RESEARCH PAPER

The NPUAP Meeting – This was No Consensus Conference

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Abstract The National Pressure Ulcer Advisory Panel (NPUAP) held a Consensus Conference on Pressure Ulcer Staging April 8–9, 2016 in Chicago, Illinois. This was conducted by a moderator and six NPUAP members who were designated as the staging task force. This consisted of 4 nurses, 2 of which were nurse practitioners, one dietician and an individual with a Ph.D. in mechanical and aerospace engineering. Their purpose was “to revise the staging definitions to further clarify and refine the system and develop new nomenclature relevant to pressure related soft tissue injury” (Consensus Conference on Pressure Ulcer Staging, 2016). Many of the changes were not made by consensus but were predetermined by the task force. This includes the following changes. Pressure ulcers are now pressure injuries. The stages are described with Arabic numbers rather than Roman numerals. There are two new pressure categories – medical device related pressure injury and mucosal membrane pressure injury. New artwork has been created to depict the stages. There were changes made to all the stages, but only some of this was by consensus. These revisions were announced by press release on April 13, 2016.

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Many changes to the staging system were made at the National Pressure Ulcer Advisory Panel (NPUAP) Consensus Conference on Pressure Ulcer Staging April 8–9, 2016 in Chicago, Illinois. Approximately 400 were in attendance. Although there was no polling of the audience, the majority appeared to be nurses. Physicians, attorneys, dieticians and industry members were also present. The conference was open to anyone with an interest in attending and lasted 1 ½ days. The planning committee consisted of 10 NPUAP members, 6 of who were designated as the staging task force. The task force was created in January 2015 and was comprised of 4 nurses, 2 of which were nurse practitioners, one dietician and an individual with a Ph.D.

in mechanical and aerospace engineering. Their purpose was to revise “the staging definitions to further clarify and refine the system and develop new nomenclature relevant to pressure related soft tissue injury.”¹ The consensus conference was conducted by a moderator and the task force. In the conference booklet, the planners noted they wanted the conference to encourage new questions, research and improve staging definitions.

The booklet itself consisted only of basic information about the workings of the conference, welcome letter, conference schedule, exhibitor information, and instructions to obtain educational credit. There was no handout of the current staging system or the proposed changes. There were three conference objectives: Discuss rationale for changes in NPUAP staging system; Analyze differences in new NPUAP Stages; Evaluate artwork & photographs with new NPUAP staging system.¹ In the booklet it was noted

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the 10 NPUAP members “listed no financial interest/arrangement or affiliation that would be considered a conflict of interest.”¹ One of the 10 NPUAP members noted a single company that might be viewed as a conflict of interest at the start of the conference.

Although it was advertised as a consensus conference, the NPUAP staging task force decided attendees would not be permitted to give consensus on all parts of the definitions. This was not disclosed to the audience but became apparent as the conference progressed. When questioned, the Co-Chair stated this was acceptable because they were the experts. The accredited provider for the conference confirmed via an email dated May 11, 2016 this was the process. She wrote “The NPUAP Staging Task Force predetermined that not all parts of the definitions were subjected to consensus. All other changes outside of the consensus conference items were unanimously agreed upon by the entire Task Force at a meeting at the end of the 1st day of the conference.”

The task force announced at the beginning of the conference pressure ulcers would now be referred to as pressure injuries. They believed this terminology was less confusing than pressure ulcers. The rationale was the word ulcer denotes an opening in the skin. The skin is intact with stage I pressure ulcers and could be intact with a deep tissue injury. The conference participants had no input regarding the terminology change. Each time a task force member used the word “ulcer” instead of “injury,” they or another task force member placed a quarter in a jar, to signify their mistake.

It is important to note the participants were not allowed to comment on any of the definitions in their entirety. The audience was allowed to give consensus on pre-selected sentences or words, but never the entire definition. Again the task force determined because of their expertise, audience input or acceptance was not necessary. It is crucial to note the significant changes with the pressure definition plus the stages. The previous definitions will be listed first then the new definitions.

