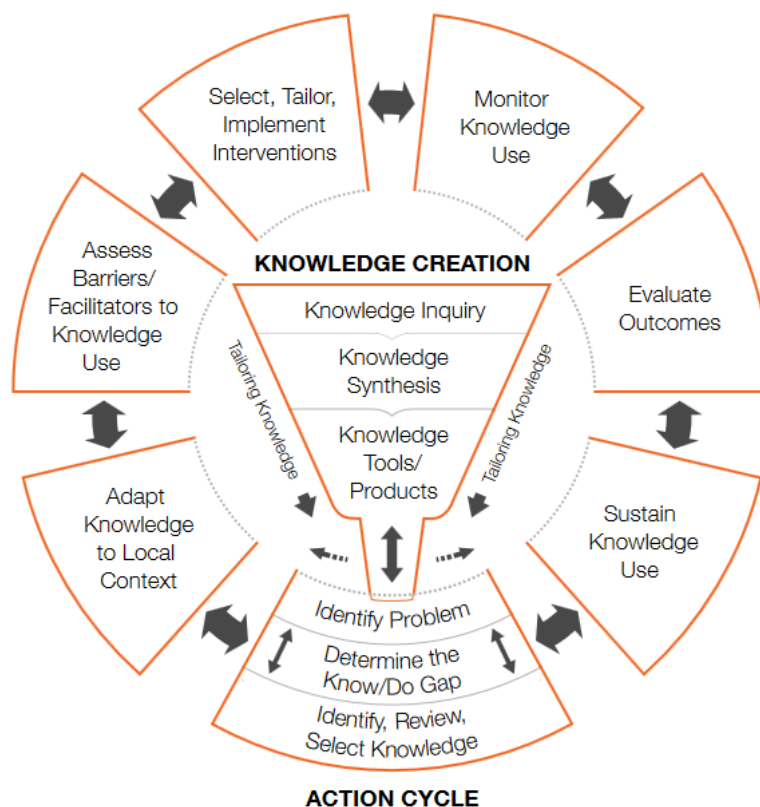


Figure 1. Knowledge to action cycle, by Straus, S.E., Tetroe, J., Graham, I.D., 2013, *Knowledge translation in health care: Moving from evidence to practice*. p.10. Copyright 1988 by Designs and Patents Act. Reprinted with permission.

The action part of the KTA process results in implementation or application of new knowledge. The development of a CPG will integrate the application of new knowledge to improve a better performance of care by providing a holistic approach that entails nurse's guidance and competence to differentiate in high-risk population the factors that influence in the development of avoidable (preventable) and unavoidable (non-preventable) PUs. The objective to integrate outcomes-focused knowledge

translation is to provide the feedback to clinicians' reference practice information, such as best-practice guidelines and feedback about change in the patient's risk factors identification. In the Table 1.1 it is described each of the KTA phases and the process in the development of the CPG. The KTA process encompasses all the steps between the creation of a new knowledge and its application to produce beneficial outcomes for nursing care.

Table 1

*Knowledge to Action Framework Phases in the Development of CPG*

Phases	
Identify problem	Lack of a comprehensive approach that assist nurses to identify risk factors associated with avoidable versus unavoidable PUs.
Adapt knowledge	Synthesized scientific evidence to create a CPG that support applicability in the nursing practice and improve clinical decision making.
Barriers to knowledge use	Costs implications, nursing time and resistance to change will be considered.
Implement interventions	Propose CPG adoption as a best practice by defining benefits of implementation to improve nursing practice and patient's care.
Monitor knowledge use	Validate the essential components of accurate and appropriate use in the nursing practice.
Evaluate outcomes	Evaluate impact of the CPGs in nursing practice, patients care, and organization outcomes.
Sustain knowledge use	Promote the use of an evidence-based CPG in health care setting to adopt and expand nursing practice. Advance nursing activities to develop engagement to evaluate the impact on patients' outcomes.

## Definition of Terms

The defining terminologies for the CPG adaptation are the following:

### *PUs definition and staging*

The NPUAP redefined the term of PU as a pressure injury on 2016; they define pressure injury (PI) as: a localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The NPUAP (2016) state that the injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue (npuap.org, add page or paragraph number). The updated staging system includes the following definitions (NPUAP, 2016):

#### 1. **Stage 1 Pressure Injury: Non-blanchable erythema of intact skin**

Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

#### 2. **Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis**

Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible.

Granulation tissue, slough and eschar are not present. These injuries

commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel.

**3. Stage 3 Pressure Injury: Full-thickness skin loss**

Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds.

Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

**4. Stage 4 Pressure Injury: Full-thickness skin and tissue loss**

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

**5. Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss**

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

**6. Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration.**

Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

*An avoidable pressure ulcer (pressure injury)* develops when the provider did not do one or more of the following: evaluate the individual's clinical condition and pressure injury risk factors; define and implement interventions consistent with individual needs, individual goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate (WOCN, 2009).

*An unavoidable pressure ulcer (pressure injury)* develops even though the provider evaluated the individual's clinical condition and PU risk factors; defined and implemented interventions consistent with individual needs, goals, and

recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate (WOCN, 2009).

*Holistic Care:* The American Holistic Nursing Association (AHNA) describes a holistic nurse as one who takes a holistic (mind-body-spirit-emotion) approach to the practice of traditional nursing, an approach that is based on a body of knowledge, sophisticated skill sets, standards of practice, and a philosophy of living and being that is grounded in caring, relationship, and interconnectedness. (Kinchen, 2014).

*Hospital acquired PU:* It is a complication, known as *never event* recognized by the Department of Health and Human Services as high-cost or high-volume events that could reasonably be prevented through the application of evidence-based guidelines (CMS, 2008).

*Guideline or practice guideline* are systematically developed statements to aid in the clinical decision-making of nurses and other healthcare professionals (National Institutes of Health, 1990).

*Risk factors* are any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury (World Health Organization, 2017, [http://www.who.int/topics/risk\\_factors/en/](http://www.who.int/topics/risk_factors/en/))

*Modifiable risk factors* are those you can take measures to change them (UCSF Medical Center, 2017)

*Unmodifiable risk factors* are those that cannot be changed (UCSF Medical Center, 2017).

### **Relevance to Nursing Practice**

A better understanding of the relation of contribution risk factors to the development of PU can improve the ability to identify patients at high risk and would enable to better target resources in practice (Coleman, 2013). The integration of a CPG is critical to ensure identification of the high-risk population and target risk factors that influence in the development of avoidable and unavoidable PUs. Consistency in the nursing assessment, documentation and timeliness in the care plan interventions will improve the prevention efforts to minimize risk for PU development. More than providing specific guideline, and processes focused on expected outcomes; spell out on first use (EBP) give directions to nursing care interventions using the critical thinking process in the implementation and evaluation of patient care outcomes. EBP creates a view of nursing care as a framework for improving healthy environments and developing a vision of a systematic method for generating nursing interventions and care based on evidence (Omery & Williams, 1999). The incidence of avoidable PUs is recognized as an important quality indicator of care. The eradication of avoidable PUs is still a challenge and continues to denote an aggregate financial problem for healthcare system and to affect patients' quality of life (Parnham, 2015). In most of cases, appropriate identification and mitigation of risk factors can prevent or minimize PU (injury) formation. However, some PUs are unavoidable (Edsberg et al., 2014). Criteria validation and further research related to accurate and applicable assessment and documentation for PU prevention and management (i.e., skin assessment, criteria of skin integrity, identification of extrinsic and intrinsic risk factors for PU development) are necessary to



determine the role of validated instruments for assessment and documentation (Alvey, Hennen, & Heard, 2012; NPUAP et al., 2014; Pittman et al., 2016). No current evidence-based guidelines on the topic is available that are suitable for use by nurses for the identification of modifiable and unmodifiable PU risk factors associated with PU development. New scientific research data is required to define a conceptual framework of PU risks and clarify the breach between the epidemiological, physiological and biomechanical evidence of the role of individual risk factors in PU development. This will enable the development of a PU standard method to apprise future risk factor research and the development of improved clinical guideline systems (Coleman, 2013).

### **Local Background and Context**

In 2008, CMS released a regulation (Inpatient Prospective Payment System Final Rule, Fiscal Year 2010) that refused reimbursement for the care of selected hospital-acquired conditions, which were denominated to be reasonably preventable (e.g., Stage 3 and 4, HAPUs) through the application of evidence-based guidelines (CMS, 2008, 2009; Stokowski, 2010). Evidence-based guideline provides essential vision to clinicians and other stakeholders related the care interventions the patient received and their outcomes (i.e., assessment, prevention, treatment), and if a HAPU develops, denote that evidence-based care was offered to support that the HAPU was unavoidable (Jacobson, Thompson, Halvorson, & Zeitler, 2016). Jacobson et al. (2016) reported that after implementation of a quality improvement initiative to improve documentation of evidence-based interventions to prevent PUs, a 67% reduction in HAPUs that were considered avoidable. The foundation and significance of documentation is further validated by CMS (2004,

2009, 2016) who has recognized that some PUs are unavoidable under evident circumstances, such as when the ulcers develop despite the provision of appropriate and accurate assessment and interventions. Consequently, for a PU to be considered unavoidable, there must be well-defined, a complete, and consistent documentation of the prevention and care interventions delivered to the patient is essential (Dahlstrom et al., 2011; Jacobson et al., 2016; Pittman et al., 2016; Worley, 2007).

Patient acuity, medical technology, nursing hours at the bedside (Hall, Doran, & Pink, 2004; Kramer & Schmalenberg, 2005), nursing practice settings (Lake & Friese, 2006), and PU risk factors identified in scientific research (Fogerty et al., 2008) have transformed in the past 20 years. Consequently, a new statistical analysis is essential in a predictive model, demonstrating possible interactions among currently identified risk factors and determining predictive contributions of each risk factor so that actions may be focused at risk factors that carry the greatest association with the development of PUs, particularly those factors that are modifiable.

