Subject: CMS RFI Responses

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Disclaimer: *William Padula, Barbara Delmore and Janet Cuddigan are full-time faculty at their respective universities. The opinions expressed herein do not necessarily reflect the views of The Johns Hopkins University, NYU Langone Health or University of Nebraska Medical Center. Furthermore, we are members of the Board of Directors for the NPUAP, and provide answers that compile our combined knowledge of peer-reviewed evidence and NPUAP guidelines; however, there was insufficient time to achieve review and approval by the entire NPUAP board of directors to offer these responses as NPUAP consensus.*

Correspondence: Feel free to contact Dr. Janet Cuddigan, Vice President of the National Pressure Ulcer Advisory Panel (NPUAP) for follow-up questions or references at jcuddiga@unmc.edu.

Questions and Answers:

1. *Does the numerator (as specified) accurately capture hospital-acquired or worsening pressure injuries while minimizing any unintended consequences?*

   Answer: The numerator does not accurately capture worsening pressure injury states. Most patients with a steep trajectory for increasing pressure injury risk begin upon admission with Stage 1 and 2 pressure injuries or a deep tissue injury caused by a traumatic event. These non- or minimally-ulcerated wounds predispose the patient to severe advancement, and can sometimes be unavoidable based on the patient's baseline acuity or levels of malnutrition. The numerator strictly observes Stage 3, 4

and unstageable pressure injuries not presenton-on-admission (POA) after the 4th day of hospitalization, which ignores patients with index pressure injuries upon admission with multiple concomitant chronic issues that are included in the patient's MS-DRG before the pressure injury. Thus, a patient on a worsening trajectory with a stage 2 pressure injury upon admission that progresses to a stage 3 or 4 before the clinical team can stabilize the acute issues that the patient faces (e.g. heart failure, respiratory failure, kidney failure, etc.) places the hospital in an unfair position to flag a PSI-03 sentinel event while providing critical care to the patient before addressing acute/chronic wound therapy.

Another scenario that may be misrepresented by the numerator is the patient that presents with an unstageable pressure injury on hospital admission. The hospital performs the correct treatment, which removes the slough/eschar and now revealing a full-thickness wound (i.e. Stage 3 or 4), and a change from the admission stage. While this scenario does not necessarily represent a "worsening" situation, it does represent a change in stage terminology that could falsely misrepresent a true POA pressure injury. A deep tissue pressure injury (DTPI) POA may also follow the same scenario after proper treatment by hospital staff and be falsely misrepresented. This is confounded by the fact that at this time, a DTPI does not have a distinct code that represents this condition. Rather, coders are forced to use the Unstageable code for an open wound. These are clearly two separate conditions and as such, should have their own distinct codes.

Furthermore, the 24-hour time frame for documenting pressure injuries POA is generally accepted. However, it is not entirely consistent with CMS post-acute care coding, the NDNQI guidelines for data collection or the 2014 NPUAP-EPUAP-PPPIA International Guidelines. See comments within the e-measure description for further details. Because DTPI changes can often not be visualized or palpated until 48 hours (or later) after a period of intense and prolonged pressure, some have advocated for a 48 hour time frame to document DTPI as POA. The NPUAP would be happy to discuss supporting literature for this change. We recommend consultation with the CMS Technical Expert Panel on Post-Acute Care to harmonize operational definitions for "worsening pressure injuries". The addition of risk adjustments might address some of the concerns expressed by my colleagues above. See additional comments embedded in attached e-measure description.

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

Answer: Evidence by Padula et al. illustrated that the implementation of PSI-03 tied to nonpayment reduced rates of hospital-acquired pressure injuries not present on admission by 2-3% between 2007 and 2012.[1] However, other evidence show that about 75% of pressure injury rate reductions in hospital were associated to improvements in coding characteristics. Controlling for these coding issues that have been enhanced since 2008, pressure injury rates have risen 58.4% since 2015

according to the CMS Office of Enterprise Data and Analytics. This is mainly because the installation of PSI-90 for composite rates of select hospital-acquired conditions has pressured hospitals to focus on "low hanging fruit" (i.e. conditions that are easily preventable with little resource use). Since pressure injuries are more complex to prevent and result in greater chronic harm to patients, the measures for assessing performance in pressure injury prevention do not align with hospital payment incentives or internal recognition of the cost-utility of pressure injury prevention with respect with what is best for the patient.
In addition, using a different methodology, NDNQI and the International Pressure Ulcer Survey report some decline in hospital acquired pressure injuries over the past decade. This may be a function of differing methodologies.[2-4] Other measures besides PSI-03 and incidence rate calculations could be explored to express true hospital performance.

