December 2016

Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs)

Deliverable 14

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> RTI International Project Number 02014077.001 CMS Contract No. HHSM-500-2013-13015I

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TECHNICAL EXPERT PANEL SUMMARY REPORT: REFINEMENT OF THE PERCENT OF PATIENTS OR RESIDENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENED (SHORT-STAY) (NQF #0678) QUALITY MEASURE FOR SKILLED NURSING FACILITIES (SNFS), INPATIENT REHABILITATION FACILITIES (IRFS), LONG-TERM CARE HOSPITALS (LTCHS), AND HOME HEALTH AGENCIES (HHAS)

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CMS Contract No. HHSM-500-2013-13015I

December 2016

This project was funded by the Centers for Medicare & Medicaid Services under contract no. 500-00-1234. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI International assumes responsibility for the accuracy and completeness of the information contained in this report.

TABLE OF CONTENTS

List	f Acronyms and Short Forms	V
Secti	on 1 Introduction And Overview	1
	1.1 Introduction	1
	1.2 Background	1
	1.3 Process of the TEP Meeting.	
	1.3.1 TEP Nomination Process	1
	1.3.2 TEP Webinar	2
	1.3.3 Pre-TEP Voting Worksheet	2
	1.4 Organization of the Report	3
Section	on 2 Addition Of Unstageable Pressure Ulcers, Including Suspected Deep Tissue	
Beeth	Injuries To The Quality Measure	5
	2.1 Summary of Proposed Changes	
	2.2 TEP Discussion	
	2.2.1 Suspected Deep Tissue Injuries	5
	2.2.2 Unstageable Due to Non-removable Dressing or Device	6
	2.2.3 Unstageable Due to Slough or Eschar	6
g	2.T	0
Secti	on 3 Transition from M0800/M1313 Items to M0300/M1311 Items	
	3.1 Summary of Proposed Changes3.2 TEP Discussion	
	3.3 Unintended Consequences3.4 Setting-Specific Discussion	
	3.5 Discussion Summary	
	5.5 Discussion Summary	10
Secti	on 4 Risk Adjustment Update	11
	4.1 Pre-TEP Voting Results	11
	4.2 Prioritization of Potential Risk Factors	11
	4.3 Discussion Summary	12
Section	on 5 New NPUAP Terminology	13
Secti	5.1 Summary of Changes	
	5.2 TEP Discussion	
Refer	ences	15
		13
	ndixes	1.7
	TEP Webiner Accords	
B C	TEP Webinar Agenda	
	FIC-ICD YOUNG WOLKSHEEL.	

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LIST OF ACRONYMS AND SHORT FORMS

CMS Centers for Medicare & Medicaid Services

HHA Home Health Agency

ICU Intensive Care Unit

IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014

IRF Inpatient Rehabilitation Facility

IRF-PAI Inpatient Rehabilitation Facility-Patient Assessment Instrument

LTCH Long-Term Care Hospital

MDS Minimum Data Set

NDNQI National Database of Nursing Quality Indicators

NF Nursing Facility

NPUAP National Pressure Ulcer Advisory Panel

NQF National Quality Forum

OASIS Outcome and Assessment Information Set

PAC Post-Acute Care

PPS Prospective Payment System

QRP Quality Reporting Program

SNF Skilled Nursing Facility

sDTI Suspected Deep Tissue Injury

RAI Resident Assessment Instrument

TEP Technical Expert Panel

WOCN Wound, Ostomy, and Continence Nurses Society

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SECTION 1 INTRODUCTION AND OVERVIEW

1.1 Introduction

On behalf of the Centers for Medicare & Medicaid Services (CMS), RTI International and Abt Associates convened a Technical Expert Panel (TEP) to seek expert input on the refinement of the quality measure, the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs). The TEP meeting consisted of a half-day webinar held on July 18, 2016.

This report provides a summary of the TEP proceedings, detailing the key issues of measure development and TEP discussion around those issues. In this section, we provide a summary of the background, process for the TEP meetings, and organization of the TEP report.

1.2 Background

CMS has contracted with RTI International and Abt Associates to develop quality measures reflective of quality of care, resource use and other measures for post-acute care (PAC) settings in order to meet the mandate of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) and to support CMS quality initiatives. The contract names are Development and Maintenance of Symptom Management Measures (HHSM-500-2013-13015I; Task Order HHSM-500-T0001) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance (HHSM-500-2013-13001I; Task Order HHSM-500-T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractor during measure development and maintenance.

The objective of the TEP meeting was to seek expert input on refinements of the cross-setting pressure ulcer measure for PAC settings, including input regarding analyses and findings related to the potential inclusion of unstageable pressure ulcers in the measure numerator and a potential change in assessment items used in measure calculation. RTI International and Abt Associates also sought input on the results of an environmental scan of potential additional risk adjustors for the pressure ulcer measure.

1.3 Process of the TEP Meeting

1.3.1 TEP Nomination Process

On May 25, 2016, RTI International posted a Call for TEP members and a TEP Nomination Form on the CMS Measures Management System website¹ to solicit for TEP nominations. The Call for TEP nomination period lasted seventeen days. Information about the opportunity to participate as a TEP member was also disseminated to national provider and professional associations, measure development experts, patient advocacy groups, potential consumer/patient representatives, and other stakeholder organizations. A total of 52 individuals were nominated (including self-nominations) to be considered as a member of this TEP. At the

close of the nomination period, RTI International and Abt Associates finalized the TEP composition by selecting 11 nominees who offered a diverse range of clinical, research, and administrative expertise. The TEP composition was chosen to include one patient representative, and others who offered expertise in the various PAC settings (SNF, IRF, LTCH, HHA), and knowledge of performance measurement with regard to new or worsened pressure ulcers, nutrition, wound care, and physical therapy. In addition, TEP members offered a range of perspectives related to quality improvement, purchaser perspective, data collection and implementation, and health care disparities. *Appendix A* provides the TEP composition, with brief biographies of each member.