Cowan (2015-2017) presented a summary of Fogerty et al. (2008) retrospective case-control study examining admission and discharge data from over six million patients in the Nationwide Inpatient Sample (NIS) to classify risk factors and demographic variances between those patients who developed PUs and those that did not. Their study can be defined as a nested case-control (Gordis, 2004) because they recognized a cohort (inpatients in the NIS dataset), trailed their records retrospectively considering hospital admission till hospital discharge (during 2003), and divided them into 2 groups: patients

who developed PUs (cases) and those that did not (controls). There were 94,758 incident PUs reported including a final discharge sample of 6,610,787 persons. Using multivariate logistic regression analysis on 45 shared conditions identified in patients with PUs, they informed probabilities ratios (appraisal of comparative risk) for the most significant risk factors related with developing PUs. Investigation was also showed classifying the sample by age, race and gender. Age over 75 years was the more significant PU risk factor recognized with an Odds Ratio (OR) of 12.63 (meaning people over 75 years are nearly 13 times more probable to develop PUs than younger age groups). Other critical risk factors classified (registered in descending order) include: diagnosis of gangrene (OR 10.94, 95% with a Confidence Interval (CI) of 10.43-11.48), septicemia (OR 9.78, 95% CI 9.33- 10.26), osteomyelitis (OR 9.38, 95% CI 8.81-9.99), nutritional deficiencies (OR 9.18, 95% CI 8.81-9.99), pneumonitis (OR 8.70, 95% CI 8.33-9.09), urinary tract infection (OR 7.17, 95% CI 6.96-7.38), paralysis (OR 10.30, 95% CI 9.69-10.96), age 59 to 75 years (OR 5.99, no CI reported), and African American race (OR 5.71, 95% CI 5.35-6.10).

Levine and Zulkowski (2015) performed a secondary analysis of PU statistics from two studies (Levinson, 2010, 2014), which were directed by the DHHS, Office of Inspector General (OIG) on adverse events among Medicare payees in acute care hospitals and Long-Term Care (LTC)/skilled nursing facilities (SNF). In the OIG studies, the concepts avoidable and unavoidable were not used. In its place, the OIG defined harm as preventable if it could have been avoided by better-quality assessment or alternative interventions. Harm was not preventable if it could not have been avoided due to the

complications of the patient's health condition or care that was required. Since the OIG did not use the terms avoidable or unavoidable, the researchers considered the terms preventable and not preventable substitutable with avoidable and unavoidable, respectively. In the OIG studies, a group of physicians defined the level of harm and determined the preventability/avoidability by implementing a decision algorithm that was specifically developed for the study of adverse events in hospitals. To determine preventability/avoidability, the OIG reviewers used medical records data, clinical expertise, literature research, and expert discussion. The OIG reviewers valued preventability integrating a 5-point scale (i.e., clearly preventable, likely preventable, likely not preventable, clearly not preventable, unable to determine). The incidence of PU in the hospitals was 2.9% and 3.4% in the LTC/SNF. Based on the OIG data, 39.1% of HAPUs and 40.9% of PUs in LTC/SNF were unavoidable leading Levine and Zulkowski to enquiry about the reliability and validity of PUs as a quality indicator with such a high rate of unavoidability. The researchers determined that while the structured algorithm/decision process used by the OIG to assess preventability was a strength of their studies, they did not identify any Stage 4, and only a few unstageable or Deep Tissue Injury consequently, their investigation might have undervalued the level of harm from facility-acquired PUs. Levine and Kulkowski suggested additional studies to establish validity and reliability for the algorithm.

Furthermore, relevant research provided in Fogerty et al., study it was described a statistically significant interaction between race and age, as it was found that African Americans age and their risk of developing PUs increases more than the risk Caucasians

age, specifying notable racial disparities. In this study, some of the strongest risk factors are non-modifiable (age, paralysis, race) while others are potentially modifiable (infection, nutritional deficiencies). Consequently, research is needed to determine when interventions are most effective in those patients with non-modifiable risk factors (such as age > 75) or if interventions must be started in all persons over 75 years old. Research must also evaluate the most effective interventions to reduce or eliminate the identified modifiable risk factors (infection and nutritional deficiencies) and ways to accurately identify them in patients (Cowan, 2015-2017).

### **Role of the DNP Student**

The literature demonstrates that there is a need to support clinician to identify patients at risk to the develop avoidable versus unavoidable PU improving clinical practice founded on current scientific evidence and accepted best practices. There is clear evidence of the need to integrate the latest evidence and scientific data in order to provide a holistic approach to identify complex risk factors in clinical situations that can be defined the patient risks factors associated with avoidable and unavoidable PUs development. The role as a DNP student encompass the use of the clinical expertise integrating the latest scientific data to generate practical solutions in nursing clinical practice through the application of an evidence-based guideline. The author is a nurse certified by the WOCNCB that will apply her clinical expertise and evidence-based skill set to improve practice trends adapting research data providing rationale feedback in the identification for avoidable/unavoidable PUs risk factors. The development of a CPG intends to translate research and current best evidence to the high standards of clinical

practice that support clinicians to interpret how modifiable and unmodifiable risk factors are associated with the development of avoidable and unavoidable PUs.

The DNP student recognize that for many years professional and organizational consensus have validated scientific data elucidating the how intrinsic factors and extrinsic risk factors can predispose patient to develops PU. But, currently there is no a single CPG that integrates and define patient's risk associated with avoidable/unavoidable PUs development. From her extensive professional experience in the field of wound care, the DNP student considers that it is essential to innovate creating a CPG to improve nursing practice which can describe the multifactorial dimension of PU development to contribute improving clinical practice and patient quality care. The literature review establishes (NPUAP, 2017; WOCN Society, 2017) that unmodifiable factors associated with disease's processes and comorbidities have a great effect in the PU development and as well the patients' medical restrictions or inability to adhere to the preventive measures. These elements are crucial to be identify in the nursing assessment and clinical documentation process to clear distinguish the modifiable and unmodifiable factors associated with the patient' risks to develop avoidable versus unavoidable PU. A well-defined knowledge about PU multidimensional risks factors will help clinician to recognize patients at risk to develop avoidable/unavoidable PU by describing the influences of the patient's unmodifiable (intrinsic factors) or patient's clinical characteristic and unmodifiable (extrinsic) factors. Improved identification of patients' risks will create accurate and realistic preventive clinical actions. Clinical guidelines benefits patients through better outcomes, less ineffective interventions, better

consistency of care, and by creating derived implementation materials. Clinicians can use guidelines to make better decisions, initiate quality improvement efforts, prioritize new research initiatives, and support coverage or reimbursement for proper services (Rosenfeld & Shiffman, 2010). The development of this CPG will add to the body of knowledge about factors that potentially contribute to the development of avoidable and unavoidable PUs by integrating patient characteristics and circumstances related to patient's health status. In addition to approaching the problem of lack of an evidence-based guideline to identify and describe risk factors related avoidable/unavoidable PU development, this guideline will provide evidence that clinicians delivered her interventions considering patient's characteristics and needs.

### **Summary**

For many patients, healthcare conditions generate complex factors of pathophysiologic processes; for which it results in the development of an unavoidable PU (Berlowitz & Brienza, 2007). The development of a PU is a multifactorial event that sometimes may not be prevented even with high quality multidisciplinary prevention and treatment strategies. Moreover, no single interventional strategy has been informed that consistently and reliably decreases PU incidence to zero (Thomas, 2003). Nevertheless, the goal of care is to do all interventions possible, given each individual's unique intrinsic and extrinsic risk factors, to prevent the development of a PUs (Padula, Osborne & William, 2009).

The use of an evidence-based CPG will help to evaluate multifactorial patients' risks. Some parts of PU prevention care are highly routinized, but care must also be

tailored to the specific risk profile of each patient. PU care planning is a process by which the patient 's risk assessment information is translated into an action plan to address the identified patient needs. This synthesis of multiple types of patient data requires the clinician to take a holistic approach rather than just relying on one specific piece of patient information (AHRQ, 2014). Quality improvement initiatives in healthcare systems are required to identify the elements that are necessary for effectively implementing and sustaining evidence-based practices into patient's care. The use of stratification guideline systems as accurate methods to identify and describe patient's risks could help clinicians in the accurate recognition of risk factors for the development of avoidable/unavoidable PUs complications. The key role of assigning modifiable and unmodifiable risk category will be guiding management efforts and the benefits of a multidisciplinary team approach (Morey & Smith, 2015).

PU prevention involves a variety of aspects in the nursing process; and the content of nurses' reasoning when identifying the individualized patient's risk factors is the first step in guiding the development of an accurate and measurable preventive care planning for nursing. Improvements in quality must be recognized that reduce practice variations and incidences of inappropriate care; providing criteria for monitoring the processes and outcomes of care. And most of all, the CPG, "Differentiating risks factors associated with the development of avoidable and unavoidable PUs," will emphasize nursing appropriate and specific competencies in order they can make informed decisions using critical think when identify and describe patients at risk to develop preventable and not preventable PUs.



Section 3 will describe the method of collection and analysis of evidence for recommendations to support an innovative method to describe risk factors related to avoidable/unavoidable PU development. This study describes evidence-synthesis resources consistent with the strength of the recommendations to describe operational criteria when assess risk factors associated with avoidable and unavoidable PU development.

### Section 3: Collection and Analysis of Evidence

#### Introduction

When creating EBP, it is necessary to evaluate the effectiveness of an intervention or practice in order to translate science into clinical practice (McCaffrey, 2012). As a wound care expert, I incorporated the NPUAP consensus statements and literature review to define and list modifiable and non-modifiable risk factors associated with the development of avoidable versus unavoidable PUs. To develop the CPG, I incorporated a systematic approach to identify the scientific evidence for the criteria that the literature recognizes as modifiable and unmodifiable risk factors for PU development. To increase the possibility that significant empirical and scientific evidence was incorporated, I conducted a literature review using appropriate key words. It included systematic reviews, controlled trials, qualitative research, expert opinions, and consensus statements. National and international conferences findings, government web site information, and relevant federal and state guidelines, and as well as professional regulations in nursing practice, were included. To locate publications the following databases were used: PubMed.gov-US National Library of Medicine National Institute of Health, PsycINFO-American Psychological Association, CINAHL database (Cumulative Index to Nursing & Allied Health Literature), MEDLINE/PubMed Resources Guide, Cochrane library, ERIC (Education Resources Information Center), TRIP database (Turning Research Into Practice) . Peer-reviewed articles published between 1970 and 2018 were examined. Key words will be selected so that all articles relevant to the d project and clinical guideline development can be identified. Principal concepts will include: *intrinsic* and *extrinsic risk*

*for PU development, modifiable and unmodifiable risks for PU development, avoidable or unavoidable PUs and factors lead to PU development.*

The development of the clinical guideline involved the identification and validation of themes and topics stating the most relevant aspects of PU risk factors to be measured. I integrated the modifiable and non-modifiable risks to PU development based on the literature review using the Agency for Health Care Policy and Research's (AHCPR) CPG (Panel for the Prediction and Prevention of PUs in Adults, 1992), WOCN Society Position Paper: Avoidable versus Unavoidable PU (2017), the Guideline of the National Institute for Health and Clinical Excellence (NICE, 2005), the Consensus and Statement of the European Pressure Ulcer Advisory Panel, and the National Pressure Ulcer Advisory Panel's Unavoidable Pressure Injury: State of the Science and Consensus Outcomes (2014). The Appraisal of Guidelines for Research & Evaluation II instrument (AGREE II, 2013) was used to assess the experts' agreement on the relevance of whether the guideline should be recommended for use. If in the opinion of the experts, a theme did not describe or evoke any relationship to the domain under study, it would be removed or amended.

