March 2, 2018

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to
https://oncprojectracking.healthit.gov/support/projects/PCQM/

Re: Project Title: Hospital Harm – Hypoglycemia; Hospital Harm – Hospital-Acquired Pressure Injury; Hospital Harm – Opioid-Related Adverse Events; and Hospital Harm – Acute Kidney Injury

Dear Workgroup:

On behalf of the Wound, Ostomy and Continence Nurses Society, we thank you for the opportunity to provide a response to your call for comments on the Hospital Harm – Hospital Acquired Pressure Injury measure. As one of the primary practitioners responsible for treating patients suffering from pressure injury we appreciate the opportunity to provide you with our thoughts on the proposed measure. The Wound, Ostomy and Continence Nurses Society™ (WOCN®) is a clinician-based, professional organization of over 5,000 members, who treat individuals with wounds, ostomies and incontinence, and are committed to cost-effective and outcome-based healthcare.

We support CMS's efforts to improve patient care with regard to pressure injury and agree it is important that we accurately document pressure injury in the acute care setting. However, in recent months we have been contacted by many members who work in the acute care setting expressing concern about the current quality measures and reporting mechanisms regarding pressure injury. As such, we are concerned with CMS's proposal to build out an electronic health record (EHR) based on these current measures. We respectfully request that CMS withdraw this pending measure and work with stakeholders to improve its effectiveness. In your call for comments CMS asked for responses to specific questions reading this measure

and its application to an EHR. Please find our response to these questions below:
1. Does the numerator (as specified) accurately capture hospital-acquired or worsening pressure injuries while minimizing any unintended consequences?

> *No, the numerator does not accurately capture hospital-acquired or worsening pressure injuries while minimizing any unintended consequences. Pressure injuries, by definition, are not stepwise in progression and suggesting that they can "worsen" despite the highest quality of care is inaccurate. The damage that exists in a pressure injury may not be visible to the eye for some time as the affected tissue is often below the visible tissue.*
>
> *Despite having received very best of care, patients may still develop pressure injuries, and existing injuries may evolve to higher stages. Furthermore, clinically speaking unstageable pressure injuries and deep tissue injuries (DTI) do not progress or "get worse" but they can evolve during a natural course of the injury despite the best quality of care. This is an important distinction that the current process does not allow for. Only once these injuries are free of necrotic tissue, can the true stage be identified. Implying these types of injuries have progressed or "worsened" during a length of stay at a facility despite quality care is clinically inaccurate.[1.] The combination of these factors leads to facilities and clinicians being penalized for situations that are out of their control.*

2. How useful is this measure in assessing and improving the quality of care for patients?

> *Unfortunately, this measure does not accurately assess the quality of care for patients. In fact, it is likely to inappropriately place blame on institutions and providers that are providing the best possible care. The natural course of a pressure injury may involve changes in stage(s) despite all known quality of care being provided. Additionally, recent research has demonstrated gaps in the knowledge in terms of pressure injury prevention and the influence of co-morbidities leading to the issue of what may be an avoidable versus and unavoidable pressure injury. [2,3]*

3. Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? Specifically, are pressure injuries present on arrival and location (on body) of pressure injury present on arrival, captured routinely and available in structured, extractable fields in EHR systems?

No, our members are reporting to us that these measures are not currently being captured accurately. These measures are routinely being captured, but facilities are not gathering accurate data during the process. One reason for this, in additional to those mentioned above, is that there is the factor of variability when identifying or diagnosing pressure injury depending on who documents the information. For example, one provider may describe a pressure injury as a Stage 2, but when examined by a wound specialist they may identify the same wound as a Stage 3, while a bedside nurse may document the wound as excoriation.

This incongruence could also result in the facility being penalized should the timing of each documentation inaccurately suggest deterioration. For example, a Stage 1 reporting by the bedside nurse or ED nurse at time of admission, a Stage 2 by a physician two hours later, then later that same afternoon, a Stage 3 by the WOC nurse. Reality is, the injury was incorrectly identified by the first clinicians but the data reflects deterioration.

4. Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems?

No, as you are aware there are various providers of EHR and even within each of these providers different versions exist, while some EHRs allow for even further customization. In our experiences, the process for reporting and identifying pressure injuries are multiple, even within the same EHR system, creating inaccurate data extrapolation. There are also no standard EHR criteria or guidelines for documentation of risk assessment, or implementation of prevention interventions, or identification of influential comorbidities.

5. Do you suggest any denominator exclusions for this measure, and why?

Yes, denominator exclusions should include all pressure injuries that are present on admission at a minimum. To be consistent with current science, the denominator should further exclude all pressure injuries that develop despite evidence of prevention measures being employed consistently. Also, please consider the exclusion of normal ObGyn /labor patients and those in hospice.

6. Currently as specified, the measure uses 24 hours as the timeframe within which any pressure injuries that were present on arrival should be documented (in a structured field). Do you agree with this timeframe as a reasonable standard for reporting?

No, this is not an appropriate time frame. Not all injuries present immediately. It is standard of care to do a total body skin assessment within 24 hours of admission; however, as current science indicates several days can pass prior to visible evidence of a pressure ulcer such as a deep tissue injury. For example, a patient may admit to a facility and the pressure injuries that were developed outside the hospital may not be visible to the naked eye until after the initial 24 hours into the patient hospitalization.

7. While our goal is to include as many patients as possible in the measure, we acknowledge that pressure injuries should be avoided in all patients. However, care practices may change for end of-life or hospice patients who have a comfort care-only order. Are comfort care-only orders feasible to capture in the EHR systems?

Not currently, in our experience many EHR's do not include comfort care bundles. Furthermore, not all palliative care patients may be on comfort orders.

