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*The National Pressure Ulcer Advisory Panel provides multidisciplinary leadership for improved patient outcomes in pressure injury prevention and management through education, public policy, and research.*

August 23, 2019

National Quality Forum

Submission of Open Comment August 23, 2019

Weblink: <http://www.qualityforum.org/map/>

As the Public Policy Committee of National Pressure Ulcer Advisory Panel (NPUAP), and the Board of Directors, please find our response to the open comment period for Measure #3498e Titled Hospital Harm Pressure Injury.

The National Pressure Ulcer Advisory Panel is an independent, not-for-profit professional organization dedicated to the prevention and management of pressure injuries. Formed in 1987, the NPUAP Board of Directors is composed of leading experts from different health care disciplines—all of whom share a commitment to the prevention and management of pressure injuries. The NPUAP serves as a resource to health care professionals, government, the public, and health care agencies; and welcomes and encourages the participation of those interested in pressure injury issues through utilization of NPUAP educational materials, participation at national conferences, and support of efforts in public policy, education and research.

**The NPUAP supports the concept of a pressure injury eCQM. However, the NPUAP has concerns regarding the reliability, validity and feasibility of NQF 3498 eCQM as currently proposed. The NPUAP, as a subject matter expert organization would be honored to assist with efforts to revise and improve this proposed eCQM. As an addendum to our previous comment regarding the adoption of this e-measure, the NPUAP request further clarification, research and/or edits for this measure pertaining to the below points:**

#### 1. Terminology

**The NPUAP supports the use of the term, pressure injury, in the measure title. We respectfully request that the term, pressure injury, be consistently used throughout the document.**

**Rationale, page 32; bullet 1:** The rationale for the use of the term, pressure injury, includes:

- Not all pressure-induced changes to skin and deeper tissues are “ulcers”, but all can be classified as injuries.[1, 2]
- ICD 11 has adopted pressure injury as a synonym.[3]
- The following organizations use the term, pressure injury: National Pressure Ulcer Advisory Panel (NPUAP), Wound Ostomy and Continence Nurses Society (WOCN), Academy of Nutrition and Dietetics, National Database for Nursing Quality Indicators (NDNQI), Partnership for Patients, Veterans Affairs, Pan Pacific Pressure Injury Alliance, Wounds Australia and others.
- CMS has incorporated pressure injury into its language in post-acute care documentation.
- A series of international surveys indicate a preference for the term, pressure injury.[4-6]
- The 2019 EPUAP-NPUAP-PPPIA International Guideline (which will be released on November 16, 2019 at a conference at the University of Southern California) will use the term, pressure injury, throughout the text of the document.

#### 2. Inclusion of Stage 2 Pressure Injuries

**The NPUAP fully supports transparency in pressure injury reporting in the acute care setting and the monitoring of hospital-acquired Stage 3 pressure injuries, Stage 4 pressure injuries, unstageable pressure injuries and deep tissue pressure injuries – DTPI.**

Although Stage 2 pressure injury is often an avoidable patient harm, the NPUAP believes there are some unintended consequences of capturing these data that should be considered before including Stage 2 in this measure.

Stage 2 is the most frequently reported category of pressure injuries.[7, 8] Therefore, if Stage 2 is included in future reporting, the NPUAP would recommend that pressure injuries be reported by Stage/Category to differentiate the exact number of those reported at each Stage/Category. When examining longitudinal trends, this would allow clinicians and policy makers to determine which changes represent true increases in pressure injury incidence and which changes are due to making Stage 2 reportable.

**Clinical Rationale:** The NPUAP defines a Stage 2 pressure injury as partial-thickness skin loss with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister.[1] Stage 2 pressure injuries differ from other partial thickness wounds such as those characterized as moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARS), or traumatic wounds (skin tears, burns, abrasions). In clinical practice, there is often confusion among bedside clinicians and providers regarding wound etiology. It is not uncommon for wounds that occur as one of the above etiologies to be erroneously identified as a Stage 2 pressure injury. As stated in our previous response to this proposed measure, accurate staging of pressure injuries has been a concern for decades and this concern crosses all disciplines. Interrater reliability of pressure injury staging averages .61 (SD = .31) with direct clinical observation. [9] Differential diagnosis from other wound types is higher at .81 in web-based testing using photographs of pressure injuries and other wounds. Reliability improves with education for all clinician and is higher for certified wound care providers than general nursing or medical staff. Lack of the availability of a wound care clinician to identify the accurate etiology of a wound as well as corroborate or assign a pressure injury stage can lead to erroneous staging, and/or improper wound etiology identification, thus inaccurate documentation, resulting in erroneous penalties for these facilities. If pressure injury stages/categories are extracted from EHR data, the NPUAP, NDNQI and other providers of pressure injury staging education will need to redouble their efforts (particularly in the case of Stage 2) to enhance the reliability of extracted data recorded by multiple providers.