Based on this procedure, I assumed that the CPG covers the domains for the identification and definition of risk factors associated with avoidable/unavoidable PU. Based on the experts' review, additional criteria were reviewed. This CPG was developed based on the most recent body of evidence, references provided from 1971 to 2018 was included to have a wide foundation of the risk factors elements. Additionally, expert consensus as the WOCN Society Position Paper, Avoidable versus Unavoidable PUs, and

the 2014 NPUAP Consensus Statement was considered. The CPG was designed to identify and describe the modifiable and unmodifiable risk factors associated with avoidable/unavoidable PU (see Appendix A). The CPG development followed a systematic method with inclusion and exclusion criteria to search the literature, and grade the strength of evidence (Moran, Burson, & Conrad, 2017). To compiling evidence and assessing evidence for quality it was used Fineout-Overholt, Melynck, Stillwell, and Williamson literature assessment for levels of evidence. The Appraisal of Guidelines Research and Evaluation (AGREE) II was used to provide the framework to assess the quality of the guideline developed. Using the AGREE II Instrument, the expert panel reviewed the guideline to validate content. A summary of findings in the wound expertise area was presented, along with references, generalizations, and conclusions obtained from review of the literature. In the conclusion, the state of knowledge and discussion of the strength of evidence was presented to support the selected problem, developing and contributing to the body of knowledge in the field of research (Gray, Grove & Sutherland, 2017).

Content validity of the clinical guideline was established by an extensive literature review (Kelechi, Arndt, & Dove, 2017; Kallman & Lindgren, 2014); Roger, 2013). This DNP study accomplished with ethics approval from Walden University IRB to assure all parameters compliance with university policies and federal regulations are met. After obtained IRB approval (number: 05-08-18-0457154), the content validity was obtained from the group of experts' reviews. Potential members of the working group were identified by student. Members were invited as representatives of their field or

discipline, some participants were content experts for the guideline topic and other content expert of research and education. The selection panel included the participation of a multidisciplinary healthcare team (physician, nurses' specialists in research, wound care, quality improvement and nurse educators). Experts' panel were familiar in the wound care practice, had prior experience with evidence-based guideline development, and demonstrated skills with using the internet, e-mail, and e-mail attachments. Anonymous questionnaires were used to conduct paper and online surveys of experts' panelist. The expert panel was e-mailed an informed consent prior to participate in this revision.

The panel of experts were asked to rate the content for relevance, clarity, comprehensiveness, and appropriateness using a content validity survey. The use of domain scores was used to discuss whether the guideline should be recommended for use. Experts were asked to review the CPG and return evaluation and feedback using secured e-mail system. The timeframe given to experts to provide feedback was two weeks. Results were integrated in a secured data base to be analyzed. IBM SPSS Statistics 21 software was used to perform descriptive statistics and evaluate results obtained. Electronic communication was convened to provide feedback throughout the CPG evaluation and before the publication plan. Conference calls were convened as needed during the evaluation process. After the content of the CPG was validated, the final guideline was converted into a document that meets publication requirements.

### Sources of Evidence

PU's description in clinical literature dated from the 1500s when Fabricius Hildanus first documented his hypotheses of the causes and characteristics of bedsores. He emphasized the role of "internal supernatural" and "external natural" factors that disturb the supply of blood and nutrients to tissue as triggers of bedsores. French surgeon de la Motte in 1722 considered that mechanical pressure and incontinence were main factors in the development of PUs by (Defloor, 1999). Main risk factors identified for PU development in the scientific literature later 1987 include increased age, impaired mobility, declined physical activity, poor nutrition, urinary and/or fecal incontinence, and sensory impairment (Allman, 1997; Ayello & Lyder, 2001; Reddy, Gill, & Rochon, 2006). Other studies have identified additional risk factors including smoking status, diabetes mellitus, coronary artery disease, intensive care unit stay greater than 3 days, ventilator dependency, pneumonia, sepsis, obesity, surgery, female gender, and peripheral vascular disease (Berlowitz et al., 2001; de Souza, & Santos, 2007; Cowan et al., 2012). Most PUs are considered to be avoidable, therefore, preventable (Jalali & Rezaie, 2005; Bryant & Nix, 2007; NPUAP, 2009). Understanding the complexity in the clinical setting in which healthcare environment strive with the complications of patients' diseases and comorbidities, create conclusions that not all PUs are avoidable or preventable. The skin is the largest organ of the body; and its integrity is affected by multiple factors as patient's age, medications, microclimate, optimal functioning of other organs, and concomitant diseases/illnesses. The development of PUs is impacted by various risk factors, which are part of patients' healthcare status. Since many initiatives have been

developed to reduce the incidence of PUs, the expectance of achieving a zero-incidence rate may not be a realistic target (Edsberg, Langemo, Baharestani, Posthauer, & Goldberg, 2014).

CMS has been part of economic, social, and political propositions on research findings regarding PU risk and coverage services. In recent symposium of the International Expert Wound Care Advisory Panel called, "Opportunities to Improve PU Prevention and Treatment: Implications of the CMS Acute Care Present on Admission (POA) Indicators/Hospital-Acquired Conditions (HAC) Ruling" (February 2008) highlights one PU specific ramification of Deficit Reduction Act of 2005. The expert panel stated successive changes in the Centers for Medicare and Medicaid Services (CMS) financial reimbursement amounts for nursing homes and hospitals. Beginning in October 2008, CMS will no longer reimburse higher rates for patients that develop Stage 3 or 4 PUs/PI (full-thickness tissue loss) after admission (Armstrong et al., 2008). This represents a potential risk for economic loss to health care providers. This is supposed to add motivation to acute and long-term care facilities to evaluate and improve their documentation and PU prevention programs. This symposium is significant, as it emphasizes the urgency of a consensus among health care providers and particularly the wound care community in providing quality research and evidence-based (and innovative) interventions that are effective.

The NHS Institute for Innovation and Improvement (2009) understand that sustainable change in PU prevention requires a strong strategy integrating well-defined delivery systems and processes. The incidence of avoidable PUs is recognized as an

important performance indicator of quality care (Fletcher 2014; Stephen-Haynes 2014). For quality improvement, such indicators must be reinforced by evidence-based standards of care. Mainz (2003) stated that clinical indicators should relate to structure, procedure and result. However, the structure partly implies the service within the organizational structure, the procedure or process represents the guidelines of the care delivery related to PU prevention, and the result specifies the achievement of that clinical practice related to the exclusion of avoidable PUs development. The need for strategies and standards for practice encompasses the creation and implementation of new documentation to incorporate multidimensional risk identification and prevention (Parnham, 2015).

### **Summary**

The literature establish that more research is needed to develop risk-adjusted models to establish which particular risk factors or combination(s) of risks are principal predictors of PU development to enhance the efficiency/effectiveness of risk assessment and define PUs that are unavoidable (Anderson et al., 2015; Levine et al., 2009).

Pressure-ulcer prevention remains an inexact science. Recent international guidelines highlight the lack of robust, high-quality research to guide practice. The only Level 1 evidence available relates to repositioning and use of nutritional supplements (EAP & NPUAP, 2009). Strategies such as the use of PU clinical screening guidelines for preventing PUs have a limited evidence base, and this is an area where much more work is needed (Webster, 2011). Data obtained from this project will be used to inform an innovative method to describe risk factors related to avoidable/unavoidable PU development. The aim of this project was to improve working policies and processes to



define key prevention strategies and provide clinicians with a clear, standardized approach to risk assessment.

The main element of PU risk is strongly associated with the general health status and severity of illness contained in the patient's intrinsic factors. Experts agree documentation provides fundamental feedback to clinicians and other key participants regarding the interventions the patient received and their effects (i.e., assessment, prevention, treatments), and if a HAPU is develop; it is necessary to provide verification that evidence-based care was delivered to support that the HAPU was unavoidable (Jacobson, Thompson, Halvorson, & Zeitler, 2016). Recent findings state that is reasonable to question the correlation that exists on the no modifiable patient-related factors and the development of unavoidable PUs (even thus receiving evidence-based prevention and treatment strategies (Hagisawa & Barbenel, 1999).

No modifiable PU risk factors can be behavioral, medical treatment related, and/or physiologic. Some examples of no modifiable risk factors include, (a) patient cognitive impairment that create inability to decrease pressure on areas at risk related to noncompliance, refusal, or neurologic impairment; (b) treatments resulting in poor tissue perfusion and fluid retention, (c) hemodynamic instability resulting in an inability to turn and/or reposition, respiratory instability, unstable spine; (d) diseases that affect tissue tolerance and response to nutrition, arterial insufficiency, and arterial emboli; and (e) inability to use pressure redistribution devices associated with other pre-existing conditions (Zaratkiewicz et al., 2010). Preventing PUs remains being a significant goal in

nursing care. The literature and scientific findings have been implemented to identify factors related to PU development (Bostrom & Kenneth, 1992).

This project sought to describe the development of a CPG to improve nursing practice that integrated evidence-based and empirical data to describe modifiable (extrinsic) and non-modifiable (intrinsic) risk factors in a patient's unique profile that are associated with the development of avoidable or unavoidable PUs. This is the first CPG that systematically evaluate the quality of description of intrinsic and extrinsic risk factors to define avoidable or unavoidable PU development. Precise identification of intrinsic and extrinsic PU predictors will help define key prevention strategies and provide clinicians with a clear, standardized approach to risk factors assessment. This study provides relevant and new comprehension sustaining recommendations in the identification of avoidable and unavoidable PUs risk factors. Inputs of this study describe evidence-synthesis resources consistent with the strength of the recommendations to describe operational criteria when assess risk factors associated with avoidable and unavoidable PU development.

Section 4 will present inputs of the evaluation of the CPG and will describe strength of the recommendations appraised when assess risk factors associated with avoidable and unavoidable PU development. Expert panel members agreed that the CPG will provide guidance and competence in the identification, description and documentation of modifiable and unmodifiable risk factors associated with PUs development and will assist to differentiate in high-risk population the factors that

influence in the development of avoidable (preventable) and unavoidable (non-preventable) pressure ulcers.