Pressure Ulcer/Pressure Injury

First **pressure ulcer** is defined as “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.”² **Pressure injury** is “localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for

pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.”³ Both definitions imply the skin damage starts at the surface and progresses to the bone. Dr. Gregory Bohn stated there is research demonstrating damage occurs from within and not from the surface.⁴⁻⁶ Dr. Caroline Fife noted the staging system does not include the pathophysiology of how pressure ulcers form. She added “Plaintiffs are anxious to link the development of pressure ulcers to elder abuse in order to avoid the cap on punitive damages. It seems highly likely that using the term “injury” will advance the agenda of plaintiffs to equate pressure ulcers with elder abuse.”⁷ Some attorneys who attended the conference and others have questioned the wisdom of using the term “injury.”

Dr. Fife commented “most concerning is a trend toward the criminalization of pressure ulcers. We know of instances in which individuals have been successfully prosecuted for manslaughter in relation to patients who died with pressure ulcers. Because the term “injury” has overtones of intentional harm, using the term “injury” may increase the possibility that pressure ulcer cases could be litigated in the criminal court system.”⁷

It is important to note medical devices are singled out in the new pressure injury definition. One of the attorneys at the conference publicly expressed concern about doing this. Another worry for attendees was the pressure injury definition initially included that the injuries were “typically painful.” This was not up for consensus but after concern from participants that this was not an accurate statement, it was changed to “may be painful.” “Prolonged pressure” was initially used in the definition. This was not up for consensus but some attendees wanted the word “prolonged” deleted as this was not backed by research. The Panel did not comment but the next day the word was deleted. Unfortunately it was replaced with “intense and prolonged pressure.” Scientific evidence does not support this but these words were not up for consensus. The sentence “A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated” was not included in the pressure injury definition. Participants questioned this as they wanted the sentence to remain as part of the definition, but this was not for consensus and the task force did not change their position.

The audience was informed Roman numerals were eliminated from the staging system. Instead Arabic numbers will be used to differentiate the stages so a Stage III will now be a Stage 3. Dr. Fife noted “numbering these categories (no matter how you do it) and calling them “stages” implies progression between the stages, regardless of your efforts to state otherwise, and the drawings of the stages on the website are used in court to demonstrate that all pressure ulcers form from the outside-in and progress from Stage 1–4. Numbering them allows attorneys to successfully make the case that a stage 4 (which occurred

from the inside-out, for example, in a nursing home) actually began with the “stage 2” documented in the hospital, and then progressed “through the numbers.” It is nearly impossible to convince jurors otherwise. Hospitals are paying large sums of money in damages as a direct result of the NPUAP “staging” system.⁷

Stage I Pressure Ulcer/Stage 1 Pressure Injury

The NPUAP defined a **Stage I pressure ulcer** as “intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” individuals (a heralding sign of risk).”² The new definition of a **Stage 1 pressure injury** is “intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.”³ It is interesting to note the task force chose to describe a pressure injury as “typically painful” but in the previous definition a Stage I pressure ulcer was described as “may be painful.” Fortunately the task force did remove the word “typical” from the new pressure injury definition based on audience concern. The sentences “Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” individuals a heralding sign of risk” were not included in the new definition.

Stage II Pressure Ulcer/Stage 2 Pressure Injury

The definition of a **Stage II pressure ulcer** is “partial-thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.* This Category/Stage should not be used to describe skin tears, tape burns perineal dermatitis, maceration or excoriation. *Bruising indicates suspected deep tissue injury.”² Now a **stage 2 pressure injury** is “partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the

pelvis and shear in the heel. This stage should not be used to describe 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).”³ There was no explanation by the task force as to why they deemed it necessary to change “partial-thickness loss of dermis” to “partial-thickness loss of skin with exposed dermis.” It is also interesting to note medical adhesive related skin injury is included in this definition. This is a traumatic wound so why is medical adhesive singled out?

Stage III Pressure Ulcer/Stage 3 Pressure Injury

A **Stage III pressure ulcer** is defined as “full-thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.”² The definition of a **Stage 3 pressure injury** is “full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.”³ The task force stated the occiput, ear and bridge of the nose did not have subcutaneous tissue so could not be classified as a Stage 3 pressure injury. They surmised if a stage 2 pressure injury occurred in any of these areas and deteriorated, it would go from a Stage 2 automatically to a stage 4. Clinicians immediately voiced concern. Several physicians in the audience noted subcutaneous tissue was present in these areas. Other participants used their cell phones to find information and literally showed the task force information from their phones. The task force then eliminated that part of the definition in question. It is not clear why the wording was changed from “full-thickness tissue loss” to “full-thickness skin and tissue loss.”

