



**NATIONAL  
PRESSURE  
ULCER  
ADVISORY  
PANEL**

2300 N Street NW  
Suite 710  
Washington DC 20037  
Tel: 202-521-6789  
Fax: 202-833-3636  
Web: [www.npuap.org](http://www.npuap.org)  
Email: [npuap@npuap.org](mailto:npuap@npuap.org)

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

May 5, 2009

The National Quality Forum  
601 13th Street NW, Suite 500 North  
Washington DC 20005

Dear Colleagues:

This letter is written in response to the proposed framework for measuring quality for prevention and management of pressure ulcers. We appreciate the extension on submission of our comments.

This letter addresses the proposed changes in pressure ulcer nomenclature and the measurement of pressure ulcer data, both through the size of the ulcer and prevalence and incidence of pressure ulcers. However, before getting to the specifics, we offer some general observations. Some rather broad statements are made in the document that imply a comprehensive review of the literature underpins this document. Statements such as “studies have shown” and “there is no evidence that....” lead the reader to believe that a comprehensive review of literature was completed. Statements are not supported by citations. Some statements are erroneous and misstate the existing scientific evidence. We understand that some evidence was available to the group; however, it does not appear to be a comprehensive review. NPUAP would be happy to share the results of a 3-year international comprehensive literature review on pressure ulcer prevention and treatment.

## **Domain One- Staging and Measuring of Pressure Ulcers**

### **Domain 1.1 Staging of Pressure Ulcers**

The NQF proposal to eliminate staging is disputed by NPUAP. The term stage is and has been used to define and describe the amount of visible tissue loss. While people do consider the stage of a pressure ulcer along a linear trajectory; having defined the problem of deep tissue injury NPUAP is well aware of the contrast in etiologies both from the outside in and the inside out. We cannot see an advantage to using the term “grade” because it also implies linear movement. NPUAP actually addressed the issue of the word “stage” last year. While writing the new international guidelines, the words “stage” and “grade” were replaced with a new word “category” for the implication of progression of the ulcer. However, when the NPUAP board examined the proposed change to the term “category”, it was not recommended due to the confusion with the new ICD-10 codes and the present on admission rule. The current present on admission rule does not allow payment for unstageable pressure ulcers. Therefore if hospitals are going to try to claim an ulcer is present on admission, it must be classified by stage. A “full thickness” ulcer would not trigger the proper ICD-9 code for payment.

The current staging system is reliable and improves communication between disciplines, allows allocation of preventive and treatment surfaces and prescription of topical treatments. The information also allows for comparison of data between settings, between patient types and between care delivery systems. Nixon and colleagues (2005) reported on a study of pressure ulcer assessment between general registered nurses and wound nurses. In this study, in addition to the usual categories of pressure ulcers, there was also a classification for blanching or nonblanching. Interrater reliability was high; there were 21% disagreements and 82% of the disagreements were within one grade. Bours and colleagues (1999) compared nurses' and wound care experts' bedside assessments of pressure ulcer grading in a variety of healthcare settings. The nurses in the hospital and nursing home had near perfect interrater reliability (IRR) (0.97 and 0.81). IRR was lower in the home setting (0.49).

The proposed change from the term "stage" to a two-part classification is also faulty:

1) While staging is difficult, it is not impossible. Adequate training in staging and differential diagnosis is required.

2) Plans of care are based on the stage. The treatment of a stage I does not equal the treatment of a stage II. Stage II ulcers are dressed or covered. Stage I pressure ulcers require no topical treatment. Adding the term "open" or "closed" to the partial thickness label is the same term as stage I and stage II.

If the phrase "partial thickness" were used, how would the quality of care provided be judged? It would appear that the inappropriate treatment to a stage II, that is letting it dry out, would be correct if the ulcer were a stage I.

Stage I and II ulcers heal; the tissue replaced is the same as the tissue lost. Epithelial and dermal tissues are regenerative. The word "closed" should be reserved for ulcers that require contracture and scar.