## Section 4: Discussion and Implications

### Introduction

Quality of nursing practice encompasses numerous components, including maintaining the integrity of patients' skin (Meraviglia, Becker, Grobe, & King, 2002). Therefore, CMS established that PU was considered a hospital-acquired condition and was no longer covered (Armstrong et al., 2008; CMS, 2006). In 2009, the CMS defined PUs (injuries) as reasonably preventable and discontinued reimbursement for the treatment of HAPUs, Stages 2 to 4 except when? these PUs were present at admission or developed within 2 days after admission. Nevertheless, clinicians state that some PUs (injuries) are unavoidable and will develop even when all preventive care interventions are applied. Examples of these circumstances are patients' hemodynamic instability which requires pharmacologic or mechanical assistance to reduce perfusion; severe protein-energy malnutrition which affects skin tolerance, and skin impairment in patients at the end of life (Black et al., 2011).

Precise identification of intrinsic and extrinsic PU predictors will help define key prevention strategies and provide clinicians with a clear, standardized approach to assess multifactorial risk factors associated to PU development. Nevertheless, it is critical to recognize that some PUs are inevitable. Recognizing the significance of this matter and the stated lack of information on PU unavoidability, the NPUAP held a scientific and professional multisector conference in 2014 to investigate the issue of PU unavoidability using a systematic structure, which contemplated the complexity of non-modifiable intrinsic and extrinsic risk factors. Before the meeting, a comprehensive literature review

was written to synthesize the state of the science in the area of unavoidable PU evolution. An interactive consensus was obtained, based on these elements, including participants in various associations and organizations. Consensus was obtained when 80% agreement was reached. The participants agreed that unavoidable PUs do happen. Unanimity was also found in areas associated with cardiopulmonary and hemodynamic status, effect of head-of-bed elevation, septic shock, body edema, burns, immobility, medical devices, spinal cord injury, terminal illness, and nutrition (Edsberg et al., 2014).

The NPUAP has guided the two international consensus conferences on PU avoidability-unavoidability. The first conference in 2010 stated consensus on the presence of some particular circumstances when PUs can occur and be considered unavoidable. Given the extensive examination of the literature on PU risk factors and PU development, in the 2014 conference consensus was established on some risk factors that, in some selected situations, have been demonstrated to increase the probability of an unavoidable PU. The effort from these revolutionary conferences continues to define more of the conditions related to unavoidable PU occurrence. Coleman (2013), stated that new scientific evidence is necessary to elaborate a conceptual framework of PU (injury) risks and to elucidate the gaps between the epidemiological, physiological, and biomechanical evidence of the risk factor interaction in PU development. These actions will support the foundation of a PU standard system to describe potential risk factors to create improved risk assessment systems (Coleman, 2013).

## Findings and Implications

This is the first CPG that systematically evaluate the quality of description of intrinsic and extrinsic risk factors to define avoidable or unavoidable pressure ulcer (pressure injuries) development. This study provides relevant and new comprehension sustaining recommendations in the identification of avoidable and unavoidable PUs risk factors. Inputs of this study describe evidence-synthesis resources consistent with the strength of the recommendations to describe operational criteria when assess risk factors associated with avoidable and unavoidable PU development. Relevant systematic review of evidence was used to validate patient intrinsic and extrinsic risk factors associated with avoidable and unavoidable PU development. The comprehensive examination resulted in approximately 77 articles that included published articles and 2 expert consensus reviews. The inclusion and exclusion criteria were applied to improve the results. A checklist of 40 elements where categorized under the intrinsic and extrinsic PU risk factors. Scientific data and combination of recommendations developed by expert external organizations as Centers for Medicare and Medicaid Services (CMS), The Joint Commission (JACHO), the Wound Ostomy Continence Nurse (WOCN) Society, and the National PU Advisory Panel (NPUAP) were considered.

The CPG, *Differentiating risk factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)*, is an evidence-based tool that is recommended to be used to assess, identify and differentiate the patient's intrinsic and extrinsic risk factors related to the development of avoidable and unavoidable PU. The CPG risk factors is focused on 2 domains: (1)- Intrinsic risk factors related to an

underlying health condition or other factors that make a patient more vulnerable to develop PUs (The Joint Commission Resources, 2012). These factors include: the length of stay of the hospitalization, age, diseases and contributing factors, history of previous PUs, use of high risk medications, certain treatment or medical procedures, mental status, cultural and or religious beliefs conflicting with patient treatment; (2)- Extrinsic risk factors related to immediate environment that place patient at risk for developing PUs (The Joint Commission Resources, 2012). These factors include: nutritional deficiencies, impaired mobility, head of bed elevation, pressure, friction, shearing, moisture and patient habits. For the extrinsic risk factors, it is recommended to describe if these risks can be modifiable or unmodifiable upon patient's health condition and treatment restrictions.

To identify CPG key development components the author used a standardized reference table to collect information and assist with preparation of tables of evidence ranking for each article in terms of the level of evidence, quality of evidence, and level of recommendations to practice. Clinical findings and levels of recommendations regarding the CPG risk factors were made by integrating critical analysis following a systematic review. A multilevel, systematic review approach was taken to identify and synthesize the literature that meets the eligibility criteria to build an evidence-based scientific data related to pressure ulcers intrinsic and extrinsic risk factors. To compiling evidence and assessing evidence for quality it was used Melnyk and Fineout-Overholt literature assessment for levels of evidence. Levels of recommendation for practice included: Level

A: High, Level B: Moderate, and Level C: Weak and Not recommended for practice.

Please see Levels of recommendations for Practice.

The GPG was validated by a group of experts in the healthcare sector, education and research. The selection for expert panel was composed of 8 participants (1 physician, two PhD nurses practicing in the nursing academic setting, one BSN wound care nurse specialist (WOCN) practicing in acute care, one DNP and one MSN both Nurse Practitioners practicing in long term care, one MSN quality improvement nurse and one MSN nurse educator both practicing in long term care setting). Experts were asked to provide their responses anonymously, to help reduce bias and any sort of pressure to respond a certain way. The panel experts rated the CPG content for relevance, clarity, comprehensiveness, and appropriateness using the Appraisal of Guidelines for Research & Evaluation II instrument (AGREE II, 2013). AGREE was used to assess the experts' agreement on the relevance to facilitate the ability to implement the instrument with confidence. AGREE II contains six domains with a total of 23 items, each scored 1–7 (Strongly Disagree through to Strongly Agree). The six domains include: Domain 1: Scope and purpose, Domain 2: Stakeholder involvement, Domain 3: Rigor of development, Domain 4: Clarity of presentation, and Domain 5: Applicability. Domain scores were calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain.

Maximum possible score = 7 (strongly agree) x # (items) x # (appraisers)

Minimum possible score = 1 (strongly disagree) x # (items) x # (appraisers)



The scaled domain score was calculated using the following formula:

$$\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}}$$

The use of domain scores was applied to discuss whether the guideline should be recommended for use. Members of the expert panel independently completed the review of the CPG using AGREE II tool and complete separate recommendations. The expert panel identified and assigned scores using the rating elements of AGREE II for quality and strength of evidence, and describes conclusions based on the review of the body of evidence. Expert reviewed the evidence-appraisal tables for each risk factors, the level of recommendations and then analyzed implications for practice. After comprehensive evaluation of the CPG healthcare expert panel expressed analysis for the methodology using AGREE II. The recommendations were appraised based on supporting evidence. The general quality of the CPGs was high; the domains that showed the highest scores were: scope and purpose 100%, applicability 100%, editorial independence 100%, rigor of development 99.7%, clarity of presentation 99.3%, while the stakeholder involvement domain showed the lowest scores 94.4%. (See Appendix C. Experts Panel Rating CPG domains using AGREE II criteria). The experts panel agreed that this guideline maintains the evidence grade assigned, and they recommend this guideline for use. Expert panel members agreed that the CPG can be adopted as a new clinical practice complementary to nursing assessment in acute or long-term healthcare settings. They all also concurred that the integration of both, intrinsic and extrinsic risk factors independently of the level of the recommendation creates a well-known multifactorial patient risk profile sustain nursing decision making in the use of evidence-based preventive care.

Experts coincided that the origin of the unavoidable PU encompass systemic and environmental multifactorial events that predisposed patient's skin to be more vulnerable under specific circumstances. Expert recommend the use of the CPG as part of a comprehensive PU prevention program as a strategy to produce consistency in the documentation of the patient risk categorization integrating intrinsic and extrinsic risk factors, and by representing individualized care interventions and measuring outcomes along with the patient health status progression. They understand that the CPG helps differentiate risk factors that are not contemplated on available assessment tools. This allows for the planning of care centered on patients' specifics. Experts understand that the CPG is clear and concise. They highlighted that interpretation of the patient risk factors can change when patient health condition change requiring reapplication of the CPG. Their feedback and comments were provided. The guideline entails individuals as a whole considering patient's preferences, cultural values and beliefs which can inhibit patients to receives PU preventive interventions. Identify risk population and their contributing factors associated with avoidable and unavoidable PU etiology provide a comprehensive visualization that will support nurse preventive interventions. As interpretation rely on nurses' skills and knowledge to understand the complex interaction of the intrinsic and extrinsic patient risk factors, an educational plan is essential. Maintaining skin integrity is a long-standing theme in the scientific literature and most nursing textbooks. However, the approach and rigor for developing these guidelines will allow nurses address those risks factors not necessarily previously considered.

At the final stage of the CGP evaluation a group of 9 registered nurses were incorporated to discuss the revised guideline to validate content and ensure usability. During the discussion 80% of the nurses understand that the CPG must be applied before performing any validated risk assessment tool. They state that the use of the CPG provides a comprehensive risk factors visualization and evaluation that will help to perform more precise the validated risk assessment tool they have in use. They considered that the application of the CPG will help nurses to be more conscious of the intrinsic risk factors that are missing in the validated PU risk factors tool. This analysis will provide to understand how patient's health conditions (intrinsic factors) directly impact the extrinsic risk factors conditions in PU development. The nurses indicated that more than visualize a numeric scale (using a validated risk assessment tool) the CPG provides a comprehensive screening bringing significance of what the scale's numbers really mean in the patient illness process. They discussed that the CPG creates best practices promoting a culture of safety and quality of care. They consider that preventive interventions require a holistic perspective based on patient individualized needs and upon patient' health status. The only concern that the group expressed during the discussion of the CPG was the implementation process in the clinical setting. Some expressed that it would take more time to perform the patient risk assessment and this will require from management to be involved and support this practice change. Also, they expressed that educational activities will be required in order that nurses can wisely understand how each risk factors categories contribute to the development of avoidable and unavoidable PU.

