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[CMS Contract No. HHSM-500-2008-00021I  
RTI Project Number: 0211942.200.003.003]

**DATE:** January 10, 2014

**SUBJECT:** Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-up Webinar

## Executive Summary

In an effort to align with the key priority of quality measure “alignment and harmonization” identified in the Centers for Medicare & Medicaid Services (CMS) Measures Management System Version 10.0,<sup>1</sup> CMS tasked RTI International to study the feasibility of, challenges in, and opportunities for developing a cross-setting pressure ulcer quality measure that can be harmonized for use across healthcare settings. As a starting point for measure development, CMS charged RTI to explore the feasibility of further developing and expanding the National Quality Forum (NQF) endorsed measure NQF #0678, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay), to additional healthcare settings.

One of a variety of approaches that RTI and CMS used to identify strengths, weaknesses, and areas for further development of NQF #0678 was for RTI to convene a Technical Expert Panel (TEP). The TEP met on June 13, 2013, and provided detailed input regarding the further development and possible expansion of NQF #0678. At the conclusion of this meeting, RTI and CMS identified eight topics for which outstanding questions remained, or for which the TEP was unable to reach a consensus during the meeting. Subsequently, RTI contacted TEP members to seek their input to help prioritize these topics for discussion. With this input from the TEP and under CMS direction, RTI selected five topics for further discussion. RTI reconvened the TEP for a follow-up meeting on November 15, 2013, to allow for in-depth discussion of these five topics.

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<sup>1</sup> Centers for Medicare & Medicaid Services. (2013, September). *A blueprint for the CMS Measures Management System (version 10.0)*. Available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>.

**Table 1** summarizes the key points made by one or more of the TEP member during this meeting. Further, it includes RTI’s recommendations based on both TEP feedback and all work completed to date (October 1, 2012–December 20, 2013) toward the development of a cross-setting quality measure for pressure ulcers.

Table 1. Summary of Follow-up TEP Meeting Findings and Recommendations

Key Points Made By the TEP on November 15, 2013	RTI Recommendations
<b>Unstageable Pressure Ulcers and Suspected Deep Tissue Injuries</b>	
<ul style="list-style-type: none"> <li>• New Suspected Deep Tissue Injuries (sDTIs) and Unstageable Pressure Ulcers should be recorded and counted separately in the quality measure for pressure ulcers.</li> <li>• If a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar it should be considered worsened in the quality measure for pressure ulcers.</li> <li>• Based on the currently available empirical evidence, it is not possible to assign a stage to sDTIs. It is important to continue to monitor the literature regarding the staging and etiology sDTIs.</li> </ul>	<ul style="list-style-type: none"> <li>• Consider including new unstageable pressure ulcers and sDTIs (reported separately) in the quality measure.</li> <li>• If a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar, consider including this as a worsened pressure ulcer.</li> <li>• Do not assign sDTIs a stage. Continue to monitor literature regarding the staging and etiology of sDTIs.</li> </ul>
<b>Inclusion of Pressure Ulcer Healing in a Quality Measure</b>	
<ul style="list-style-type: none"> <li>• “Healed” and “Healing” are different concepts and should be reported separately in the quality measure for pressure ulcers.</li> <li>• Although “healing” is an important concept, it creates too great a data collection burden to implement as part of a quality measure at this time.               <ul style="list-style-type: none"> <li>– A “healing” measure would require CMS to track each individual pressure ulcer separately, which the TEP advised against at the June 13, 2013 meeting.</li> </ul> </li> <li>• CMS should consider developing a quality measure to assess “healed” pressure ulcers as a higher priority and retain “healing” pressure ulcer as a concept for future development.</li> <li>• The definition of “healed” pressure ulcers should include all possible indicators of “healed” ulcers (e.g., scar tissue formation, surgical closure, epithelialized).</li> <li>• For public reporting purposes, it is important to define the word “healed.”</li> <li>• The Bates Jensen Wound Assessment Tool (BWAT) is more comprehensive than the Pressure Ulcer Scale for Healing (PUSH) Tool.</li> </ul>	<ul style="list-style-type: none"> <li>• Consider developing a quality measure for healed pressure ulcers.               <ul style="list-style-type: none"> <li>– Ensure that the definition of “healed” pressure ulcer includes all possible indicators of “healed” ulcers (e.g., scar tissue formation, epithelialized, surgical closure).</li> <li>– For public reporting purposes (when CMS integrates “healed” into the pressure ulcer measure), CMS needs to ensure that the word “healed” is clearly defined.</li> </ul> </li> </ul>

(continued)

Table 1. Summary of Follow-up TEP Meeting Findings and Recommendations  
(continued)

Key Points Made By the TEP on November 15, 2013	RTI Recommendations
<b>Inclusion or Exclusion of Stage 1 Pressure Ulcers</b>	
<ul style="list-style-type: none"> <li>• The majority of TEP members did not support the inclusion of Stage 1 pressure ulcers in the quality measure at the June 13, 2013 TEP meeting.</li> <li>• One TEP member strongly recommends inclusion of Stage 1 pressure ulcers in the quality measure.</li> <li>• At the time of the TEP meeting, there was no additional feedback from other TEP members</li> </ul>	<ul style="list-style-type: none"> <li>• Continue to monitor literature regarding the reliability of assessing Stage 1 pressure ulcers and the use of Stage 1 pressure ulcers as an indicator of quality.</li> </ul>
<b>Malnutrition as a Risk Factor for Pressure Ulcers &amp; Indicators of Malnutrition</b>	
<ul style="list-style-type: none"> <li>• One TEP member stated the importance of the joint consensus statement by the Academy of Nutrition and Dietetics (the Academy) and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). They recommend the identification of <i>two or more</i> of six characteristics to assess malnutrition status: insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, localized or generalized fluid accumulation that may sometimes mask weight loss, and diminished functional status as measured by hand grip strength.</li> <li>• All TEP members agreed that unintended weight loss is a valid indicator of malnutrition.</li> <li>• Functional status (for example, hand grip strength, as noted above) is also a valuable indicator of malnutrition.</li> <li>• The TEP does not consider BMI a reliable indicator of malnutrition.</li> </ul>	<ul style="list-style-type: none"> <li>• Continue to monitor literature regarding indicators of malnutrition. <ul style="list-style-type: none"> <li>○ Further explore the recommendation to include two indicators of malnutrition in the quality measure, as suggested by the Academy and A.S.P.E.N.</li> <li>○ Further explore the recommendations to add unintended weight loss and decline in functional status as indicators for malnutrition.</li> </ul> </li> <li>• Continue to assess and discuss the reliability of low BMI as an indicator for malnutrition.</li> </ul>
<b>Exclusion Criterion: Patients or Residents at the End of Life</b>	
<ul style="list-style-type: none"> <li>• The TEP did not have time to discuss this topic. Two TEP members provided written responses to the end-of-life discussion questions.</li> <li>• Indicators of end of life recommended by these TEP members include hospice care/palliative care; Do Not Resuscitate status; withdrawal of life support; unstable, multiple organ failure; and failure to thrive.</li> </ul>	<ul style="list-style-type: none"> <li>• Continue to monitor literature and explore TEP and NPUAP input to evaluate whether patients or residents at the end-of- life should be excluded from the quality measure. (In the current measure, exclusion of assessments that occur at the time of death, likely does not reliably capture end-of-life patients or residents.)</li> </ul>

## Introduction

In the Blueprint for the Centers for Medicare & Medicaid Services (CMS) Measures Management System Version 10.0, CMS identifies “alignment and harmonization” as one of the key priorities for quality measure development.<sup>2</sup> In accordance with this priority, CMS tasked RTI International to study the feasibility of, challenges in, and opportunities for developing a cross-setting pressure ulcer quality measure that can be harmonized for use across healthcare settings. As a starting point for measure development, and in effort to align with the CMS and NQF<sup>3</sup> goals of measure harmonization, CMS requested that RTI explore the feasibility of further developing and expanding NQF #0678, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay).

RTI used a variety of approaches to identify strengths, weaknesses, and areas for refinement for NQF #0678, including an environmental scan of commentary received from experts and stakeholders regarding NQF #0678, a series of interviews, a review of quality measures for pressure ulcers, and a Technical Expert Panel (TEP). The findings from this work are available in the OY2: Information Gathering Final Report.<sup>4</sup>

The TEP met on June 13, 2013, and provided detailed input regarding the further development and possible expansion of NQF #0678. At the conclusion of the TEP meeting, RTI and CMS identified eight topics for which outstanding questions remained, or for which the TEP was unable to reach a consensus (see **Table 2** for a list of topics identified). RTI reconvened the TEP for a follow-up meeting on November 15, 2013, to allow for more in-depth discussion of these topics. This memo summarizes the results of the follow-up meeting. The conclusions will be used, in conjunction with findings stated in the OY2 final report, to inform next steps for quality measure development.

## Methods

The follow-up meeting was held via webinar on November 15, 2013, from 2:00 pm to 4:00 pm, Eastern Standard Time. Ten of the 12 TEP members attended this meeting. See **Appendix A** for

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<sup>2</sup> Centers for Medicare & Medicaid Services. (2013, September). *A blueprint for the CMS Measures Management System (version 10.0)*. Available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>.

<sup>3</sup> National Quality Forum. (2008, April). *National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers*. Available from [http://www.qualityforum.org/Projects/Pressure\\_Ulcers.aspx](http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx).

<sup>4</sup> Schwartz, M., Nguyen, K., Swinson, T., Thaker, S., & Bernard, S. (2013, October). *Development of a cross-setting quality measure for pressure ulcers, OY2: Information gathering*. Final report prepared for the Centers for Medicare & Medicaid Services. Research Triangle Park, NC: RTI International.

a list of all TEP members and meeting attendees. The two TEP members who were unable to attend were invited to submit written feedback to the discussion questions addressed during the meeting. RTI polled TEP members via e-mail to request their individual input to prioritize the eight topics for which outstanding questions remained. Nine (of 12) TEP members provided responses indicating their priorities. The items included in the poll and the results of TEP member input are displayed in **Table 2**.

Table 2. TEP Member Priority Rankings—(Low Number = High Ranking) (N=9)

TEP Member	Inclusion of Unstageable Pressure Ulcers	Inclusion of Deep Tissue Injuries	Inclusion or Exclusion of Stage 1 Pressure Ulcers	Inclusion of Pressure Ulcer Healing in a Quality Measure for Pressure Ulcers	Exclusion of Patients or Residents at the End of Life	Other Specific Exclusions	Malnutrition as a Risk Factor/ Indicator of Malnutrition	Other Specific Risk-Adjustment Variables
ABC	4	3	2	1	5		6	
DEF	1	1	1	5	1		5	
GHI	5	2	6	1	4		3	
JKL	2	1	6	4	3		5	
MNO	3	2	5	1	6		4	
PQR	1	2	3	5	6		4	
STU	3	4	7	2	5			1
VWX	5	8	2	6	1	3	7	4
YZ	1	2	6	4	5		3	
<b>Mean</b>	<b>2.8</b>	<b>2.8</b>	<b>4.2</b>	<b>3.2</b>	<b>4.0</b>	<b>3.0</b>	<b>4.6</b>	<b>2.5</b>
<b>Mode</b>	<b>1</b>	<b>2</b>	<b>6</b>	<b>1</b>	<b>5</b>	<b>N/A</b>	<b>5</b>	<b>N/A</b>

\* Each TEP member ranked the eight topics, from 1 (indicating the most important) to 8 (indicating the least important). The lower the score, the higher the importance, as ranked by the TEP members. Similarly, lower mean and lower mode indicate higher importance for the topic as indicated across all nine TEP members.