1.3.2 TEP Webinar

The half-day TEP webinar was held on July 18, 2016. Each of the 11 selected TEP members attended the meeting virtually. Discussion was facilitated by the measure lead, Julie Seibert, RTI International, with support from various members of the RTI International and Abt Associates measure development team. Representatives from CMS were also in attendance. The following key topics were discussed:

- (i) addition of unstageable pressure ulcers to the measure numerator, including suspected deep tissue injuries (sDTIs);
- (ii) the transition from M0800/M1313 to M0300/M1311 items in the measure calculation. The M0800/M1313 items, Worsening in Pressure Ulcer Status Since Admission, collect the number of pressure ulcers at each stage that are new or worsened at discharge compared with admission. The M0300/M1311 items, Current Number of Unhealed Pressure Ulcers at Each Stage, collect the number of pressure ulcers present at each stage, and the number of these pressure ulcers that were present upon admission;
- (iii) updates to the risk adjustment model and the prioritization of potential additional risk factors; and
- (iv) the incorporation of updated National Pressure Ulcer Advisory Panel (NPUAP)^a terminology into measure items and quality measure specifications. The meeting was audio recorded and transcribed by a professional transcriptionist for the purpose of summarizing TEP proceedings in this report.

1.3.3 Pre-TEP Voting Worksheet

Prior to the TEP webinar, RTI International distributed a Voting Worksheet to TEP members (see *Appendix C*). The worksheet collected input on prioritizing the addition of potential risk factors to the measure's risk adjustment model. RTI International asked TEP members to indicate their prioritization of several potential risk factors to add to the quality measure that were proposed based on an environmental scan of pressure ulcer risk factors. The TEP feedback was summarized and incorporated into the pre-TEP materials and informed discussion during the TEP webinar.

^a National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury | The National Pressure Ulcer Advisory Panel - NPUAP. (2016, April 13), from http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/

1.4 Organization of the Report

The following sections of the report discuss the measure changes explored by the TEP, and a summary of the feedback obtained from TEP members during the TEP webinar. Section 2 summarizes the addition of unstageable pressure ulcers in the measure calculations, including sDTIs, and Section 3 summarizes the transition from M0800/M1313 to M0300/M1311 items in the measure calculation. Section 4 summarizes the potential risk adjustment update and summarizes pre-TEP voting results on the proposed risk adjustors. Section 5 focuses on TEP member feedback regarding the implications of NPUAP updates for future iterations of this measure.

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SECTION 2

ADDITION OF UNSTAGEABLE PRESSURE ULCERS, INCLUDING SUSPECTED DEEP TISSUE INJURIES TO THE QUALITY MEASURE

2.1 Summary of Proposed Changes

Based on feedback from prior TEPs and clinical experts from the National Pressure Ulcer Advisory Panel (NPUAP), RTI International and Abt Associates explored the inclusion of unstageable pressure ulcers to the numerator of the pressure ulcer quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). The unstageable pressure ulcers included in the numerator are: 1) suspected deep tissue injuries (sDTI), 2) unstageable due to non-removable dressing or device and 3) unstageable due to slough or eschar.

RTI International provided analyses regarding the impact of the addition of the three unstageable categories to the facility score for IRFs, LTCHs and SNFs.^b These analyses indicated that measure scores increased across all post-acute care settings when including unstageable pressure ulcers. This increase ranged from a 0.16 % increase for median LTCH score, to a 0.37% increase for the median IRF score, to a 1.10% increase for the median SNFc score. The analyses also indicated greater variability across facilities with the proposed specifications, which allows for better discriminability between high and low performing facilities.

2.2 TEP Discussion

2.2.1 Suspected Deep Tissue Injuries

RTI International and Abt Associates proposed the inclusion of patients/residents with new sDTIs at discharge compared with admission in the cross-setting pressure ulcer measure. While there was support for inclusion of new sDTIs, several TEP members expressed concern for including this type of pressure ulcer in the numerator and some requested that this category be considered separately from the other two unstageable categories. One TEP member expressed concerns about adding sDTIs to the numerator as in some cases it could be difficult to determine whether the sDTI was acquired within the post-acute care facility or prior to admission. The TEP member described her understanding that current practice for some clinicians is to over-claim the presence of sDTIs during admission assessments. The TEP member further indicated there seemed to be lack of consensus regarding the time it can take for an sDTI to appear and indicated that sDTIs that appeared within 48 hours of admission should be considered as community acquired and not be attributed to the PAC facility. Other TEP members indicated that NPUAP guidance and additional literature support a 48 to 72 hour window for the sDTI to present itself.

b This analysis was not conducted in HHAs because the data was not available. Additional items necessary to calculate the modified measure will be collected effective January 1, 2017, in OASIS C2.

^c SNF scores were calculated for short-stay residents who had both PPS 5-day assessment and discharge assessment, which approximates a SNF stay.

One TEP member requested that an ongoing review of the literature could be conducted in order to determine the amount of time for an sDTI to appear.

There was consensus among TEP members that clear instructions in the assessment manuals regarding how to document if an sDTI were present on admission as well as consistent instruction across the manuals would be warranted. One TEP member indicated that current instruction in the OASIS manual was clear for the purposes of documenting sDTIs that were present on admission. One TEP member also requested that consideration be given to provision of an additional mechanism to ensure documentation of where the sDTI was acquired, outside or inside the PAC facility.

2.2.2 Unstageable Due to Non-removable Dressing or Device

RTI International and Abt Associates explored the inclusion of new pressure ulcers that are unstageable due to non-removable dressing or device in the pressure ulcer measure. While there was support for inclusion of this category, some TEP members requested that additional information be provided for this category. The TEP clarified that an example of a pressure ulcer that was unstageable due to non-removable dressing or device would include a pressure ulcer that was covered by a cast or back brace. Further clarification was provided that this type of pressure ulcer is typically low incidence. One TEP member clarified that this category represented less than one percent of all ulcers in the National Database of Nursing Quality Indicators (NDNQI).

One TEP member expressed concern that sometimes PAC facilities are unaware that a pressure ulcer exists under a dressing or device and are not aware of its existence until the device is removed during a stay. The TEP member indicated that the facility would not be aware of covered pressure ulcers if a patient or resident did not complain of pain. Several TEP members concurred that it would be important to provide further guidance to providers regarding identifying pressure ulcers that are unstageable due to non-removable dressing or device, and ensure the guidance is consistent across settings.