Thank you again for allowing us the opportunity to comment on this important issue. In addition, to the available research cited in our responses we are including with our comments WOCN's position paper on "Avoidable Versus Unavoidable Pressure Ulcers/Injuries." It includes the following information: statement of position, purpose/rationale for the position, definitions of avoidable versus unavoidable pressure injuries, alternative definitions, historical overview, supportive statements from expert opinion and research in the literature, and recommendations for research. We are hopeful that this document will provide helpful background on the clinical complexities of treating pressure injuries.

We look forward to working with you on our shared objectives to improve patient care. If we can be of assistance to you in any way, please contact Chris Rorick of the Society's staff at chris.rorick@bryancave.com.

Sincerely,

Kelly Jaszarowski, MSN, RN, CNS, ANP, CWOCN

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1. Zaratkiewicz, S., Whitney, J., Baker, M., Lowe, J. (2015) Defining unstageable pressure ulcers as full thickness wounds: Are these wounds being misclassified. *Journal of Wound, Ostomy, and Continence Nursing 42 (6)*

2. Schmitt, S., Andries, M., Ashmore, P. Brunette, G., Judge, K., Bonham, P. (2017) WOCN Position Paper: Avoidable versus Unavoidable pressure ulcer/injuries. *Journal of Wound Ostomy and Continence Nursing (44) 5*

3. Pittman, J., Beeson, T., Colin, T., Unavoidable Pressure Ulcers: Development and testing of the Indiana University Health pressure ulcer inventory. *Journal of Wound Ostomy and Continence Nursing (43) 1*

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WOCN Society Position Paper

Avoidable Versus Unavoidable Pressure Ulcers/Injuries

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ABSTRACT

The issue of whether pressure injuries are avoidable or preventable has been and continues to be an issue of great debate and discussion for many years, and it has significant legal and regulatory implications related to prevention of wounds due to pressure. The following position paper outlines the position of the Wound, Ostomy and Continence Nurses Society (WOCN) on avoidable versus unavoidable pressure injuries. It includes the following information: statement of position, purpose/rationale for the position, definitions of avoidable versus unavoidable pressure injuries, alternative definitions, historical overview, supportive statements from expert opinion and research in the literature, and recommendations for research.

KEY WORDS: Avoidable pressure injury, Avoidable pressure ulcer, Bedsore, Never event, Position paper, Pressure injury, Pressure sore, Pressure ulcer, Unavoidable pressure injury, Unavoidable pressure ulcer.

STATEMENT OF POSITION

Given the clinical complexities and constellation of comorbidities commonly encountered in today's healthcare environment, it is reasonable to state that not all pressure ulcers/injuries are avoidable or preventable. The skin is the largest organ of the body, and its integrity is impacted by age, medications, microclimate, optimal functioning of other organs, and concomitant diseases/illnesses. The development of pressure injuries is impacted by numerous risk factors, which are commonly seen in patients. While there has been progress in reducing the incidence of pressure injuries, an incidence of zero may not be an attainable goal.[1]

Note: Recently, the National Pressure Ulcer Advisory Panel (NPUAP)[2,3] changed the term for pressure ulcer to pressure injury. The change in terminology has not yet been universally adopted and may take time for assimilation into the literature. Therefore, hereafter, in this document, the term pressure ulcer reflects the terminology used by the author(s) in the literature that is cited, and it is considered equivalent/interchangeable with the term pressure injury.

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PURPOSE (RATIONALE FOR POSITION)

The purpose of this position paper is to lend support to the theory that some pressure ulcers/injuries are unavoidable and provide supporting evidence and/or expert opinion. This document updates a previous position statement developed by the Wound, Ostomy and Continence Nurses Society (WOCN)[4]: "Position Statement: Avoidable Versus Unavoidable Pressure Ulcers."

DEFINITIONS

1. *Avoidable and unavoidable pressure ulcers.* In the original position statement, the WOCN Society[4] included definitions of avoidable and unavoidable pressure ulcers (see the Appendix) that were developed by the Centers for Medicare & Medicaid Services (CMS)[5,6] for long-term care (LTC) standards. In 2010, the NPUAP[7] provided broader definitions of these terms, which could be applied to all clinical practice settings versus only LTC settings:
   - *Avoidable pressure ulcer*. An avoidable pressure ulcer can develop when the provider did not do one or more of the following: evaluate the individual's clinical condition and pressure ulcer 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.[7]
   - *Unavoidable pressure ulcer*. An unavoidable pressure ulcer can develop even though the provider evaluated the individual's clinical condition and pressure ulcer 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.[7]

2. *Alternative definitions*. Other terms used to describe clinical events or circumstances related to adverse events/patient harm, such as pressure ulcers that occur in hospitalized patients, include preventable, not preventable, and unable to be determined[8]:
   - *Preventable*. Patient harm could have been avoided through improved assessment or alternative actions.[8]
   - *Not preventable*. Patient harm could not have been avoided given the complexity of the patient's condition or the care required.[8]
   - *Unable to determine*. Physicians were unable to determine preventability because of incomplete documentation or case complexity.[8]

PREVIOUS STATEMENT

In the previous position statement on avoidable versus unavoidable pressure ulcers, the WOCN Society[4] recommended further research to:

- Examine the extent to which comorbidities and intrinsic factors contribute to pressure ulcer development and determine the corresponding implications for clinical practice.
- Develop an expanded list of risk factors that would be more predictive of pressure ulcer development.
- Provide greater scientific evidence to support pressure ulcer preventive measures and guide decision-making when modifications are needed to accommodate conflicting priorities related to goals of care.

In addition, the recommendations included developing reliable processes to assure consistent implementation of evidence-based, preventive interventions in all care settings and palliative care guidelines to address patient management for terminal patients that included patient comfort measures and family support. Also, it was recommended that preventive measures used for risk reduction should be accurately documented, and the documentation should include any clinical contraindications to preventive care so that the rationale would be evident if a pressure ulcer was determined to be unavoidable.