### Overall Guideline Assessment

Expert panel and end user members understand that nursing practice transformation is necessary, and the integration of a comprehensive evaluation of intrinsic and extrinsic risk factors in the PU prevention is needed to improve clinical outcomes. Create a new method to ensure identification of the high-risk population and target risk factors that influence in the development of avoidable and unavoidable PU represent a change in practice. The use of the CPG will provide guidance and competence in the identification, description and documentation of modifiable and unmodifiable risk factors associated with PUs development and will assist to differentiate in high-risk population the factors that influence in the development of avoidable (preventable) and unavoidable (non-preventable) pressure ulcers. This will offer consistency and appropriate nursing documentation in circumstances when a PU is identified as unavoidable. The CPG structure will support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan.

This CPG (CPG) was recommended to be applied in conjunction with a validated PU risk assessment to categorize the patient risk factors associated with develop avoidable versus unavoidable pressure ulcers. This, will support to implement effective, realistic and individualized preventive measures along with the continuous of the patient's illness evolution. It is recommended to implement the CPG in acute and long-term care setting in vulnerable population with chronic conditions and comorbidities (Grade B), especially those critical ill and in patient with terminal conditions (Grade A), using high risk medications (Level B) or receive treatment that could affect: mobility

(Level B), cognitive status (Level C), nutrition (Level B) and can impair cardiac and/or respiratory status (Level A) leading to the PU development.

The recommendations are to develop reliable processes assuring consistent implementation of an evidence-based CPG in care settings to address nursing decision making through the assessment of vulnerable population. It is recommended to implement the CPG as part of a comprehensive PU preventive program and as quality improvement project to evaluate the effect of clinical interventions and patients' outcomes. The use of the CPG can be implemented before or after the use of a validated PU risk assessment tool. The use of the CPG can support accurately risk factors documentation and interventions when preventive clinical measures are contraindicated.

Healthcare conditions create complex factors of pathophysiologic processes in vulnerable population; for which it result in the development of an unavoidable PU (Berlowitz & Brienza, 2007). The development of a PU is a multifactorial event that sometimes may not be prevented even with high quality multidisciplinary prevention and treatment strategies. Moreover, no single interventional strategy has been informed that consistently and reliably decreases PU incidence to zero (Thomas, 2003). Nevertheless, the goal of care is to do all that is possible, given each individual's unique intrinsic and extrinsic risk factors, to prevent the development of a pressure ulcer/injury (Edsberg et al., 2014).

The use of an evidence-based CPG will help to evaluate patients' risks. Some parts of PU prevention care are highly routinized, but care must also be tailored to the specific risk profile of each patient. PU care planning is a process by which the patient 's

risk assessment information is translated into an action plan to address the identified patient needs. This synthesis of multiple types of patient data requires the clinician to take a holistic approach rather than just relying on one specific piece of patient information (AHRQ, 2014). Quality improvement initiatives in healthcare systems are required to identify the elements that are necessary for effectively implementing and sustaining evidence-based practices into patient's care. The use of CPG as an accurate method to identify patients intrinsic and extrinsic risk could help nurses in the accurate recognition of risk factors for the development of PUs complications. The key role of defining patients a risk factors category will be guiding management efforts and the benefits of a multidisciplinary team approach (Morey & Smith, 2015).

### **Recommendations**

This CPG recognizes nursing assessment as a continuous process in the clinical practice. The use of this CPG will assist nursing to screen high-risk population taking in consideration the risk factors associated with the development of avoidable or unavoidable pressure ulcers. This guideline will offer a structure to identify and differentiate multifactorial intrinsic and extrinsic patient risk factors associated with the patient health profile. This CPG intend to provide structure that support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan and ensure consistency documentation in circumstances when PU development must be classify as an unavoidable event. The use of a CPG must be recognized that reduce practice variations and incidences of inappropriate care; providing criteria for evaluating the patient' risk profile and outcomes of care. CPGs are systematically statements to

contribute in clinical practice and patient decisions about applicable health care for specific clinical circumstances (Woolf et al., 1999). The key role of identify risk categories in PU development will guide clinical management efforts and quality improvement strategies creating and sustaining changes at the institutional and policy levels.

The new CPG will assist to redefine population at risk to develop unavoidable PU and reconsider the inclusion of acute, intensive care and palliative vulnerable high-risk care settings. New scientific data obtained from this CPG will support the evaluation of current local and national policies and regulations related quality clinical indicators considering the probability of unavoidable PU development in other care setting from long term care. Clinical documentation obtained from the CPG will demonstrate the need for revision of local and national reimbursement policies when organizations manage complex risk processes and when special care interventions are required for PU prevention. Furthermore, the use of the CPG (CPG): *Differentiating risk factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)* can produce an important function in health policy formation and could change the PU prevention strategies across the health care continuum. Data from this project may be used to inform a new assessment method, which would innovate nursing clinical practice. It is critical to comprehend the need to integrate new research on PU risk assessment to predicts not only if the patient will develop a PU but, it also if this PU can be classified as an avoidable versus unavoidable.

### **Strengths and Limitations of the Project**

This study had several strengths, the author of the CPG is an expert matter in wound care who integrated her expertise and clinical skills in the use of the scientific evidence incorporating intrinsic and extrinsic risk factors that define patient risk profile associated with the development of preventable or not preventable PU. The experts' panel included expertise and interdisciplinary composition including healthcare professionals, direct patient care nurses, wound care expertise, educators and researchers. These experts were crucial in the review of the CPG to evaluate the impact from a multifactorial scenarios and foresight a new perspective in the clinical practice. The study provides an innovative tool that provides a new perspective of analysis and interpretation of how the patient's health status and preferences can impact risk factors associated with preventable and not preventable PU. It is the first time that an evidence-based screening tool integrates and define intrinsic and extrinsic risks factors associated with avoidable or unavoidable PU development. Qualities of CPG, includes ease of use, clear systematic basis, and strong association among research and level of recommendations. However, further research is needed to aim in whether the use of CPG makes any difference to provide effective interventions based on risk factors categorization. Future research should ensure that the use of a CPG can provide to evaluate how multifactorial extrinsic and intrinsic risks factors can help to clinically define patient risk profile supporting definition of avoidable versus unavoidable PUs.

The author anticipated that the lack of previous evidence consistent with the CPG used to evaluate the impact of the categorization of the risk factors associated with



avoidable and unavoidable PU limits interpretation and overall conclusions. This GPG has not been tested before to determine strength and limitation in clinical practice. Practical utility of the CPG instrument was defined by the experts' panel recommendations and convenience in use but not testing on predictive performance. The small number of experts' panel participation in the review of the CPG limits generalizability of the findings and recommendations. The summative evaluation method used in this project limit to accurately interpret the multifactorial risks factors correlations to inform future implementation efforts. Multivariable estimation methods were not applied to define the quantitative impact of risk factors associated with avoidable and unavoidable PU development. There is a need to conduct further research directed to evaluate among high-risk groups and whether conduct the CPG help to accurate define avoidable and unavoidable PU.

In Section 5, I will discuss the translation of new knowledge to produce change in practice, and the way that the CPG will be disseminated throughout the wound care sector, policy makers, organizations and clinicians to prove and implement the findings of my project.

### **Section 5: Dissemination Plan**

The development of the CPG brings me the opportunity to publish important evidence in the wound care sector. A new methodology to evaluate individualized risks factors associated with the development of avoidable versus unavoidable PU requires that nurses create a holistic approach when identify patient's risk factors. This CPG can be published in a wound care professional journal contributing to the discussion of new scientific knowledge and knowledge translation when defining vulnerable population and risk to develop avoidable or unavoidable PU. This opportunity provides me sharing knowledge through an innovative methodology to improve nursing practice, quality of care and a safe culture. The translation of new knowledge to produce change in practice benefit to congregate policy makers, organizations and clinicians to prove and implement the findings of my project. Additional value of this study comprise help to promote other research-related activities by health professionals where there are gaps in knowledge and innovation. Nurses will be the primary audience to share the project findings promoting new improvement strategies to advanced levels of clinical judgment, systems thinking, delivering, and evaluating evidence-based care to improve patient outcomes (AACN, 2006). Translating outcome data is essential in the redesign of healthcare systems, organizational policies, and change in procedures. At the end, evidence-based practice is established in the desire to improve clinical performance and quality (Hinshaw & Grady, 2010).

### **Analysis of Self**

The journey of my DNP project enhanced my leadership competencies to advance my role of specialty. The develop of a CPG helped me to reflect on a new clinical practice model that proposed proficient nursing practice based on evidence. The integration of my clinical competences and the use of scientific groundwork created the correct route to initiate the process to reach a new vision to develop a change in nursing practice. The use of evidence-based practice in wound care practice supporting the desired change of improvement in patients' quality of life, clinical outcomes, satisfaction and cost-effectiveness were integrated as the foundation of the reason to develop the CPG. During this process I had the opportunity enhance my nursing advanced role applying theories models and research to appropriate delineate my project journey. Understand how theory, research, and evidence-based practice can guide a change in practice contributed to integrate nursing knowledge translation in to an evidence-based CPG. The evaluation of theoretical literature and empirical data positively influenced to define my project development. New skills in leading change through the translation and application of evidence in clinical practice were obtaining during this process. The CPG developed creates strategies that provides strong emphasis on care quality to persuade in the importance to integrate intrinsic and extrinsic risk factors to target risk population vulnerable to develop avoidable and unavoidable PU.

The development of the evidence-based CPG to evaluate the effectiveness of nursing interventions will improve clinical practice and patient outcomes. Having the opportunity to collaborate utilizing scientific findings to develop and evaluate care

delivery approaches that meet the current needs of vulnerable populations, helped me to obtain the expertise to understand the processes which positive changes can provide to better outcomes. A new approach of nursing assessment considering the use of the CPG including the non-modifiable and modifiable patient's risk factors fulfil not only with the standard of care in nursing, but also with the important goal and concept of the patient-centered care. The fact of identify the non-modifiable and modifiable risk factors in the patient profile is a central component to help nurses determining avoidable versus unavoidable PUs development and validate best practices to decrease the incidence of avoidable PUs. Nursing science can be transformed through the use of evidence-based practice. This learning experience built on my advanced nursing practice specialization provided additional preparation in the formulation, interpretation, and utilization of evidence-based practices to translate into a CPG. Leadership skills and innovation have been part of the foundation to promote new knowledge to impact the clinical practice and patients' outcomes promoting culture change through nursing knowledge translation and solving healthcare dilemmas and gaps in practice.