2.2.3 Unstageable Due to Slough or Eschar

RTI International and Abt Associates proposed inclusion of patients/residents with new pressure ulcers that are unstageable due to the slough or eschar during a stay in the numerator of the pressure ulcer measure. There was consensus among TEP members to include this category. However, there was some discussion regarding confusion among providers around slough and eschar and emerging new research. Some TEP members indicated that a strong case could be built for inclusion of pressure ulcers that are unstageable due to slough or eschar because these pressure ulcers likely could be categorized as Stage 2, 3 or 4 ulcers, if one could observe the base of the ulcer. Other TEP members advised caution in stating a potential stage because new research suggests that eschar or slough could be present in a Stage 2 ulcer. The TEP advised continuing to monitor research related to pressure ulcers with slough or eschar.

RTI International and Abt Associates proposed that 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. TEP feedback supported this statement. One TEP member provided

feedback following the meeting indicating the new NPUAP definitions maintain that slough does not appear until the wound is Stage 3 and one should not see it in Stage 2 pressure ulcers. The TEP member further maintained that therefore, a Stage 1 or 2 pressure ulcer that becomes unstageable due to slough should be considered worsened.

Some TEP members engaged in discussion around exclusion criteria stating that individuals who are in palliative care or hospice should not be included in the measure. One TEP member further indicated that some individuals with cancer or other end-stage disease could develop pressure ulcers despite the very best efforts of the provider. Clarification was provided that individuals who die in post-acute care are excluded from the measure. Further clarification was provided that while individuals who are in hospice are not excluded, this variable is being considered as a potential risk adjustor.

It was emphasized by some TEP members that making proposed changes to the measure would increase the rates of pressure ulcers for facilities and that this could cause some potential concern among providers. TEP members indicated that offering a webinar and a one-page fact sheet that explained the changes and the impact on the measure would be helpful to providers.

A few TEP members indicated the term "unstageable pressure ulcer" is not the preferred terminology for the three types of pressure ulcers discussed during the TEP meeting and further explained that these types of pressure ulcers are considered staged, though not staged numerically. In order to illustrate this concept, one TEP member requested that one type of pressure ulcer should be referred to as "not numerically staged due to non-removable dressing or device" as opposed to "unstageable due to non-removable dressing or device".

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SECTION 3 TRANSITION FROM M0800/M1313 ITEMS TO M0300/M1311 ITEMS

3.1 Summary of Proposed Changes

Although this cross-setting measure is currently harmonized across PAC settings, there are some remaining differences in the approaches to data collection and measure calculation across settings. CMS, RTI International, and Abt Associates are working to ensure standardization across all settings before the measure is publicly reported in 2018 (SNF, IRF, LTCH) and 2019 (HHA). To facilitate standardization of the measure, RTI International and Abt Associates explored transitioning to M0300/M1311 items for measure calculation. The data reported in these items affect the payment, while the M0800/M1313 items are used in the measure calculation as currently specified. This change is expected to reduce redundancies and data collection burden across settings. RTI International and Abt Associates presented two alternatives to the TEP for discussion: 1) a transition to calculation of the measure using M0300/M1311 items for numerically staged pressure ulcers only; and 2) a transition to calculation of the measure using M0300/M1311 items and inclusion of unstageable pressure ulcers in the measure calculation.

The M0800/M1313 items, Worsening in Pressure Ulcer Status Since Admission, collect the number of pressure ulcers at each stage that are new or worsened at discharge compared with admission. The M0300/M1311 items, Current Number of Unhealed Pressure Ulcers at Each Stage, collect the number of pressure ulcers present at each stage, and the number of these pressure ulcers that were present upon admission. Measure calculation using the M0300/M1311 items would involve a subtraction method. At each pressure ulcer stage, the number of pressure ulcers that were present on admission is subtracted from the number of pressure ulcers currently present at that stage to determine whether there are any new or worsened pressure ulcers.

3.2 TEP Discussion

Some TEP members expressed preference for the M0300 items over the M0800 items due to differences in wording. The M0800 items collect data on "worsening in pressure ulcer status," while the M0300 items collect data on "current number of unhealed pressure ulcers." One TEP member stated a preference for the neutral wording of the M0300 items over the M0800 items, which could potentially be interpreted to assign blame for the worsened pressure ulcers. Another TEP member stated a preference for the perceived clarity of the M0300 items, which collect both the current number of pressure ulcers and the number that were present on admission, over the M0800 items, which require the data abstracter to perform a mental calculation to determine the number of new or worsened pressure ulcers, thus providing an opportunity for error.

One TEP member expressed support for the inclusion of unstageable pressure ulcers including sDTIs. The TEP member expected that this change would likely improve quality of care by encouraging providers to pay attention to unstageable pressure ulcers and sDTIs. In addition, the change may encourage care for debriding pressure ulcers that are unstageable, since each pressure ulcer will be counted in the measure whether it is numerically stageable or not. In general, the TEP supported adding unstageable pressure ulcers to the measure and switching to M0300/M1311 items for measure calculation.

3.3 Unintended Consequences

TEP members discussed possible unintended consequences of the switch to M0300/M1313 items and addition of unstageable pressure ulcers. One TEP member pointed out that this change in measure specifications will likely affect rankings, and that it should be made clear to providers and consumers that such shifts in quality measure scores may be due to changes in measure calculation, and are not necessarily reflective of a shift in quality of care. Regarding the addition of unstageable pressure ulcers, one TEP member stated that this change would be likely to affect all providers similarly, with a general increase in scores. If measure scores are interpreted by comparing providers to one another, then this change is not expected to negatively impact any given provider.

3.4 Setting-Specific Discussion

TEP members discussed the importance of implementing the measure consistently across settings. Members agreed that it would be important for CMS to demonstrate consistency across training materials and assessment manuals in all settings.

TEP members discussed whether the proposed changes would have setting-specific effects in any of the healthcare settings in which it is implemented. One member indicated that in the home health setting, there may be patients who decline assistance such as changes in support services. Some of these patients may be appropriate candidates for hospice or palliative care, but decline this type of care. The TEP member expressed concern that this situation may increase the number of pressure ulcers seen in home health as compared to other settings. The effect may be mitigated in public reporting by comparing providers to other agencies within the same setting, rather than setting an absolute goal of 0 percent for the measure.