The treatment of a stage III is not the same as a stage IV, nor is it the same as the treatment for an unstageable ulcer or Deep Tissue Injury (DTI). The proposal recommends using the word "closed" to signify a healed state; we agree because biologically these ulcers never "heal" and are subject to future breakdown.

Using the proposed words "closed" to distinguish DTI and unstageable from "open" stage III and IV is also faulty. Again, how could the quality of care be judged when the ulcer is labeled as a closed full thickness pressure ulcer? What if the ulcer was débrided? DTI should not be débrided; some unstageable ulcers should not be débrided. Deep tissue injury can be rescued, and if it were lost in the nomenclature of "full thickness", the clinical science of DTI would be lost.

Using the term "deep structure involvement" says little. Again, could quality standards be applied to this label?

NPUAP can see no benefit to simplifying the staging system. The combined work of the NPUAP and our European colleagues (EPUAP) over the past 3 years has resulted in the development of an international classification system that is based on decades of basic science

(histology), clinical use, and results of educational initiatives that improve inter rater reliability. We have made great progress in achieving international agreement based on available scientific evidence and expert input. Treatments are clearly distinct for different stages/grades/categories of ulcers. The EPUAP-NPUAP guideline was reviewed by 950 stakeholders in 53 countries on 6 of the 7 continents. This broad base of support should give us “pause” before changing the current internationally accepted classification system for pressure ulcers to a full-thickness vs partial thickness dichotomy that is untested.

If the terms NQF proposes were to be used, we do not see how it clarifies communication. In an effort to simplify, the diagnostic labels would be unclear and not drive clinical care. As other nomenclatures have developed and been refined, they become increasingly distinct. For example, right and left sided heart failure was the old categorization where today, heart failure is classified as left ventricular systolic failure and other similar diagnostic labels.

### **Domain 1.2 Measuring Pressure Ulcers**

NPUAP has studied the measurement of pressure ulcers, examining both validity and reliability. NPUAP recommends that pressure ulcers be measured from head to toe, using the longest dimension of the ulcer from head to toe as the length. Width is measured at a 90 degree perpendicular orientation at the ulcers widest area. This method was studied and reported on by Langemo and colleagues in 2008 as the most accurate and reliable measurement method. Important to pressure ulcer measurement is the ability of any instrument to have reliability over time. This important component of measurement is not addressed in the NQF documents at all.

There is evidence that exudate is a marker of healing/nonhealing. This component of the PUSH scale was validated by Stotts (2001). The role of exudate as a marker of healing was also validated by the European Wound Management Association (2005).

NPUAP is in support of photographs as one measure of pressure ulcer status and for comparison to determine if healing is occurring. Material on standardizing photographs has been published by NPUAP.

### **Domain 1.3 Tracking Outcomes and Severity of Pressure Ulcers**

This section of the document is a bit unclear and we will respond here to what we believe the NQF is proposing. NPUAP would be happy to dialogue with the NQF group on this issue if needed. If the data on pressure ulcers changed as NQF is recommending, how would outcome tracking work? If a patient had a “partial thickness” ulcer that became a “full thickness ulcer”, that could be an ulcer going from a stage I or II to a stage III or IV or deep tissue injury or unstageable. There is a huge difference between a stage I becoming a III than becoming an unstageable pressure ulcer!

These paragraphs demonstrate a lack of understanding of the clinical tools that have been developed and validated to “monitor progress... or a lack of progress toward healing”. These include the PUSH tool by

NPUAP and the BWAT by Bates-Jensen. Sonata is also mentioned.... Perhaps the authors are referring to the work of Hiromi Sanada. A comprehensive review of the literature completed for the EPUAP-NPUAP International guidelines revealed much more reliability and validity testing than represented in this document. Both the PUSH Tool and the BWAT have been used in research studies to measure healing and found to be reliable and valid

NPUAP supports the outcome measure of healed stage II pressure ulcers at 30 and 60 days. We believe that it is biologically possible to heal stage II ulcers in that time with proper care. Therefore, we would not see this measure of “healed” versus “not healed” as only an internal measure of quality.

NPUAP supports the idea that other wounds than pressure ulcers should not be measured along the same rubric as pressure ulcers. We would also add to your list arterial ulcers, which are commonly confused with pressure ulcers.

