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**Technical Expert Panel Summary Report: Refinement of a
Cross-Setting Pressure Ulcer/Injury Quality Measure for
Skilled Nursing Facilities, Inpatient Rehabilitation Facilities,
Long-Term Care Hospitals, and Home Health Agencies**

Deliverable 14

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TECHNICAL EXPERT PANEL SUMMARY REPORT: REFINEMENT OF A CROSS-
SETTING PRESSURE ULCER/INJURY QUALITY MEASURE FOR SKILLED NURSING
FACILITIES, INPATIENT REHABILITATION FACILITIES, LONG-TERM CARE
HOSPITALS, AND HOME HEALTH AGENCIES

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LIST OF ACRONYMS AND SHORT FORMS

ACO	Accountable Care Organization
CMS	Centers for Medicare & Medicaid Services
DTI	Deep Tissue Injury
eCQM	Electronic Clinical Quality Measure
HHA	Home Health Agency
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
LTCH CARE Data Set	LTCH Continuity Assessment Record and Evaluation Data Set
MAP	Measure Application Partnership
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
PSHRH	Penn State Hershey Rehabilitation Hospital
QRP	Quality Reporting Program
QI	Quality Improvement
RAI	Resident Assessment Instrument
SNF	Skilled Nursing Facility
TEP	Technical Expert Panel
WCET	World Council of Enterostomal Therapists
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 risk adjustment models for the quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury 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 full-day conference held June 13, 2019.

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 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); for the period ending January 13, 2019, Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance (HHSM-500-2013-13001I; Task Order HHSM-500-T0002); and, for the period beginning January 14, 2019, Home Health and Hospice Quality Reporting Program Quality Measures and Assessment Instruments Development, Modification and Maintenance, & Quality Reporting Program Oversight Support (HHSM-75FCMC18D0014; Task Order HHSM 75FCMC19F0001). 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.

As part of CMS' efforts to meet the requirements of the IMPACT Act and to support CMS quality initiatives, RTI and Abt Associates developed the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) quality measure that was originally implemented in the NH setting in 2010 and later expanded to SNFs, LTCHs, and IRFs in October 2012, followed by HHAs in January 2017.¹ As part of its measure development process, CMS convened the same TEP on July 18, 2016, and January 30, 2018, during which TEP members provided feedback on potential improvements to the pressure ulcer quality measure, including the addition of unstageable pressure ulcers/injuries to the measure numerator, potential updates to risk adjustment, and the use of M0300/M1311 patient assessment items to calculate the quality measure.

¹ The measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) was endorsed by the National Quality Forum (NQF) with the NQF number #0678, from March 3, 2011, until June 28, 2019.

CMS used this feedback to guide the development of an updated cross-setting pressure ulcer quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which replaced the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay). The new quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, was finalized in the FY/CY 2018 Final Rules. Data collection for this new measure began July 1, 2018 for LTCHs, October 1, 2018 for IRFs and SNFs, and January 1, 2019 for HHAs. This cross-setting quality measure reports the percentage of stays of patients/residents with Stages 2–4 pressure ulcers, or unstageable pressure ulcers/injuries due to slough/eschar, non-removable dressing/device, or deep tissue injury (DTI), that are new or worsened since admission.^{2,3,4,5,6}

1.3 Process of the TEP Meeting

The objective of this TEP meeting was to seek expert input on refinements of the cross-setting pressure ulcer measure for PAC settings, including input related to risk-adjustment models, manual guidance and coding, and future directions for pressure ulcer/injury care.

1.3.1 TEP Members

On June 13, 2019, RTI reconvened the TEP members who provided input during the July 18, 2016, and January 30, 2018, TEP meetings. The TEP composition consisted of 12 TEP members 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 about new or worsened pressure ulcers, nutrition, wound care, and physical therapy. In addition, TEP members offered a range of perspectives related to quality improvement, payer perspective, data collection and implementation, and health care disparities. *Appendix A* provides the TEP composition, with brief biographies of each member.

² <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/IRF-Measure-Calculations-and-Reporting-Users-Manual-V30.pdf>

³ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/LTCH-Measure-Calculations-and-Reporting-Users-Manual-V30.pdf>

⁴ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-ORP-Measure-Calculations-and-Reporting-Users-Manual-V20.pdf>

⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-ORP-QM-Users-Manual-V10-August-2019.pdf>

⁶ Among post-acute care providers, terminology can vary, especially between HHAs and other post-acute care settings. For the purposes of this report, we define an “admission” as the beginning of a quality episode. For facility-based providers (IRFs, LTCHs, and SNFs), this would be an admission into the facility. For HHAs, an admission represents the start of care or the resumption of care. Additionally, we will use the term “provider” to represent a facility for IRFs, LTCHs, and SNFs and use the term “agency” for HHAs.

1.3.2 TEP Conference

The full-day, in-person TEP conference was held June 13, 2019 in Baltimore, MD. The agenda is provided in **Appendix B**. Discussion was facilitated by the measure lead, Julie Seibert, RTI, with support from members of the RTI and Abt Associates measure development teams. Representatives from CMS were also in attendance. The following topics were discussed:

- potential risk adjustment models for the new cross-setting pressure injury quality measure;
- findings from item-level and measure-level analysis of the new pressure injury measure; and
- guidance for potential updates to the quality reporting program manual definitions and guidance.

1.4 Organization of the Report

The following sections of the report discuss the guidance updates explored by the TEP and summarize the feedback obtained from TEP members during the conference. **Section 2** summarizes an analysis of initial data collected for calculation of the new Skin Integrity quality measure. **Section 3** summarizes TEP feedback on help desk questions and guidance. **Section 4** summarizes TEP feedback on proposed risk adjustment models for the Skin Integrity measure. **Section 5** summarizes TEP feedback on future pressure ulcer/injury quality measure development.

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SECTION 2

REVIEW OF DATA ELEMENT AND QUALITY MEASURE TESTING OF THE SKIN INTEGRITY MEASURE

2.1 Data Element and Quality Measure Testing Overview

RTI has been developing a testing plan to monitor implementation of the new Skin Integrity quality measure. The plan would include analyses to assess data coding and reporting trends, and quality measure calculations under the new specifications. Currently, the plan includes:

- review data element response frequencies for each type of pressure injury at admission and discharge;
- assess high-level coding accuracy by reviewing response concordance between related pressure injury items: M0210, Unhealed Pressure Ulcers/Injuries, and M0300, Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage;
- review prevalence of pressure injuries at admission and discharge, as well as prevalence of new or worsened pressure injuries using the new measure specifications; and
- review distribution of the quality measure provider-level scores.