HISTORY

There are many complexities involved in the etiology, prevention, and management of pressure ulcers/injuries. Recorded history suggests the presence of pressure ulcers since ancient times; they have been found in human mummies that were more than 5000 years old.[9,10] Early publications proposed that the occurrence of a pressure ulcer signaled impending death.[11] However, the study of pressure ulcer prevention is a relatively new phenomenon, and the knowledge base is still being researched and developed.

Since the early 1960s, a variety of pressure ulcer risk assessment tools have been developed for adults, including the Braden,[12,13] Gosnell,[14,15] Norton,[16,17] and Waterlow Scales.[18,19] Tools designed specifically for risk assessment of pediatric patients have also been developed such as the Braden Q Scale.[20,21]

It is well established that the development of pressure ulcers is a complex process involving multiple, often nonmodifiable, intrinsic risk factors, which are not fully measured by pressure ulcer risk assessment tools.[1,22-24] More than 100 potential risk factors have been identified.[25] The volume and diversity of risk factors present challenges to the caregiver to choose and implement appropriate preventive interventions in a timely manner. Although the process is not completely understood, it seems logical that the greater number of risk factors present, the more difficult it will be to prevent the development and/or deterioration of pressure ulcers.[26]

In 1990, there was a government-sponsored effort to develop a standardized/consistent approach to pressure ulcer prevention and treatment. At that time, several healthcare disciplines from different organizations collaborated to develop clinical practice guidelines (CPGs) for prevention and treatment of pressure ulcers. In May 1992, the Agency for Health Care Policy and Research,[27] part of the US Department of Health & Human Services, published a CPG for the prediction and prevention of pressure ulcers in adults. In that guideline, Bergstrom and colleagues[27] stated, "Even the most vigilant nursing care may not prevent the development and worsening of ulcers in some very high risk individuals." Two years later, the Agency for Health Care Policy and Research[28] published a companion CPG for the treatment of pressure ulcers in adults in which they reaffirmed their previous position: "Unfortunately, not all pressure ulcers will be prevented and those that do develop may become chronic." The Agency for Health Care Policy and Research guidelines were based on published, scientific literature that was available at the time. When scientific evidence was limited or inconsistent, recommendations were based on the consensus of expert opinion. Those CPGs were made available to the public and became landmark documents and key resources for the prevention and management of pressure ulcers in adults.

Since that time, multiple organizations have developed and updated best practice guidelines or CPGs for the prevention and treatment of pressure ulcers. In 2003, the WOCN Society published a CPG for the prevention and management of pressure ulcers, which was revised in 2010 and 2016 to keep it current.[29-31] The purpose 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/or are at risk for pressure ulcers. In addition, the WOCN Society published a guideline in 2008 that was updated in 2016 to facilitate the evaluation and documentation of pressure ulcers in a variety of clinical settings.[32]

In 2007, the Registered Nurses Association of Ontario[24,33] published a best practice guideline for risk assessment and prevention of pressure ulcers, which was updated in 2011. Also, the NPUAP's[34] pressure ulcer–staging system was expanded in 2007 to include suspected deep-tissue injury and unstageable pressure ulcers. The staging system is based on changes to the skin and the tissue, many of which are not visible until irreversible damage has occurred.[34-36] It may take hours to days before the clinical findings of a pressure-related tissue injury are evident.[4] Therefore, "when a patient develops a rapidly deteriorating pressure ulcer within several days of hospitalization, it is possible the damage may have occurred prior to hospitalization."[4]

In 2009, an international CPG for the prevention and treatment of pressure ulcers was published in which the pressure ulcer classification system was refined, and friction was removed from the definition of a pressure ulcer.[37] According to

the NPUAP,[38,39] the rationale for removing friction from the definition was that friction alone can cause superficial injuries, but it is not considered to be a direct cause of the deeper-tissue injuries found in most full-thickness pressure ulcers.

In 2014, from a collaborative effort between the NPUAP, European Pressure Ulcer Advisory Panel, and the Pan Pacific Pressure Injury Alliance; an updated international CPG was released for the prevention and treatment of pressure ulcers.[40] The document provides guidelines for all disciplines across all settings and includes specific recommendations for high-risk populations, including pediatrics, geriatrics, bariatrics, spinal cord–injured patients, and individuals in palliative care, critical care, and the operating room.[40]

Over the last 16 years, the NPUAP has published multiple educational materials, white papers, and position statements on a wide array of topics related to pressure ulcers: avoidable/unavoidable pressure ulcers, deep-tissue injury, mucosal pressure ulcers, pressure ulcer pain, pediatric pressure ulcers, pressure ulcers in palliative care patients, pressure ulcer staging, friction versus pressure-related injuries, staging ulcers with exposed cartilage, prevention points, and nutrition. Following a consensus conference in April 2016, the NPUAP[2,3] revised the terminology for pressure ulcer to pressure injury and updated its staging system. Those documents and the new staging terminology and definitions are available on NPUAP's Web site (www.npuap.org).

Despite educational efforts from multiple organizations, robust, scientific evidence that supports specific interventions for prevention of pressure ulcers is lacking.[40] Often, current research does not address the multiple medical and clinical situations that may affect a patient's risk and vulnerability for developing pressure ulcers.

Regulatory Changes

In the 2004 regulations and guidance for surveyors of LTC facilities, CMS[5,6] acknowledged that some pressure ulcers are unavoidable. Long-term care facilities are required to evaluate a resident's risk factors for pressure ulcers and implement preventive interventions consistent with the resident's needs and goals. A pressure ulcer is determined to be unavoidable if it develops in spite of the facility's efforts to prevent it (see the Appendix).