To determine the severity of a pressure ulcer, NQF recommends three factors:

- Size, necrotic tissue, undermining etc

- Multiple pressure ulcers

- Partial vs full thickness, dimensions of largest ulcer

NPUAP recommends that the Pressure Ulcer Scale for Healing (PUSH) be considered for tracking outcomes. The PUSH Tool was developed based on a principal components analysis of existing databases to identify the best model for monitoring healing in pressure ulcers. The model includes length x width, exudate amount and tissue type. Factors such as undermining, tunneling and depth were entered into the model, but did not emerge as principal components of the indicators of pressure ulcer healing. The BWAT provides a comprehensive assessment of the wound; scores are correlated to healing outcomes; and, contrary to the statements in the NQF, the BWAT has been tested in relation to patient outcomes (Bolton et al, 2004). Rather than adding a new metric for measurement, it makes the most sense for obtaining reliable and valid data to use an existing, tested instrument.

Measuring the quality of care in outcomes and severity cannot be based on a single measure of patient data. NPUAP would also recommend adding a quality marker to express likelihood of healing. Such a marker would distinguish those patients in whom healing is impossible from providers who provide substandard care making healing impossible.

#### **Domain 1.4 Public Reporting of Pressure Ulcers**

NPUAP believes that most pressure ulcers are preventable and supports public reporting of pressure ulcer data. The reporting of all pressure ulcer data would be burdensome and prone to misunderstandings by the public. It is NPUAP’s opinion that Stage III, IV and unstageable ulcers be publicly reported. When the diagnosis of deep tissue injury is more reliable, NPUAP will make a determination if DTI should also be reported. NPUAP also supports public reporting of risk stratification, so

that better comprehension of the underlying risk factors for pressure ulcer development can be understood.

### **Domain 2.1 Incidence and Prevalence**

NPUAP supports the collection of both prevalence and incidence at local and national levels. Prevalence data can provide a view of the “burden of pressure ulcers” at a national or local level. We do not support the use of prevalence as a measure of quality because facilities which accept and treat patients with pressure ulcers could be seen as providing substandard care based on “numbers alone”.

NPUAP supports the concept of agency or facility acquired pressure ulcer incidence. Due to the potential for error when the medical record is used as the baseline, we further recommend that the facilities audit these results with “spot checks” to validate the accuracy of the baseline report.

The established definitions for incidence and prevalence provided by the NQF document do little to help clarify the terms. For example, “the event in question” in this document is a pressure ulcer. A recent consensus document (2009) on Pressure Ulcer Prevention: Prevalence and Incidence in Context provides clear definitions and examples of how to compute the numbers. Common errors in determining prevalence and incidence are also discussed. NPUAP has long asked for consistency in measurement so that meaningful comparisons can be made. If the NQF is going to have an opinion on how to measure prevalence and incidence, we hope it can clarify and amplify the work of others.

### **Domain 2.2 Measuring Prevalence and Incidence**

NPUAP supports the concept of beginning the assessment of pressure ulcers upon admission to any facility. This conclusion is premised on the belief that all nurses in all settings can identify and diagnose pressure ulcers and distinguish them from other skin lesions. This is also premised on the belief that at a local system level, root cause analysis and quality improvement projects are currently performed based on the stage of the pressure ulcers. NPUAP does not see a clear method of examining system issues if “partial” and “full thickness” were the only descriptors. Many facilities today are looking into the problem of deep tissue injury and examining the operating room table mattresses, the Emergency Department carts and lengths of stay in these two settings.

We believe that each system should follow their policies on the time frame acceptable for admission assessment. Mandating a specific period of time for admission assessment is impractical; there will be too many legitimate exceptions to it.

### **Domain 2.3 Inclusion and Exclusion Principles**

NPUAP agrees with the exclusion of low risk patients, such as obstetrics and short stay patients. These criteria appear to be clear and logical. However, the recommended exclusion of very high risk patients, such as immobile patients who refuse support surfaces or the malnourished patient who will not be tube-fed creates a huge loop hole in data monitoring. These are the very patients that the hospital will not

receive payment for the pressure ulcer in the new payment system. These are the very patients that we need to understand how to help. The NQF should recognize that these patients also need quality care and strive to improve outcomes in these patients also.