RTI conducted this testing on the earliest available data, Quarter 3, 2018, LTCH data, and presented initial results to the TEP for consideration on the following overarching questions:⁷

1. Are there any setting-specific concerns regarding provided analysis?
2. Are there any clinical considerations that need to be taken into account in these analyses?

2.2 TEP Discussion: Frequencies of Unstageable Pressure Injuries

RTI presented results showing the counts for all types of pressure injuries as reported on admission and then at discharge. Given that reporting of unstageable pressure injuries and DTIs is a new component of the Skin Integrity measure, RTI asked the TEP for their feedback regarding the reported number of unstageable pressure injuries and DTIs. Specifically, RTI highlighted the relatively higher number of reported unstageable pressure injuries with slough, eschar, and DTIs and asked whether the counts appeared to be consistent with what they observe in facilities and clinical practice.

TEP members confirmed that the reported counts of pressure injuries seemed reasonable and emphasized the importance of monitoring frequencies of reported unstageable pressure injuries and DTIs specifically. They noted that in clinical practice, staff may be more likely to code a wound as an unstageable pressure injury and that this may be related to staffing limitations and cautionary behavior. They noted the difficulty of properly identifying these types of pressure injuries in clinical settings and articulated related issues and care practices or protocols that may impact provider reporting. One TEP member noted that, in particular, DTIs

⁷ Testing of HHA, IRF, and SNF data will occur when data are available.

may be overcalled despite efforts of NPUAP to refine the definition of a DTI. Providers often depend on wound specialists for accurate staging and, when needed, debridement of pressure injuries. Other provider staff may document observed injuries conservatively to avoid misidentification. For example, a provider trying to avoid erroneously coding a stage 4 as a stage 3 may end up documenting stage 3 pressure ulcers as being stage 4.

TEP members explained there are sometimes few wound care specialists in PAC settings to debride and/or stage and that nurses may not feel confident enough to stage pressure injuries themselves. Not all providers have a wound care clinician, which may result in more wounds remaining unstageable due to slough or eschar, if no one is available to do the debridement or recommend alternative treatments. Another TEP member noted that the decision to not debride is not necessarily poor care, and may be clinically justified in some situations, for example because of the patient's health status.

As part of this conversation, TEP members discussed a potential unintended consequence of including unstageable pressure injuries in the quality measure. One TEP member indicated that some providers may perceive that it is preferable to not debride a wound, in order to avoid the possible situation of debriding to a stage 3 pressure ulcer, which later worsens to a stage 4.

TEP members also agreed on the need for further education for providers on how to document pressure injuries and identify unstageable pressure injuries and DTIs. Additional comments and discussion around this topic are addressed in subsequent sections.

2.3 TEP Discussion: Documentation of Pressure Injuries Across Care Settings

RTI asked the TEP whether there is information about pressure injuries that needs to be collected and provided for transfers of information during care transitions. In response, the TEP discussed the issue of inconsistent clinical documentation across care settings and the difficulties this can create for accurate documentation of pressure injuries at receiving PAC settings during transitions in care. This is in part due to limited access to wound care specialists for staging. The TEP further suggests this cautionary behavior is related to provider efforts to ensure that they are not held responsible for a pressure injury that did not occur during their care. One TEP member noted that staff at PAC facilities are sometimes not permitted to stage, in order to avoid an erroneously low initial stage, which would make the wound appear to be "worsened" in documentation if it is later accurately staged. This can result in a low number of wound specialists covering a high number of patients at some providers.

Documentation discrepancies are also related to the variations in electronic health records systems used by different providers, and unstandardized documentation practices. When describing medical record extraction and assessment work at a specific health system, TEP members noted that there may be multiple different stages noted for one wound within a medical record, or that the record might not clearly state the location of the wound. These issues were noted especially for transfers between acute care settings and PAC settings. In addition, pressure ulcers are not always indicated on the discharge summaries that the PAC settings receive on admission.

TEP members also offered that these same issues related to variations in electronic health record systems and documentation efforts also occur within larger PAC facilities. For example, if a patient moves between floors, the receiving floor may assume that a pressure ulcer was present on admission, not realizing that it developed on the previous floor. The lack of full integration

between electronic health record systems and the lack of standardization across these systems is a barrier to consistent medical documentation. In electronic medical records, the same information might be copied and pasted throughout the record, making it difficult to track the timing of wound development. TEP members also noted that a way to address discrepancies in written documentation would be greater integration of imagery for pressure injuries, use of tissue analytics, and volumetric measurement.

In light of these cross-setting and cross-facility discrepancies, the TEP recommended assessing pressure ulcer frequencies between settings. This would include assessing concordance between discharge information from the transferring provider and admissions assessment information at the receiving provider.

TEP members stressed the importance of increasing physician involvement in staging and reporting of pressure injuries, as well as the importance of care teams working together to make these determinations. The TEP pointed out that the clinicians conducting skin assessments are often not empowered to write orders for care. The classification of a pressure injury should drive care, and there may currently be a disconnect.

2.4 Discussion Summary

After review and discussion of the testing plan, preliminary output, and clinical considerations, the TEP agreed that:

- Continued analysis and monitoring of coding of unstageable pressure injuries across PAC settings should occur.
- There is a need for further education for providers on how to document pressure injuries and identify unstageable pressure injuries and DTIs.
- It would be helpful to assess pressure injury documentation in acute care discharge and admissions assessments, and conduct a study comparing discharge and admissions documentation in PAC settings, to better understand how the clinical issues discussed in this section manifest in the data.

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SECTION 3 REVIEW OF MANUAL GUIDANCE AND CODING

3.1 Manual Guidance Overview

RTI and Abt identified topics of frequent confusion for providers and sought the TEP’s input on how to best clarify guidance around these topics. Some of the most frequent cross-setting help desk question topics included unstageable pressure ulcers/injuries, coding for present on admission items, and changes in presentation of the wound from time of admission to time of discharge. To guide TEP discussion, RTI presented three sample questions related to these topics and then asked the TEP members to provide feedback on additional guidance needed so that providers could more easily understand coding concepts.

3.2 Unstageable Pressure Ulcers/Injuries

The first sample question described a wound that is unstageable on admission due to non-removable device, and unstageable on discharge due to slough or eschar, and asks whether this would trigger the numerator of the pressure ulcer quality measure.