RTI considered both TEP member and CMS priorities to identify the final agenda items for discussion. The final agenda included the following topics:

- Unstageable Pressure Ulcers and Suspected Deep Tissue Injuries
- Inclusion of Pressure Ulcer Healing in a Quality Measure for Pressure Ulcers
- Inclusion/Exclusion of Stage 1 Pressure Ulcers
- Malnutrition as a Risk Factor for Pressure Ulcers & Indicators of Malnutrition

- Exclusion Criterion: Patients or Residents at the End of Life

Prior to the meeting, TEP members were provided with an agenda and a description of quality measure NQF #0678. In addition, TEP members were provided with the following:

- The executive summary from RTI's final report summarizing the work completed during October 2012–September 2013<sup>4</sup>
- Summaries of two focused literature scans conducted by RTI:
  - *Malnutrition and Pressure Ulcers (Appendix B)*: A review of the literature related to malnutrition as a risk factor for pressure ulcers and appropriate indicators for malnutrition.
  - *Stage 1 Pressure Ulcers (Appendix C)*: A review of the literature related to the reliability of assessing Stage 1 pressure ulcers and the use of Stage 1 pressure ulcers as a quality indicator.
- Discussion Questions (*Appendix D*)
- Links to Pressure Ulcer Healing Tools:
  - Pressure Ulcer Scale for Healing (PUSH) Tool:  
<http://www.npuap.org/resources/educational-and-clinical-resources/push-tool/>
  - Bates-Jensen Wound Assessment Tool (BWAT):  
[http://www.geronet.med.ucla.edu/centers/borun/modules/Pressure\\_ulcer\\_prevention/puBWAT.pdf](http://www.geronet.med.ucla.edu/centers/borun/modules/Pressure_ulcer_prevention/puBWAT.pdf)

The meeting was organized to facilitate in-depth discussions of each agenda item. During the meeting, the RTI cross-setting pressure ulcer project lead provided a brief summary of conclusions from the June 13, 2013, TEP meeting, and asked questions regarding NQF #0678, pressure ulcer assessment, and quality measurement. A PDF version of the PowerPoint slide deck used during the meeting is provided in a separate attachment, along with this memo. Data for this TEP report came from meeting transcripts and notes.

On the day of the TEP meeting, several TEP members shared articles with RTI, which they felt would support one or more of the arguments made during the TEP meeting or would help RTI, CMS, and TEP members to further their understanding of specific issues. RTI reviewed these articles and integrated them into this memo. RTI also distributed these articles to all TEP members after the meeting.

Below, we list the key points made by TEP members, followed by a summary of the discussion around each of the five agenda items. The memo concludes with RTI's recommendations regarding future work and next steps for development of the quality measure.

## **Key Points Made by TEP**

### *Unstageable Pressure Ulcers and Suspected Deep Tissue Injuries*

- New Suspected Deep Tissue Injuries (sDTIs) and Unstageable Pressure Ulcers should be recorded and counted separately in the quality measure.
- If a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar it should be considered worsened in the quality measure for pressure ulcers.
- Based on the currently available empirical evidence, it is not possible to assign a stage to sDTIs. It is important to continue to monitor the literature regarding the staging and etiology sDTIs.

### *Inclusion of Pressure Ulcer Healing in a Quality Measure*

- “Healed” and “Healing” are different concepts and should be reported separately in the quality measure for pressure ulcers.
- Although “healing” is an important concept, it creates too great a data collection burden to implement as part of a quality measure at this time.
- CMS should consider developing a quality measure to assess healed pressure ulcers as a higher priority and retain “healing” pressure ulcer as a concept for future development.
- The definition of “healed” pressure ulcers should include all possible indicators of healed ulcers (e.g., scar tissue formation, surgical closure, epithelialized).
- For public reporting purposes, it is important to define the word “healed.”
- The Bates Jensen Wound Assessment Tool (BWAT) is more comprehensive than the Pressure Ulcer Scale for Healing (PUSH) Tool.

### *Inclusion or Exclusion of Stage 1 Pressure Ulcers*

- The majority of TEP members do not support the inclusion of Stage 1 pressure ulcers in the quality measure.
- One TEP member strongly recommends inclusion of Stage 1 pressure ulcers in the quality measure.

### *Malnutrition as a Risk Factor for Pressure Ulcers & Indicators of Malnutrition*

- One TEP member stated the importance of reviewing the joint consensus statement by the Academy of Nutrition and Dietetics (the Academy) and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). In their statement the Academy and A.S.P.E.N recommend the identification of *two or more* of the following six characteristics to assess malnutrition status: insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, localized or generalized fluid accumulation that may sometimes mask weight loss, and diminished functional status as measured by hand grip strength.

- All TEP members agreed that unintended weight loss is a valid indicator of malnutrition. One TEP member expressed that this would be the best indicator, if only one indicator is to be selected.
- Functional status (using an indicator such as hand grip strength) is also a valuable indicator of malnutrition.
- The TEP does not consider BMI to be a reliable indicator of malnutrition.

*Exclusion Criterion: Patients or Residents at the End of Life*

- The TEP did not have time to discuss this topic. Two TEP members provided written responses to the discussion questions regarding end of life.
- Indicators of end of life recommended by these two TEP members include hospice care/palliative care; Do Not Resuscitate status; withdrawal of life support; unstable, multiple organ failure; and failure to thrive.

## Discussion

### **Inclusion of Unstageable Pressure Ulcers and Suspected Deep Tissue Injuries**

*Recommendations from June 13, 2013, Meeting*

- Both new unstageable ulcers and new sDTIs should be counted in the quality measure.
- Based on the currently available empirical evidence, it is not possible to assign a stage to sDTIs.

*Discussion at November 15, 2013, Meeting*

The TEP engaged in a lengthy discussion regarding the inclusion of unstageable pressure ulcers and sDTIs in a quality measure for pressure ulcers, and confirmed their recommendation that new unstageable pressure ulcers<sup>5</sup> and sDTIs<sup>6</sup> should be counted in the quality measure.. However, they stressed the importance of recording each separately, rather than bunching them together, because they are very different clinical concepts. The TEP also reconfirmed that at this time sDTIs should not be assigned a stage, as scientific literature remains inconclusive regarding their etiology and stage. Several TEP members referenced both personal experience and empirical evidence that suggests that sDTIs are not always full-thickness wounds and should not automatically be

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<sup>5</sup> According to input from a pressure ulcer subject matter expert (consulting for RTI International) a “new” unstageable pressure ulcer is not always a reason for concern. A Stage 3 pressure ulcer may cover with slough and be debrided, and still remain a Stage 3 pressure ulcer, but would be coded as unstageable. In this instance it is not clear what capturing the “new” unstageable pressure ulcer would provide to CMS. Since CMS does not track pressure ulcers individually, there would be no way to tease these instances out from newly acquired unstageable pressure ulcers.

<sup>6</sup> According to input from a pressure ulcer subject matter expert (consulting for RTI International), according to the MDS 3.0 Frequency Report posted on CMS’ website, on average 91% of facilities report no sDTI in the facility and only 6% report at least one sDTI. This may not indicate enough of a concern to include sDTIs in a quality measure. The expert recommends CMS consider tracking sDTIs on the back end, and re-assessing their impact at a later date.

considered Stage 3 or 4 pressure ulcers. One TEP member specifically referenced a 2-year retrospective review of the evolution of 128 sDTIs, published in September 2013.<sup>7</sup> Sullivan found that only 12% of the sDTIs developed into full-thickness wounds, and 66% were completely resolved at the end of the study and never went on to become Stage 3 or 4 pressure ulcers.<sup>4</sup>

All TEP members agreed that a Stage 1 or 2 pressure ulcer that becomes unstageable due to slough or eschar should be considered worsening. Two TEP members expressed concerns regarding this statement. One TEP member mentioned upcoming findings refuting the National Pressure Ulcer Advisory Panel's notion that any slough makes a pressure ulcer higher than a Stage 2, and stated that slough may not indicate dead tissue<sup>8</sup>. The other TEP member suggested that some providers may confuse biofilm with slough and highlighted the importance of training providers regarding the difference. Both were ultimately comfortable with the statement above; however, they, along with the other TEP members, felt it is very important to continue to follow the upcoming research regarding both sDTIs and slough.

One TEP member also shared the results of a study that indicates a recent increase in the identification of sDTIs and identifies several differences in the risk factors for and outcomes from sDTIs, compared to pressure ulcers. This improved identification and knowledge of sDTIs, is likely due to improved education. The researchers stressed the importance of continued research and the need for a better understanding of the sDTIs including etiology, prevention, and treatment.<sup>9</sup> Although the TEP is currently in favor of including sDTIs in the quality measure, these findings further support the importance of continuing to monitor future literature regarding sDTIs and continuing to assess the quality measure.

### **Inclusion of Pressure Ulcer Healing in a Quality Measure**

#### *Recommendations from June 13, 2013, TEP Meeting*

- Either include healed ulcers in the quality measure, or develop a second measure that reflects provider success in healing pressure ulcers.
- It is important to consider burden when selecting a measurement tool for healing.

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<sup>7</sup> Sullivan, R. (2013). A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients. *Ostomy Wound Management*, 59(9), 30-39.

<sup>8</sup> According to input from a pressure ulcer subject matter expert (consulting for RTI International), every available definition of slough refers to "dead" or "non-viable" tissue. Slough is made up of proteins, and carbon, but is essentially non-viable and cannot be turned into good tissue. Once debrided slough usually yields additional tissue loss beyond the dermis. The subject matter expert states that assessors will not have the ability to distinguish "good slough" from "bad slough" and it is better to have "any slough" as a distinguishing marker, than not.

<sup>9</sup> VanGilder, C., MacFarlane, G. D., Harrison, P., Lachenbruch, C., & Meyer, S. (2010). The demographics of suspected deep tissue injury in the United States: An analysis of the International Pressure Ulcer Prevalence Survey 2006-2009. *Advanced Skin Wound Care*, 23(6), 254-261.

- A healing tool should be applicable across settings, completed at discharge, and sensitive enough to detect small changes in ulcers. The PUSH tool is not sensitive enough.

*Discussion at November 15, 2013, Meeting*

In regard to pressure ulcer healing, the TEP stressed the difference between the concepts of “healed” and “healing” pressure ulcers. TEP members stated that the two concepts are not the same and should be measured and reported separately. All of the TEP members felt it was important to measure pressure ulcer “healing,” especially in those facilities where patients are not admitted for enough time to fully heal pressure ulcers. However, as they stated at the June TEP meeting, assessing pressure ulcer “healing” would create a significant data collection burden for both healthcare facilities and CMS, because several data points would need to be tracked individually for each pressure ulcer. The TEP suggested that the concept of “healed” pressure ulcers would be less complex to operationalize and that CMS should consider first developing a measure of “healed” pressure ulcers, while keeping “healing” pressure ulcer as a concept for future development.<sup>10</sup>

Although all TEP members were comfortable with the development of a quality measure to assess “healed” pressure ulcers, they felt it was critical to remember that the length of stay and patient population varies significantly across facilities; thus, it is important to ensure that healthcare facilities are only compared to other facilities of the same type (e.g., long-term care hospitals [LTCHs] should only be compared to other LTCHs).