Evidence-based CPGs may help bridge the gap between research and practice. Accurate risk pressure injury is critical to ensure identification of the high-risk population and target risk factors that influence in the development of avoidable and unavoidable PUs. The consistency in the nursing documentation and timeliness in the care plan interventions will provide to support the prevention efforts to minimize risk for PU development (PU Prevention Toolkit: Joint Commission Resources, 2012). Adopt the purpose of provide safer, higher-quality patient care though the uses of clinical guidelines

were essential to advance to quality transformation of the preventing PU/PI. Culture change have been achieved through nursing education which influenced in positive attitudes about value of implementation of clinical guidelines.

### Summary

PU's are considered to be an avoidable injury and continue to be a key quality indicator (National Patient Safety Agency (NPSA) 2010, NHS Improving Quality (2009), and as the goal to prevent PU's remains essential, the number of PU's classified as preventable remains uncertain. A better understanding of the relation of modifiable and non-modifiable contribution risk factors and the development of PU's can improve ability to identify patients at high risk to enable better target resources in clinical practice (Coleman, 2013). EBP will create a view of nursing care as a framework for improving healthy environments and developing a vision of a systematic method for generating nursing interventions and care based on evidence (Omery & Williams, 1999).

The link between the evidence-based improvement intervention (e.g., the application of the CPG) and the outcome to be assessed needs to be clear. Even with clear linkages, at least seven challenges have been identified that interfere in one's ability to trace a direct relationship between the cause (application of an evidence-based intervention) and its effect (effect on the outcome of interest; Minnick, 2009). Using evidence-based practice guidelines based on the translation of research to practice and now to policy, is important to standardizing and improving access to appropriate treatment for patients. The benefits should be significant to health care (White, 2008). to

be called on to use all available methods to improve the quality and safety of health care delivered so that the most important outcome, patient health, is optimized.

### **Conclusions**

The CPG *Differentiating risks factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)*, is the first step in the literature that incorporate a screening process tool that combine and define intrinsic and extrinsic risk factors to identify the population at risk to develop avoidable and unavoidable PU. This CPG creates the opportunity to clinicians to incorporate a new standard of care to evaluating risk factors centered on the patient' health condition, preferences and environmental factors. A new screening approach that integrates a new vision to evaluate patient's risk factors from the use of a numeric category of risk interpretation to a comprehensive individualized perspective will produce a new evidence for PU advanced prevention and clinical strategies. The inclusion of the critical thinking process to provide conclusions of who is at risk and why is at risk to develop unavoidable and unavoidable PU will change the routine clinical process into a new standard of care. The use of this new instrument initiates a process to prove how a CPG support to identify high-risk population and target risk factors that influence in the development of avoidable and unavoidable PU. This CPG will provide structure that support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan to ensure consistency and precise risk factors documentation in circumstances when PU development requires to be defined as avoidable versus unavoidable. Data from further research can be useful to demonstrate how the use of an evidence best practices guideline

founded on a holistic perspective can help to decrease the incidence of avoidable PUs.

The CPG: *Differentiating risks factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)*, emphasize nursing appropriate and specific competencies to make informed decisions using critical think when identify and describe patients at risk to develop preventable and not preventable PUs.

The foundation for the implementation of a reliable and effective prevention guidelines require individualized risk management incorporating a comprehensive risk factors tool (Joint Commission Resource, 2012). A better understanding of the relation of contribution risk factors and the development of PUs can improve ability to identify patients at high risk and would enable to better target resources in practice. Interventions guided towards the application of CPGs must embrace strategies to help, educate and empower clinicians to practice using evidence base. Applicability of research into practice evaluating PU risk profile categorization and patients' outcomes can lead to more research on preventative measures to implement better treatment modalities.

Accurate and comprehensive documentation is essential for effective prevention and management of PUs. Ayello et al., 2009 state that “good documentation must be comprehensive, consistent, concise, chronological, continuing and also reasonably complete.” Other specialists agree that documentation provides essential vision to clinicians and other stakeholders related the care interventions the patient received and their outcomes (i.e., assessment, prevention, treatment), and if a HAPU develops, denote that evidence-based care was offered to support that the HAPU was unavoidable (Jacobson, Thompson, Halvorson, & Zeitler, 2016). Jacobson et al., (2016) reported that

after implementation of a quality improvement initiative to improve documentation of evidence-based interventions to prevent PUs, a 67% reduction in HAPUs were considered avoidable. The foundation and significance of documentation is further validated by CMS (2004, 2009, 2016) who has recognized that some PUs are unavoidable under evident circumstances, such as when the ulcers develop despite the provision of appropriate and accurate assessment and interventions. Consequently, for a PU to be considered unavoidable, there must be well-defined, a complete, and consistent documentation of the prevention and care interventions delivered to the patient is essential (Dahlstrom et al., 2011; Jacobson et al., 2016; Pittman et al., 2016; Worley, 2007). Furthermore, the precision and quality of documentation is vital in any legal process that could result from the development of PUs (Ayello et al., 2009).



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## Appendix A: Clinical Guideline Development- Using AGREE II

Clinical Practice Guideline Development requires a systematic method with inclusion and exclusion criteria to search the literature, and grade the strength of evidence (Moran, Burson, and Conrad, 2017). The Appraisal of Guidelines Research and Evaluation (AGREE) II provides the framework that the DNP student can use to guide the development of Clinical Practice Guidelines and to assess the quality of the guideline developed. The AGREE II is both valid and reliable and consists of 23 key items organized within six domains (<http://www.agreetrust.org>). The six domains include:

### **Domain 1: Scope and purpose**

Description: The Scope and Purpose domain is concerned with the overall aim of the guideline, the specific health questions and the target population.

Items:

#### **1. The overall objective(s) of the guideline is (are) specifically described.**

The Clinical Practice Guideline (CPG): *Differentiating risk factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)* is an evidence-based clinical guide used to assess, identify and differentiate the patient's intrinsic and extrinsic risk factors related to the development of PUs. This CPG recognizes nursing assessment as a continuous process in the clinical practice. The use of this CPG will assist nursing to screen high-risk population profile taking in consideration the risk factors associated with the development of avoidable or unavoidable PUs. This guideline will provide a structure to identify and differentiate multifactorial intrinsic and extrinsic patient risk factors associated with the development of avoidable (preventable)

and unavoidable (non-preventable) pressure ulcers and specifying if extrinsic risk factors could be modifiable or unmodifiable. This Clinical Practice Guideline provides structure that support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan and to ensure consistency and precise risk factors documentation in circumstances when pressure ulcer development requires to be defined as avoidable versus unavoidable.

The guideline criteria were focused on 2 domains: (1)- Intrinsic or Unmodifiable risk factors related to an underlying health condition or other factors that make a patient more vulnerable to develop pressure ulcers (The Joint Commission Resources, 2012). These factors include: the length of stay of the hospitalization, age, diseases and contributing factors, history of previous pressure ulcers, use of high risk medications, certain treatment or medical procedures, mental status, cultural and or religious beliefs conflicting with patient treatment; (2)- Extrinsic risk factors related to immediate environment that place patient at risk for developing pressure ulcers (The Joint Commission Resources, 2012). These factors include: nutritional deficiencies, impaired mobility, head of bed elevation, pressure, friction, shearing, moisture and patient habits. For extrinsic risk factors it has been provided the option to select if these risks could be modifiable or unmodifiable upon patient's health condition.

**The health question(s) covered by the guideline is (are) specifically described.**

- a. What modifiable (extrinsic) and non-modifiable (intrinsic) risk factors are associated with pressure ulcer development?

- b. What modifiable (extrinsic) and unmodifiable risk factors (intrinsic) influence in the development of avoidable versus unavoidable pressure ulcer development.
3. The population (patients, pressure ulcerblic, etc.) to whom the guideline is meant to apply is specifically described.

This guideline will be recommended to be used in adults and old age patients admitted to acute /or long-term care institutions that have been already identified as risk population for pressure ulcers development using a standardized risk assessment tool.

### **Domain 2: Stakeholder involvement**

Description: This domain focuses on the extent to which the overall aim of the guideline was developed by the appropriate stakeholders and represents the views of its intended users.

Items:

4. The guideline development group includes individuals from all the relevant professional groups.

This guideline was developed by the DNP student who possess the experience, competencies, and educational background as a WOCN and as board certified wound care nurse.

5. The views and preferences of the target population (patients, pressure ulcerblic, etc.) have been sought.

The target population is adult or old age patients with acute, chronic and/or terminal condition/s who are admitted in an acute healthcare setting, palliative and or long-term care setting.

6. The target users of the guideline are clearly defined.

The users will be licensed registered nurses with a bachelor's degree as a minimum academic requirement.

### **Domain 3: Rigor of development**

Description: This domain relates to the process used to gather and synthesize the evidence, the methods to formulate and update recommendations.

Items:

7. Systematic methods were used to search for evidence. A multilevel, systematic review approach was taken to identify and synthesize the literature that meets the eligibility criteria to build an evidence-based scientific data related to PUs risk factors.

8. The criteria for selecting the evidence are clearly described.

A systematic approach was taken to identify the scientific evidence for the criteria that the literature recognizes as risk factors in the development of PUs. To increase the possibility that significant empirical and scientific evidence were incorporated in the final evidence-based criteria, the author conducted the review of the literature by systematically searching literature using relevant key words and then summarized the primary findings of articles that met standard inclusion criteria retrieved from systems that provided access to articles in the domains as systematic reviews, qualitative research, existing federal and state guidelines, national and organizational consensus, and as well as professional regulations in nursing practice: Pressure ulcer PubMed ([www.ncbi.nlm.nih.gov/sites/entrez](http://www.ncbi.nlm.nih.gov/sites/entrez)). To locate publications the following databases were used: PubMed.gov-US National Library of Medicine National Institute of Health,

PsycINFO-American Psychological Association, CINAHL database (Cumulative Index to Nursing & Allied Health Literature), MEDLINE/PubMed Resources Guide, Cochrane library, ERIC (Education Resources Information Center), TRIP database (Turning Research into Practice). Peer-reviewed articles published between 1970 and 2018 were inquired in the 3 search mechanisms. Key words were selected with the intent of including all possible articles that might have been relevant to the questions of interest. The principal concept included the following terms: “pressure ulcer risk factors”, “avoidable or unavoidable pressure ulcers” and “factors lead to pressure ulcer development” A second, independent concept was conducted to identify articles related to modifiable and unmodifiable pressure ulcer risks. For this concept, the same search terms were used as in the previous procedure along with the additional condition term “avoidable versus unavoidable pressure ulcers” to allow for the inclusion of studies of high risk factors considered in the development of avoidable and unavoidable pressure ulcers.