Sample Pressure Ulcer Help Desk Question and Response—Unstageable

Sample Question 1

Provider Question:

If a wound is unstageable on admission for one reason (e.g., non-removable device) and unstageable on discharge for another reason (e.g., slough /eschar), does this trigger the numerator for the pressure ulcer quality measure?

Response:

A pressure ulcer/injury reported at discharge and not coded as “present upon admission” on the Discharge Assessment would be considered a new or worsened pressure ulcer/injury. A pressure ulcer/injury reported at discharge and coded as present upon admission on the Discharge Assessment would not be considered new or worsened.

If a patient is admitted with an unstageable pressure ulcer due to a non-removable device and that pressure ulcer is observed as an unstageable pressure ulcer due to slough/eschar when the device is removed, and it remains unstageable due to slough/eschar when the patient is discharged, M0300F1 = 1 and it is considered present on admission on the discharge assessment (M0300F2 = 1).

The TEP agreed with the helpdesk response provided, that the scenario described should be coded so as to not trigger the measure numerator. The scenario prompted several discussion topics, including what constitutes worsening, accountability for wounds caused by a device, and clarification of correct coding of a pressure injury that is numerically unstageable at admission.

The TEP agreed that there is a need for further guidance for clinicians regarding what constitutes pressure injury worsening in this quality measure. There is likely confusion among clinicians about what is considered worsened, as well as how the measure is calculated. Worsening based on numerical stage is clear (i.e., a stage 2 that progresses to a stage 3 pressure ulcer is worsened). Other types of pressure injury evolution may involve clinical judgement of what is worsened and may be more complicated. There was not full TEP consensus regarding which wound progressions should be considered worsened. Current training manual guidance instructs that a stage 3 or 4 pressure ulcer (at admission) that becomes unstageable due to slough or eschar (at discharge) should be coded as unstageable at discharge and should not be coded as present on admission on the discharge assessment. This coding scenario triggers the numerator of the quality measure. Some TEP members described a potential unintended consequence of this coding guidance: considering a stage 3 or 4 that becomes unstageable due to slough or eschar to be “worsened” might encourage debridement even if it is inappropriate. In addition, there may be provider confusion around “staging” an “unstageable” pressure ulcer. For purposes of these assessments and this measure, the three unstageable categories are considered non-numerical stages, and this should be further clarified for providers.

The TEP discussed accountability for a pressure ulcer/injury that is caused by a device that was put in place by a previous facility. There is an important distinction between pressure ulcers/injuries that are unstageable due to coverage of the wound by a non-removable dressing or device (that is, the wound is known and documented, but cannot currently be visualized), as opposed to a pressure ulcer/injury **caused by** a device. In the second situation, the wound is unknown until the device is removed. The TEP described provider frustration with situations in which the receiving provider might remove a dressing/device that was applied by a previous provider and find a pressure injury that they were not aware of at the time of admission. If the wound is still present on discharge, the pressure injury would be considered new (that is, present on discharge and not on admission), and would trigger the quality measure numerator for the receiving provider. Despite the perceived unfairness of this scenario, the TEP expects that this situation is relatively rare. One TEP member suggested excluding these wounds.

In keeping with current manual guidance, a wound that is unstageable at admission should later be considered present on admission at its first numerical stage. A TEP member pointed out that this should be emphasized in the RAI manual, as there may be additional confusion after the removal of certain interim assessments.

3.3 Coding for Present on Admission Items

The sample question described two wounds presenting as DTIs, which have opened to either partial or full-thickness wounds. RTI and Abt proposed clarifying language for training materials: “a pressure wound presenting with characteristics of a DTI is reported as a DTI unless full thickness tissue loss is present.”

The TEP recommended altering the guidance recommended by RTI and Abt. The TEP came to agreement that a DTI should continue to be coded as a DTI until the wound is fully demarcated. The wound should only be numerically staged when other characteristics of DTI are no longer present, or when the DTI is fully evolved. The TEP recommended that future versions of training manuals and help desk responses, should better acknowledge DTI evolution.

Sample Pressure Ulcer Help Desk Question and Response—DTI

Sample Question 2

Provider Question:

A patient is admitted with two dark purple DTIs. One has a stage 3 in the center and the other a stage 2 with a dusky red base in the center of a purple DTI. Coding is done on admit as one Stage 2 and one Stage 3. Three days later these are both covered with black eschar and are now unstageable. If I code unstageable at discharge, it appears the wounds have worsened. Again, patient was admitted during the progression of a DTI.

Response:

Visualization of the wound bed is necessary for accurate staging. If the extent of soft tissue damage cannot be observed or palpated, the pressure ulcer/injury is considered unstageable. Evolution of DTIs may be rapid, exposing additional layers of tissue even with optimal treatment. We would like to clarify that a **pressure wound presenting with characteristics of a DTI is reported as a DTI unless full thickness tissue loss is present.**

In this scenario, one wound is described as a stage 3 that began as a DTI. The second is described as a DTI in evolution. This DTI has not opened to reveal the full thickness tissue loss.

The Admission assessment would be coded as follows: M0300C1, Number of stage 3 pressure ulcers = 1, and M0300G1, Number of unstageable pressure injuries presenting as deep tissue injury = 1.

If the stage 3 pressure ulcer increases in numerical stage or is unstageable due to slough/eschar at discharge, it would not be considered present on admission on the discharge assessment.

If the DTI becomes numerically stageable during the stay, it should be considered as “present on admission” at the stage at which each first becomes numerically stageable. If, however, when completing this patient’s discharge assessment, the numerical stage increases or the pressure ulcer become unstageable due to slough/eschar at discharge, then it would not be considered present on admission on the discharge assessment. If a patient is admitted with a closed DTI, and the first time the DTI is able to be numerically staged it is a stage 4, and if that stage 4 is observed at discharge, this is considered present upon admission. On the discharge assessment, item M0300D2, Number of these stage 4 pressure ulcers that were present on admission, = 1 and would not be counted as a new or worsened pressure ulcer/injury for this quality measure.

The TEP recommended additional detail in the guidance, specifically stating which numerical stages might follow a DTI. For example, the TEP recommended that the manuals should clarify that a DTI would never be staged as a stage 2 pressure ulcer after opening, because a DTI by definition involves a level of tissue damage greater than a stage 2 pressure ulcer. An open stage 2 pressure ulcer is partial thickness, while a DTI that has evolved and is numerically stageable would be a full-thickness wound (stage 3 or 4).

3.4 Changes in Presentation of the Wound

The sample question described a wound that was unstageable due to slough/eschar on admission and asked whether it would be considered reverse staging to later code the wound as a stage 2.