3.5 Discussion Summary

In general, the TEP was supportive of adding unstageable pressure ulcers to the measure and switching to M0300/M1311 items for measure calculation. To implement the changes, the TEP recommended clear and consistent training across settings. The TEP also recommended providing information to providers and consumers about how to interpret the results of the new calculation of the measure, and any shifts that may occur with the new calculation.

SECTION 4 RISK ADJUSTMENT UPDATE

4.1 **Pre-TEP Voting Results**

The cross- setting pressure ulcer measure is currently risk adjusted for four factors: functional limitation (bed mobility), bowel incontinence, diabetes or peripheral vascular disease/peripheral arterial disease, and low body mass index. Prior to the TEP, RTI International and Abt Associates asked each TEP member to select risk factors that would be important to test as risk adjusters from a list of factors previously identified in an environmental scan. The pre-TEP voting worksheet is included as *Appendix C*.

The risk factors recommended for testing by at least one member are listed here and sorted by domain:

- Comorbidities: depression, dialysis, hip fracture, impaired circulation, multiple organ failure, neurological disorders, pulmonary disease, sepsis, spinal cord injury, stroke
- Sociodemographic: older age
- Nutritional status and weight: low albumin level, high BMI, malnutrition, weight, weight loss
- Skin issues: admission with pressure ulcer, friction and shear, history of pressure ulcer, skin moisture
- Function and mobility: FIM score, mobility
- Devices and treatments: G-tube, mechanical ventilation, restraints, wheelchair
- Neurological and cognitive: neurologic conditions involving paralysis
- Blood pressure: hypotension, vasopressors
- Incontinence: urinary incontinence, incontinence associated dermatitis
- Other: hospice or end of life, pelvic or long-bone fracture, recent hospitalizations, smoker

4.2 Prioritization of Potential Risk Factors

The TEP was generally supportive of conducting testing of all of the risk factors identified through the pre-TEP voting process. Members did not have concerns about using any of the identified risk factors to adjust this measure, and did not recommend that any other risk factors be added to the list created through pre-TEP voting. However, members did caution against using a high number of risk adjusters and pointed out that some of the identified factors are related to others. Members recommended multivariate adjustment rather than univariate. One

TEP member provided additional literature regarding pressure ulcer risk factors, prevention, and methods for risk adjustment in pre-TEP and post-TEP feedback.²⁻⁴ TEP members were supportive of moving forward with testing the identified factors for use as risk adjusters in this measure.

The TEP discussed the possibility of using a more comprehensive pressure ulcer risk assessment (e.g., Braden Scale). Such a scale would include many of the identified risk factors. However, some TEP members raised concerns about the data collection burden that would result from including a full pressure ulcer risk assessment scale in the admission assessment. In addition, members indicated that the Braden Scale, for example, is commonly used to assess risk at approximately day 7 of a patient or resident stay, but may not be as effective an indicator during the time window that the admission assessment is completed.

One TEP member indicated that pressure ulcer risk factors may vary by setting and recommended examining the appropriateness of each risk adjuster in each setting.

4.3 Discussion Summary

The TEP supported testing of the pressure ulcer risk factors listed in *Section 4.1* to inform future risk adjustment of this measure, and encouraged consideration of multivariate adjustment.

SECTION 5 NEW NPUAP TERMINOLOGY

5.1 Summary of Changes

RTI International presented changes in regards to the National Pressure Ulcer Advisory Panel (NPUAP) Injury Staging System terminology to the TEP. These changes included use of the term "pressure injury" to replace the term "pressure ulcer." According to the NPUAP, this "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin." The NPUAP also reported that "previous staging system Stage 1 and Deep Tissue Injury described injured intact skin, while the other stages described open ulcers. This led to confusion because the definitions for each of the stages referred to the injuries as "pressure ulcers." Thus, the change in terminology from "pressure ulcer" to "pressure injury" is intended to clarify this confusion and maximize accuracy. In addition, the NPUAP removed the word "suspected" from the Deep Tissue Injury diagnostic label. RTI International and Abt Associates requested feedback from the TEP regarding the use of these new terms.

5.2 TEP Discussion

Many TEP members urged CMS to adopt the term "pressure injury" in place of the term "pressure ulcer;" no TEP members opposed this change in terminology. One TEP member, who supported the term "pressure injury," emphasized that the term "injury" is not associated with blame or harm by another entity and that this may need to be clarified through training. Another TEP member preferred the use of "injury" rather than "ulcer" because it includes those that occur as a result of action and other incidents. The TEP member also stated that "ulcer" may have a negative connotation to patients and the general public, and indicated that the term "pressure injury" may resonate more positively with patients, residents and family members. This TEP member supported the idea of educating patients and families on the new terminology, but perceived that additional strategies should be explored regarding best way to accomplish such education.

A TEP member, who expressed agreement with the change, stated that although pressure injuries are along the continuum of pressure ulcers, including the two different names creates confusion. Another TEP member recommended that CMS consider consistency across settings and resources when implementing the change.

Timing of the change was an important issue for TEP members. One TEP member stated that CMS should implement the change to pressure injury terminology as soon as possible; TEP members suggested making the change as soon as January 2017 to align with timing with the National Database of Nursing Quality Indicators (NDNQI) or the next version of the OASIS

d National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury | The National Pressure Ulcer Advisory Panel - NPUAP. (2016, April 13), from http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/

tool. Another TEP member encouraged CMS to make all changes regarding this terminology to documents simultaneously, if possible.

Ensuring the coordination of changes in terminology with other stakeholders was a concern for TEP members. One TEP member indicated that other stakeholders are working towards adopting the new terminology, stating that the Wound, Ostomy, and Continence Nurses Society (WOCN) and other associations, such as the NDNQI are also gaining momentum in preparing to change their terminology from "pressure ulcer" to "pressure injury." One member also indicated that it would be important to ensure that similar changes in terminology were occurring with SNOMED and LOINC coding. One TEP member also suggested coordinating the change in terminology with other stakeholders such as journal editor groups once the decision is finalized, as this would ensure consistency in indexing for peer-reviewed journals.