The major limitation of this e-measure (as currently described) is that it does not differentiate between avoidable and unavoidable pressure injuries. NPUAP has reviewed the literature in this area and developed definitions of unavoidable pressure injuries that are consistent with the criteria used in the CMS LTC State Surveyor Manual.[5,6] An unavoidable pressure injury as defined by NPUAP: "can develop even though the provider valuated the individual's clinical condition and pressure injury 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.[5] Pittman et al, (2016) estimated that 39% of hospital-acquired pressure injuries are unavoidable according to the NPUAP definition.[7] In the absence of risk adjustment and modifications for unavoidable pressure injuries the proposed e-measure should not be considered a reliable and valid measure in "assessing and improving the quality of care for patients".

The National Database for Nursing Quality Indicators (NDNQI) developed a pressure injury e-measure and conducted reliability testing in several academic medical centers and community-based hospitals. Data extracted from the EHRs were compared to NDNQI quarterly surveys which included bedside verification of all pressure injuries. As part of their methodology, they extracted documentation that preventive interventions had been implemented (e.g., skin assessments, risk assessments, nutrition support, repositioning). The e-measure was written to MAT specifications. HAPI were identified with reasonable reliability. Reliability of preventive measure documentation in relation to NDNQI survey data varied. The major barrier to reliable extraction of data was related to difference in data fields among EHRs, even EHRs from the same vendor. NDNQI worked with the major EHR vendors in developing the e-measure and trying to achieve some level of standardization. Some subsequent work has been done updating LOINC and SNOMED CT and mapping EHRs to LOINC and SNOMED CT codes, however I anticipate you would run into similar difficulties in developing a pressure injury e-measure in 2018. I think there are a lot of "lessons learned" from the NDNQI e-measure trial. If you would like further

details, please contact, Janet Cuddigan, Judith Warren, Nancy Dunton (KUMC) or Sandra Bergquist-Beringer (KUMC).

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?*

   Answer: No. Because CMS has declined payment for hospital-acquired conditions, clinical workflow is dependent on those actions that lead to reimbursable routines that create revenue for facilities. As a result, most facilities have to invest in prevention protocols that are add-on features of other protocols rather than stand-alone practices that benefit the patient. While we would acknowledge that CMS is saving money and drawing a line for hospital performance, hospitals struggle to generate independent revenue to invest in an area of critical patient care that is not monetized.
   In addition, one may be able to extract date and time of admission, date and time of first skin assessment to see if the skin was assessed in a timely manner. Other preventive measures (i.e. process measures to guide quality improvement and evaluate avoidability) would be more difficult to extract. The outcome data (pressure injury, time and date of first documentation, stage) would be more challenging to extract given the wide variation in EHR structures. This is complicated by the generally poor accuracy of bedside care provides when identifying and staging pressure injuries. Many facilities have developed protocols to override initial staging after a certified wound care nurse has evaluated the pressure injury. The other protocol that many have implemented to ensure reimbursement is developing a communication system whereby the existence of a pressure injury is communicated to the physician so that he or she can document it in a location for coders to find.

   We believe that documentation of "worsening pressure injuries" would be more difficult. The shorter LOS makes it difficult to track changes. You might be able to pick up Stage 1 to 2, Stage 2 to 3 and Stage 3 to 4 in the EHR. Decision rules for the various evolutions of DTPI would be complex. If an unstageable pressure injury is debrided, is it "worse" if it is now a Stage 3 or 4?

   What is documented in the "normal course of clinical workflow" is highly variable. Some EHRs provide fields that allow detailed documentation of pressure injuries as an outcome and preventive interventions as process measures. Some facilities consider this "standard care" which does not need to be documented in detail. For example, there has been an ongoing debate on whether you should document every time you reposition the patient and hope it matches the "every 2 hours recommended in the care plan" or just check a box at the end of the shift.
   The major barrier is the lack consistent, structured extractable fields in the various EHR systems. We would recommend that CMS investigate the lessons learned by NDNQI and Press Ganey with their pressure injury e-measure.

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

   Answer: The major barrier is the lack consistent, structured extractable fields in the various EHR systems. Thus, the extraction of important fields related to pressure injury care depends on the individual hospital EHR. A federal mandate for the structure of all hospital EHRs to capture important measures of pressure injury prevention, such as Braden scores, would be a meaningful improvement. Because these measures are not required by CMS, many health systems are forgoing evidence-based guidelines to save on nursing time and hope that the lack of predictive validity of the Braden Scale risk-assessment saves them money at a fair tradeoff to patient harm. The greatest deficit caused by structured EHR-based entry of pressure injury predictors such as the Braden Scale is a clinician's ability to "copy/paste" risk scores from a patient's previous assessment. Thus, a 5-10minute risk assessment can be gamed in several seconds without looking at the patient if the clinician does not have enough time or support to perform a complete risk assessment. Incentives (e.g. Pay for Performance) that reward meaningful use of EHR data entry for pressure injury prevention tactics would be preferred. For instance, when a clinician opens up a Braden Scale entry window on the EHR, they cannot enter the physical scores for 3-5 minutes after the presumed time it takes to perform a thorough skin check and risk assessment. It should be noted that not all facilities can afford an EHR system, a system that has such capability, or may only be able to purchase partial modules (e.g., labs only). Additionally, some EHR systems do not provide modules on current evidence and care standards in a timely fashion or a facility may not be able to afford an "update" immediately or at all.