9. The strengths and limitations of the body of evidence are clearly described. To compiling evidence and assessing evidence for quality the student used Fineout-Overholt, Melynck, Stillwell, and Williamson literature assessment for levels of evidence. When data were lacking, particularly in the risk factors categorization, a combination of recommendations developed by expert external organizations (Centers for Medicare and Medicaid Services (CMS), The Joint Commission, the Wound Ostomy Continence Nurse (WOCN) Society and the National Pressure Ulcer Advisory Panel (NPUAP) and expert

consensus were adopted.

10. The methods for formulating the recommendations are clearly described.

A systematic approach was taken to capture the impact of several prognostic variables on pressure ulcer development. These variables were classified in two categories: intrinsic and extrinsic risks factors supporting nurses' competence in the identification, description and documentation of modifiable and unmodifiable risk factors associated with pressure ulcers development. This guide integrates scientific knowledge to improve skill to differentiate in high-risk population the factors that influence in the development of avoidable (preventable) and unavoidable (non-preventable) PUs, providing consistency and appropriate nursing documentation in circumstances when a pressure ulcer is identified as unavoidable.

11. The health benefits, side effects and risks have been considered in formulating the recommendations. The Clinical Practice Guideline (CPG) is intended to assist nurses to identify and differentiate multifactorial intrinsic and extrinsic patient risk factors associated with the development of avoidable (preventable) and unavoidable (non-preventable) PUs identifying if these risk factors are modifiable or unmodifiable. This Clinical Practice Guideline provides structure that support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan and ensure consistency and precise risk factors documentation in circumstances when pressure ulcer development requires to be defined as avoidable versus unavoidable.

Patient's risk factors that are inappropriately categorized as modifiable or unmodifiable risks factors might affect the definition or categorization in the analysis of the pressure

ulcer development.

12. There is an explicit link between the recommendations and the supporting evidence.

It is considered that the etiology of pressure ulcers (injuries) is a complex process relating multiple, often non-modifiable, intrinsic risk factors, which are not entirely categorized by assessment tools (Berlowitz & Brienza, 2007; Edsberg et al., 2014; Lyder, 2003; Registered Nurses Association of Ontario [RNAO], 2011). The incidence of avoidable pressure ulcers is recognized as an important performance indicator of quality care (Fletcher 2014, Stephen-Haynes 2014). For quality improvement, such indicators must be reinforced by evidence-based standards of care. Mainz (2003) stated that clinical indicators should relate to structure, procedure and result. However, the structure partly implies the service within the organizational structure, the procedure or process represents the guidelines of the care delivery related to pressure ulcer prevention, and the result specifies the achievement of that clinical practice related to the exclusion of avoidable pressure ulcers development. The need for strategies and standards for practice encompasses the creation and implementation of new documentation to incorporate multidimensional risk identification and prevention (Parnham, 2015).

13. The guideline has been externally reviewed by experts prior to its publication. Once the content of the clinical practice guideline be validated the final guideline will be converted into a document that meets publication requirements.

14. A procedure for updating the guideline is provided. This guideline contains the modifiable and unmodifiable pressure ulcer risk factors best supported by evidence and consensus. Additional factors for risk criteria can go under review to add or modify new



health related conditions and circumstances once new scientific data is obtained, but changes will not be available until at least 1 year after the publication of this current guideline. An anticipated change in the age of patient for when is considered at risk to develop pressure ulcer could be take in consideration upon the care setting in which the guideline is applied.

#### **Domain 4: Clarity of presentation**

Description: This domain deals with the language, structure and format of the guideline.

Items:

15. The recommendations are specific and unambiguous.

The use of the CPG: *Differentiating risks factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)*, is an evidence-based guideline to ensure identification of the high-risk population and target risk factors that influence in the development of avoidable and unavoidable pressure ulcers (pressure injuries).

16. The different options for management of the condition or health issue are clearly presented.

The CPG is recommended in high-risk populations defined by the use of a standardized risk assessment tool. Patients at risk for pressure ulcer development should commence screening after initial pressure ulcer risk assessment has been performed to differentiate specific risks factors associated with the development of avoidable and unavoidable pressure ulcers followed when a change in condition is presented in patient's health condition.

17. Key recommendations are easily identifiable.

The CPG will provide understanding of integrating the analysis of the modifiable and unmodifiable risk factors to define clinical situations that contribute to pressure ulcer unavailability. The guideline was systematically developed to provide consistency and appropriate nursing documentation that support nurses' decision process and knowledge needed to implement appropriate care plan that support the nursing interventions and define circumstances when an unavoidable pressure ulcer can result.

#### **Domain 5: Applicability**

Description: This domain pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and cost implications of applying the guideline.

Items:

18. The guideline describes facilitators and barriers to its application.

The guideline integrates explicit clinical terminology consistent with nurses' educational background and integrate the process of the nursing assessment and documentation. Costs implications for adaptability on data system, nursing time and resistance to change could be considered as potential barriers. The application of this new initiative required the support and participation of the facility stakeholders', and educational activities to reinforce on the clinical staff the reasons and use of this guideline.

19. The guideline provides advice and/or tools on how the recommendations can be place into practice.

The guideline will provide the categorization of intrinsic and or extrinsic risk factors associated with the development of avoidable and unavoidable pressure ulcers.

20. The potential resource implications of applying the recommendations have been considered.

The identification of intrinsic and extrinsic patient's risks factors for pressure ulcers development will support the implementation of a higher standard of care in the nursing practice. This will allow nursing to implement the use of an evidence-based system making accurate identification and documentation to help define avoidable versus unavoidable pressure ulcers development.

21. The guideline presents monitoring and/or auditing criteria.

Patient's assessment and documentation is a continuous nursing process which include the revision of patient's needs, evaluate progress and identify potential risks in the patient's health status. This guideline would be applied as a quality improvement measurement/indicator to define/categorize the incidence of acquired pressure ulcers at the organization, and monitoring safety and compliance with patients' standards of care.

#### **Domain 6: Editorial independence**

Description: This domain is concerned with the formation of recommendations not being unduly biased with competing interests.

Items:

22. The views of the funding body have not influenced the content of the guideline.

No funding body applied.

23. Competing interests of guideline development group members have been recorded and addressed.

Not applicable.

Appendix B: Clinical practice guideline: *Differentiating risks factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)*

The Clinical Practice Guideline (CPG): *Differentiating risk factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)* is an evidence-based clinical guide used to assess, identify and differentiate the patient's intrinsic and extrinsic risk factors related to the development of pressure ulcers. This CPG recognizes nursing assessment as a continuous process in the clinical practice. The use of this CPG will assist nursing to screen high-risk population taking in consideration the risk factors associated with the development of avoidable or unavoidable pressure ulcers. This guideline will offer a structure to identify and differentiate multifactorial intrinsic and extrinsic patient risk factors associated with the patient health profile. This Clinical Practice Guideline intend to provide structure that support nurses' decision process and knowledge needed to implement timely and appropriate prevention plan and ensure consistency documentation in circumstances when pressure ulcer development must be classify as avoidable versus unavoidable.

The guideline criteria are focused on 2 domains: (1)- Intrinsic or Unmodifiable risk factors related to an underlying health condition or other factors that make a patient more vulnerable to develop pressure ulcers (The Joint Commission Resources, 2012). These factors include: the length of stay of the hospitalization, age, diseases and comorbidities, history of previous pressure ulcers, use of high risk medications, certain treatment and medical procedures, mental status, cultural and or religious beliefs conflicting with patient treatment or refusal; (2)- Extrinsic risk factors related to

immediate environment that place patient at risk for developing pressure ulcers (The Joint Commission Resources, 2012). These factors include: nutritional deficiencies, impaired mobility, head of bed elevation, pressure, friction, shear, moisture and patient habits. For both risk factors categories (intrinsic and extrinsic) it has been provided the option to select if these risk factors are modifiable or unmodifiable upon patient's health condition.

Table 1.0

*Rating System for the Hierarchy of Evidence*

Evidence Rating	Evaluation Criteria
Level I	Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs
Level II	Evidence obtained from at least one well-designed RCT
Level III	Evidence obtained from well-designed controlled trials without randomization
Level IV	Evidence from well-designed case-control and cohort studies
Level V	Evidence from systematic reviews of descriptive and qualitative studies
Level VI	Evidence from a single descriptive or qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

Table 1.2

*Grading the Quality of the Evidence*

I. Acceptable Quality: No concerns
II. Limitations in Quality: Minor flaws or inconsistencies in the evidence
III. Major Limitations in Quality: Many flaws and inconsistencies in the evidence
IV. Not Acceptable: Major flaws in the evidence

Table 1.3

*Levels of Recommendation for Practice*

<u>Level A Recommendations: High</u>
<ul style="list-style-type: none"> <li>• Reflects a high degree of clinical certainty</li> <li>• Based on availability of high quality Level I, II and/or III evidence available using Melnyk &amp; Fineout-Overholt grading system</li> <li>• Based on consistent and good quality evidence; has relevance and applicability to nursing practice</li> <li>• Is beneficial</li> </ul>
<u>Level B Recommendations: Moderate</u>
<ul style="list-style-type: none"> <li>• Reflects moderate clinical certainty</li> <li>• Based on availability of Level III and/or Level IV and V evidence using Melnyk &amp; Fineout-Overholt grading system</li> <li>• There are some minor flaws or inconsistencies in quality of evidence; has relevance and applicability to nursing practice</li> <li>• Is likely to be beneficial</li> </ul>
<u>Level C Recommendations: Weak</u>
<ul style="list-style-type: none"> <li>• Level V, VI and/or VII evidence available using Melnyk &amp; Fineout-Overholt grading system</li> <li>• Based on consensus, usual practice, evidence, case series for studies of treatment or screening, anecdotal evidence, and/or opinion</li> <li>• There is limited or low-quality patient-oriented evidence; has relevance and applicability to nursing practice</li> <li>• Has limited or unknown effectiveness</li> </ul>
<u>Not Recommended for Practice</u>
<ul style="list-style-type: none"> <li>• No objective evidence or only anecdotal evidence available; or the supportive evidence is from poorly controlled or uncontrolled studies</li> <li>• Other indications for not recommending evidence for practice may include: <ul style="list-style-type: none"> <li>○ Conflicting evidence</li> <li>○ Harmfulness has been demonstrated</li> <li>○ Cost or burden necessary for intervention exceeds anticipated benefit</li> <li>○ Does not have relevance or applicability to emergency nursing practice</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. For example: <ul style="list-style-type: none"> <li>○ Heterogeneity of results</li> <li>○ Uncertainty about effect magnitude and consequences</li> <li>○ Strength of prior beliefs</li> <li>○ Publication bias</li> </ul> </li> </ul>