Stage IV Pressure Ulcer/Stage 4 Pressure Injury

The definition of a **Stage IV pressure ulcer** is “full-thickness tissue loss with exposed bone, tendon or muscle.

Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose ear occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable. A **Stage 4 pressure injury** is defined as “full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.”³

Unstageable Pressure Ulcer/Unstageable Pressure Injury

An **unstageable pressure ulcer** is defined as full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as “the body’s natural (biological) cover” and should not be removed. **Unstageable pressure injury** is “full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be removed.”³

Suspected Deep Tissue Injury/Deep Tissue Pressure Injury

The definition of **suspected deep tissue injury** is a “purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.”² **Deep tissue pressure injury (DTPI)** is defined as “Intact or non-intact skin with localized area of persistent non-blanchable deep red,

maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuro-pathic, or dermatologic conditions.”³ Initially, the definition of deep tissue pressure injury (DTPI) included the description “great and prolonged pressure.” This was not up for consensus. The task force stated this described DTPI only. There was concern from the audience that the word “prolonged” was in the pressure injury definition as well even though the task force stated it was meant only to describe DTPI. The task force gave no explanation. There continued to be concern regarding these descriptors even though the audience was not allowed to have consensus on these terms. The next day the definition of DTPI reflected the change to “intense and prolonged pressure.” Again this was not up for consensus. Some participants wanted the sentence “Evolution may be rapid exposing additional layers of tissue even with optimal treatment” to remain in the definition. This was not up for consensus and the task force deleted it. Interestingly the task force wanted consensus on where to place DTPI in the staging system. All agreed the staging system was not a linear progression but the task force deemed it necessary to place it. The choices included placing it before stage 1, after stage 1 or after unstageable. The task force stated on the NPUAP website it was currently placed before stage 1. A conference participant corrected them and stated it actually was listed after unstageable. The task force acknowledged the participant was correct and consensus was reached the DTPI would be placed after unstageable.

Medical Device Related Pressure Injury and Mucosal Membrane Pressure Injury

The conference attendees were informed the staging task force created two new pressure injury definitions – medical device related pressure injury and mucosal membrane pressure injury. **Medical device related pressure injury** “result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.”³ It is important to remember an attorney had expressed concern that medical devices were specifically named in the pressure injury definition. The audience learned there was now a specific category for skin breakdown related to

a medical device. Participants questioned whether a wheelchair cushion or mattress would be considered a medical device. If so, if the patient had unstageable skin breakdown would it be classified as an unstageable pressure injury or a medical device pressure injury? Clarification of how to classify it was not evident.

Mucosal membrane pressure injury “is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these ulcers cannot be staged.”³ The audience agreed with the staging task force that mucosal injuries could not be staged with the present staging system due to anatomical differences in the tissue. In the long term care setting, oral mucosal injuries are classified as abnormal mouth tissue. This is documented in the Minimum Data Set (MDS) which is a clinical assessment tool completed on residents in long term care. The oral mucosal ulcers are not documented in the skin section nor reported as pressure ulcers.⁸

The task force was asked to consult legal and CMS (Centers for Medicare and Medicaid Services) experts before finalizing any changes to the staging system. They replied there was no need to discuss legal implications as the staging system was a clinical matter. It is ironic the task force was not concerned about the legal implications of the new staging system yet legal concerns regarding the conference itself were addressed on page 4 of the conference booklet. It read as follows: “The information presented herein is provided for educational and informational purposes only. It is for the attendees’ general knowledge and is not a substitute for legal or medical advice. Although every effort has been made to provide accurate information herein, laws change frequently and vary from state to state. The material provided herein is not comprehensive for all legal and medical developments and may contain errors or omissions. If you need advice regarding a specific medical or legal situation, please consult a medical or legal professional. The National Pressure Ulcer Advisory Panel shall not be liable for any errors or omissions in this information.”¹ Only basic information was included in the booklet. The other irony is NPUAP members work with attorneys and a significant amount of work is for plaintiff attorneys. It seems obvious it would be necessary to disclose this relationship to conference participants; however, in an email dated May 11, 2016, the accredited provider for the conference stated this information did not need to be disclosed to the audience.