Sample Pressure Ulcer Help Desk Question and Response—Reverse Staging

Sample Question 3

Provider Question:

Guidance indicates that slough and/or eschar in the wound bed signify deeper tissue involvement and would not be found in a partial thickness wound. Would it then be correct to say that a wound first staged as unstageable due to slough/eschar and then staged as stage 2 would be reversed staged?

Response:

Yes, a full thickness pressure ulcer (stage 3 or stage 4) would not be reverse staged to a stage 2 as the pressure ulcer heals.

The TEP agreed with the provided help desk response, that this would be reverse staging. To further clarify this issue for providers, the TEP recommends a clarification in the guidance to explain that a stage 2 pressure ulcer would never include necrotic tissue.

The TEP described that providers often respond well to being validated for improvement. The current items and measure do not acknowledge improvement or healing in a pressure ulcer/injury. Providers might be tempted to reverse stage in their coding in order to document improvement in the wound, since there is no way to document that improvement occurred within the current assessment items. Creating an alternate way to document improvement may help to address this issue. For example, TEP members pointed to the Pressure Ulcer Scale for Healing (PUSH) tool which includes documentation of improvement.

3.5 Discussion Summary

After review and discussion of the help desk questions and responses, the TEP agreed that cross-setting training materials would benefit from additional clarification in the following areas:

- Additional information regarding what constitutes pressure injury worsening in this quality measure.
- Additional information clarifying coding for the progression of a DTI; and
- Additional information clarification that a stage 2 pressure ulcer would never include necrotic tissue, and that a DTI would never open to reveal a stage 2 pressure ulcer.

SECTION 4 RISK ADJUSTMENT

4.1 Risk Adjustment Overview

The purpose of risk adjustment when comparing outcome rates across PAC facilities is to statistically compensate for differences in the patient/resident populations so that the outcomes can be appropriately compared despite the differences in risk factors. For the new quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, a logistic regression model is used for risk adjustment, and the current covariates are assessed at admission. The current risk adjusters are function/mobility (bed mobility), bowel incontinence, diabetes or peripheral vascular disease/peripheral arterial disease, and low body mass index. Based on stakeholder feedback received through previous TEP meetings and rulemaking, it was determined that additional risk adjustment factors should be considered for inclusion in this measure. RTI and Abt identified and tested several risk factors for potential inclusion in the Skin Integrity quality measure and developed and tested both cross-setting and setting-specific models for consideration.

CMS asked RTI and Abt to convene a TEP to provide advice on the most clinically and methodologically appropriate risk adjustment model for the measure. The TEP was also convened to obtain expert input on the overall risk factor selection, thresholds used for risk factor construction, risk adjustment model selection, the need for additional analyses and implementation plans. TEP members were asked to provide feedback on the following questions:

Discussion of Overall Risk Factor Selection

1. *Are there additional factors that should be considered in the overall approach to risk adjustment?*
2. *Are there additional clinical considerations that should be considered?*
3. *Are there any additional considerations for how social risk factors should be addressed in this measure?*

Discussion of Thresholds used for Risk Factor Construction

4. *What additional considerations should be considered in risk adjustment variable construction?*
5. *Are the thresholds selected acceptable across settings?*
6. *Should the threshold vary by setting?*

Discussion of Model Selection

7. *The purpose of risk adjustment is to level the playing field across providers. Which of the three model types best achieves this?*
8. *Should the risk adjustment model be setting-specific, or standardized across PAC settings (in terms of risk factor selection or risk factor construction, i.e., cut points)?*

Additional Analyses

9. *Does the TEP recommend any further testing of these risk adjustment models?*
10. *Are any potential risk adjusters not addressed in these models?*

Implementation Issues

11. *Are there any special considerations that need to be taken into account in conveying information to stakeholders?*
12. *Are there any special considerations that need to be taken into account in conveying information about the changes to stakeholders?*

4.2 Methods

In order to identify potential additional risk adjustment factors for testing, RTI and Abt conducted an environmental scan of additional pressure ulcer risk factors over multiple years, including review of empirical literature, stakeholder feedback, and PAC setting help desk queries. RTI narrowed the resulting list to risk factors that could be obtained from assessment data in the PAC settings and that were expected to have clinical relevance. The list of risk factors tested is found in Appendix C. Additional testing was conducted to determine appropriate thresholds for the risk adjustment variables. Testing results for variable thresholds are found in Appendix D.

RTI and Abt reviewed the results of frequency analysis, bivariate analysis with heatmaps, and correlation analysis to determine which risk factors to test in the model. After correlation analysis, eight risk factors were excluded from testing because of high correlations with one existing risk factor—functional limitation (bed mobility). For logistic regression modeling, RTI and Abt used an iterative process, adding one assessment-based risk factor to the model at a time. The selection of the final set of risk adjusters was based on stepwise logistic model results, as well as clinical review. RTI and Abt presented the testing results to the TEP for their feedback.

4.3 TEP Discussion: Selection of Additional Risk Factors and Coding

In general, the TEP supported the selection of risk factors that were tested for inclusion in the risk adjustment model, citing their clinical relevance for inclusion.⁸ TEP members were also supportive of the thresholds for the risk adjustment variables and supported the proposed recodes for the bowel incontinence and bed mobility risk adjusters. The TEP raised questions about the approach used for some specific risk adjusters, including those for individuals with both bowel and bladder incontinence, extremely high BMI and advance age.

RTI noted they tested the effects of dual incontinence and that it was associated with higher incidence of new-or-worsened pressure ulcers. However, models with separate covariates for bladder and bowel incontinence had higher predictive power than models with bladder-bowel interaction term: having separate terms allows for the inclusion of more people in high-risk categories that are high risk because of single incontinence as opposed to dual incontinence (having separate terms and interaction terms in the same models creates collinearity issues). TEP members expressed appreciation for the discussion and agreement with keeping the items as

⁸ The complete list of risk factors tested is located in Appendix C.

separate risk covariates. One TEP member noted a danger with over-coding of pressure injuries for some of individuals with urinary incontinence. Some patients could actually have moisture-associated skin damage (MASD) because of incontinence that may be inaccurately reported as pressure ulcers/injuries.

RTI and Abt also tested high BMI and found it generally protective against the incidence of new-or-worsened pressure ulcers. Outlier BMI values—the top 1% of observations—were associated with greater incidence, but because that group was relatively small, the TEP concurred that extremely high BMI did not lend itself for inclusion in the model as a single risk covariate. TEP members noted that there are an increasing number of morbidly obese patients/residents served in PAC settings and that these patients are at very high risk for the development of pressure injuries. The TEP supported the possibility of constructing a general high-risk BMI variable that included individuals with low BMI and extremely high BMI for inclusion in the model.