The TEP also discussed the definition of “healed” and stated that it is important that “healed” not be defined using only the term “epithelialized.” Some pressure ulcers close by scar formation<sup>11</sup> and others undergo surgical closure and are reclassified as surgical wounds. A measure of “healed” pressure ulcers should include all indicators of “healed” ulcers. One TEP member suggested that patients and family members may not understand that the word “healed” means the wound is closed, but that healing may still be occurring internally and the patient may still

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<sup>10</sup> A pressure ulcer subject matter expert (consulting for RTI International), suggests that creating a quality measure for “healed” pressure ulcers would not be valuable for CMS. The subject matter expert explains that the MDS 3.0 includes an item that captures healed pressure ulcers from assessment to assessment, and CMS already tracks “healed” pressure ulcer outside of a quality measure. However, it is unclear what an increase or decrease in the number of healed pressure would indicate regarding quality. The subject matter expert notes that facilities are welcome to report the results of NQF #0678, by stating the percent of residents or patients that do *not* have new or worsened pressure ulcers and are also welcome to provide a count of healed pressures.

<sup>11</sup> According to input from a pressure ulcer subject matter expert (consulting for RTI International), “In wounds that are partial thickness, involving only the epidermis and superficial dermis, epithelialization is the predominant method by which healing occurs. Wound contracture is not a common component of this process if only the epidermis or epidermis and superficial dermis are involved. Wound contraction and scar formation usually occur in larger wounds that involve full thickness tissue loss, but either way, epithelial cells still cover the wound.”

experience discomfort resulting from his or her closed wounds. The TEP concluded that the word “healed” should be accompanied by a clear definition for public reporting.

In regard to measuring pressure ulcer “healing,” TEP members agreed that the BWAT is more comprehensive than the PUSH Tool. Several TEP members shared that in their facilities all nurses are trained and held accountable for assessing wounds using BWAT, BWAT is integrated into their electronic health record, and they consider BWAT to be part of minimum nursing education. However, one TEP member pointed out that in many healthcare facilities nurses are not educated on, or held accountable for, the BWAT<sup>12</sup>, and that in long-term care settings Licensed Practical Nurses frequently replace Registered Nurses and are often not held responsible for assessments. If CMS develops a cross-setting “healing” pressure ulcer measure in the future, it will need to consider how to make sure the measure is achievable in all settings.

After the meeting, one TEP member directed RTI to two published studies about the development of wound healing indexes. In one, researchers developed a comprehensive stratification system for patients with wounds that predicts healing likelihood.<sup>13</sup> In the other, researchers conducted a systematic review of the literature related to healing measurement tools and developed a scale for measuring progress toward healing for chronic wounds.<sup>14</sup> Both of these articles will be valuable in the future, if CMS begins to more seriously consider the development of a quality measure of pressure ulcer “healing”.

### **Inclusion or Exclusion of Stage 1 Pressure Ulcers**

*Recommendations from June 13, 2013, TEP:*

- The TEP did not reach a conclusion regarding whether Stage 1 pressure ulcers should be included in the quality measure.

*Discussion at November 15, 2013, Meeting*

During the follow-up meeting one TEP member continued to feel very strongly that Stage 1 pressure ulcers should be included in a quality measure for pressure ulcers and shared that current recent research indicates reliability in assessing Stage 1 pressure ulcers<sup>15</sup>. This TEP member specifically cited several studies regarding Stage 1 pressure ulcers, and shared several

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<sup>12</sup> Note that the use of a particular tool to assess pressure ulcers is up to the discretion of the facility. CMS does not specifically tell facilities what types of tools they must use in their assessment documentation practices.

<sup>13</sup> Horn, S. D., Fife, C. E., Smout, R. J., Barrett, R. S., & Thomson, B. (2013). Development of a wound healing index for patients with chronic wounds. *Wound Repair and Regeneration*, Oct 17.

<sup>14</sup> Medrano, J. C., & Soriano, J. V. (2012). Development of a wound healing index for chronic wounds. *EWMA Journal*, 12( 2), 39-46.

<sup>15</sup> A pressure ulcer subject matter expert (under contract with RTI International), reports that based on the current literature, if an individual develops a Stage 1 pressure ulcer, there is not a guarantee that it will get worse. The expert indicates that it is important to ask how quality would be improved if Stage 1 ulcers are reported, and that at this time the literature does not indicate that Stage 1 pressure ulcers should be included in the quality measure.

articles with the group after the TEP meeting. One study she referenced used the National Database of Nursing Home Quality Indicators to demonstrate consistent reporting of all pressure ulcers over time.<sup>16</sup> Another demonstrated reliability in assessing pressure ulcers across all stages (including Stage 1).<sup>17</sup> The TEP member shared that a secondary analysis of the data (conducted outside of the published results) suggested that Stage 3 (not Stage 1) pressure ulcers were the least reliably assessed. Finally, the TEP member referenced a study conducted in the long-term care setting. The study challenges the assertion (often made by experts) that non-pressure related wounds are often falsely identified as Stage 1 pressure ulcers. The researchers found that that wounds identified as Stage 1 pressure ulcers are indeed related to pressure, and suggest that Stage 1 pressure ulcers are thus reliably identified and would be a valuable indicator of quality.

At the time of the TEP meeting, there was no additional feedback from other TEP members.

### **Malnutrition as a Risk Factor for Pressure Ulcers & Indicators of Malnutrition**

#### *Recommendations from June 13, 2013, Meeting*

- The TEP recommended inclusion of malnutrition as a risk factor for pressure ulcers.
- There was a lack of consensus regarding indicator(s) of malnutrition.

#### *Discussion at November 15, 2013, Meeting*

During the follow-up meeting the TEP focused on identifying the appropriate indicators for malnutrition to use in the quality measure. One TEP member directed the group to the joint consensus statement from the Academy and A.S.P.E.N.<sup>18</sup> and stressed that this is the first time these groups have provided concrete guidelines for indicators of malnutrition<sup>19</sup>, and that they should be taken seriously. In their statement the Academy and A.S.P.E.N recommend the identification of *two or more* of the following six characteristics to make a diagnosis of malnutrition: insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, localized or generalized fluid accumulation that may sometimes mask weight loss, and diminished functional status as measured by hand grip strength.

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<sup>16</sup> Piepar, B. (ed.) with the National Pressure Ulcer Advisory Panel (NPUAP). (2012). *Pressure ulcers: Prevalence, incidence, and implications for the future*. Washington, DC: NPUAP.

<sup>17</sup> Bergquist-Beringer, S., Gajewski, B., Dunton, N., & Klaus, S. (2011). The reliability of the National Database of Nursing Quality Indicators pressure ulcer indicator: A triangulation approach. *Journal of Nursing Care Quality*, 26(4), 292-301.

<sup>18</sup> White, J. V., Guenter, P., Jensen, G. L., Malone, A., & Schofield, M. (2012). Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics recommended for the identification and documentation of adult malnutrition. *Journal of the Academy of Nutrition and Dietetics*, 112(5), 730-738.

<sup>19</sup> A pressure ulcer subject matter expert (under contract with RTI International), states that the etiology of the malnutrition and weight loss is very complex and is important to understand before adding malnutrition as a risk factor for pressure ulcers.. Adding malnutrition or unintended weight loss as risk factors without qualification may be looked poorly upon by the provider community. The subject matter expert recommends CMS consider developing a process measure related to ensuring that a nutritional assessment gets completed as part of the risk assessment for pressure ulcers.

All TEP members agreed that unintended weight loss is a valid indicator of malnutrition, and that it would be a valuable indicator to use in a quality measure. One TEP member stated that if she could only select one indicator for malnutrition, unintended weight loss would be the best choice. The TEP stressed that it is imperative to provide a clear definition of unintended weight loss, weight loss without any specific purpose, to ensure that there is no confusion among providers. TEP members also supported the use of decline in functional status to indicate malnutrition, because decreased functional status may lead to a decreased ability to feed oneself, and eventually lead to malnutrition<sup>20</sup>. One TEP member pointed out that unintended weight loss (Item K0300) and decreased functional status (Items G0110) are both already captured on the Minimum Data Set (MDS) 3.0,<sup>21</sup> which means that nursing home/skilled nursing facility providers are already reporting this information, and it would be relatively easy to add to the quality measure in this setting. The Long Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set<sup>22</sup> and Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)<sup>23</sup> also include indicators of function (items GG0160 and 39, respectively). However, it is important to note, that the decline in functional status captured in the MDS 3.0, LTCH CARE Data Set, and IRF-PAI are not the same as the measure of diminished functional status as measured by hand grip strength, which is recommended by the Academy and A.S.P.E.N.

TEP members shared that there are also several validated tools available to help providers assess whether a patient is at high risk for malnutrition. These tools may be helpful for identifying patients with or at high risk for malnutrition.

Finally, TEP members discussed the use of body mass index (BMI) as an indicator for malnutrition. Although they recognized that malnutrition is already included as a covariate in NQF #0678 (used to identify individuals with boney prominences who may be at higher risk for developing pressure ulcers, as well as to identify individuals with malnutrition), the TEP reported that BMI is not a reliable indicator of malnutrition because of high variability in muscle to fat ratios. In addition, some people may have had low BMI their entire life and their BMI would not always indicate their risk for malnutrition. The TEP preferred the use of unintended weight loss, over BMI, as an indicator for malnutrition.

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<sup>20</sup> Although malnutrition is associated with a decline in functional status, there is disagreement amongst experts regarding whether or not the converse is true. The relationship between functional status and malnutrition is complex and difficult to define.

<sup>21</sup> MDS 3.0 Nursing Home Comprehensive (NC) Version 1.12.0 Effective October 1, 2014.

<sup>22</sup> Long Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set, v2.01 Effective July 1, 2014.

<sup>23</sup> Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI\_ Version 1.2 Effective October 1, 2014.

## **Exclusion Criterion: Patients or Residents at the End of Life**

### *Recommendations from June 13, 2013, Meeting*

- The TEP recommended exclusion of patients or residents at the end of life from the quality measure.
  - Although NQF #0678 excludes assessments conducted at the time of death, this does not sufficiently cover all patients or residents at the end of life<sup>24</sup>.
- The TEP was unable to reach a conclusion regarding how to identify patients or residents at the end of life.

### *Discussion at November 15, 2013, Meeting*

This topic was not discussed during the follow-up webinar because of the time constraints. TEP members were asked to submit written feedback to two discussion questions. Two of the TEP members responded.