Moreover, Stage 2 pressure injuries, as partial thickness wounds heal as a result of epidermal repair. Partial thickness wounds heal through resurfacing of the wound (epidermal proliferation and migration and the reestablishment of epidermal layers to restore the barrier function of the outer skin (epidermal) layers. Unlike full thickness pressure injuries, shallow Stage 2 pressure injuries often heal without long-term consequences, loss of skin function or scar tissue formation. Healing occurs in a more predictable manner and depending on the underlying comorbidities, occurs in a shorter timeframe than full thickness wounds. The median time for healing in long term care facilities is 46 days, with longer healing times required for larger Stage 2 pressure injuries.[10]

Based on the healing capabilities inherent in these partial thickness wounds, it is the opinion of the NPUAP that the presentation of a Stage 2 pressure injury does not carry the same longstanding negative consequences to patients as full thickness pressure injuries. Stage 2 pressure injuries constitute a very real patient harm that should be monitored and addressed; however, the relative level of harm is less than with Stage 3, Stage 4. Unstageable and potentially DTPI. A clinical analogy to this would be patient falls. While patient falls are a serious adverse event in hospitalized patients, all falls are not penalized, as many falls result in no adverse effects or minimal adverse patient effects.

### **3. Unavoidability of Pressure Injuries in Acute Care**

**Any discussion of pressure injury quality measurement in acute care should consider a mechanism for determining “unavoidability” as currently exists for CMS surveyor assessments in long term care.**

The NPUAP agrees that the incidence of pressure injuries can be reduced through the use of best practices, but would like to add the following comments for NQF consideration:

- Some pressure injuries are unavoidable despite best practices.[11, 12] This is particularly true in end-of-life situations and in other vulnerable populations such as the critically ill.
- A CMS definition for “unavoidable pressure ulcers/injuries” has been available in the long-term care setting since 2004, when the Centers for Medicaid and Medicare Services (CMS) created regulatory language addressing PI prevention, stating Based on the comprehensive assessment of an individual, the facility must ensure that an individual who enters the facility without pressure sores does not develop pressure sores unless the individual’s clinical condition demonstrates that they were unavoidable.[13] This allows LTC providers to avoid penalties in situations where they can document that the pressure injury was unavoidable. There is no such option in the acute

care setting, although there is a growing body of research in this area.[14] NPUAP has advocated for the extension of this definition to all clinical settings,[11] and recognizes the need for greater clarity in operationally defining “unavoidable”.

**Clinical Rationale:** Due in part to the advancement and availability of medical technology, hospitalized patients today are surviving illness that even a decade ago would have been insurmountable. Moreover, those that do survive experience a higher burden of acute illness, which is often complicated by a concomitant chronic illness, resulting in a substantially increased pressure injury risk. In some cases, pressure injuries are unavoidable because the magnitude and severity of risk are overwhelmingly high or preventive measures are either contraindicated or inadequate, given the magnitude and severity of risk. Mounting empirical evidence supports that there are many pressure injury risk factors that confront hospitalized patients that may be considered non-modifiable, especially in vulnerable populations such as the critically ill.[12, 15-17]

In addressing the unavoidable pressure injury, the NPUAP has been on the cutting edge of the issue. NPUAP provided a series of national and regional conferences in the early 2000s regarding this issue. In 2010 NPUAP held a multidisciplinary consensus conference, with unanimous agreement that most (but not all) pressure injuries are avoidable.[11] In 2014, the NPUAP hosted a multidisciplinary conference to evaluate the issue of unavoidable PIs within an organ system framework, considering the complexities of non-modifiable intrinsic and extrinsic risk factors.[12] This group of experts again achieved consensus that unavoidable PIs do occur. In February 2020, a conference sponsored by the NPUAP will again address the topic of unavoidable pressure injuries in relation to skin failure and pressure injuries at the end of life.