TEP members urged CMS to maintain current aspects of staging pressure ulcers. Several TEP members supported continued use of CMS' current guidance for blisters. TEP members agreed that the current CMS guidance for blisters should be maintained. Current CMS guidance looks beyond the color of fluid in the blister, recommending holistic assessment, including assessing for signs of deep tissue injury.

TEP members also discussed additional changes that will be implemented by NPUAP, including the definition of mucosal and medical-device related pressure ulcers. One TEP member stated that currently the RAI manual states that mucosal ulcers are not staged using the skin pressure ulcer staging system because anatomical tissue comparisons cannot be made. TEP members appreciated the clarity of the statement and suggested that consistent language be included in the manuals for each setting. TEP members recommended adding clear guidance for medical-device related pressure injuries, which should be staged using the staging system.

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APPENDIX A: TEP MEMBERS

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President; Clinical Editor for Advances in Skin and Wound Care

Ayello, Harris & Associates, Inc Hillis Hills, NY Senior Adviser The John A Hartford Foundation Institute for Geriatric Nursing New York, NY

Dr. Elizabeth Ayello is a board certified wound and ostomy nurse who is recognized as an expert in pressure ulcers, wounds, skin, ostomy and continence practice, education and research. In addition to serving as the clinical editor for the journal *Advances in Skin and Wound Care*, she is a faculty member at Excelsior College School of Nursing, VP of World Council of Enterostomal Therapists (WCET), and is executive editor emeritus for *WCET Journal*. Dr. Ayello served on the Board of Directors, was former president of the National Pressure Ulcer Advisory Panel (NPUAP), and holds several other leadership positons in a range of other wound care organizations. In addition to her clinical background, Dr. Ayello has experience working with quality improvement processes through her role as a consultant on several pressure ulcer quality initiatives, including consulting on the development of Minimum Data Set (MDS) 3.0 section M skin conditions for Long-Term Care, Long-Term Acute Care Hospital and Inpatient Rehabilitation Units. Furthermore, Dr. Ayello has published over 100 peer review journal articles, and has co-authored various educational wound care resources.

Laurie Crookenden, BS, RN, CWOCN, CRRN

Wound, Ostomy, and Continence Nurse Carolinas Rehabilitation *Charlotte*, *NC*

Ms. Crookenden is recognized as an expert in rehabilitation and wound care as demonstrated by her certifications in these areas and her election by her peers to serve as President of the North Carolina Wound, Ostomy, and Continence Nurses (WOCN) Group. She is Board Certified in wound, ostomy, and continence care by the Wound, Ostomy, and Continence Nursing Certification Board. Ms. Crookenden possesses a firm foundation in quality improvement and performance measurement for pressure ulcers in post-acute care. She also served on several quality improvement teams during her career. Ms. Crookenden is a certified rehabilitation registered nurse and has been a WOCN for ten years at Carolinas Rehabilitation, a large rehabilitation hospital in Charlotte. Carolinas Rehabilitation participated in the Hospital Engagement Network (HEN), a Centers for Medicare and Medicaid (CMS) initiative supported by a grant, which advises and implements strategies to prevent hospital-acquired pressure ulcers and skin breakdown. Ms. Crookenden served as a member of the grant's implementation team since it was awarded in 2012. In addition, Ms. Crookenden is Chair of Carolinas Rehabilitation's Skin Care Liaison Team where she has helped maintain a hospital-acquired pressure ulcer rate of less than two percent.

❖ Janet Cuddigan, PhD, RN, CWCN, FAAN

Associate Professor

University of Nebraska Medical Center School of Nursing *Omaha, NE*Adjunct Professor
Kansas University Medical Center School of Nursing *Kansas City, KA*

As a board certified wound care nurse, Dr. Janet Cuddigan brings clinical knowledge of pressure ulcers and wound care in a range of settings including acute care, long term care, skilled nursing facilities, nursing homes, and home health care. Over the course of her career, she has served as an expert clinician, educator, and researcher across multiple settings. Since 1995, she has held multiple positions on the NPUAP Board of Directors. Given her commitment and contributions to the organization, Dr. Cuddigan received the NPUAP Kosiak Award in 2011. Additionally, in 2015, she received the NPUAP President's Award for Leadership in developing the international pressure ulcer guidelines. Dr. Cuddigan also has experience in quality improvement and performance measurement, development, and implementation through her role as the Pressure Ulcer Consultant to the National Database of Nursing Quality Indicators (NDNQI). At NDNQI, she contributed to the ongoing refinement of NDNQI pressure ulcer indicators, participated in data collection and analysis of measures, and reviewed and revised the pressure ulcer value sets. In her current role as educator and researcher, Dr. Cuddigan continues to contribute to the ongoing refinement of pressure ulcer guidelines and serves as an expert speaker and consultant on pressure ulcers and wound care.

❖ Barbara A. Dale, RN, BSN, CWOCN, CHHN, COS-C

Director of Wound Care

Quality Home Health *Livingston, TN*

Ms. Barbara Dale serves as Director of Wound Care for Quality Home Health, a large proprietary home health agency in rural middle/east Tennessee serving an average daily census of 1600 patients. In this role, she serves as a patient consultant, conducting: comprehensive wound assessments and recommendations, ostomy care and teaching, continence assessments, and education. Ms. Dale has led and participated in numerous QI projects in her current role, including surgical wound improvement initiatives, which eventually led to policy and practice change. Currently, Ms. Dale conducts monthly QI audits on the 5 potentially avoidable events that are wound or continence related, working closely with OASIS data items related to skin/wounds, diabetes, and Braden scale scoring. In addition to her clinical experience and quality improvement knowledge, Ms. Dale is board certified in the following: CWOCN- Wound, ostomy, & continence nursing by the Wound Ostomy Continence Nurses Certifying Board; CHHN- Home health nursing by the American Nurses Credentialing Center; COS-C- Certificate OASIS Specialist-Clinical by the OASIS Certificate & Competency Board. Additionally, Ms. Dale has participated in various projects related to wound care and home health, has published on the topics of wound care and pressure ulcers, and has been invited to present on her work and expertise.