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

   Answer: Multiple types of diagnoses and patient conditions exist that should be added to the denominator. We recommend that CMS review the exclusions currently used by CMS for post-acute care reporting in the interest of consistency. We have considered several cases for which evidence exists to support their exclusion below.

   First, Padula et al. identified the ICD-9 for spinal cord injury as having a 14-to-1 greater odds of PSI03 flag than the average hospitalized patient.[8] Currently spinal cord injury diagnosis is not excluded from PSI03. While there are diagnoses for "paraplegia, quadriplegia and hemiplegia" as part of the explicit exclusion criteria for PSI03, which is commonly co-diagnosed with spinal cord injury, we believe that spinal cord injury should be its own exclusion criteria. Many scientists believe that there are biomarkers in spinal cord injured patients that predispose them to unavoidable skin deterioration, in addition to the fact that this is poor clinician consistency to co-diagnosing spinal cord injury along with a form of paralysis in the EHR free text.

Second, there is a growing body of evidence on skin failure at the end of life. NDNQI excludes patients from their pressure injury surveys who are "actively dying". Technically, we are all dying from the time we are born, making this term is poorly defined and open to interpretation. Patients who have opted for palliative care that limit nutrition and activity could also be excluded from the denominator. Pressure injury prevention may no longer be a "goal of care". How this information would be extracted from the EHR requires further guidance.

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?*

   Answer: Yes. The NPUAP Guideline recommends that a skin check and risk-assessment performed upon admission is the best way to plan for future preventive care for pressure injury occurrence and/or progression. Documentation within 24 hours is a display that Guideline recommendations are being followed carefully.

   There is some debate about the time period allowed for documentation of present-on-admission (POA) pressure injuries. NDNQI and CMS state on admission (however admission is defined within the setting). The NPUAP International Guideline says that a skin assessment should be done with a risk assessment "as soon as possible (but within a maximum of 8 hours after admission)." NDNQI refers to the admission skin assessment as being performed as soon as possible after admission.

   Skin assessment done within 24 hours have become the de facto standard for identifying POA pressure injuries.

   Because it takes DTPI longer to be visualized on the surface, some are advocating for a 48-hour window of time to designate DTPI as a POA pressure injury. For additional references, contact NPUAP.

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?*

   Answer: It is a possibility based on the capability of the EHR and the features that the hospital has purchased. However, along with this EHR feature, there needs to be a proper code for acute care that exists currently in long-term care that acknowledges the presence of an end-of-life injury/ulcer. At this time, even if a patient is placed on hospice resulting in a "discharge" from an "inpatient" admission, and still in the same facility, the same code that is used for long-term care cannot be applied. At this time, there is no code, specific instructions or guidance provided to coding staff for how to address this scenario. Acute care facilities also need specific instructions and

guidance for how to address the patient that presents with a pressure injury on admission, then becomes a hospice or palliative care patient after admission and still has the same pressure injury that was present on admission. The scenario demonstrates how an originally acute care admission becomes a hospice/end-of-life/terminal care admission and has not left the facility. Yet-they are treated as two different accounts and two separate admissions. At this time, a special code for end-of-life skin injuries is not available to the coders and perhaps this code should not contain the word "pressure." Overall, hospice admissions are excluded from the denominator but scenarios may occur where the patient enters the facility as "acute" care with a condition such as cancer, and may not transfer to palliative or hospice care within the acute admission. However, the medical team after an acute event decides that the patient should now be on comfort care; the patient develops an end-of-life injury/ulcer but is still under the same acute admission. In this scenario, the end-of-life injury/ulcer will be counted as not present on admission because the injury/ulcer occurred "somewhere" else. Again, specific instructions and guidelines are needed.

We would differentiate between patients who (1) opt for comfort cares that preclude adequate pressure injury prevention (e.g. nutrition and turning). In these cases, pressure injury prevention is no longer a goal of care. AND (2) All patients who nearing the end of life. The duty to prevent pressure injuries remains, unless the patient/ family opt out. Pressure injuries that occur despite our best efforts in dying patients should be considered unavoidable. Differentiating skin failure and pressure injury is a subject of ongoing research and debate that cannot be currently extracted from an EHR.[9-12]

Please see comments in the pdf file describing the proposed e-measure.

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