#### **Domain 2.4 Development of Risk Adjustment Models**

NPUAP supports the development of risk adjustment models and believes that all patients should be included in the model, especially the high risk patients discussed in Domain 2.3.

#### **Domain 3.1 Assessment**

NPUAP supports the idea of expecting full assessment of skin at the time of admission. This expectation can be easier said than done however; some patients are extremely low risk such as obstetric patients and outpatients for surgery. Therefore, the broad over-generalized statement needs refinement to those at risk now or who will likely be at risk of pressure ulcers.

We do not know of a “head-to-toe pressure ulcer risk assessment”; head-to-toe assessments are modified physical examinations. The reference to the PUSH tool also seems out of place, since the PUSH tool measures pressure ulcers not pressure ulcer risk. NPUAP does not believe that a rigid time frame for assessment can be mandated, especially to acute care hospitals. Reasonable parameters for assessment of risk will be published in the International Guidelines for Pressure Ulcer Prevention early this summer.

#### **Domain 3.2 Training and Education**

NPUAP supports the concept of training and education. NPUAP has had a published core curriculum for prevention and treatment of pressure ulcers in nursing curricula for over 10 years.

#### **Domain 3.3 Prevention Strategies**

NPUAP supports the principles of pressure ulcer prevention listed in the document. The wording on number 4 is unclear; it states “turn for bed and chair”. Perhaps you meant “turning and/or repositioning schedules”? More specifics for pressure ulcer prevention in usual and unusual patients will be published in the International Guidelines for Pressure Ulcer Prevention early this summer.

#### **Domain 3.4 Care Transitions**

While NPUAP supports the concept NQF relates in the section on transition, we stand on our previous objections to portions of this document. The proposed data set for communication would be largely driven by a standard transfer document to replace document 3008 in current use. We are surprised that such a recommendation is not in this report.

#### **Domain 3.5 Plan of Care**

NPUAP supports the notions detailed in this section but would add many other aspects of planning care, including compliance or likely adherence to the plan, ability to adhere to the plan when considering cost of care, loss of wages, loss of independence, ability to procure needed supplies. The second statement indicates that a “realistic plan of

care be developed” and again, realistic is a complex term for which much more discussion should be included, especially if this care planning would become one of the quality measures.

### **Domain 3.6 Wound Management**

NPUAP agrees with the list of wound management strategies; if it is understood that each and every treatment begins with the patient’s desires. It is unclear how these management strategies will be used as data points in a quality measurement. Phrases such as is written “Careful consideration of medications or therapies that may inhibit wound healing” does not guide care or set a quality measurement. From a clinical perspective, antineoplastics and antiinflammatories are given to control underlying disease and seldom can be or should be adjusted to promote healing. Clinicians often instruct patients that healing will be delayed or that the development of infection may be more difficult to control because of these underlying treatments.

If the wound fails to heal or make progress toward healing in a certain amount of time appears as though it could be a quality measure, however no such language is found in the document. This outcome would be analogous to the measurement of glycated hemoglobin in diabetes.

### **Domain 3.7 Strategies to avoid**

NPUAP in general agrees with the list of “don’ts”, but again we are not clear on how these issues would or could become quality measures. NPUAP will be publishing the new International Guidelines on Pressure Ulcer Treatment which will include research guided interventions on appropriate seat cushion cut-outs for pressure redistribution, sheepskins that do prevent ulcers and gauze based negative pressure therapy.

### **Research Needs**

NPUAP supports the need for research in all domains surrounding pressure ulcers. We find it ironic that the first research need listed in this NQF document is technology to help with pressure ulcer staging, when the NQF wants to eliminate staging.

Thank you for allowing us to comment on the NQF document.

Sincerely,



Laura Edsberg, PhD  
NPUAP, President



Joyce Black, PhD, RN  
Chair, Public Policy