The questions and their answers are bulleted below:

1. Should patients or residents at the end of life be excluded from the quality measure?
  - Yes—because of patient’s clinical status the focus shifts from healing to comfort, pain control, and prevention of infections/sepsis.
2. How should end of life be defined?
  - End-of-life care should be defined by the following factors: patient is in hospice care, Do Not Resuscitate (DNR) status, unstable, multiple organ failure and prediction of death, patient/patient’s family decision to focus on symptom management and withdraw life support.
  - If the patient is identified on the MDS 3.0 as being in Hospice – O0100k.
  - ICD codes located on MDS 3.0 item # I8000 related to failure to thrive (783.7) or palliative care (V66.)

Because this topic was not discussed during the November 15, 2013 webinar, additional in depth discussion by the TEP is recommended in order to make meaningful recommendations and decisions regarding next steps.

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<sup>24</sup> A pressure ulcer subject matter expert (under contract with RTI International), recommends adding an item to capture end of life ulcers (Kennedy Ulcers) and excluding residents or patients that have the item checked from the quality measure. The subject matter expert agrees that defining end-of-life is very complicated and recommends CMS avoid trying to define it.

## Recommendations

Based on the findings and recommendations of the TEP, in conjunction with our earlier findings indicated in the OY2: Information Gathering Final Report, RTI has the following suggestions regarding next steps for quality measure development:

- Consider inclusion of both new unstageable<sup>25</sup> pressure ulcers and sDTIs<sup>26</sup> (reported separately) in the quality measure.
- Do not assign sDTIs a stage. Continue to monitor literature regarding the staging and etiology of sDTIs.
- If a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar, consider including this as a worsened pressure ulcer in the quality measure.
- Consider developing a quality measure for “healed” pressure ulcers.<sup>27</sup>
  - Ensure that the definition of “healed” pressure ulcer includes all possible indicators of “healed” ulcers (e.g., scar tissue formation, epithelialized, surgical closure).
  - For public reporting purposes (at a time when CMS integrates “healed” into the pressure ulcer measure), CMS needs to ensure that the word “healed” is clearly defined.
- Continue to monitor literature regarding the reliability of assessing Stage 1 pressure ulcers and the use of Stage 1 pressure ulcers as an indicator of quality.
- Continue to monitor literature regarding indicators of malnutrition<sup>28</sup>.
  - Further explore the recommendation to include two indicators of malnutrition in the quality measure, as suggested by the Academy and A.S.P.E.N.

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<sup>25</sup> According to a pressure ulcer subject matter expert (under contract with RTI International), the reporting of new unstageable pressure ulcers would not provide CMS with any additional valuable data. Additionally, the subject matter expert suggests that this recommendation would be challenging to operationalize in LTCHs and IRFs.

<sup>26</sup> A pressure ulcer subject matter expert (under contract with RTI International) does not agree with the recommendation to include new sDTI in the quality measure, as the data does not currently suggest that there is a major quality concern surrounding sDTIs.

<sup>27</sup> A subject a pressure ulcer subject matter expert (under contract with RTI International), does not agree with the recommendation to develop a quality measure for “healed” or “healing” pressure ulcers. See the discussion of pressure ulcer healing for more information.

<sup>28</sup> A pressure ulcer subject matter expert (under contract with RTI International) recommends that CMS explore low BMI, unintended weight loss, and acute illness, as indicators of malnutrition. Additionally, the expert recommends CMS consider the use of the Malnutrition Universal Screening Tool (MUST): [http://www.bapen.org.uk/pdfs/must/must\\_full.pdf](http://www.bapen.org.uk/pdfs/must/must_full.pdf) and the Minin Nutritional Assessment (MNA), <http://www.mna-elderly.com/>.

- Further explore the recommendations to add indicators of unintended weight loss and decline in functional status (such as hand grip strength) as indicators for malnutrition in the quality measure.
- Continue to assess and discuss the reliability of low BMI as an indicator for malnutrition in the quality measure.
- Continue to monitor literature and explore TEP and NPUAP input to evaluate whether patients or residents at the end-of-life should be excluded from the quality measure. (In the current measure, exclusion of assessments that occur at the time of death, likely does not reliably capture end-of-life patients or residents.)

## Appendix A: Technical Expert Panel Members and Meeting Attendees

### Technical Expert Panel Members

Name	Title/Organization
<b>In Attendance at November 15, 2013, TEP Follow-up Meeting</b>	
1. Elizabeth Ayello, PhD, RN, ACNS-BC, CWON, ETN, MAPWCA, FAAN	President Ayello, Harris & Associates, Inc.
2. Sandra Berquist-Beringer, PhD, RN, CWCN	Associate Professor The University of Kansas, School of Nursing
3. Michele Cournan, DNP, RN, CRRN, CNS, FNP, ANP-BC	Director, Clinical Operations Sunnyview Rehabilitation Hospital
4. Kathleen Deck, RN, CWON	Wound Care Specialist Barlow Respiratory Hospital
5. Jean de Leon, MD	Clinical Professor University of Texas
6. Nancy Merlino Leveille, RN, MS	Senior Director, Member Operational Support New York State Health Facilities Association
7. Lynn Moore, RD, LD	President Nutrition Systems Consulting, Inc.
8. Conchita Rader, RN, MA, CFCN, CWCN	Wound Care Coordinator Kessler Institute for Rehabilitation
9. Sheri Slater, BS	Patient Representative
10. Darlene Thompson, RN, CRRN, NE-BC	Vice President Clinical Information Systems and Training Kindred Healthcare
<b>Unable to Attend at November 15, 2013, TEP Follow-up Meeting</b>	
11. Donna Bliss, PhD, RN, FAAN, FGSA <i>Not Available to Attend Follow-up Meeting</i>	Professor University of Minnesota School of Nursing
12. Aamir Siddiqui, MD, FACS <i>Not Available to Attend Follow-up Meeting</i>	Division Head, Plastic and Reconstructive Surgery & Medical Director of Wound Care Services Henry Ford Hospital

**<sup>29</sup>Centers for Medicare & Medicaid Services Staff**

<b>Name</b>	<b>Title/Affiliation</b>
Stella Mandl, BSW, BSN, PHN, RN	Contracting Officer's Representative, Development and Maintenance of Symptom Management Measures Project Division of Chronic and Post Acute Care (DCPAC)
Charles Padgett, RN	Contracting Officer's Representative, Development and Maintenance of Symptom Management Measures Project Division of Chronic and Post Acute Care (DCPAC)
Daniel Andersen, PhD	Research Analyst Survey and Certification Group
Kristy Baus, RN, MS	Technical Advisor Quality Measure Health Assessment Group
Ellen Berry, PT	Technical Director, Data Specifications and Data Collection, Division of National Systems (DNS)
Carolyn Gallaher, JD, BSM, RN	Division of Chronic and Post Acute Care (DCPAC)
Lori Grocholski, MSW, LCSW	Technical Advisor Survey and Certification Group
Ian Kramer, MS	Social Science Research Analyst Survey and Certification Group
Tara McMullen, MPH, MPP	Health Insurance Specialist Division of Chronic and Post-Acute Care (DCPAC)

**RTI International Project Staff and Consultants**

<b>Name</b>	<b>Title/Role on Project</b>
Samruddhi Thaker, MBBS, MHA, PhD	Project Director, Development and Maintenance of Symptom Management Measures Project
Margot Schwartz, MPH	Task Lead, Cross-Setting Pressure Ulcer Quality Measure
Karen Reilly, PhD	Project Director, Nursing Home Quality Measures Project
Laura Smith, PhD	Associate Project Director, Nursing Home Quality Measures Project
Magdalena Ignaczak, BS	Public Health Analyst
Tammeka Swinson-Evans, MOP	Public Health Analyst
Teresa Mota, BSN, RN, CALA	Subject Matter Expert, Pressure Ulcers Development and Maintenance of Symptom Management Measures Project & Nursing Home Quality Measures Project HealthCentric Advisors

<sup>29</sup> In addition to the CMS staff who attended the TEP meeting, CMS and RTI consulted with a wide range of CMS staff, including representatives from the Home Health Agency and Acute Inpatient teams, during the measure development process.

## Appendix B: Malnutrition as a Risk Factor for Pressure Ulcers

**Background:** At the June 13, 2013, cross-setting pressure ulcer technical expert panel (TEP) meeting, several TEP members recommended that malnutrition be included as a risk factor in the quality measure NQF #0678, *Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (short-stay)*. However, the TEP did not reach a consensus regarding the best indicator(s) for malnutrition to include in the quality measure.

**Methods:** RTI International conducted a scan of the relevant scientific and grey literature to answer two questions (below), and to facilitate discussion at the November 15, 2013, TEP meeting:

- Is malnutrition a risk factor for pressure ulcers that should be included in the quality measure?
- What is/are the appropriate indicator(s) of malnutrition that should be considered for inclusion in a quality measure for pressure ulcers?

The scan included a search of PubMed and Google Scholar (as of October 1, 2013) using the search terms “Indicators of malnutrition in pressure ulcers,” “malnutrition and pressure ulcers,” and “nutrition and pressure ulcers,” and a review of websites of key stakeholders<sup>30</sup> (as of October 10, 2013) for white papers, commentary, or additional information regarding malnutrition and pressure ulcers.

We focused the PubMed, Google Scholar, and key stakeholder website searches on identifying review and summary articles (rather than individual studies), consensus statements, and recommendations by stakeholders, dated 2007 or later, and identified 11 articles for our review, to facilitate answering the two research questions listed above.

A summary of the findings and recommendations is included below, followed by a brief summary of the key findings relevant to malnutrition and pressure ulcer from each article.

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<sup>30</sup> Stakeholder websites reviewed include Agency for Healthcare Research and Quality, Joint Commission, U.S. Department of Veterans Affairs, National Pressure Ulcer Advisory Panel, Wound Ostomy and Continence Nurses Society, National Alliance of Wound Care, Association for the Advancement of Wound Care, Institute for Health Improvement, National Committee for Quality Insurance, American Nursing Association, American Medical Association, American Medical Directors Association, American Healthcare Association Advancing Excellence in America’s Nursing Homes, National Association of Long Term Hospitals, American Medical Rehabilitation Providers Association, National Association for Home Care & Hospice, American Hospital Association, American Physical Therapy Association, and Academy of Nutrition and Dietetics.