The TEP questioned why some risk factors well known to clinicians were not included in the risk model. In particular, some TEP members questioned why some specific measures of patient function, such as chair-bound status, were not tested. RTI shared that all possible function assessment items were tested prior to inclusion in the model and there was a high level of collinearity with the existing bed mobility risk adjustor. Because the bed mobility item had the highest predictive power of any of the mobility items, it was retained in the risk adjustment model. The TEP suggested inclusion of additional risk adjustors, including severe protein malnourishment, results of blood testing, and history of pressure injuries, but understood that these risk adjustment factors are not currently collected on the PAC assessment tools and no data are currently available for testing.

4.4 Risk Adjustment Model Approaches

RTI and Abt also presented the results of logistic regression analysis. The frequencies of observed risk factor conditions are given in *Table 1*.

RTI presented three different sets of model-selection criteria: the *strict model*, the *relaxed model*, and the *setting-specific* model. The criteria for each model are found in Appendix D.

Parameter estimates and C-statistics for the strict, relaxed, and setting-specific models are presented in *Table 2*, *Table 3*, and *Table 4*, respectively.

Table 1. Frequency of risk factors for testing

	HHA	IRF	LTCH	SNF
Bed mobility	1,566,321 (25%)	129,017 (26%)	91,143 (56%)	656,933 (34%)
Bowel incontinence	707,467 (12%)	85,216 (22%)	101,458 (62%)	806,187 (42%)
Diabetes/PVD/PAD	2,467,334 (40%)	47,582 (41%)	77,651 (48%)	899,999 (47%)
Low BMI	319,001 (5%)	25,395 (5%)	13,182 (8%)	678,810 (35%)
Urinary incontinence	3,513,072 (57%)	122,749 (25%)	102,834 (66%)	194,250 (10%)
Advanced age (≥ 90)	716,752 (12%)	34,952 (7%)	4,764 (3%)	291,555 (15%)
Parenteral or tube feeding	106,554 (2%)	19,520 (4%)	8,986 (6%)	92,964 (5%)
Paralysis	396,213 (6%)	122,371 (25%)	11,583 (7%)	95,675 (5%)
Multiple sclerosis	52,003 (0.8%)	6147 (1%)	1,278 (0.8%)	14,225 (0.7%)
Coma	30 (0%)	56 (0.01%)	2,982 (2%)	1,140 (0.06%)
Sepsis	—	268 (5%)	53,066 (33%)	—
Chronic kidney disease	—	935 (19%)	—	—
Incomplete paraplegia	—	104 (2%)	—	—
Complete paraplegia	—	46 (1%)	—	—
Other spinal injuries	—	658 (13%)	—	—
ALS	—	< 11 (0%)	—	—
Acute respiratory conditions	—	1,043 (21%)	—	—
Chronic respiratory conditions	—	1,583 (32%)	—	—
Renal failure	—	1,194 (24%)	—	—

Source: RTI analysis of IRF-PAI, LTCH CARE and MDS data spanning October 1, 2016–September 30, 2017; program references: AB31, AK13_v2(20181017); Abt analysis of HHA data spanning January 1, 2017–December 31, 2017.

Table 2. HH, IRF, LTCH, and SNF risk adjustment strict models, FY 2017

Variable	HHA	IRF	LTCH	SNF
Intercept	-7.2526	-5.0584	-4.5743	-5.0523
Bed mobility	1.4178*	0.8398*	0.8916*	0.9018*
Bowel incontinence	1.1820*	0.3887*	0.2939*	0.3894*
Diabetes/PVD/PAD	0.3158*	0.5093*	0.1868*	0.3399*
Low BMI	0.5131*	0.5509*	0.3143*	0.3156*
Urinary incontinence	0.4615*	0.4708*	0.5177*	0.6341*
Advanced age (≥ 90)	0.3503*	0.1761*	0.1364	0.2203*
C-statistic	0.7852	0.693	0.6656	0.721

Note: * indicates the coefficient is statistically significant with $p < 0.05$.

Source: RTI Analysis of IRF-PAI, LTCH CARE, and MDS data spanning October 1, 2016–September 30, 2017; program references: AB31, AK14(20181010); Abt analysis of HHA data spanning January 1, 2017–December 31, 2017.

Table 3. HH, IRF, LTCH, and SNF risk adjustment relaxed models, FY 2017

Variable	HHA	IRF	LTCH	SNF
Intercept	-7.2583	-4.9781	-4.6069	-5.0542
Bed mobility	1.4089*	0.8564*	0.8504*	0.8815*
Bowel incontinence	1.1570*	0.4155*	0.2685*	0.3813*
Diabetes/PVD/PAD	0.3300*	0.5124*	0.2304*	0.3423*
Low BMI	0.4850*	0.5229*	0.2978*	0.2957*
Urinary incontinence	0.4664*	0.4948*	0.4899*	0.6173*
Advanced age (≥ 90)	0.3706*	0.1428*	0.2055*	0.2431*
Parenteral or tube feeding	0.6727*	0.2601*	0.0078	0.2823*
Paralysis	-0.1976*	-0.4966*	0.6244*	-0.0393*
Multiple sclerosis	0.2915	-0.1403	0.1341	0.4877*
Coma	—	-8.7157	0.3856*	0.5105*
C-statistic	0.7867	0.701	0.6797	0.7230

Note: * indicates the coefficient is statistically significant with $p < 0.05$.

Source: RTI Analysis of IRF-PAI, LTCH CARE, and MDS data spanning October 1, 2016–September 30, 2017; program references: AB31, AK13_v2(20181017); Abt analysis of HHA data spanning January 1, 2017–December 31, 2017.