In 2006, CMS[41] identified pressure ulcer prevention as a nursing quality indicator, and full-thickness pressure ulcers were deemed "never events." The CMS[41] defined never events as preventable medical errors that result in serious consequences for the patient (ie, injury or death) and unnecessary treatment costs. While pressure ulcer prevention is considered a quality of care indicator for nursing, many contributing factors are beyond the purview of nursing. Pressure ulcer occurrence can signal a patient's overall decline medically.[36,42] There are times when preventive measures may be contraindicated or inconsistent with the goals of care, particularly in the palliative care population.[43,44] Another issue in providing preventive care is that a patient may refuse care, despite education about the need for the care.[36,45,46] In such cases, the development of a pressure ulcer would likely be considered unavoidable.

In 2008, CMS[41,47,48] issued a regulation (Inpatient Prospective Payment System Fiscal Year 2009 Final Rule) that withheld reimbursement for the care of selected hospital-acquired conditions, which were determined to be reasonably preventable (eg, stage 3 and stage 4, hospital-acquired pressure ulcers [HAPUs]) through the application of evidence-based guidelines. The Inpatient Prospective Payment System Fiscal Year 2009 Final Rule does not specifically state that pressure ulcers are always or entirely preventable—only that they are reasonably preventable; however, there is no recourse for hospitals to receive additional reimbursement for the treatment of HAPUs, even if clinicians consider them unavoidable.[48]

The Inpatient Prospective Payment System Fiscal Year 2009 Final Rule resulted in controversy and opposing points of view. In contrast to CMS's ruling, many clinicians believe that pressure ulcers will occur, in certain patients, even if the best guidelines and most up-to-date preventive interventions and skin protection are utilized.[48] As previously mentioned, CMS[5,6] has acknowledged that not all pressure ulcers are preventable as indicated by its guidance to state and federal surveyors for LTC facilities. In its guidance, CMS[5,6] stated, "A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable." The CMS has not applied this same standard in other healthcare settings. When the CMS rules regarding payment were revised, equivalent exemptions were not made for acute care HAPUs. This led some clinicians to suggest that the policy was confusing and inconsistent for a pressure ulcer to be considered avoidable in one setting but not in another, particularly, when caring for similar patients with the same conditions and comorbidities and when individuals in hospitals are more acutely ill.[48]

SUPPORTIVE STATEMENTS (RELEVANT RESEARCH OR PUBLISHED EXPERT OPINIONS)

Based on evidence from research, literature reviews, and expert opinions, the following supportive statements can be made regarding avoidable versus unavoidable pressure ulcers:

1. Avoidable versus unavoidable pressure ulcers: Associated risks and comorbidities.
   - Based on a retrospective study of 20 patients who developed HAPUs (ie, stage 3, 4, or unstageable), despite appropriate risk assessment and provision of preventive measures, Levine and colleagues[49] identified 10 physiological comorbidities that were most commonly present when the ulcers were identified: hypoalbuminemia, respiratory failure with intubation, severe anemia, hypoxia with sedation or chemical paralysis, hypotension, infection or sepsis, malignancy, diabetes mellitus, renal failure (acute or chronic), and/or congestive heart failure. In addition, 30% of the patients had a major surgical procedure prior to discovery of the pressure ulcer, and most were in an intensive care unit (ICU) and immobile due to a variety of comorbid factors. On average, HAPUs developed within 12.1 days (range: 3-23 days). Levine and colleagues[49] concluded, "There is a subset of patients where skin breakdown is unavoidable with current prevention technologies."
   - Accurate identification of risk factors is a prerequisite for determining appropriate strategies to prevent pressure ulcers, and according to Cox[50] better risk assessment tools are needed for critical care patients. Cox conducted a retrospective study of medical-surgical ICU patients (N = 347) and found 65 patients (18.7%) who developed a pressure ulcer. The most predictive variables for pressure ulcer

development were age, length of stay, mobility, friction/shear, use of norepinephrine, and cardiovascular disease. Cox reported that adequate prevention of pressure ulcers in critically ill patients with multiple risk factors can be difficult, particularly, when prevention strategies (eg, turning an individual who is hemodynamically unstable) may be medically contraindicated. Cox concluded that even with consistent and ongoing skin assessment, early identification of skin changes, and implementation of appropriate prevention strategies to minimize damage, skin and tissue damage can occur in critically ill patients.