## Summary of Overall Findings

### **Is malnutrition a risk factor for pressure ulcers that should be included in the quality measure?**

#### **Key Findings:**

- Several studies suggest that malnutrition is related to the development of pressure ulcers.<sup>1,3,4,9</sup>
- Although there is evidence that supports the relationship between malnutrition or undernutrition and pressure ulcers, this relationship has not been conclusively demonstrated in the literature.<sup>7,8,9</sup>
- Although the National Pressure Ulcer Advisory Panel (NPUAP) recognizes that there is some inconsistency in the literature, it states in its white paper, *The Role of Nutrition in Pressure Ulcer Prevention and Treatment*<sup>7</sup>, that “the general consensus indicates that nutrition is an important aspect of a comprehensive care plan for prevention and treatment of pressure ulcers,” and that “early nutrition screening and assessment is essential to identifying risk of undernutrition, protein energy malnutrition and unintentional weight loss, all of which may precipitate pressure ulcer development and delay healing.”<sup>7</sup>
- Among those articles that support the relationship between malnutrition and pressure ulcers, several indicators are used to identify malnutrition, including undernourishment;<sup>9</sup> undesired weight loss, low body mass index, and low nutritional intake;<sup>5</sup> inadequate dietary intake;<sup>6</sup> weight loss, protein-calorie malnutrition, dehydration, and negative energy balance (low resting energy expenditure plus decreased intake).<sup>1</sup>
- NPUAP states that the literature defines “undernutrition” as pure protein and energy deficiency which is reversed solely by the administration of nutrients. This definition suggests that undernutrition is reversible because it can be improved by providing nutrients.<sup>7</sup>

**Conclusion:** Research is not conclusive regarding the relationship between malnutrition and pressure ulcers. However, many studies suggest a relationship. The NPUAP notes a general consensus regarding the importance of identifying undernutrition, protein energy malnutrition, and unintentional weight loss, all of which may precipitate pressure ulcer development and delay healing.<sup>7</sup>

### **What is/are the appropriate indicator(s) of malnutrition that should be considered for inclusion in a quality measure for pressure ulcers?**

#### **Key Findings**

- There is no universally accepted approach to assess, diagnose, and document malnutrition and there is controversy regarding the best way to conduct a nutritional assessment for patients with or at risk for pressure ulcers.<sup>2,4,7,9,10</sup>

- Most authors agree that the assessment of nutritional status should include the consideration of several clinical indicators.<sup>1, 2,4, 7,10, 11</sup> Assessment and documentation of malnutrition may include review of history and clinical diagnosis, physical exam/clinical signs, anthropometric data, laboratory data, food/nutrient intake, and functional assessment.<sup>2</sup>
  - In their joint consensus statement, *Characteristics Recommended for the Identification and Documentation of Adult Malnutrition*,<sup>2</sup> the Academy of Nutrition and Dietetics (the Academy) and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) recommend the identification of *two or more* of the following six characteristics to make a diagnosis of malnutrition:
    - insufficient energy intake
    - weight loss
    - loss of muscle mass
    - loss of subcutaneous fat
    - localized or generalized fluid accumulation that may sometimes mask weight loss
    - diminished functional status as measured by hand grip strength
  - In their joint consensus statement the Academy and A.S.P.E.N.<sup>2</sup> recommend that indicators to detect and diagnose malnutrition
    - be few in number,
    - support a nutrition diagnosis,
    - characterize severity,
    - change as nutritional status changes,
    - be evidence based when possible or consensus derived, and
    - be able to change over time as evidence of validity accrues.
- The assessment of nutritional status requires the individual clinician to use his or her clinical judgment.<sup>2, 4, 7</sup>
- Posthauer<sup>11</sup> and Little<sup>1</sup> encourage the use of validated nutrition screening tools for patients with or at risk for pressure ulcers. Examples of these tools include the Subjective Global Assessment (SGA), the Malnutrition Universal Screening Tool (MUST), the Mini-Nutritional Assessment,<sup>1</sup> and the nutrition subscale included in the Braden Risk Assessment Scale.<sup>11</sup>
- Both Little<sup>1</sup> and the Academy and A.S.P.E.N.<sup>2</sup> state that unintended weight loss is a well-established indicator of malnutrition. They also note the use of functional tests, such as handgrip strength, to assess malnutrition.<sup>1,2</sup>
- Research is not conclusive regarding the use of serum albumin or prealbumin as an indicator for malnutrition,<sup>1,7</sup> or as a risk factor for pressure ulcers.<sup>9</sup>

- The relationship between protein calorie intake or nutritional intake and pressure ulcer development is inconclusive. Additional research is needed regarding this relationship.<sup>6,8,9</sup>
- Little<sup>1</sup> and Cereda<sup>3</sup> discuss the importance of resting energy expenditure (REE) and its relationship to pressure ulcers. Cereda<sup>3</sup> concludes that patients with pressure ulcers are characterized by increased REE and reduced energy intake, which results in a negative energy balance.

**Conclusion:** At this time, there is no universally accepted approach to the assessment of malnutrition for patients with or at risk for malnutrition. Research suggests that the ideal approach would include the assessment of several different indicators, along with the use of clinical judgment.

## Summary of Individual Articles and Whitepapers

<b>Citation</b>	1. Little MO. Nutrition and skin ulcers. Curr Opin Clin Nutr Metab Care. 2013 Jan;16(1):39-49.
<b>Setting</b>	N/A
<b>Article Type:</b>	Review Article
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• It has been well established that weight loss, protein-calorie malnutrition, and dehydration are risk factors for pressure ulcers.</li> <li>• Several screening tools have been developed and validated for assessing nutritional status. Tools include the Subjective Global Assessment (SGA), Malnutrition Universal Screening Tool (MUST), and the Mini-Nutritional Assessment.</li> <li>• Screening for malnutrition using multiple assessment tools should be completed for all patients with or at risk for skin ulceration.</li> <li>• Anthropomorphic measurements alone are useful for assessing chronic malnutrition, but in the case of acute malnutrition, other parameters must be used to more accurately evaluate nutritional status.</li> <li>• Albumin, pre-albumin (with or without C-reactive protein), and transferrin are highly correlated with the risk of morbidity and mortality, however, none are specific to nutritional status.</li> <li>• Functional tests, such as handgrip strength and assessment of lean body muscle, may be useful to identify malnourished patients with normal anthropomorphic measurements and acute inflammation.</li> <li>• Resting energy expenditure should be calculated as part of the nutritional status evaluation.</li> </ul>

<b>Citation</b>	2. White, J.V., Guenter, P., Jensen, G.L., Malone, A., Schofield, M. 2012. Consensus Statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition. Journal of the Academy of Nutrition and Dietetics. 112(5):730-738
<b>Setting</b>	N/A
<b>Type of Article:</b>	Consensus Statement
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Currently, there is no single, universally accepted approach to the diagnosis and documentation of adult malnutrition.</li> <li>• Identification of two or more of the following six characteristics is recommended for diagnosis of malnutrition:             <ul style="list-style-type: none"> <li>• insufficient energy intake</li> <li>• weight loss</li> <li>• loss of muscle mass</li> <li>• loss of subcutaneous fat</li> <li>• localized or generalized fluid accumulation that may sometimes mask weight loss</li> <li>• diminished functional status as measured by hand grip strength</li> </ul> </li> <li>• Unintended weight loss is a well-validated indicator of malnutrition.</li> <li>• The relevance of laboratory tests of acute-phase protein levels (such as serum albumin and prealbumin), as indicators of malnutrition, is limited, although acute-phase protein levels are probable indicators of an inflammatory response.</li> <li>• Indicators to detect and diagnose malnutrition should have the following attributes:             <ul style="list-style-type: none"> <li>• be few in number,</li> <li>• support a nutrition diagnosis,</li> <li>• characterize severity,</li> <li>• change as nutritional status changes,</li> <li>• be evidence based when possible or consensus-derived,</li> <li>• be able to change over time as evidence of validity accrues.</li> </ul> </li> <li>• Assessment and documentation of malnutrition includes history and clinical diagnosis, physical exam/clinical signs, anthropometric data, laboratory data, food/nutrient intake, and functional assessment.</li> <li>• It is important to develop a standardized format for data collection to validate and establish those characteristics that are the most or least reliable in the identification and treatment of malnutrition.</li> </ul>

<b>Citation</b>	3. Cereda et al. Energy Balance in Patients with Pressure Ulcers: A Systematic Review and Meta-Analysis of Observational Studies. American Dietetic Association. 2011.
<b>Setting</b>	Acute Inpatient, Long-Term/Post-Acute Care
<b>Article Type</b>	Systematic Literature Review and Meta-Analysis
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Researchers reviewed all full-text research articles published between January 1, 1950, and July 31, 2010, and conducted a meta-analysis of five studies to evaluate the resting energy expenditure (REE) of patients with pressure ulcers compared to matched control groups.</li> <li>• Compared to controls (n=101), patients with pressure ulcers (n=92) presented higher measured REE (weighted mean 20.7±0.8 vs. 23.7±2.2 kcal/kg/day; <math>P&lt;0.0001</math>).</li> <li>• Patients with pressure ulcers are characterized by increased REE and reduced energy intake which results in a negative energy balance.</li> <li>• Nutritional assessment should be mandatory for patients with pressure ulcers.</li> <li>• The findings underscore the importance medical nutrition therapy in wound healing.</li> </ul>

<b>Citation</b>	4. Doley J. Nutrition management of pressure ulcers. Nutr Clin Pract 2010; 25:50–60.
<b>Setting</b>	N/A
<b>Article Type</b>	Review Article
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Limitations in current research make it difficult to develop evidence-based nutrition guidelines for pressure ulcer prevention.</li> <li>• Undernutrition is a risk factor for pressure ulcers, and nutrition therapy plays a crucial role in pressure ulcer treatment.</li> <li>• Very little research has been done on the supplementation of specific nutrients to prevent pressure ulcers.</li> <li>• For patient with pressure ulcers, clinicians must conduct a comprehensive assessment that takes into account history, biochemical data, and comorbidities, as well as symptoms that may affect the intake, absorption, or excretion of nutrients. These data, combined with clinical judgment, and an assessment of the size and severity of the ulcer, must be used to estimate energy and protein needs for the individual patient.</li> </ul>

<b>Citation</b>	5. Shahin ES, Meijers JM, Schols JM, Tannen A, Halfens RJ, Dassen T. The relationship between malnutrition parameters and pressure ulcers in hospitals and nursing homes. Nutrition. 2010 Sep;26(9):886-9. doi: 10.1016/j.nut.2010.01.016. Epub 2010 May 4
<b>Setting</b>	Acute Inpatient Hospitals, Nursing Homes
<b>Article Type</b>	Cross-Sectional Study
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• In April 2007 researchers conducted a cross-sectional study across hospitals and nursing homes in Germany to examine the relationship between pressure ulcers and malnutrition. Malnutrition was assessed using low body mass index (BMI), undesired weight loss, and insufficient nutritional intake.</li> <li>• Pressure ulcers in both hospital and nursing home patients were significantly (<math>P &lt; 0.01</math>) related to undesired weight loss (5%–10%).</li> <li>• Low nutritional intake and low BMI (<math>&lt;18.5</math>) were also significantly related to pressure ulcers in hospitals and nursing homes.</li> </ul>

<b>Citation</b>	6. Iizaka S, Okuwa M, Sugama J, Sanada H. The impact of malnutrition and nutrition-related factors on the development and severity of pressure ulcers in older patients receiving home care. Clin Nutr. 2010;29:47-53.
<b>Setting</b>	Home Health Agencies
<b>Article Type</b>	Case Control Study
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Researchers conducted a case control study of 207 randomly selected home care offices in Japan. A total of 290 patients with home-acquired pressure ulcers were compared to 456 without pressure ulcers.</li> <li>• The study team collected data on nutritional status, caregiver knowledge, and health professional's nutritional management and categorized pressure ulcers as superficial or full-thickness.</li> <li>• Malnutrition was significantly and most strongly associated with a higher rate of the pressure ulcers, after adjusting for other risk factors (OR, 2.29; 95% CI, 1.53–3.44).</li> <li>• Assessment of the patient's nutritional status and adequate dietary intake by a health professional was significantly associated with lower odds for developing pressure ulcers (OR, 0.43, 0.47; 95% CI, 0.27–0.68, 0.28–0.79, respectively).</li> <li>• The quality of home care for risk factors such as pressure redistribution has improved, making nutritional management more critical for pressure ulcer prevention.</li> </ul>