Table 4. IRF, LTCH, and SNF setting-specific models, FY 2017

Variable	IRF-specific model	LTCH-specific model	SNF-specific model
Intercept	-5.2125	-4.6521	-5.0545
Bed mobility	0.8225*	0.8047*	0.8798*
Bowel incontinence	0.3643*	0.2348*	0.3805*
Diabetes/PVD/PAD	0.4199*	0.2274*	0.3417*
Low BMI	0.5414*	0.2743*	0.2963*
Urinary incontinence	0.4228*	0.4667*	0.6162*
Advanced age (≥ 90)	0.2575*	0.1681*	0.2447*
Parenteral or tube feeding	0.1739*	—	0.2782*
Paralysis	—	0.6386*	—
Multiple sclerosis	—	0.1365	0.4877*
Coma	—	0.3444*	0.5126*
Chronic kidney disease	0.8329*	—	—
Incomplete paraplegia	0.2632*	—	—
Complete paraplegia	1.0450*	—	—
Other spinal injuries	0.4402*	—	—
ALS	1.0807*	—	—
Acute respiratory conditions	0.2968*	—	—
Chronic respiratory conditions	0.1040*	—	—
Renal failure	0.3809*	—	—
Sepsis	0.1825*	0.0894*	—
Malnutrition	—	0.0921*	—
Dementia	—	0.1979*	—
Parkinson's	—	0.2965*	—
Ventilator	—	0.1706*	—
C-statistic	0.713	0.6847	0.723

Note: * indicates the coefficient is statistically significant with $p < 0.05$.

Source: RTI Analysis of IRF-PAI, LTCH CARE, and MDS data spanning October 1, 2016–September 30, 2017; program references: AB31, AK13_v2(20181017)

4.5 TEP Discussion: Risk Adjustment Model

In general, the TEP members supported the risk-adjustment testing approach employed by RTI and Abt. Of the three models presented, TEP members generally favored the setting-specific models, but allowed that the other harmonized models would be acceptable as well. The TEP members discussed the concordance statistics of the three models, which hover at or above 0.7 for the three models across settings, which is generally accepted to indicate a good model. TEP members generally agreed that the observed C-statistics for the models were good, with one TEP member noting that 0.7 is the typical goodness of fit statistic for the Braden Scale for predicting pressure injuries.

The TEP discussed the relative merits of the three models, observed that the statistical results were similar for all the models and acknowledged that other policy considerations would likely form the basis for selecting a risk-adjustment approach. One TEP member noted that some in the industry have identified that the different PAC settings are serving similar patients and that a harmonized risk adjustment model would help improve patient care regardless of setting. Some TEP members noted that a risk adjustment model acknowledging the different challenges faced in each setting is helpful (that is, setting-specific models), but that harmonization could help increase the quality of care between providers. One TEP member also noted that it is important to remember that risk adjustment models help prevent risk selection and that adding additional risk factors to the model would help providers perceive they could accept high-risk patients with no penalty. TEP members also discussed whether the model was designed to be additive (that is, included covariates for patients that had multiple risk factors). The tested models included each risk factor separately.

TEP members noted the importance of training to providers regarding risk adjustment. TEP members stated that harmonization was a good goal for risk adjustment, but if a model with less setting specificity were implemented, clear communication from CMS describing the intended goals for the risk adjustment model would be necessary. The TEP also noted that a harmonized data-collection instrument would help providers know what they are getting at admission and what to expect. Harmonization with similar acute care measures was also discussed.

4.6 Discussion Summary

In summary, after review and discussion of the risk adjustment analyses and models under consideration, the TEP offered the following feedback and suggestions:

- TEP members generally favored the setting-specific models but were amenable to implementation of the harmonized risk-adjustment model, given the similar statistical performance and the potential for a harmonized model to increase quality of care between providers. However, the TEP stressed the importance of clearly communicating risk adjustment goals if the cross-setting models are adopted.
- While the TEP suggested inclusion of additional risk adjustors, including severe protein malnourishment, results of blood testing, and history of pressure injuries, they recognized the limitations of current PAC assessment tools and lack of available data for testing these factors.

- The TEP supported the possibility of constructing a high-risk BMI variable that would include individuals with low BMI and extremely high BMI for inclusion in the model.

SECTION 5 NEW DEVELOPMENTS IN PRESSURE ULCER QM

5.1 Potential Development of a PAC Pressure Injury eCQM

RTI and Abt asked the TEP for feedback regarding implementation of pressure injury eCQMs that could be used across different settings. TEP members expressed an interest in including the acute care setting in any cross-setting quality measurement efforts. Most PAC admissions come directly from the acute care setting, and one TEP member stated that documentation of existing pressure injuries is often incorrect. A single documentation system that accurately tracked pressure injuries from the time of development until healing would be very helpful.

Several TEP members noted that the cross-setting infrastructure needed to move forward with eCQMs for this metric is not currently present. TEP members also pointed to the lack of universally standardized understanding and application of pressure injury definitions in identification and staging, which is a barrier to a standardized e-measure.

5.2 Use of Imaging Technology for Pressure Injury Coding

As an offshoot of the discussion regarding implementation of eCQMs, the TEP expressed a strong interest in incorporating image technology to assist providers in monitoring pressure injuries. Several TEP members discussed how image technology has helped them identify and stage pressure injuries and ensure accurate reporting in assessments. One TEP member related that as she is the only wound care nurse in the facility, the technology has enabled them to better identify pressure injuries and has also been helpful for determining what is present on admission. Photographic documentation has also helped correct inaccurate earlier documentation. Telemedicine has also helped in this arena by expanding resources and then accuracy.

There are structural limitations for integrating these technologies into the process. One TEP member noted the legal considerations involved in broader use of the technology in long-term care. Variations in medical record systems lead to related limitations, such as lack of image access. Even when pictures are taken, they may not be accessible across different systems. Furthermore, image standards, or rather standardized specifications to ensure the quality and utility of the image being captured and documented, do not exist. This, as one TEP member explained, can lead to documentation of non-useful photos.

The TEP discussed the level of agreement in language and staging determinations throughout the clinical community. TEP members noted a need for better standardized nomenclature, which would also help with the creation of eCQMs in the future. Some members suggested that photography may help standardize staging determinations. One TEP member provided email feedback suggesting that CMS adopt a standard for taking photos of wounds with a process for measuring conformance to that standard and require photos to be taken of all wounds within 24 hours of transfer and included in any transfer packet. The TEP member indicated it would be relatively simple to construct e-measures from this process.

5.3 Need for a Quality Measure to Assess for “Healed” Pressure Ulcers

Some TEP members suggested a skin integrity measure of positive facility outcomes such as healed pressure ulcers, noting that many providers feel they do not currently get credit for excellent care.

5.4 Discussion Summary

As a result of the discussion of the feasibility of the development of a pressure injury eCQM, the TEP agreed:

- Cross-setting efforts, such as further development of data elements and tools, as well as development of any pressure injury electronic clinical quality measure (eCQM), should include acute and post-acute care settings.
- There is a need for better care integration and coordination across acute care and PAC settings. This would be facilitated by more-integrated, more-interoperable health information systems.