Clinical practice guideline: Differentiating risks factors associated with the development of avoidable and unavoidable pressure ulcers (pressure injuries)

Intrinsic or Unmodifiable Risk Factors
<p>1. Time of hospitalization (LOS) &gt; 5 days Level B- Moderate (Cox, 2011; Rogenski and Santos, 2005; Eachempati et al., 2001).</p>
<p>2. Age 70 years or more Level B - Moderate (Stojadinovic et al., 2013); Allman, 1989; Cox, 2011; Cox, 2017; Perier et al., 2002; Lyder et al., 2012; Eachempati et al., 2001; Baumgarten et al., 2006; Bours et al., 2001).</p>
<p>3. Patient health status:</p> <p>( ) Chronic disease Level B- moderate (Lyder et al., 2012).</p> <p>( ) Critically ill Level A- High (Coyer &amp; Nahla, 2017; Cox, 2017; Rao et al 2016; Delmore et al., 2015).</p> <p>( ) Terminal condition Level A- High (Langemo &amp; Brown, 2006).</p>
<p>Contributing factors:</p> <p>( ) Cardiovascular disease Level A- Moderate (Cox et al., 2017; Van Marum et al., 2001).</p>
<p>( ) Cerebrovascular disease Level B- Moderate (Lyder et al., 2012); Van Marum, 2001).</p>
<p>( ) Peripheral vascular disease Level – A- High (Thomas et al., 1999).</p>
<p>( ) Respiratory Failure Level A- High (Cox, 2017; Delmore et al., 2015; Yamaguti et al., 2014).</p>
<p>( ) Acute/Chronic- Renal failure Level B- Moderate (Becker et al., 2017; Larson et al., 2012; Levine et al., 2009).</p>
<p>( ) Liver dysfunction Level A- High (Delmore et al., 2015).</p>
<p>( ) Sensorial dysfunction Level B- Moderate (Defloor and Grypdonck, 2005; Halfens et al., 2000).</p>

( ) Diabetes Level A- (Brandeis et al., 1994; Berlowitz and Wilking, 1989; Cox, 2017; Ooiet al., 1999; Stordeur et al., 1998; Halfens et al., 2000; Feuchtinger et al., 2006; Nixon et al., 2006; Donnelly, 2006; Schultz et al., 1999; Rademakers et al., 2007; Vanderwee et al., 2009; Compton et al., 2008).
( ) Obesity / Morbid obesity Level B- Moderate (Compher et al., 2007).
( ) Severe anemia Level B- Moderate (Levine et al., 2009).
( ) Hemodynamic instability Level B- Moderate (Shanks, Kleinhelter, Baker, 2009; Langemo & Brown, 2006).
( ) Body edema /anasarca Level B- Moderate (Margolis et al., 2003; Exton-Smith and Sherwin, 1961; Zaratkiewicz et al., 2010).
( ) Infection / Sepsis Level B- Moderate (Curry et al., 2012); Levine et al., 2009; Redelings, Lee, Sorvillo, 2005).
( ) Multiple organ failure Level B: Moderate (Beare, Myers, 1998).
( ) Hip fracture Level B- moderate (Chiari,2017; Baumgarten et al., 2009; Maher et al., 2013; Lindholm et al., 2008).
( ) History of previous PRESSURE ULCER Level B- Moderate (Lyder et al., 2012).
( ) Burns Level A- (Ladd, Ekanem & Caffrey, 2018).
4. Use of medical devices / equipment Level A- High (VanGilder et al., 2009; Holden-Mount & Sieggreen, 2015; Murray et al., 2013).
5. High Risk medications
( ) Vasoconstrictors



Level B- Moderate (Cox, 2011; Pittman et al., 2016; Cox& Roche, 2015).
( ) Hypotensive Level B- Moderate (Levine et al., 2009).
( ) High dose of steroids Level B- Moderate (Lyder et al., 2012).
( ) Sedatives Level B- Moderate (Levine et al., 2009; Pittman et al., 2016; Nedergaard et al., 2018).
( ) Anesthetics Level B- Moderate (Primiano et al., 2011; Armstrong and Bortz, 2001).
6. Surgical procedure > or = 4 hours Level A- High (Schoonhoven et al., 2002; Connor et al., 2010).
7. Altered Mental status Level C- Weak (Garcia-Fernandez et al: 2014).
8. End stage dementia Level B- Moderate (Margolis et al., 2003).
8. Patient cultural and/or religious belief conflicting with patient treatment or Refuse treatment Level A- High (Goodman et al., 1999).
<b>Extrinsic or Modifiable Risk Factors</b>
1. Nutritional impairments Level B- Moderate (Fry et al., 2010; Perier et al., 2002; Shahin et al., 2010).
2. Impaired Mobility Level B- Moderate (Lindgren, 2004).
3. Head-of-bed (HOB) elevation of 30 grade or more Level A-High (Peterson et al., 2008).
4. Pressure Sources: ( ) surface ( ) medical device Level A- High (Seiler & Stahelin, 1979; Gawlitta et al., 2007; Ahmed et al., 2016; Breuls et al., 2003; Kawamata et al., 2015).
5. Friction Sources: ( ) surface ( ) medical device Level B- Moderate (Lumbley, Ali, Tchokouani, 2014).

6. Shearing Level A- High (Wert et al., 2015; Kenichi et al., 2014)
7. Moisture      ( ) urinary/fecal incontinence ( ) wound exudate ( ) sweat Level A- High (Bates-Jensen, McCreath, & Patlan, 2017); Shaked and Gefen, 2013; Sopher & Gefen,2011).
8. Patient's habits ( ) smoking Level A- High (Krause and Broderick, 2004); (Smith et al., 2008).

## Appendix C: Experts Panel Rating CPG domains using AGREE II criteria

**Domain 1: Scope & Purpose 100%**

1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, pressure ulcerbolic, etc.) to whom the guideline is meant to apply is specifically described.

Table 1.0

*Domain 1: Scope & Purpose*

Appraiser	Item 1	Item 2	Item 3	Total
1	7	7	7	21
2	7	7	7	21
3	7	7	7	21
4	7	7	7	21
5	7	7	7	21
6	7	7	7	21
7	7	7	7	21
8	7	7	7	21
Total	56	56	56	168

Maximum possible score =  $7 \times 3 \times 8 = 168$

Minimum possible score =  $1 \times 3 \times 8 = 24$

$$\frac{168 - 24}{168 - 24} = 144/144 = 100\%$$

**Domain 2. Stakeholder Involvement** 94.4%

4. The guideline development group includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, pressure ulcerblic, etc.) have been sought.
6. The target users of the guideline are clearly defined.

Table 1.2

*Domain 2. Stakeholder Involvement*

Appraiser	Item 4	Item 5	Item 6	Total
1	6	7	7	20
2	6	7	7	20
3	6	7	7	20
4	6	7	7	20
5	6	7	7	20
6	6	7	7	20
7	6	7	7	20
8	6	7	7	20
Total	48	56	56	160

Maximum possible score  $7 \times 3 \times 8 = 168$

Minimum possible score  $1 \times 3 \times 8 = 24$

$$\frac{160 - 24}{168 - 24} = 136/144 = 94.4\%$$

**Domain 3: Rigor of Development** 99.7%

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

Table 1.3

*Domain 3: Rigor of Development*

Appraiser	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Total
1	7	7	7	7	7	6	7	7	55
2	7	7	7	7	7	7	7	7	56
3	7	7	7	7	7	7	7	7	56
4	7	7	7	7	7	7	7	7	56
5	7	7	7	7	7	7	7	7	56
6	7	7	7	7	7	7	7	7	56
7	7	7	7	7	7	7	7	7	56
8	7	7	7	7	7	7	7	7	56
Total	56	56	56	56	56	55	56	56	447

Maximum possible score  $7 \times 8 \times 8 = 448$

Minimum possible score  $1 \times 8 \times 8 = 64$

$$\frac{447 - 64}{448 - 64} = \frac{383}{384} = 99.7\%$$

**Domain 4. Clarity of Presentation 99.3%**

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

Table 1.4

*Domain 4. Clarity of Presentation*

Appraiser	Item 15	Item 16	Item 17	Total
1	7	7	7	21
2	7	6	7	20
3	7	7	7	21
4	7	7	7	21
5	7	7	7	21
6	7	7	7	21
7	7	7	7	21
8	7	7	7	21
Total	56	55	56	167

Maximum possible score  $7 \times 3 \times 8 = 168$

Minimum possible score  $1 \times 3 \times 8 = 24$

$\frac{167-24}{168-24}$

$= 143/144 = 99.3 \times 100 = 99.3\%$

**Domain 5. Applicability 100%**

18. The guideline describes facilitators and barriers to its application.

19. The guideline provides advice and/or tools on how the recommendations can be placed into practice.

20. The potential resource implications of applying the recommendations have been considered.

21. The guideline presents monitoring and/or auditing criteria.

Table 1.5

*Domain 5. Applicability*

Appraiser	Item 18	Item 19	Item 20	Item 21	Total
1	7	7	7	7	28
2	7	7	7	7	28

3	7	7	7	7	28
4	7	7	7	7	28
5	7	7	7	7	28
6	7	7	7	7	28
7	7	7	7	7	28
8	7	7	7	7	28
Total	56	56	56	56	224

Maximum possible score  $7 \times 4 \times 8 = 224$

Minimum possible score  $1 \times 4 \times 8 = 32$

$$\frac{224 - 32}{224 - 32} = 192/192 = 1 \times 100 = 100\%$$

### **Domain 6. Editorial Independence 100%**

22. The views of the funding body have not influenced the content of the guideline.

23. Competing interests of guideline development group members have been recorded and addressed.

Table 1.6

### *Domain 6. Editorial Independence*

Appraiser	Item 22	Item 23	Total
1	7	7	14
2	7	7	14
3	7	7	14
4	7	7	14
5	7	7	14
6	7	7	14
7	7	7	14
8	7	7	14
Total	56	56	112

Maximum possible score  $7 \times 2 \times 8 = 112$

Minimum possible score  $1 \times 2 \times 8 = 16$

$$\frac{112 - 16}{112 - 16} = 100/100 = 1 \times 100 = 100\%$$