<b>Citation</b>	7. Dorner et al. The Role of Nutrition in Pressure Ulcer Prevention and Treatment: National Pressure Ulcer Advisory Panel White Paper. NPUAP. 2009.
<b>Setting</b>	N/A
<b>Article Type</b>	White Paper
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Although there is limited empirical evidence to support the relationship between nutrition and pressure ulcers, the general consensus indicates that nutrition is an important aspect of a comprehensive care plan for prevention and treatment of pressure ulcers.</li> <li>• There is limited evidence related to medical nutrition therapy for preventing pressure ulcers. However, early nutrition screening and assessment is essential to identifying risk of undernutrition, protein energy malnutrition, and unintentional weight loss, all of which may precipitate pressure ulcer development and delay healing.</li> <li>• Undernutrition has been defined in the literature as pure protein and energy deficiency, which is reversed solely by the administration of nutrients. This definition suggests that undernutrition is reversible.</li> <li>• Although laboratory tests may help identify nutrition issues, laboratory tests alone cannot specifically identify an individual's nutrition status.</li> <li>• Serum albumin levels have historically been used as an indicator of undernutrition; however, they are a poor indicator of visceral protein status.</li> <li>• Each clinician must conduct a thorough medical and nutritional assessment and use his or her clinical judgment to make individualized recommendations regarding nutrition.</li> <li>• All individuals, particularly those with pressure ulcers, should have a nutritional assessment upon admission and with each condition change.</li> </ul>

<b>Citation</b>	8. Langer G, Knerr A, Kuss O, et al. Nutritional interventions for preventing and treating pressure ulcers. Cochrane Database Syst Rev 2008.
<b>Setting</b>	N/A
<b>Article Type</b>	Systematic Literature Review
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Researchers conducted a systematic review of randomized controlled trials in the Cochrane Wounds Group Specialized Trials Register and the Cochrane Central register of Controlled Trials, as well as a search of PubMed and Cinahl, and a hand search of conference proceedings.</li> <li>• The review includes all randomized controlled trials that evaluated the effectiveness of enteral or parenteral nutrition on the prevention and treatment of pressure ulcers by measuring the incidence of new ulcers, ulcer healing, or changes in pressure ulcer severity. A total of eight randomized controlled trials were included.</li> <li>• The correlation between nutritional intake and the development of pressure ulcers is supported by several studies, but the results are inconsistent.</li> <li>• It is not possible to draw any firm conclusions on the effect of enteral and parenteral nutrition on the prevention and treatment of pressure ulcers.</li> </ul>

<b>Citation</b>	9. Lyder CH, Ayello EA. Pressure Ulcers: A Patient Safety Issue. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 12. Available from: <a href="http://www.ncbi.nlm.nih.gov/books/NBK2650/">http://www.ncbi.nlm.nih.gov/books/NBK2650/</a>
<b>Setting</b>	N/A
<b>Article Type</b>	Book Chapter
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• There is controversy regarding how best to conduct a nutritional assessment for patients at risk of developing pressure ulcers.</li> <li>• The literature does not consistently demonstrate the relationship between nutrition intake and pressure ulcers. Some randomized controlled trials do not support this relationship; however, some research supports the finding that undernourishment on admission to a healthcare facility is related to an increased risk of developing a pressure ulcer.</li> <li>• The research regarding the value of serum albumin as an indicator for increased risk of pressure ulcers is not conclusive. One study suggests that current dietary protein intake is more important.</li> <li>• The role of protein-calorie malnutrition and pressure ulcer development remains understudied.</li> </ul>

<b>Citation</b>	10. Reuben DB. Quality indicators for the care of undernutrition in vulnerable elders. J Am Geriatr Soc. 2007 Oct;55 Suppl 2:S438-42.
<b>Setting</b>	N/A
<b>Article Type</b>	Literature Review
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Researchers sought to identify a quality indicator for undernutrition in elderly individuals. This was particularly challenging because there is no universally accepted clinical definition of undernutrition and the research conducted on undernutrition in older persons has not focused on quality of care.</li> <li>• Experts reviewed 116 articles to assess the validity of 16 quality indicators for undernutrition.</li> <li>• Of the 16 indicators, experts judged 9 to be valid indicators for malnutrition: <ul style="list-style-type: none"> <li>• Weight measurement</li> <li>• Vitamin D supplementation</li> <li>• Oral intake evaluation in the hospitalized older person</li> <li>• Weight loss documentation</li> <li>• Evaluation of causes of poor nutritional intake for patients with weight loss or hypoalbuminemia</li> <li>• Alternative alimentation in hospitalized older persons</li> <li>• Evaluation of comorbid conditions for patients with weight loss or hypoalbuminemia</li> <li>• Swallowing training</li> <li>• Oral protein and energy supplementation in hospitalized patients</li> </ul> </li> </ul>

<b>Citation</b>	11. Posthauer ME. The role of nutrition in wound care. Adv Skin Wound Care. 2006 Jan-Feb;19(1):43-52; quiz 53-4.
<b>Setting</b>	N/A
<b>Article Type</b>	Invited Commentary
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• The evaluation of biochemical data is only one component of the nutritional assessment process and should be considered along with other factors, including weight changes, current food/fluid intake, diagnosis, and medication.</li> <li>• All stages of healing require adequate protein. Research supports a protein allowance of 1.2 to 1.5 g/kg of body weight for individuals with pressure ulcers.</li> <li>• Early detection of malnutrition is important. Clinicians should use validated nutrition screening and assessment tools to determine nutritional status. The author specifically mentions the nutrition subscale included in the Braden Risk Assessment Scale.</li> </ul>

## Appendix C: Summary of Stage 1 Pressure Ulcer Literature

**Background:** At the June 13, 2013, cross-setting pressure ulcer technical expert panel (TEP) meeting the TEP discussed the inclusion of Stage 1 pressure ulcers in *NQF#0678, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay)* and was unable to reach a conclusion. A few TEP members referenced published studies which they felt would be valuable to review to reach a consensus regarding the inclusion of Stage 1 pressure ulcers in the quality measure.

**Methods:** RTI conducted a scan of the relevant scientific and grey literature to achieve two research goals (below), and to facilitate discussion at the November 15, 2013, TEP meeting:

- To examine the reliability of assessing Stage 1 pressure ulcers, and
- To assess the evidence supporting addition of Stage 1 pressure ulcers for quality measure reporting as an indicator of healthcare quality

We reviewed the articles provided by TEP members and scanned the references listed in these articles to identify additional relevant articles. Additionally, we conducted PubMed and Google Scholar searches (as of October 1, 2013) using the search terms “Stage 1 Pressure Ulcer,” “Reliability of Pressure Ulcer Staging,” and “Stage 1 Pressure Ulcer and Quality.” We also conducted a search of key stakeholder<sup>31</sup> websites (as of October 3, 2013) to identify white papers, commentary, and additional information, related to the research goals stated above. Because of the limited number of relevant studies, all articles dated 2000 or later were included. A total of eight relevant resources were identified.

Teresa Mota, BSN, RN, CALA at Healthcentric Advisors, in her role as the Subject Matter Expert and consultant to RTI’s pressure ulcer team, reviewed all articles and summarized the relevant findings. A summary of findings and recommendations is included below, followed by a brief summary of the key findings from each article.

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<sup>31</sup> Stakeholder websites reviewed include Agency for Healthcare Research and Quality, Joint Commission, U.S. Department of Veterans Affairs, National Pressure Ulcer Advisory Panel, Wound Ostomy and Continence Nurses Society, National Alliance of Wound Care, Association for the Advancement of Wound Care, Institute for Health Improvement, National Committee for Quality Insurance, American Nursing Association, American Medical Association, American Medical Directors Association, American Healthcare Association Advancing Excellence in America’s Nursing Homes, National Association of Long Term Hospitals, American Medical Rehabilitation Providers Association, National Association for Home Care & Hospice, American Hospital Association, American Physical Therapy Association, Academy of Nutrition and Dietetics.

## Summary of Overall Findings

### 1. Reliability of assessing Stage 1 pressure ulcers

- The accuracy of assessment of Stage 1 pressure ulcers is still not much better than “moderate” and “inconsistent” reliability. There is also no accurate criteria or method to assess Stage 1 pressure ulcers consistently (glass plate compression, finger press), which may reduce the reliability of the staging.<sup>1,2,3</sup>
- Non-blanchable erythema is considered a nonspecific clinical sign. Therefore, the accuracy of differentiating incontinence associated dermatitis, allergic dermatitis, candidiasis, fungal infections, etc. from Stage 1 pressure ulcers as they are currently defined is suspect. One study reported that these issues were misidentified as Stage 1 pressure ulcers 44% of the time.<sup>8</sup>
- The presence of a Stage 1 pressure ulcer is an important indicator of increased risk of pressure ulcers; this knowledge should lead to the initiation of clinical interventions so that the ulcer does not deteriorate.<sup>1,7</sup>
- Studies have refuted the idea that if an individual has a Stage 1 pressure ulcer that it will predictably move from Stage 1, to Stage 2, then to Stage 3 and finally Stage 4 as the development of Stage 1 and 2 pressure ulcers and Stage 3 and 4 pressure ulcers may be reflective of different causes (“top down” damage vs. “bottom up” damage, respectively).
- The implication that intervention at the Stage 1 level can reliably prevent progression to a Stage 4 ulcer has been proven in several studies to be inaccurate as preventive methods are the same for any stage pressure ulcer, and even with the best prevention, sometimes progression does occur that is unavoidable as is seen with deep tissue injury.<sup>6,7,8</sup>
- There has been confusion regarding the staging of Stage 1 pressure ulcers and deep tissue injury along with inconclusive science surrounding the development of deep tissue injury. Some studies suggest that deep tissue injury is a progression from Stage 1 pressure ulcers, others argue that it is deeper injury that evolves from the base of the wound outward until it erupts on the surface of the skin.<sup>1,3,6</sup> In deep tissue injury, there is a rapid progression to full-thickness ulcers even when appropriate interventions are provided. Most inflammatory responses associated with Stage 1 pressure ulcers resolve with intervention. Therefore, the assumption that intervention can reliably prevent Stage 1 pressure ulcers from progressing to Stage 4 pressure ulcers is unfounded. What is presumed to be Stage 1 may in fact be DTI, which will progress despite optimal care.<sup>6,7,8</sup>
- Stage 1 and 2 lesions heal quickly so they have little correlation with risk for deeper lesions.<sup>6,7,8</sup>
- Stage 1 pressure ulcers are reversible in most patients within hours.<sup>1</sup> Deep tissue injury can be initially staged as Stage 1 incorrectly by surface inspection. One study concluded that 10% of pressure ulcers initially staged as Stage 1 by visual inspection evolved to Stage 3 or 4 within days.<sup>8</sup> This is because even though the skin may be

intact and erythematous (mimicking Stage 1) the underlying tissue damage is not be visible to the naked eye and additional clinical signs will become evident only days later. These tissues deteriorate rapidly despite optimal treatment that meets the current standard of care.<sup>6,7,8</sup>