SECTION 6 SUMMARY AND NEXT STEPS

6.1 TEP Meeting Summary

RTI and Abt Associates reconvened the pressure ulcer TEP in June 2019 to provide feedback on potential risk adjustment models for the new Skin Integrity quality measure, findings from item level and measure level analysis of the measure and guidance for potential updates to the quality reporting program manual definitions and guidance.

The TEP supported ongoing testing efforts at the item and measure level. The TEP encouraged testing approaches that would follow patients through different settings, comparing discharge assessments from one provider with the admission assessments of the receiving provider. They recommended that continuing measure development should consider both acute and PAC settings.

The TEP supported additional clarity in training materials and guidance. In particular, the TEP recommended clarification regarding what constitutes pressure injury worsening, coding for the progression of a DTI, and clarifying the progression and tissue involvement in a pressure ulcer that is unstageable due to slough or eschar.

Prior to the in-person TEP meeting, members were provided with an overview of risk adjustment testing results. The TEP supported RTI's proposed adjustments to the high- and low-risk categories of the existing risk factors. The TEP acknowledged the different strengths of the different risk adjustment models presented. The TEP favored the setting-specific models, to best address the different challenges faced in different settings. However, the TEP also agreed that if harmonization is a main goal for the measure, then the relaxed model is also suitable and may help increase quality of care between providers. Some members would prefer a harmonized model unless there is a large improvement in predictive power seen by using a setting-specific model.

The TEP brought up a few additional topics, including potential future development of an eCQM, and use of imaging technology to improve skin assessments and coding. Regarding an eCQM, the TEP supported the idea of a fully cross-setting measure and documentation system that would include acute care as well. The TEP noted that the current infrastructure is not universally standardized and is likely insufficient for such a measure. The TEP expressed interest in exploring the use of photographs and imaging technology for improving skin assessment and documentation for quality measure development.

6.2 Next Steps

RTI and Abt Associates will consider TEP feedback and make recommendations to CMS for potential refinements to risk adjustment for the quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. TEP feedback will be used to inform revisions and updates to future work related to measure modifications, guidance, and coding scenarios.

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**APPENDIX A:
TEP MEMBERS**

► **Elizabeth A. Ayello, PhD, RN, ACNS-BC, CWON, ETN, MAPWCA, FAAN**

Co-Editor-in-Chief; 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 executive editor emeritus for *WCET Journal*. Dr. Ayello serves on the Board of Directors, was former president of the National Pressure Ulcer Advisory Panel (NPUAP) and holds several other leadership positions 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.

► **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 post-acute care quality measurements.

► **Jennifer Simpson, BSN RN, CRRN, CWOCN**

Wound Ostomy Continence Nurse

Carolinas Rehabilitation

Charlotte, NC

Ms. Jennifer Simpson serves as a wound ostomy continence nurse with Carolinas Rehabilitation in Charlotte, NC. In her role, she is responsible for evaluating and creating treatment plans for patients with wound, ostomy, and/or continence-related issues under supervision of physicians. Ms. Simpson has held clinical nursing roles for over 10 years. In addition to her certification in wound ostomy continence nursing, Ms. Simpson maintains certifications in basic life support for health care professionals and is a registered rehabilitation nurse. With Carolinas Rehabilitation, Ms. Simpson contributed to a quality improvement project titled “Improving Wound Care Order Compliance” and serves as Chair for the Skin & Wound Assessment Team (SWAT). Additionally, Ms. Simpson maintains memberships the Wound Ostomy and Continence Nurses Society and the Atrium Health Pressure Injury Prevention-Quality Safety Operations Council (PIP-QSOC).

► **Janet Cuddigan, PhD, RN, CWCN, FAAN**

Professor

University of Nebraska Medical Center College of Nursing

Omaha, NE

President

National Pressure Ulcer Advisory Panel

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.

► **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).

► **Aamir Siddiqui, 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.

► **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 on the Board of Governors 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.

► **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.

► **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, and 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.

► **Sheri Slater, MS**

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 and the July 2016 cross-setting pressure ulcer TEP.

► **Terrence O'Malley, MD**

Geriatrician

*Massachusetts General Hospital
Boston, MA*

Terrence O'Malley, MD, is a geriatrician at Massachusetts General Hospital and Spaulding Nursing and Therapy Center North End with experience providing care to patients with complex medical needs. He is also an instructor at Harvard Medical School. His areas of expertise are in quality measurement and process improvement, systems design, and clinical care, particularly in long-term and post-acute settings.

**APPENDIX B:
TEP WEBINAR AGENDA**

**Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Technical Expert Panel (TEP) Meeting**

Agenda

10:00 am–3:00 pm EST, Thursday, June 13, 2019

—TEP Schedule—

<i>Time</i>	<i>Agenda Item</i>	<i>Lead</i>
10:00–10:15 am	Welcome and Introductions	RTI
10:15–10:30 am	Background and Overview of Issues Needing TEP Input	RTI
	<ul style="list-style-type: none"> • Background and summary of feedback from previous TEP (January 2018) • Update on measure in FY2018 rule • Roadmap of PU measure changes and next steps 	
10:30–12:00 pm	Review of Risk-Adjustment Models	RTI
	<ul style="list-style-type: none"> • Background on need to update pressure ulcer measures risk adjustment • Review of literature and risk-adjustment approach • Data sources and testing methods • Model testing results <ul style="list-style-type: none"> ○ Overview of thresholds used for risk factor construction for specific risk adjustors ○ Strict model ○ Relaxed model ○ Setting-specific models • Topics for discussion: <ul style="list-style-type: none"> ○ Discussion of overall risk factor selection <ul style="list-style-type: none"> ▪ <i>Are there additional factors that should be considered in the overall approach to risk adjustment?</i> ▪ <i>Are there additional clinical considerations that should be considered?</i> ▪ <i>Are there any additional considerations for how social risk factors should be addressed in this measure?</i> ○ Discussion of thresholds used for risk factor construction <ul style="list-style-type: none"> ▪ <i>What additional considerations should be considered in risk adjustment variable construction?</i> ▪ <i>Are the thresholds selected acceptable across settings?</i> 	

- *Should the threshold vary by setting?*
- Discussion of model selection
 - *The purpose of risk adjustment is to level the playing field across providers. Which of the three model types best achieves this?*
 - *Should the risk adjustment model be setting-specific, or standardized across PAC settings (in terms of risk factor selection or risk factor construction i.e., cut points)?*
- Additional analyses
 - *Does the TEP recommend any further testing of these risk adjustment models?*
 - *Are any potential risk adjusters not addressed in these models?*
- Implementation issues
 - *Are there any special considerations that need to be considered in conveying information to stakeholders?*
 - *Are there any special considerations that need to be taken into account in conveying information about the changes to stakeholders?*