Jean M. deLeon, MD, FAPWCA

Professor; Physical Medicine & Rehabilitation; Medical Director of Wound Care University of Texas Southwestern Medical Center *Dallas, TX*

Dr. Jean deLeon, board certified in Physical Medicine and Rehabilitation, received her degree from the University of Oklahoma. Dr. deLeon has focused her career on wound care with particular clinical experience in Long-Term Care Hospitals (LTCHs) and Inpatient Rehabilitation Facilities (IRFs). She was responsible for developing the first wound care program and outpatient wound care center at Baylor Specialty Hospital in Dallas, Texas, and the first inpatient wound care unit in the Baylor Health Care system. She left the Baylor Healthy Care System in 2012 and took a position of Professor in the Department of Physical Medicine and Rehabilitation at UT Southwestern Medical Center in Dallas, TX. She helped open the first outpatient wound care clinic for the University. She currently serves as Medical Director of the UT Southwestern University Wound Care and Hyperbaric Clinic and as Medical Director of Wound Care at Lifecare Dallas Long Term Acute Care Hospital. Her area of interest is improving clinical outcomes and developing process improvement initiatives. She also serves as the wound care quality consultant for the Parkland Healthcare System. UT Southwestern and Texas Health Resources have recently formed an ACO, and Dr. deLeon is helping to lead the Post-Acute Care strategy for the ACO. She has also provided expertise on a range of national wound and postacute care quality measurements.

❖ Aimee Garcia, MD, CWS, FACCWS

Director, Clinical Wound Care Fellowship; Associate Professor of Medicine and Geriatrics

Baylor College of Medicine

Houston, TX

Medical Director, Wound Care Clinic and Consult Service

Michael E. DeBakey VA Medical Center

Houston, TX

Dr. Aimee Garcia has spent her entire career serving the geriatric population, focusing her career on Geriatric Medicine and wound care. In her current role as Medical Director at the Michael E. DeBakey VA Medical Center (MEDVAMC) in Houston Center, she serves an elderly veteran population in acute care, long-term care, skilled nursing, and hospice settings. She has clinical expertise on wound care in all care settings, including outpatient care. Dr. Garcia has published on the topics of wound care and pressure ulcers and has presented nationally and internationally on the prevention and treatment of pressure ulcers. Additionally, Dr. Garcia was President of the NPUAP from 2012-2013 and has served as the Chair of the Public Policy Committee for the NPUAP since 2008, where she has contributed to the ongoing prevention and treatment of pressure ulcers, working with CMS to develop a standardized, cross-setting tool to track pressure ulcers across the care continuum.

Brenda Mallory, MD

Professor of Physical Medicine and Rehabilitation

Penn State College of Medicine *Hummelstown*, *PA*

Dr. Mallory serves as the Chief Medical Officer of the Penn State Hershey Rehabilitation Hospital (PSHRH), where she is tasked with overseeing the medical care of persons receiving treatment in: PSHRH's 98 bed Inpatient Rehabilitation Facility and Transitional Care (which provides SNF level of care), Outpatient Rehabilitation Therapy Department and Wound Care Center. At the PSHRH, the integration of wound care specialists, inpatient teams and outpatient teams in both the IRF and Skilled Nursing Facility (SNF) settings, has resulted in a standardized, evidence driven approach to quality care for persons at risk for pressure injury. She has worked to facilitate best practices to improve patient outcomes for pressure ulcers in multiple settings and levels of care. Her professional experience includes consulting in an acute care hospital, where strategies to prevent pressure injury are at the forefront. Additionally, she is familiar with outpatients with spinal cord injury and extensive pressure ulcers. Dr. Mallory has coordinated care with Home Services and Plastic Surgeons, as well as physical and occupational therapists and certified rehabilitation technology specialists. She also holds a firm grounding in quality improvement and performance measurement. She implements the PSHRH's quality assessment and performance improvement and served as the Director of Quality Assurance for the Department of PM&R from 2010 to 2015. Among her numerous professional memberships, Dr. Mallory is a Fellow of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), a member of the American Association of Academic Physiatrists (AAP), and a member of the American Spinal Injury Association (ASIA).

Benjamin Peirce, BA, RN, CWOCN

VP of Utilization and Quality Management

Wound Technology Network *Plantation, FL*

Mr. Benjamin Peirce serves as Vice President of Utilization and Quality Management for a physician based provider of wound management services in the home for health plan and medical group patients in Florida, California, Nevada and Texas. In addition to his clinical experience, Mr. Peirce has worked in quality improvement (QI) for the past four years and has led and participated in numerous QI projects including the Post-Acute Care Payment Reform Demonstration project in 2008, while employed by Gentiva Home Health and Hospice. Currently, Mr. Peirce serves as Chair of the OASIS Task Force of the Wound Ostomy Continence Nursing Society (WOCN). This Task Force is responsible for maintaining the WOCN OASIS Guidance document to facilitate accurate classification of wounds by home health clinicians when answering Integumentary items in OASIS. He also previously served as Co-Chair of the Pressure Ulcer Framework Steering Committee for the NQF in 2009.