- To differentiate erythema and hypoechoic regions in suspected pressure areas to assess for Stage 1 pressure ulcers or deep tissue injury, study nursing homes were provided with technology not normally available to them (ultrasonography, thermography, image analysis software). Without these types of devices, it makes it very difficult to make a diagnosis of deep tissue injury.<sup>4</sup>
2. Adding Stage 1 pressure ulcers for quality measure reporting as an indicator of healthcare quality
- Preventive measures are the same regardless of pressure ulcer stage. There is no clear relationship between the clinical course of Stage 1 ulcers, patient characteristics, and the use of preventive measures and best practices (including nutritional deficits and position changes) that would indicate that preventive measures will prevent subsequent stage pressure ulcers from developing.<sup>1,4</sup> Therefore, the onset of a Stage 1 pressure ulcer may be best used as a “trigger for clinical intervention rather than making it part of a publicly reported quality measure.”<sup>7</sup> This by no means implies that preventive measures do not help at all as they could help pressure ulcers from deteriorating to higher stages, but studies show that some pressure ulcers still deteriorate despite optimal care.<sup>6,7,8</sup>
  - Because there is little correlation with increased risk of developing Stage 2, 3, or 4 ulcers when a Stage 1 ulcer is identified, and preventive measures do not differ between the stages, and because the healing process is different for Stage 1, partial-thickness, and full-thickness wounds, adding Stage 1 to the current quality measure would make it more difficult to monitor, target, and address the more serious lesions.<sup>7</sup>

## Overall Recommendation

- We do not recommend<sup>32</sup> that Stage 1 pressure ulcers be added to the pressure ulcer quality measure and in prevalence and incidence studies as there are clinical, regulatory, legal, and economic ramifications.
- There is incomplete/inconclusive science related to progression and development of pressure ulcers through the pressure ulcer stages.
- There is lack of accurate criteria and reliable and consistent methods for assessing Stage 1 pressure ulcers and differentiating them from deep tissue injury.
- There are current limitations in the staging system, especially with regard to the definition of Stage 1 pressure ulcers and the potential inclusion of deep tissue injury.

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<sup>32</sup> The recommendations and summary provided in this document represent the findings of the pressure ulcer subject matter expert who reviewed the articles. The findings and recommendations are presented here to facilitate TEP review and discussion, and are not meant to represent the opinions or final recommendations of the cross-setting pressure ulcer TEP.

- Misidentification of Stage 1 pressure ulcers as deep tissue injury can artificially inflate the prevalence of Stage 1 pressure ulcers, which will expose the facility to regulatory and legal liability.
- There is no conclusive evidence that pressure ulcers move from a less-severe (Stage 1, Stage 2) to a more-severe stage (Stage 3, Stage 4) because of negligent or poor quality care. Some pressure ulcers (e.g., deep tissue injury) are not affected by the most optimal preventive care.

## Summaries of Individual Articles

<b>Citation</b>	1. Halfens RJG, Bours GJJW, Van Ast W. Relevance of the diagnosis ‘Stage 1 pressure ulcer’: an empirical study of the clinical course of Stage 1 ulcers in acute care and long-term care hospital populations. J Clin Nurs. 2001 Nov;10(6):748-57.
<b>Setting</b>	Acute Inpatient Hospitals, Long-Term Care Hospitals
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Stage 1 pressure ulcers are difficult to diagnose. Several prevalence studies have shown that almost half of the pressure ulcers identified are Stage 1. The present study investigated the importance of Stage 1. The following research questions were formulated: Is there a difference between the prevalence of Stage 1 pressure ulcers identified in the institutions participating in the present study and that found in the other institutions participating in the Dutch National Prevalence Survey? What percentage of Stage 1 pressure ulcers are reversible within a few hours? What is the clinical course of Stage 1 pressure ulcers? Which patient characteristics and preventive interventions are related to the clinical course of Stage 1?</li> <li>• The study used a prospective, descriptive, and comparative design.</li> <li>• All patients of six long-term care hospitals and six acute care hospitals in whom Stage 1 pressure ulcers were identified during the 1999 National Prevalence Survey in the Netherlands were followed for 1 week (acute care hospitals; n = 68 patients) or 2 weeks (long-term care hospitals; n = 115 patients).</li> <li>• The patients were reassessed using the questionnaire developed for the National Prevalence Survey (patient characteristics, assessment of risk of pressure ulcers, characteristics of the pressure ulcers and use of preventive methods) on the same day as the national survey itself, and again after 3 days, after 7 days, and after 14 days (only long-term care hospitals).</li> <li>• The results showed fewer Stage 1 pressure ulcers in the institutions participating in the present study than in the National Prevalence Survey, the difference being almost 50%. The first reassessment found the prevalence of Stage 1 to be further reduced by an average of almost 50%, a reduction which was greater for the long-term care hospitals than for the acute care hospitals. However, some of the ulcers that had disappeared reappeared in subsequent reassessments.</li> <li>• In the long-term care hospitals, 8.7% of the Stage 1 pressure ulcers deteriorated to a higher stage, vs. 22.1% in acute care hospitals.</li> <li>• No significant patient characteristics were found to affect the course of Stage 1, except that women in acute care hospitals more often had a Stage 1 pressure ulcer at the first reassessment than men.</li> <li>• In general, patients whose Stage 1 ulcer deteriorated were undergoing more preventive interventions; not all differences were significant.</li> <li>• We conclude that, although Stage 1 is reversible in most cases, it can be interpreted as an important warning sign for nurses and patients to act. If no adequate interventions are applied, the pressure ulcer may deteriorate.</li> </ul>

<b>Citation</b>	2. Bergquist S. Pressure ulcer prediction in older adults receiving home healthcare: implications for use with the OASIS. <i>Adv Skin Wound Care</i> . 2003 May-Jun;16(3):132-9.
<b>Setting</b>	Home Health Agencies
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• To determine whether admission data routinely collected on the Outcome and Assessment Information Set (OASIS) might be used to identify the older adult at risk for pressure ulcer development in home healthcare.</li> <li>• Secondary analysis of data from a retrospective cohort study. The sample included 1,711 nonhospice patients 60 years or older and free of pressure ulcers who were admitted to the intermittent skilled nursing division of a large Midwestern home healthcare agency between January 1995 and March 1996.</li> <li>• Data on potential risk factors were extracted from admission information. Those identical to items on the admission OASIS assessment were included in the study. Patient records were followed forward chronologically to either pressure ulcer development or absence.</li> <li>• Cox regression analysis showed that limitation in activity to bed, dependence in dressing, urinary incontinence, and needing assistance with transferring predicted Stage I pressure ulcer development (<math>P \leq .001</math>). Bowel/bladder incontinence, oxygen use, a current fracture, and dependence in dressing predicted Stage 2 and greater pressure ulcer development (<math>P \leq .001</math>). Predictors of Stage 1 plus Stage 2 and greater pressure ulcers included those predictors from each of the individual models, including limitation in activity to bed, dependence in dressing, a current fracture, oxygen use, needing assistance with transferring, and urinary incontinence (<math>P \leq .001</math>).</li> <li>• These findings suggest that the admission OASIS assessment may provide a method for identifying elderly patients who are at risk for developing Stage 1 and Stage 2 pressure ulcers in home healthcare.</li> </ul>

<b>Citation</b>	3. Hart S, Bergquist S, Bajewski B, Dunton N. Reliability testing of the national database of nursing quality indicators pressure ulcer indicator. <i>J Nurs Care Qual</i> . 2006 21(3):256-265.
<b>Setting</b>	Acute Inpatient Hospitals
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• A three-part criterion-referenced Web-based test was designed and administered to 256 individuals at 48 randomly sampled National Database of Nursing Quality Indicators (NDNQI) member hospitals to determine the reliability of the NDNQI pressure ulcer indicator.</li> <li>• High-quality digital pictures of ulcerous wounds were used in this study. Nineteen of the 25 pictures were obtained from and used with permission from the NPUAP.</li> <li>• Guidelines of the NPUAP and the AHRQ for pressure ulcer tagging and expert opinion were used to assess and stage ulcers in each picture.</li> <li>• Overall kappa values for pressure ulcer identification, staging, and sourcing indicate moderate to near perfect reliability.</li> <li>• Findings suggest that nurses can accurately differentiate pressure ulcers from other ulcerous wounds in Web-based photographs, reliably stage pressure ulcers, and reliably identify community versus nosocomial pressure ulcers.</li> </ul>

<b>Citation</b>	4. Sato M, Sanada H, Konya C, Sugama J, Nakagami G. Prognosis of Stage 1 pressure ulcers and related factors. <i>Int Wound J</i> . 2006 3:355-362.
<b>Setting</b>	Long-Term Care
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• The prognosis of Stage 1 pressure ulcers cannot be predicted; therefore, nursing interventions for preventing their deterioration have not been clearly established. This study describes the clinical course of Stage 1 pressure ulcers and prospectively investigates the factors related to their deterioration.</li> <li>• Thirty-one Stage 1 pressure ulcers in 30 patients in a long-term care facility were studied, and morphological changes were assessed every day until the ulcers healed or deteriorated. The physiological changes were assessed by ultrasonography and thermography.</li> <li>• Twenty ulcers healed, and 11 deteriorated. The characteristics of deterioration were as follows: (1) double erythema; (2) nonblanchable erythema across the whole area determined by glass plate compression; (3) erythema away from the tip of the bony prominence; and (4) expanding erythema on the following day.</li> <li>• Researchers analyzed the sensitivity, specificity, positive predictive value, negative predictive value, and positive likelihood ratio for the diagnostic utility of the indicators of deterioration double erythema and distance from the tip of bony prominence, which can be instantly assessed without the use of any special device. The values were 36.4%, 95.0%, 80.0%, 73.1%, and 7.28, respectively.</li> <li>• These results suggest that clinicians can predict the prognosis of Stage 1 pressure ulcers by initial assessment and provide appropriate care based on the assessment.</li> </ul>

<b>Citation</b>	5. Stausberg J, Lehmann H, Kröger K, Maier I, Niebel W. Reliability and validity of pressure ulcer diagnosis and grading: an image-based survey. <i>Int J Nurs Stud</i> . 2007 44:1316-1323.
<b>Setting</b>	Long-Term Care
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• The reliability and validity of pressure ulcer diagnosis and grading are major methodological issues in studies and reports on pressure ulcer frequency. The aim of the study was to estimate the reliability and validity of pressure ulcer diagnosis and grading within the interdisciplinary pressure ulcer project of the University Clinics of Essen, Germany.</li> <li>• Fifty images of wounds from the foot/heel region and 50 images of wounds from the buttock/hip region were classified using a 4-grade scale. A gold standard was established by consensus of two senior physicians. The images were assessed PC-based, independently by each rater. Five nursing experts and two physicians participated.</li> <li>• Mean simple Kappa and percent agreement were calculated to assess reliability and validity. Mean simple Kappa values showed a moderate interrater agreement for grading and a fair interrater agreement for diagnosis. The percentage of agreements was highest for pressure ulcer <i>diagnosis</i> in the buttock/hip region with 90.5% and lowest for pressure ulcer <i>grading</i> in the buttock/hip region with 63.5%. No differences could be found between nurses and physicians.</li> <li>• The differentiation between pressure ulcers and other skin lesions is rather difficult. It is important to assign the lower grade when the available information does not definitely support the higher grade. The level of agreement found was intermediate in the range of published results. A substantial level of agreement should be obtainable through further standardization and training. Future studies should control for dependency in the assessment situation and dispense with the category “uncertain.”</li> </ul>