**The NPUAP advocates for the development of options in acute care to determine which pressure injuries are unavoidable and can be excluded from consideration in quality measures and reimbursement decisions as is currently available in the long-term care sector.**

#### **4. Present on admission timeframe: Deep Tissue Pressure Injury**

**The NPUAP recommends extending the window of time for documentation of Deep Tissue Pressure Injury (DTPI) to 48 hours following admission. The 24-hour window for other stages/categories of pressure injuries is reasonable.**

**Clinical Rationale:** We reiterate our previous response regarding the timeframe for presentation of a DTPI. The science surrounding the evolution of a Deep Tissue Pressure Injury (DTPI) continues to advance, and it has been postulated that the appearance of a DTPI can take up to 48 hours or longer to manifest and become visible to the clinician.[18, 19] Therefore, a 24-hour timeframe to declare a pressure injury (specifically a deep tissue pressure injury) as hospital acquired may erroneously penalize institutions for pressure injuries that may have developed prior to admission, but are not visible to clinicians. Moreover, current and emerging technologies such as the use of infrared thermographic devices and subepidermal moisture devices support that changes in tissues may be developing below the skin surface, and before visible signs are present to the clinician.[20] Thus, there are some pressure injuries that may actually be present on admission, however not visible within the first 24 hours. Similarly, in darker pigmented skin, it may be difficult to visualize a potential deep tissue pressure injury or Stage 1 pressure injury in its early stages, which can also contribute to the erroneous labelling of a hospital acquired pressure injury in these individuals, as skin changes may not be readily detected within the first 24 hours of the hospital admission.

#### **5. Reliability, Validity and Feasibility Concerns**

Abstracting pressure injury data from the electronic health record is more comprehensive than claims reports of Stage 3 and 4; however, NPUAP has some concerns about reliability and validity of EHR data based on trials reported in the NQF document and the NDNQI e-measure attempt.

**Reliability/Validity: Rationale, page 32; bullet 3.2. Scientific Acceptability of Measure Properties: The reliability and validity data reported is not sufficiently robust to use as a measure of quality that may affect reimbursement.** Please refer to the previous NPUAP response for a more detailed analysis. Also note that the National Database for Nursing Quality Indicators (NDNQI) conducted a much larger trial of an electronic health record (EHR) data extraction for pressure injury process and outcome measures. The lessons learned from the NDNQI experience could be very helpful in refining this proposed NQF eCQM.

**Feasibility: Rationale Page 32, 3.: Pressure injury staging documentation may not be available in structured fields in many EHRs.** There is variability in the degree to which structured data fields are mapped to LOINC, SNOMED-CT, VSAC or CIMI/FHIR models. The wide variability in locations within the EHRs for pressure injury documentation, timing of documentation in relation to admission (even with time stamps), and the wide variability and lack of reliability of various care providers entering the documentation challenges the feasibility of a pressure injury e-measure at this time.

**Related and Competing Measures, Page 32,5.** The reliability and validity of PSI-03 should improve with the addition of codes for Deep Tissue Pressure Injury in ICD-10. However, development of an e-measures is a better long-term strategy than continued analysis of ICD codes on hospital discharge. There does not seem to be a provision for detecting “worsening of existing pressure injuries” in the proposed e-measure for acute care, despite the continued measurement of this quality indicator in post-acute care.

**Additional comments by NQF report page**

**Page 82, description:** The NPUAP generally supports this statement. Please refer to previous comments regarding potential unintended consequences regarding Stage 2.

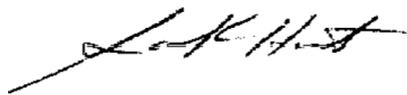
**Page 82, numerator statement:** The NPUAP recommends that the window of time for DTPI documentation be extended to 48 hours following admission.

**Page 82, numerator detail:** NPUAP supports the time period for data collection as beginning at hospital arrival (whether through Emergency Department, observation stay or direct admission). Greater emphasis should be placed on pressure injury prevention in the ED.[21]

**Page 82-83, additional comments:** Exclusions, risk adjustment/stratification should be reconsidered. Stratification by Stage/category should be considered. The first qualifying event may not be the worst; MDS evaluates the worst pressure injury when multiple pressure injuries are recorded during an encounter period. The algorithm flowchart was not attached as an appendix to this document.

Thank you for this opportunity to comment NQF Measure #3498e Titled Hospital Harm Pressure Injury. The NPUAP appreciates the bold and innovative efforts of NQF in development an eCQM for pressure injury reporting in acute care. The NPUAP would be happy to assist with further development of this measure as subject matter experts and the leading professional organization dedicated to improving patient outcomes in pressure injury prevention and management.

Sincerely,



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