- Based on a secondary analysis of data from 51,842 Medicare patient hospital discharges in 2006 and 2007, Lyder and colleagues[26] reported that the nationwide incidence rate for HAPUs was 4.5%. The prevalence of pressure ulcers on admission was 5.8%, and 16.7% (n = 502) of the 2999 individuals admitted with a pressure ulcer developed at least one new ulcer in a different location during hospitalization. Patients with HAPUs had significantly higher rates ($P < .001$) of inhospital mortality (11.2%), mortality within 30 days of discharge (15.3%), readmission to the hospital within 30 days of discharge, and longer hospital lengths of stay, compared to those without HAPUs. Individuals who developed HAPUs had significantly higher rates of chronic diseases (ie, congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, and diabetes mellitus [$P < .001$]). Individuals with HAPUs also had higher rates of obesity ($P < .003$), which can impair systemic perfusion and cause an inadequate blood supply to the fatty tissue, resulting in chronic skin and wound problems. Additionally, corticosteroid use was higher in patients with HAPUs ($P < .003$). The chronic conditions and use of corticosteroids might have increased the individuals' vulnerability for HAPUs. Therefore, the investigators stated that individuals who enter the hospital with a constellation of these conditions should be identified at admission as being at a very high risk for developing a HAPU, and preventive care should be promptly implemented. Lyder and colleagues acknowledged that HAPUs may develop, despite the provision of appropriate care; therefore, some HAPUs may be unavoidable.
- Other experts have also reported that pressure ulcers are most likely to occur in patients who are malnourished, elderly, dehydrated and/or obese, and in those with underlying medical conditions.[51]
- Pressure ulcer development is a multicausal event.[1] In the vast majority of cases, appropriate identification and mitigation of risk factors can prevent or minimize the formation of pressure ulcers. However, in some cases, pressure ulcers are unavoidable because the magnitude and severity of risk are overwhelmingly high, or preventive measures are contraindicated or inadequate. In 2014, the NPUAP[1] conducted a multidisciplinary consensus conference to explore the unavoidability of pressure ulcers using an organ system framework that considered a variety of nonmodifiable intrinsic and extrinsic risk factors. Consensus (ie, 80% agreement of the participants) was reached on several areas, which were considered to increase the likelihood of the development of an unavoidable pressure ulcer (ie, cardiopulmonary status, hemodynamic stability, impact of head-of-bed elevation, septic shock, body edema, burns, immobility, medical devices, spinal cord injury, terminal illness, and nutrition). The group concluded that "unavoidable pressure ulcers *do* occur."[1]
- Critical care patients are at high risk for unavoidable pressure ulcers.[52] Cox and Roche[52] conducted a retrospective study of 306 patients in a medical-surgical ICU and a cardiovascular ICU. The investigators found that although 92% of patients had documentation of compliance with an evidence-based, prevention protocol, 13% (n = 41) developed a HAPU. Several variables were significant predictors of HAPUs: a cardiac diagnosis at the time of admission to the ICU ($P = .03$); cardiac arrest ($P = .05$); mechanical ventilation longer than 72 hours ($P < .001$); number of hours the mean arterial pressure was less than 60 mm Hg during treatment with vasopressors ($P = .01$); and administration of vasopressin ($P = .004$). Norepinephrine and vasopressin were significantly associated with the development of pressure ulcers, and the use of vasopressin increased the risk almost 5 times. The peripheral vasoconstriction induced by vasopressors shunts blood away from the skin and underlying structures and may further contribute to deep-tissue injury, especially, in the already susceptible anatomical areas of the sacrococcygeal region. The addition of vasopressin administered concomitantly with a first-line agent (often norepinephrine) may represent the point at which the risk for pressure ulcers escalates and may be an early warning to heighten strategies to prevent pressure ulcers. Because vasopressors cannot be terminated to avert development of pressure ulcers, these findings may add to the body of knowledge about factors that potentially contribute to the development of unavoidable pressure ulcers.[52]
- Levine and Zulkowski[53] completed a secondary analysis of pressure ulcer data from 2 studies that were conducted by the US Department of Health & Human Services, Office of Inspector General (OIG)[8,54] on adverse events among Medicare beneficiaries in acute care hospitals and LTC/skilled nursing facilities (SNF). In the OIG studies,[8,54] the terms avoidable and unavoidable were not used. Instead, the OIG defined harm as preventable if it could have been avoided by improved assessment or alternative actions. Harm was not preventable if it could not have been avoided due to the complexity of the patient's condition or care that was required. While the OIG did not use the terms avoidable or unavoidable, Levine and Zulkowski[53] considered the terms preventable and not preventable interchangeable with avoidable and unavoidable, respectively. In the OIG studies,[8,54] a panel of physicians classified the level of harm and determined the preventability/avoidability by using a decision algorithm that was specifically developed for the study of adverse events in hospitals. To determine

preventability/avoidability, the OIG reviewers[8,54] used information in the medical records, clinical experience, published research, and group discussion. The OIG reviewers[8,54] rated preventability using a 5-point scale (ie, clearly preventable, likely preventable, likely not preventable, clearly not preventable, unable to determine). The incidence of pressure ulcers 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 pressure ulcers in LTC/SNF were unavoidable leading Levine and Zulkowski[53] to question the reliability and validity of pressure ulcers as a quality indicator with such a high rate of unavoidability. Levine and Zulkowski[53] concluded 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 ulcers, and only a few were unstageable or suspected deep-tissue injury; therefore, their analysis might have underestimated the level of harm from facility-acquired pressure ulcers. Levine and Zulkowski[53] recommended further studies to establish validity and reliability for the algorithm.

- Pittman and colleagues[55] conducted a retrospective study of 31 hospitalized patients with HAPUs. The most common clinical characteristics were identified in the 12 patients who developed unavoidable HAPUs and included the following: critical care, mechanical ventilation, chemical sedation, pressor agents, hemoglobin less than 7 mg/dL, febrile, cancer, nothing by mouth, fecal incontinence, and length of stay greater than 5 days.