<b>Citation</b>	6. Doughty D, Ramundo J, Bonham P, Beitz J, Erwin-Toth P, Anderson R, Rolstad B. Issues and challenges in staging of pressure ulcers. J WOCN. 2006 Mar-Apr;33(2):125-132.
<b>Setting</b>	N/A
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Wound assessment is a key element of effective wound care, and assessment of pressure ulcers includes accurate determination of wound stage. Although the original staging system established by Shea was based on his understanding of the pathology involved in pressure ulcer development, subsequent staging systems (and the one currently in use) were intended simply to establish the level of tissue damage.</li> <li>• Recently, clinicians have drawn attention to numerous limitations associated with the current staging system, including the inability to differentiate between an inflammatory response involving intact skin and a deep tissue injury (deep bruising) underneath intact skin. This is a clinically significant difference because clinicians have noted that most inflammatory responses resolve with intervention, whereas most areas of deep tissue injury progress to full-thickness ulcers even when appropriate intervention is provided.</li> <li>• A second area of controversy involves partial-thickness (Stage 2) lesions; because many of these lesions are caused by maceration or friction (as opposed to pressure), clinicians are frequently unclear regarding which of these lesions should be staged.</li> <li>• In response to these concerns, the National Pressure Ulcer Advisory Panel convened a consensus forum and published white papers to clearly outline the issues; they solicited clinician feedback on the white papers and the Wound, Ostomy, Continence Nurses Society provided a written response.</li> <li>• Currently confusion exists regarding the intent of the current staging system and more data are needed on the process of pressure ulcer development, but there is agreement on the need for a physiologically sound validated staging system. Until then, we should remain cognizant that ulcer stage is only one parameter in comprehensive wound assessment and we should be particularly aware of the unresolved issues surrounding Stage 1 and Stage 2 ulcers and resist efforts to assign undue significance to staging.</li> <li>• In considering the validity and reliability of the current staging system, it is important to consider the intent of a staging system, that is, what is the staging system designed/expected to provide? If the staging system is intended simply to reflect the level of tissue damage, the modifications suggested by the participants in the consensus conference would do that. On the other hand, if the staging system is intended to reflect the pathologic process by which a pressure ulcer develops, we must answer two questions definitively before we can develop an evidence-based and physiologically accurate staging system: (1) we need to clearly articulate whether the pressure ulcer staging system is intended to reflect the process of pressure ulcer development (an ulcer produced by unrelieved pressure or shear) or whether it is also intended to reflect the development of other skin and soft tissue lesions, such as those produced by maceration and friction, and (2) we need to clearly establish whether pressure ulcers develop from the “top-down” (as suggested by the current system) or whether they actually begin at the muscle layer and then erupt at the surface (the process supported by most of the scientific data).</li> <li>• Once we come to consensus on the intent of the staging system and gather additional data on the process of pressure ulcer development, we will be able to develop a staging system that is physiologically sound (and therefore valid). We will then need to conduct reliability studies to ensure that the descriptors are clear and that the system demonstrates both interrater and intra-rater reliability.</li> <li>• We also need to use our combined clinical practices to begin to track the natural history of Stage 1 and Stage 2 ulcers and the natural history of ulcers now being described as “deep tissue injury.”</li> <li>• It is critical to realize that the consensus forum was the beginning of a process; the dialogue and review of existing literature were essential “first steps” in identifying areas for possible</li> </ul>

	<p>revision and issues to be resolved. However, at this point no decisions have been made, and the staging system has not been revised.</p> <ul style="list-style-type: none"> <li>• Thus, clinicians should continue to stage pressure ulcers as accurately as possible using the current staging system and should be encouraged to use narrative descriptors to augment the data provided by staging.</li> </ul>
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<b>Citation</b>	7. Lynn J, West J, Hausmann S, Gifford D, Nelson R, McGann P, Bergstrom N, Ryan J. Collaborative clinical quality improvement for pressure ulcers in nursing homes. <i>J Am Geriatr Soc.</i> 2007 Oct;55(10):1663-9.
<b>Setting</b>	Nursing Homes
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• The National Nursing Home Improvement Collaborative aimed to reduce pressure ulcer (PU) incidence and prevalence. Guided by subject matter and process experts, 29 quality improvement organizations and six multistate long-term care corporations recruited 52 nursing homes in 39 states to implement recommended practices using quality improvement methods.</li> <li>• Facilities monitored monthly PU incidence and prevalence, healing, and adoption of key care processes.</li> <li>• In residents at 35 regularly reporting facilities, the total number of new nosocomial Stage 3 to 4 PUs declined 69%. The facility median incidence of Stage 3 to 4 lesions declined from 0.3 per 100 occupied beds per month to 0.0 (<math>P &lt; .001</math>) and the incidence of Stage 2 to 4 lesions declined from 3.2 to 2.3 per 100 occupied beds per month (<math>P = .03</math>). Prevalence of Stage 3 to 4 lesions trended down (from 1.3 to 1.1 residents affected per 100 occupied beds (<math>P = .12</math>)). The incidence and prevalence of Stage 2 lesions and the healing time of Stage 2 to 4 lesions remained unchanged. Improvement teams reported that Stage 2 lesions usually healed quickly and that new PUs corresponded with hospital transfer, admission, scars, obesity, and immobility and with noncompliant, younger, or newly declining residents.</li> <li>• The publicly reported quality measure, prevalence of Stage 1 to 4 lesions, did not improve.</li> <li>• Participants documented disseminating methods and tools to more than 5,359 contacts in other facilities.</li> <li>• Results suggest that facilities can reduce incidence of Stage 3 to 4 lesions, that the incidence of Stage 2 lesions may not correlate with the incidence of Stage 3 to 4 lesions, and that the publicly reported quality measure is insensitive to substantial improvement.</li> <li>• The project demonstrated multiple opportunities in collaborative quality improvement, including improving the measurement of quality and identifying research priorities, as well as improving care.</li> </ul>

<b>Citation</b>	8. Sibbald R, Krasner DL, Woo KY. Pressure ulcer staging revisited: superficial skin changes & deep pressure ulcer framework <sup>®</sup> . Adv Skin Wound Care. 2011 Dec;24(12):571-80.
<b>Setting</b>	Long-Term Care
<b>Summary of Methods and Key findings</b>	<ul style="list-style-type: none"> <li>• Deficiencies in the current pressure ulcer classification system create the impetus for the current discourse on the clinical, legal, and economic implications of staging and considering shifting the paradigm in pressure ulcer description and assessment.</li> <li>• Pressure ulcers do not usually progress in sequence from Stage 1 to Stage 4. The so-called Stage 1 pressure ulcers are defined as intact skin and not an ulcer (dermal or deeper base). Superficial skin injuries occur from the outside in and are linked to excess moisture and friction. Some of these skin injuries are actually erosions (loss of epidermis with epidermal base) and not true ulcers. Deep pressure ulcers occur from inside out because of shear and pressure. Deep tissue injury may evolve over time, and an alternate approach is proposed to describe the appearance of skin damage.</li> <li>• The proposed delineation of superficial skin changes and deep pressure ulcers based on distinct mechanisms would allow accurate communication of causative factors and resulting skin conditions. The proposed paradigm would also avoid unfair penalty as deep pressure ulcers do not always begin as a superficial skin damage.</li> </ul>

## Appendix D

### **Technical Expert Panel Meeting Development of a Cross-Setting Quality Measure for Pressure Ulcers November 15, 2013: 2 p.m. – 4 p.m. EST**

#### **Questions for TEP Members**

##### Unstageable Pressure Ulcers and Suspected Deep Tissue Injuries (sDTIs)

At the June 13, 2013, meeting, the TEP recommended that new unstageable pressure ulcers and new sDTIs should be counted in the quality measure for pressure ulcers. The TEP also concluded that at this time it is not possible to assign sDTIs a stage.

Questions:

1. Are there any changes to your recommendation regarding inclusion of unstageable pressure ulcers and sDTIs in a quality measure for pressure ulcers?
2. Please indicate or share additional/existing evidence regarding the etiology and staging of sDTIs.
3. If a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar, should this be coded as a worsened pressure ulcer?

##### Inclusion of Pressure Ulcer Healing in a Quality Measure for Pressure Ulcers

At the June 13, 2013, meeting, the TEP recommended that CMS include healed pressure ulcers in the quality measure, or develop a second measure that reflects provider success in healing pressure ulcers.

Questions:

4. Should healing be included in a separate quality measure or should it be combined with new or worsening?
5. How would pressure ulcer healing be operationalized in a data collection instrument?
  - 5a. What are the strengths and weaknesses of the Pressure Ulcer Scale for Healing (PUSH) Tool?
  - 5b. What are the strengths and weaknesses of the Bates-Jensen Wound Assessment Tool (BWAT)?
6. How can we balance the burden of data collection with the need to assess pressure ulcer healing?
7. How can pressure ulcer healing be publicly reported (at a facility level, by setting) to inform patients'/family members' decision-making? To what extent will patients and family members find this information relevant to inform their healthcare decision-making process?

##### Inclusion or Exclusion of Stage 1 Pressure Ulcers in Quality Measure for Pressure Ulcers

At the June 13, 2013, meeting, the TEP did not reach a consensus regarding inclusion or exclusion of Stage 1 pressure ulcers in the quality measure. RTI, in collaboration with a pressure

ulcer subject matter expert at Healthcentric Advisors, reviewed and summarized the relevant literature to facilitate further discussion regarding Stage 1 pressure ulcers.

Questions:

- What are your recommendations regarding inclusion of Stage 1 pressures ulcers in a quality measure?

#### Malnutrition as a Risk Factor for Pressure Ulcers & Indicators of Malnutrition

At the June 13, 2013, meeting the TEP recommended inclusion of malnutrition as a risk factor for pressure ulcers, but was unable to reach consensus regarding the appropriate indicator(s) for malnutrition. RTI reviewed and summarized the relevant literature to facilitate further discussion regarding malnutrition as a risk factor for pressure ulcers.

Questions:

- Please provide your recommendations regarding whether malnutrition is a risk factor for the development and worsening of pressure ulcers.
- What is/are the appropriate indicator(s) to use to identify malnutrition?

#### Exclusion of Patients or Residents at the End of Life From the Quality Measure

At the June 13, 2013, meeting the TEP recommended exclusion of patients or residents at the end of life; however, the TEP was unable reach a conclusion regarding how to identify residents or patients at the end of life.

Questions:

- Should patients at the end of life be excluded from the quality measure?
- How should end of life be defined?
  - Specific time period?
  - Specific clinical state?
  - Specific care plan?