Tara Roberts, PT

VP of Rehabilitation and Wound Care Services

Nexion Health Management, Inc. *Sykesville, MD*

Ms. Tara Roberts has 21 years of experience as a Physical Therapist, where she has practiced in acute, subacute, and post-acute care settings, serving the inpatient, outpatient, IRF, LTCH, SNF, and home health patient populations. In her most recent role serving the SNF and LTCH settings, Ms. Roberts authored the SUCCESS (Securing Unmatched Clinical Competence in an Evolving Skin System) skin and wound care platform as well as the iCARE approach to effective clinical management for skin and wound care. In addition, Ms. Roberts developed the 3 Cs of Skin and Wound Care training module, a skin and wound care program that emphasizes Competence, Confidence, and Continuous quality assurance. In her current role as Vice President of Rehabilitation and Wound Care Services with Nexion Health, Ms. Roberts educates nursing and physical therapy staff on skin and wound care management. Additionally, Ms. Roberts serves as the Board of Governor for the National Association for the Support of Long Term Care (NASL), serving on the IMPACT Act and Medical Services committees. She is also a member of the American Health Care Association, serving on the Quality Improvement and Political Involvement committees, and participating in the development of a Short and Long Stay Quality Measure for Unintended Healthcare Outcomes and development of an Infection Prevention Control Officer Tract and Certification; American Physical Therapy Association member of Geriatrics, Clinical Electrophysiology and Wound Management, Cardiovascular and Pulmonary section, and Regulatory section sub-committees. Ms. Roberts currently co-chairs the LNHA Quality Improvement Initiative Committee for Pressure Ulcers. Given her extensive wound care clinical experience and knowledge, Ms. Roberts is frequently a guest columnist for McKnight's Long Term Care News and has provided continuing education on the topic of wound care and pressure ulcers, with emphasis on MDS Coding and Quality of Care and Quality Improvement Strategies for pressure ulcers.

Aamir Siddigui, MD

Division Head of Plastic Surgery Henry Ford Hospital

Detroit, MI

Dr. Aamir Siddiqui serves as the Division Head of Plastic Surgery at Henry Ford Hospital and the Medical Director of Wound Care Service, where he has focused his career on wound care and reconstructive surgery. In his current role, Dr. Siddiqui treats pressure ulcer patients in both inpatient and outpatient settings and contributes to clinical and benchtop research. Dr. Siddiqui has also worked on quality improvement initiatives and currently serves on the Board of Directors of the NPUAP. Dr. Siddiqui was named the American Society of Plastic Surgeons representative to the AMA Physician Consortium for Performance Improvement and served on the work group that developed the Medicare Physician Quality Reporting Initiative (PQRI) chronic wound measures approved by the National Quality Forum. Dr. Siddiqui is also active in the Wound Healing Society and serves as the co-program chairperson for the 2013 annual meeting. As an educator, he is involved in the training of surgery

residents and plastic surgery fellows and travels internationally as part of medical missions for the correction of acquired and congenital deformities.

Sheri Slater, M.S.

Patient Representative

Forest Hills, MD

Ms. Sheri Slater received her Master of Science in Child Life from the University of La Verne in La Verne, California and brings a valuable patient perspective to the TEP. Ms. Slater has volunteered and worked as a Child Life Specialist and has studied the effectiveness of various therapies for children, focusing on helping children cope with being in the hospital by providing therapeutic interventions to relieve anxiety through play, preparing children for procedures and helping children and families have the best experience they can while in the hospital. Ms. Slater also served as the patient representative on the 2013 cross-setting pressure ulcer TEP. Furthermore, Ms. Slater has firsthand experience with this subject matter as she was a patient seeking treatment and services for a wound that took over five years to properly heal.

APPENDIX B: TEP WEBINAR AGENDA

Refinement of a Cross-Setting Pressure Ulcer Quality Measure for Post-Acute Care Agenda

Technical Expert Panel (TEP) Meeting Development of Pressure Ulcer (PU) Measures for Post-Acute Care

1:00pm-5:00pm EST, Monday, July 18th, 2016 Dial-in Number: 1-888-706-0584 / Access Code 9432967# (see attachment for instructions to join the webinar)

-TEP Schedule-

Time	Agenda Item	Lead
1:00–1:30 pm	Welcome and Introductions	RTI
1:30–1:45 pm	Overview of Key Issues Needing TEP Input	RTI
1:45–2:45 pm	Addition of Unstageable Pressure Ulcers, including sDTIs, to Measure	RTI

- Background and summary of feedback from previous TEP (2013)
- Analysis results
- Topics for Discussion:
 - Should the definitions of unstageable pressure ulcers currently in the assessment tools be clarified or modified?
 - Are there any unintended consequences that could occur with the addition of unstageable pressure ulcers to the pressure ulcer measure? If so, what steps should be taken to ameliorate them?
 - Are there any setting-specific concerns regarding this proposed addition?
 - Are there any special considerations that need to be taken into account in conveying information about the changes to stakeholders?
 - Should special consideration be taken in inclusion of unstageable pressure ulcers due to non-removable dressing or device in the

measure? How should we frame this in consideration of the new NPUAP guidance?

- From the patient and family perspective, is there any concern about adding unstageable pressure ulcers to the measure?
- Is the differentiation between different stages (and unstageable pressure ulcers) important to patients and their families?

2:45-3:00 pm Break

RTI

- Background
- Steps toward harmonization
 - Switching to stay instead of episode in SNF
 - Move away from use of Interim assessments in SNF
 - Harmonize exclusions exclude all Residents who died in SNFs
 - Future move towards all payer measure
- Analysis results
- Topics for Discussion:
 - RTI analyses indicate that using the M0300 items instead of the M8000 items has an impact on measure scores in all three post-acute care settings; however, this impact is not consistent across the settings. What are potential reasons for these differences?
 - Are there any unintended consequences that could occur with the change in calculation of the pressure ulcer measure? If so, what steps should be taken to ameliorate them?
 - Are there any setting-specific concerns regarding this proposed change?
 - Are there any special considerations in training providers regarding this potential change

RTI 3:45-4:15 pm Risk Adjustment Update Overview of current risk adjustment Overview of lit review findings Presentation of pre-TEP voting results Topics for Discussion: Which risk adjustment items should be prioritized? Should any items not be used for risk adjustment? Are there other risk adjustment items that should be considered for inclusion? - Are any of the proposed risk adjustment items concerning from the patient perspective? **New NPUAP Terminology** RTI 4:15-4:45 pm Overview of changes Topics for Discussion: What are the pros and cons related to making changes to the quality measure and assessment items to be in line with new NPUAP terminology? Are there any special considerations to consider in making the changes?

Wrap-Up and Next Steps

4:45-5:00 pm

Are there special considerations that need to be taken to educate

RTI

patients and families regarding the new terminology?