2. Medical device–related pressure ulcers
   - Medical devices cause pressure ulcers in patients across the life span primarily in acute and critical care settings, but injuries can also occur in LTC settings and home care.[56-58] In a device-related injury, the tissue injury mimics the outline of the device. Tissue intolerance has been noted by many experts as the key to development of pressure ulcers, which may affect a patient's vulnerability to developing device-related injuries. The anatomical location of device-related ulcers differs from that of non–device-related ulcers. Most device-related ulcers occur in areas without adipose tissue and tend to progress to a higher stage more quickly than non–device-related ulcers.[59,60] In addition to pressure-induced ischemia on the underlying skin from a medical device, heat, humidity/moisture, and edema may develop under the device, which can further impair the skin's tolerance to pressure.[57,60,61] While most device-related pressure ulcers are avoidable, not all are avoidable.[60]
   - Black and colleagues[61] reported that although most pressure ulcers develop over bony prominences, pressure ulcers can occur on any tissue under pressure; therefore, pressure injuries can develop beneath medical devices. Based on a secondary analysis of data from hospitalized patients (n = 2079), Black and colleagues found that the overall HAPU rate was 5.4% (n = 113), and 34.5% (n = 39) of those were related to medical devices. Black and colleagues concluded that if a patient had a medical device, he or she was 2.4 times more likely to develop a pressure ulcer of any kind. The study confirms that device-related pressure ulcers are significant problems for the healthcare industry, which warrant more intensive efforts for prevention, early identification, and intervention.
   - Based on an integrative review of 32 data-based articles and clinical reviews regarding medical device–related pressure ulcers in pediatric patients, Murray and colleagues[57] found instances of medical device–related injuries, which could have been prevented with appropriate preventive interventions.
   - In a review of HAPUs, Apold and Rydrych[59] found that 29% of the pressure ulcers were device-related, and 70% of the device-related pressure ulcers were located on the head, face, and neck, whereas 84% of non–device-related pressure ulcers were located on the sacrum and coccyx/buttocks. Apold and Rydrych reported that there was often no documentation of a skin inspection under or around the device until an ulcer was found. Three-quarters (74%) of the device-related pressure ulcers were not identified until they were stage 3, stage 4, or unstageable, compared to 54% of non–device-related pressure ulcers. In some cases, there were orders from a physician that the device could not be removed. However, the investigators reported that the most common problems were an apparent lack of awareness of the need to periodically remove or reposition the device to maintain skin integrity and a lack of guidance on when and how to remove or reposition devices. Also, in several instances, the devices did not fit well.
   - The 2014 NPUAP consensus panel[1] indicated that a device-related pressure ulcer may be deemed unavoidable when it is medically contraindicated to adjust or move the device, when a medical device prevents turning/repositioning of the patient, and when there is tissue edema or moisture under a device that could compromise tissue tolerance and increase the risk for pressure/shear forces.
   - It is important for healthcare providers to recognize that the use of any medical device puts a patient at higher risk for a pressure ulcer, and implementation of preventive interventions is an essential part of the plan of care.[57,59,61]

3. End-of-life changes
   - Many healthcare providers believe that pressure ulcers, which occur at the end of life are often not preventable due to multiple risk factors, comorbid conditions, and the frail condition of the patient.[36,62,63] Physiologic changes that occur as a result of the dying process, over days to weeks, may affect the skin and soft tissues and manifest as observable (objective) changes in the skin's color, turgor, or integrity, or as subjective symptoms such as localized pain. These changes can be unavoidable and may occur even with the application of appropriate interventions that meet or exceed the standard of care.[64] This recognition has resulted in a focus on a palliative care approach for patients with unavoidable pressure ulcers, instead of a typical curative methodology.[62,65] Therefore, patients must be properly assessed and appropriate prevention and treatment implemented

with a realistic understanding of the achievable results, and the patient's response to all interventions should be clearly documented.[62,65,66]

4. Prevention strategies
   - Facilities are expected to meet standards of care to reduce or relieve pressure to patients with/or at risk of a pressure ulcer. Facilities should implement comprehensive programs to prevent and manage pressure ulcers, and they should carefully evaluate and determine if their scope and standards of care, policies, procedures, and wound care practices are consistent with evidence-based, best practices and nationally recognized CPGs.[46] This includes implementation of pressure ulcer prevention protocols in at-risk patients (eg, incontinence protocol), in addition to implementation of protocols for patient assessment and treatment.[46]
   - An evidence-based, pressure ulcer prevention protocol that has been endorsed by the NPUAP and Agency for Healthcare Research and Quality consists of the following key elements: risk stratification; patient turning and repositioning; management of moisture, incontinence, and nutrition; use of modern support surfaces (eg, beds and overlays); and ongoing clinician education about prevention.[67-69]
   - Based on a systematic review of 26 studies on using multicomponent strategies to prevent pressure ulcers, Sullivan and Schoelles[70] reported that the integration of several core components was effective in improving the processes of care and reducing pressure ulcer rates. The key strategies included simplification and standardization of specific interventions and documentation for pressure ulcers, engaging multidisciplinary teams and leadership, use of designated skin champions, ongoing staff education, and ongoing audit and feedback.
   - Prophylactic dressings.
     - Based on a systematic review of 21 studies, Clark and colleagues[71] reported that early preventive initiatives such as applying prophylactic-type dressings to vulnerable sites may offer an alternative approach to help reduce the incidence of superficial pressure ulcers by modifying the effects of mechanical loads applied to the skin and soft tissues and/or affecting the microclimate. Clark and colleagues[71] found that the pressure ulcer incidence was lower in patients (0%-8.5%) who had prophylactic dressings applied to the sacrum, heels, nose (under medical devices), and trochanter compared to individuals without dressings (0%-40%).
     - In a randomized controlled trial (N = 440), Santamaria and colleagues[72] compared the effectiveness of a silicone foam dressing applied to the sacrum and heels in 219 trauma and critically ill patients to a control group without dressings (n = 221). The investigators found that there were significantly fewer patients overall who developed pressure ulcers in the intervention group compared to controls (7 vs 27, $P = .002$), fewer sacral ulcers (2 vs 8, $P = .05$), and fewer heel ulcers (5 vs 19, $P = .002$).
     - Another recent study[73] investigated if the application of a silicone foam dressing was associated with decreased interface pressures. The investigators measured interface pressures on the heels in 50 healthy volunteers and reported that the application of a dressing was associated with a significant decrease in interface pressures compared to no dressing (40.14 mm Hg vs 50.43 mm Hg, $P < .001$).[73]
     - Experts have recommended that prophylactic dressings at the sacrum, buttocks, heels, and under medical devices should be considered for pressure ulcer prevention in patients who are at high risk for pressure, friction, and/or shear injury, particularly, immobile and critically ill patients in the emergency department, ICU, cardiac care unit, and operating room.[56,72,74,75]