During the last part of the conference, the audience was shown approximately 32 wound photographs with a brief history. The intent was to determine how the attendees would stage the wounds. Approximately 318 people participated in this. The following are examples of some of these case studies. One picture was of a sacral scar with a wound located within the scar. 57% of the audience thought it was a stage 4, 19% thought a stage 2 and 22% did not think it was a pressure ulcer. Another example was an ischial wound. 71% determined it was a stage 2, 23% said stage 3 and 5% stated it was not a pressure ulcer. A necrotic neck wound

was classified by 63% as a medical device injury. 34% stated it was unstageable and 3% determined it was not a pressure ulcer. A superficial wound on the inner buttocks was classified as a stage 2 by 73% and 22% stated it was not a pressure ulcer. 80% of the audience then classified a sacral wound case study as a deep tissue injury. 12% said it was a stage 3. The task force informed the participants it was a stage 3! A photograph of a chest wall wound was determined to be stage 2 by 42%. 47% stated it was a medical device injury while the task force stated it was a stage 2 injury. Necrotic tissue under a tracheostomy tie was classified as a medical device injury by 74% and 23% said it was unstageable. 3% of the audience did not believe this was a pressure ulcer. Another picture was an open wound of the penile shaft with a foley catheter in place. 54% of the audience classified it as a medical device pressure injury. 43% said it was a mucosal pressure injury. A linear non-blanchable area of erythema was noted on the buttocks when transferring a patient. 80% thought it was a stage 1 while 10% did not think it was related to pressure. A tracheostomy tube appeared to have caused an open area on a tongue. 78% classified it as a mucosal pressure injury while 19% classified it as a medical device pressure injury. A wheelchair bound multiple sclerosis patient was noted to have thickened skin with open areas. It was noted she used slide transfers to get in and out of the wheelchair. 42% thought the wounds were stage 2, 46% thought it was not a pressure ulcer, 6% thought it was a medical device pressure injury and 4% said deep tissue pressure injury. A sacral ulcer was classified a stage 3 by 62% of the audience. 20% thought it was a stage 2 and 18% said it was a stage 4. The task force classified it as a stage 2. Another patient with diabetes and peripheral arterial disease had a heel ulcer. 92% stated it was a stage 4 and 7% determined it was not a pressure ulcer. There was no mention this ulcer could have been the result of diabetes and arterial disease. These examples demonstrate the confusion with the staging system and lack of inter-rater reliability. The clinician now has a choice of 8 categories – stage 1, stage 2, stage 3, stage 4, unstageable, deep tissue pressure injury, medical device related pressure injury and mucosal membrane pressure injury. It appears a system with 8 categories may confuse even an experienced clinician.

Concerns about the staging system are not new. In 2010 a 14 member international panel convened (Shifting the Original Paradigm Expert Panel) to look at the staging system as well as the cause of pressure ulcers. This group determined the staging system was problematic for the regulatory, clinical, economic and legal communities. They noted that having a system with stages implied the stages were progressive and that this simply was not true. In addition the panel stated “because there are problems with both validity and reliability of current classification systems, clinical practice guidelines and protocols based on these classification systems should not be considered the legal standard of care.”⁹ This was a distinguished interprofessional group.

It is important to note essentially 6 people have changed the pressure ulcer staging system. They were asked to consult with CMS and legal experts before announcing any changes to the public. The conference ended Saturday, April 9, 2016 and the changes were announced April 13, 2016. There was little time to do this. Long term care facilities use the MDS to assess residents. This form does not work with the proposed changes. Dr. Fife noted “because the terminology of the pressure ulcer ICD-10 diagnosis codes remain unchanged, using the term “injury” in referring to pressure ulcers in a patient’s medical record will confound billing and coding functions.”⁷

It appears the NPUAP’s staging system revisions have been made in haste. Thousands, perhaps millions of health care dollars and man hours should not be wasted on these changes. A true consensus among interprofessional leaders is needed to consider what is next and what is best for all disciplines. Until such time, the revisions need to be placed on hold or rescinded.

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