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APPENDIX C: PRE-TEP VOTING WORKSHEET

Refinement of Pressure Ulcer Measures for Post-Acute Care Technical Expert Panel: Pre-TEP Feedback

Recommendations for Risk Adjustment Testing, Percent of Residents or Patients with New or Worsened Pressure Ulcers (Short-Stay)

This pressure ulcer quality measure is currently risk adjusted for functional status, bowel incontinence, diabetes or peripheral vascular disease, and low BMI. Prior TEP feedback indicated that we should consider additional risk adjustors. An environmental scan resulted in the following list of potential pressure ulcer risk factors, which are under consideration for risk adjustment testing.

Please select 10 risk factors from the list below that you consider high priority for risk adjustment testing. If you wish to provide additional information about your recommendations, please include it in the final column.

Selected Factor	Risk Factor	Data available for testing	Additional feedback on risk factor			
	Comorbidities					
	Primary diagnosis or	MDS, IRF-PAI, LTCH CARE Data				
	comorbidities, general	Set, OASIS** and claims				
	Anemia	MDS, IRF-PAI, OASIS** and Claims				
	Cardiovascular Disease	MDS, IRF-PAI*, OASIS** and Claims				
	Cataracts	MDS, IRF-PAI*, OASIS** Claims				
	Depression	MDS, IRF-PAI*, OASIS** and Claims				
	Dialysis	MDS, IRF-PAI*, OASIS and Claims				
	Edema	Claims				
	Hip fracture	MDS, IRF-PAI* OASIS** and Claims				
	HIV+	MDS*, IRF-PAI*, OASIS** and Claims				
	Impaired circulation	MDS, IRF-PAI* and Claims				
	Multiple organ failure	Claims				
	Neurological Disorders	MDS, IRF-PAI*, OASIS** and Claims				
	Pneumonia	MDS*, IRF-PAI*, OASIS** and				
		Claims				
	Pulmonary Disease	MDS, IRF-PAI*, OASIS** and Claims				
	Renal insufficiency/failure	MDS, IRF-PAI*, OASIS** and Claims				
П	Sepsis	MDS*, IRF-PAI* OASIS** and				
	-	Claims				
	Spinal Cord Injury	MDS*, IRF-PAI*, OASIS** Claims				
	Stroke	MDS, IRF-PAI*, OASIS** and Claims	((1)			

(continued)

Selected Factor	Risk Factor	Data available for testing	Additional feedback on risk factor
	So	ciodemographic	
	Sociodemographic factors, general		
	Employment/ income	Link address to geo-related income measures, or using Medicaid status as a proxy	
	Gender/Sex	MDS, IRF-PAI, LTCH CARE Data Set, OASIS and Claims	
	Older Age	MDS, IRF-PAI, LTCH CARE Data Set, OASIS and Claims	
	Race	MDS, IRF-PAI, LTCH CARE Data Set, OASIS and Claims	
	Nutrition	nal Status and Weight	
	Low Albumin Level	Claims	
	Dehydration	MDS and IRF-PAI*	
	High BMI	MDS, IRF-PAI, LTCH CARE Data Set and OASIS+	
	Malnutrition	LTCH CARE Data Set, OASIS** and Medicare FFS Claims	
	Weight	MDS, IRF-PAI, LTCH CARE Data Set and OASIS+	
	Weight loss	MDS, OASIS (for abnormal weight loss in risk item) and Claims (for abnormal weight loss)	
		Skin Issues	
	Admission with Pressure Ulcer	MDS, IRF-PAI, LTCH CARE Data Set, OASIS and Claims	
	Friction and Shear	MDS (skin tears)	
	History of Pressure Ulcer	MDS, OASIS** and Claims	
	Skin Moisture	MDS	
		ction and Mobility	
	Falls	MDS, IRF-PAI, OASIS and Claims	
	FIM Score	IRF-PAI	
	Mobility (bed mobility is currently adjusted for)	MDS, IRF-PAI, LTCH CARE Data Set and OASIS	
		es and Treatments	
	G-tube	MDS and IRF-PAI	
	Mechanical ventilation	MDS, IRF-PAI*, OASIS and Claims	
	Restraints	MDS	
	Wheelchair	MDS, IRF-PAI, OASIS and Claims	
		ogical and Cognitive	
	Altered Mental Status	MDS, IRF-PAI and OASIS	
	Cognitive decline/impairment	MDS, IRF-PAI and OASIS	
	Communication difficulties	MDS, IRF-PAI and OASIS	
	Neurologic conditions involving paralysis	MDS, IRF-PAI* and OASIS**	
	Sensory perception	MDS and OASIS	
-			(continued)

(continued)

Selected Factor	Risk Factor	Data available for testing	Additional feedback on risk factor			
Blood Pressure						
	Hypertension	MDS, IRF-PAI*, OASIS** and Claims				
	Hypotension	MDS, IRF-PAI*, OASIS** and Claims				
	Vasopressors	Claims				
	Stool and	Urinary Incontinence				
	Incontinence (bowel incontinence is currently adjusted for)	MDS (bowel and bladder), IRF-PAI (bowel and bladder), LTCH CARE Data Set (bowel), OASIS (bowel and bladder) and Claims				
	Incontinence Associated Dermatitis	MDS*, IRF-PAI* and OASIS**				
	Urological disorders	MDS, IRF-PAI*, OASIS** and Claims				
	UTI	MDS, IRF-PAI*, OASIS and Claims				
		Other				
	Fever	MDS, IRF-PAI* and Claims				
	Having an ICU stay	Claims				
	Hospice/end of life	MDS				
	Pelvic or long-bone fracture	IRF-PAI* and Claims				
	Previous Trauma	Claims				
	Recent hospitalizations	IRF-PAI and OASIS				
	Seasonal Variation	LTCH CARE Data Set and Claims				
	Shock/collapse	Claims				
	Smoker	MDS and OASIS				

^{*}Indicates data reported as "other" diagnoses using ICD codes. These fields may be completed less consistently, and therefore may be less reliable. On the MDS this is item I1800, and on IRF-PAI, Item 24.

^{**}Diagnoses will appear in OASIS data if present AND identified by clinician as significantly related to the home health plan of care; thus, some comorbid conditions patients have are not identified in the data. Some historical diagnoses (e.g. history of hip fracture, not recent, history of pneumonia, not recent) are also less likely to be included in OASIS data.

⁺ Indicates items that will be included on OASIS-C2