5. Role of documentation
   - Accurate and thorough documentation is essential for effective prevention and management of pressure ulcers. "Good documentation must be comprehensive, consistent, concise, chronological, continuing and also reasonably complete."[66]
   - According to Dahlstrom and colleagues,[76] initiation of appropriate treatment of pressure ulcers is dependent on the identification and complete documentation of the ulcer (ie, location, stage, size), and ongoing measurements and descriptions are necessary to monitor the progression of the wound and effectiveness of interventions. However, based on a retrospective chart review, Dahlstrom and colleagues[76] found that documentation of the characteristics of pressure ulcers was frequently missing key descriptors, such as the stage, location, and size and, therefore, was not meeting quality guidelines. The investigators suggested that the first step to improving pressure ulcer care is to improve the identification and documentation of the ulcer, which is necessary for treatment, communication within the healthcare team, and reimbursement.
   - Documentation should be in place regarding pain assessment and intervention, treatment effectiveness, consultations/referrals, nutritional assessment, use of formal pressure ulcer risk assessment tools (eg, Braden Scale, Norton Scale), and prevention protocols, and should include the emotional status of the patient regarding the success of treatment.[46]
   - Other experts concur that documentation provides essential feedback to healthcare providers and other stakeholders regarding the interventions the patient received and their effects (ie, assessment, prevention, treatments), and if a HAPU occurs, provides verification that evidence-based care was delivered to support that the HAPU was unavoidable.[77] For example, after implementation of a quality improvement initiative to improve documentation of evidence-based interventions to prevent pressure ulcers, Jacobson and colleagues[77] reported a 67% decrease in reportable, full-thickness HAPUs that were deemed avoidable.
   - The importance and value of documentation is further validated because CMS[5,6,47] has recognized that some pressure ulcers are unavoidable under certain circumstances, such as when the ulcers develop

despite the provision of appropriate and accurate assessment and interventions. Therefore, for a pressure ulcer to be deemed unavoidable, there must be clear, complete, and consistent documentation of the prevention and treatment interventions provided to the patient.[55,65,76,77] In addition, the accuracy and quality of documentation play a key role in any litigation that might result from the development of pressure ulcers.[66]

6. Quality improvement programs for prevention
   - Multiple internal and external factors influence the adoption of hospital quality improvement programs that are designed to implement evidence-based practices to prevent HAPUs.[67,69] While factors such as high rates of HAPUs and nursing turnover affect quality improvement initiatives, based on the majority of survey responses from 55 hospitals, Padula and colleagues[69] found that the most influential internal factors were the availability of nurse specialists for wound consultation, existence of hospital prevention campaigns, and the level of preventive knowledge. The key external factors were financial concerns, application for Magnet recognition, data sharing with peer institutions, and regulatory issues.
   - It is important to recognize and address the barriers to achieving expected outcomes when implementing quality improvement programs. For example, Peterson and colleagues[78] reported that their initial quality improvement efforts to recognize, prevent, and treat pressure ulcers in pediatric patients in their children's hospital were insufficient. By reevaluating and revising their performance improvement plan, they were able to identify gaps and deficiencies needing correction. Through extensive collaboration, interprofessional efforts, and organizational changes led by the clinical nurse specialists, there was a significant and sustained reduction in the incidence of pressure ulcers. From year 2010 to 2013, there was a 32% decrease in the incidence of pressure ulcers from 155 to 105. The investigators concluded that reducing the incidence of pressure ulcers is achievable through collaboration, creativity, and engagement of multiple disciplines.
7. Education
   - Education about pressure ulcer prevention and healing should be provided to the patient and/or family/caregiver(s) when possible.[46] If care is refused or patients and/or family/caregiver(s) are nonadherent to the plan of care, the basis for refusal/nonadherence should be assessed and documented along with any instructions that were provided about alternatives.[46,79]
   - To effectively prevent pressure ulcers, ongoing education is necessary for healthcare providers to attain and maintain current knowledge about pressure ulcer risk, prevention, staging, and treatment.[80,81] There are several nationally recognized, evidenced-based, pressure ulcer guidelines available; yet, prevention strategies are not consistently performed and pressure ulcers remain a significant problem, particularly, in acute and LTC settings.[82] Although pressure ulcer educational programs have been shown to increase knowledge, and in one older study improved care, overall, improved knowledge has not been linked consistently with improved care, particularly, prevention.[81] Several research studies have shown low levels of knowledge about pressure ulcer prevention and low application of preventive care.[81,82] Based on a review of 7 studies, Waugh[82] reported that even when pressure ulcer knowledge was adequate, preventive interventions were not consistently performed and were often delegated to other staff (eg, licensed practical nurses, nurse assistants, and nursing students). While preventive care may be provided by others, it is important for RNs to recognize that they remain responsible for ensuring that patients receive effective interventions to prevent pressure ulcers.[82] Therefore, frequent and ongoing education regarding pressure ulcers is important for nurses to have the necessary confidence and skill required to recognize, assess, stage, document, and implement appropriate interventions to prevent and treat pressure ulcers.[80] Additionally, other healthcare providers should have education about pressure ulcers according to their role in the delivery of patient care.[80]

RECOMMENDATIONS

Experts have identified many unmet needs and gaps in prevention and treatment of pressure ulcers. There is a need to expand the science for determining avoidable versus unavoidable pressure ulcers and validate best practices to reduce the incidence of avoidable pressure ulcers. Additional robust/rigorous research and/or development and testing are warranted in the following areas:

- Establish standardized approaches for measuring and reporting prevalence and incidence data to facilitate national and international benchmarks.[40]
- Establish standardized methods for measuring and reporting wound-healing data.[40]
- Determine the effectiveness of evidence-based, pressure ulcer prevention and management strategies and the support systems that are designed to meet the unique needs of pediatric/neonatal patients.[78,83]
- Develop and validate skin risk assessment tools that include risks of medical devices for pediatric/neonatal patients.[78,84]
- Determine/compare the effectiveness of preventive and treatment interventions, including prophylactic dressings, and develop strategies for sustaining effective programs.[40,50,70,71,75,85]
- Examine the interrelationships between etiological factors and the prevention and development of pressure ulcers, including the following: microclimate, pressure and shearing, tolerance of adipose tissue, role of lymph vessel blockage, incontinence and incontinence-associated dermatitis, and skin failure.[40,86-88]
- Investigate device-related pressure ulcers across the life span in all healthcare settings by conducting studies to describe device-related injuries and determine the risk factors as a basis for developing risk assessment tools, best practices, quality improvement initiatives, and safer materials to prevent the injuries.[56-59,61,74]
- Develop risk-adjusted models to determine which specific risk factors or combination(s) of risks are most

predictive of pressure ulcer development to increase the efficiency/effectiveness of risk assessment and facilitate determining which pressure ulcers are unavoidable.[25,49]
- Create risk assessment tools utilizing advanced technology for the screening and detection of early pressure damage, especially in critical care.[40,50]
- Examine the impact of nutrition (including nutritional screening tools and interventions), hydration, and supplements on prevention and healing of wounds due to pressure for critically ill patients.[40,51,89]
- Determine the most effective pain management strategies and develop protocols and algorithms to guide healthcare professionals in managing pressure ulcer–related pain in all care settings.[40,63]
- Determine the effectiveness of modalities such as phototherapy, electrical stimulation, laser therapy, hyperbaric oxygen therapy, and traditional, culturally based interventions for the prevention and/or treatment of pressure ulcers.[40]
- Compare support surfaces for supine and seated pressure redistribution to determine which are most effective for prevention and treatment of full-thickness pressure ulcers, and develop improved products.[40,90,91]
- Examine the effectiveness of repositioning for the prevention of pressure ulcers, including the heels, and determine the most effective regimens.[40,92]
- Identify and validate risk factors for the development of heel pressure ulcers and determine the effectiveness of prevention strategies, including heel elevation.[40,92,93]
- Validate the essential components of accurate and appropriate assessment and documentation for pressure ulcer prevention and management (ie, skin assessment, description of skin integrity, identification of extrinsic and intrinsic risk factors for pressure ulcer development [including hemodynamics and comorbidities], wound assessment/staging and monitoring, interventions) and determine the role of validated instruments, computer-based algorithms, digital technology, ultrasonography, and other modalities for assessment and documentation.[40,55,94]
- Examine the skin care needs/issues for palliative care patients to identify the characteristics of individuals with avoidable versus unavoidable pressure ulcers and the factors related to healing versus nonhealing as a basis for developing a CPG that can address skin/wound issues and help determine the value of healing versus nonhealing in patients at the end of life.[62,63]
- Investigate quality improvement initiatives in healthcare systems to identify the elements that are necessary for effectively implementing and sustaining evidence-based practices to reduce avoidable pressure ulcers (eg, organizational leadership and support, resources/tools) and address barriers to implementation and maintenance of the initiatives.[53,67,68]
- Design internal incidence tracking systems and develop and test instruments and algorithms that can be used in process improvement programs (applicable to all healthcare settings) to identify HAPUs, distinguish avoidable from unavoidable HAPUs, and improve clinical decision-making for determining proper preventive and treatment interventions.[55,95–97]
- Explore the relationship of intrinsic and extrinsic risk factors to the development of unavoidable HAPUs.[55]
- Identify and validate gaps in healthcare providers' knowledge about prevention and management of pressure ulcers, including educational barriers, as a basis for developing strategies to meet the educational needs using formal education and informal methods such as mentoring/coaching, and peer-to-peer collaboration.[81,95,98-100] Such gaps may include inadequate knowledge of the following areas: risks and causative factors, assessment, differentiation of pressure ulcers from other types of injuries and wounds, staging, use and scoring of risk assessment tools (Braden Scale), and evidence-based prevention and treatment strategies.
- Evaluate the attitudes, beliefs, and knowledge of healthcare providers (eg, physicians, nurses, nurse assistants, other disciplines) about the value and importance of assessment, documentation, prevention, and proper management of pressure ulcers, and determine if these factors affect the prevention and treatment delivered by healthcare providers.[81,96,99]

CONCLUSION

The WOCN Society supports the following measures to prevent pressure ulcers in all care settings for individuals:

- An initial (within 24 hours of admission) and ongoing pressure ulcer risk assessment and skin assessment.
- Utilization of evidence-based, preventive interventions, which are consistent with the individual's goals and needs.
- Evaluation of the effectiveness of the interventions and their expected outcomes.
- Accurate, thorough, and complete documentation, including documentation of the following: risk and skin assessments, preventive interventions, the individual's response(s), and effectiveness of the interventions in meeting the expected outcomes.

The WOCN Society acknowledges that at times, despite provision of the best preventive efforts across the continuum of care, pressure ulcers occur and may be deemed unavoidable. The WOCN Society encourages and supports ongoing research and quality improvement initiatives to expand the science and knowledge base in the following areas:

- Differentiation of avoidable and unavoidable pressure ulcers.
- Identification of factors and conditions that lead to an unavoidable pressure ulcer.
- Validation of best practices for the prevention of pressure ulcers.

KEY POINTS

- Given the clinical complexities and constellation of comorbidities commonly encountered in today's healthcare environment, it is reasonable to state that not all pressure ulcers/injuries are avoidable or preventable.
- The skin is the largest organ of the body and its integrity is impacted by age, medications, microclimate, optimal functioning of other organs, and concomitant diseases/illnesses.

- The development of pressure ulcers/injuries is impacted by numerous risk factors, which are commonly seen in patients.
- While there has been progress in reducing the incidence of pressure ulcers/injuries, an incidence of zero may not be an attainable goal.

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APPENDIX

42CFR 483.25.c F314 Definitions: Avoidable/Unavoidable Pressure Ulcers

According to CMS:

"Avoidable" means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident's clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.[5,6]

"Unavoidable" means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.[5,6]