12:00–1:00 pm

Lunch

1:00–2:00 pm

Review of Item-Level and Measure-Level Analysis of Pressure Injury Measure

RTI

- Review of item-level analysis across four settings
- Topics for discussion:
 - *Are there any setting-specific concerns regarding provided analysis?*
 - *Are there any special considerations that need to be taken into account in conveying information to stakeholders?*

2:00–2:45pm

Review of Manual Guidance and Coding

RTI

- Review of measure-specific Frequently Asked Questions submitted to the helpdesk

2:45–3:00 pm

Wrap-Up and Next Steps

RTI

- Review consensus decisions and areas for further exploration
- Review next steps

**APPENDIX C:
IDENTIFIED RISK FACTORS FROM ASSESSMENT DATA**

**Table C-1
Identified Risk Factors from Assessment Data**

	OASIS item	IRF-PAI item	LCDS item	MDS item	Coding
Risk factors recommended for testing across settings					
Bed mobility	GG0170C	GG0170C	GG0170C	GG0170C	Risk adjuster = 1 if GG0170C (Lying to sitting on side of bed) = 01 (Dependent), 02 (Substantial/maximal assistance), 07 (Patient refused), 09 (Not applicable), 88 (Not attempted)
Bowel incontinence	M1620	H0400	H0400	H0400	<ul style="list-style-type: none"> IRF/LTCH/SNF: Risk adjuster = 1 if H0400 (Bowel Continence) = 2 (frequently incontinent), 3 (always incontinent), 9 (not rated) HHA: 1 = any problems (M1620 = 1, 2, 3, 4, 5); 0 = otherwise (includes NA and UK)
Diabetes/PVD/PAD	M1028	I0900/ I2900	I0900/ I2900	I0900/ I2900	<ul style="list-style-type: none"> IRF/LTCH/SNF: Risk adjuster = 1 if I0900 (PVD or PAD) or I2900 (Diabetes) = 1 HHA: 1 = PVD or DM (M1028 = 1, 2); 0 = otherwise
Low BMI	M1060/ M1060	25A/26A	K0200A/ K0200B	K0200A/ K0200B	Risk adjuster = 1 only for values of BMI of 12 through 19
Urinary incontinence	M1610	H0350	H0350	H0300	<ul style="list-style-type: none"> IRF/LTCH: Risk adjuster = 1 if H0350 (Bladder Continence) = 3 (incontinent daily), 4 (always incontinent), 5 (no urine output), or 9 (not applicable) SNF: Risk adjuster = 1 if H0300 = 2, 3, 9 HHA: 1 = any problems (M1610 = 1, 2 [catheter]); 0 = otherwise

(continued)

Table C-1 (continued)
Identified Risk Factors from Assessment Data

	OASIS item	IRF-PAI item	LCDS item	MDS item	Coding
Advanced age	M0066	Item 6	A0900	A0900	Risk adjuster = 1 if age ≥ 90
Parenteral tube feeding	M10230	K0110C	O0100N	H0510A2/ K0510B2	<ul style="list-style-type: none"> • IRF: Risk adjuster = 1 if K0100C = 1 • LTCH: Risk adjuster = 1 if O0100N = 1 • SNF: Risk adjuster = 1 if K0510A2 = 1 OR K0510B2 = 1 • HHA: 1 = parenteral or enteral nutrition (M1030 = 2, 3); 0 = otherwise
Paralysis	M1021 M1023_1 M1023_2 M1023_3 M1023_4 M1023_5	Items 21 and 24	I5000, I5101, I5102, I5110	I4900, I5100	<ul style="list-style-type: none"> • IRF: coding based on primary diagnosis codes used in IRF-PAI item 21 and ICD-10 codes used in item 24 • LTCH: Risk adjuster = 1 if I5000 = 1 OR I5101 = 1 OR I5102 = 1 OR I5110 = 1 • SNF: Risk adjuster = 1 if I4900 = 1 OR I5100 = 1 • HHA: Any of primary or secondary diagnoses match the ICD list provided by RTI on 10/12
Multiple sclerosis	M1021 M1023_1 M1023_2 M1023_3 M1023_4 M1023_5	Items 21 and 25	I5200	I5200	<ul style="list-style-type: none"> • LTCH/ SNF: Risk adjuster = 1 if I5200 = 1 • IRF: coding based on primary diagnosis codes used in IRF-PAI item 21 and ICD-10 codes used in item 24 • HHA: Any of primary or secondary diagnoses match the ICD list provided by RTI on 10/12
Coma	M1021 M1023_1 M1023_2 M1023_3 M1023_4 M1023_6	Items 21 and 26	B0100	B0100	<ul style="list-style-type: none"> • LTCH/SNF: Risk adjuster = 1 if B0100 = 1 • IRF: coding based on primary diagnosis codes used in IRF-PAI item 21 and ICD-10 codes used in item 24 • HHA: Any of primary or secondary diagnoses match the ICD list provided by RTI on 10/12

(continued)

**Table C-1(continued)
Identified Risk Factors from Assessment Data**

	OASIS item	IRF-PAI item	LCDS item	MDS item	Coding
Recommended risk factors in some settings					
Malnutrition			I5601		Risk adjuster = 1 if I5601 = 1
Dementia			I4801		Risk adjuster = 1 if I4801 = 1
Parkinson's			I5300		Risk adjuster = 1 if I5300 = 1
Ventilator			O0100F3, O0100F4		Risk adjuster = 1 if O0100F3 = 1 OR O0100F4 = 1
Sepsis		Items 21 and 24	I2101, I2600		<ul style="list-style-type: none"> • LTCH: Risk adjuster = 1 if I2101 = 1 OR I2600 = 1 • IRF: coding based on primary diagnosis codes used in IRF-PAI item 21 and ICD-10 codes used in item 24
Chronic kidney disease		Items 21 and 24			IRF: coding based on primary diagnosis codes used in IRF-PAI item 21 and ICD-10 codes used in item 24
Incomplete paraplegia		Items 21 and 24			
Complete paraplegia		Items 21 and 24			
Other spinal injuries		Items 21 and 24			
ALS		Items 21 and 24			
Acute respiratory conditions		Items 21 and 24			
Chronic respiratory conditions		Items 21 and 24			

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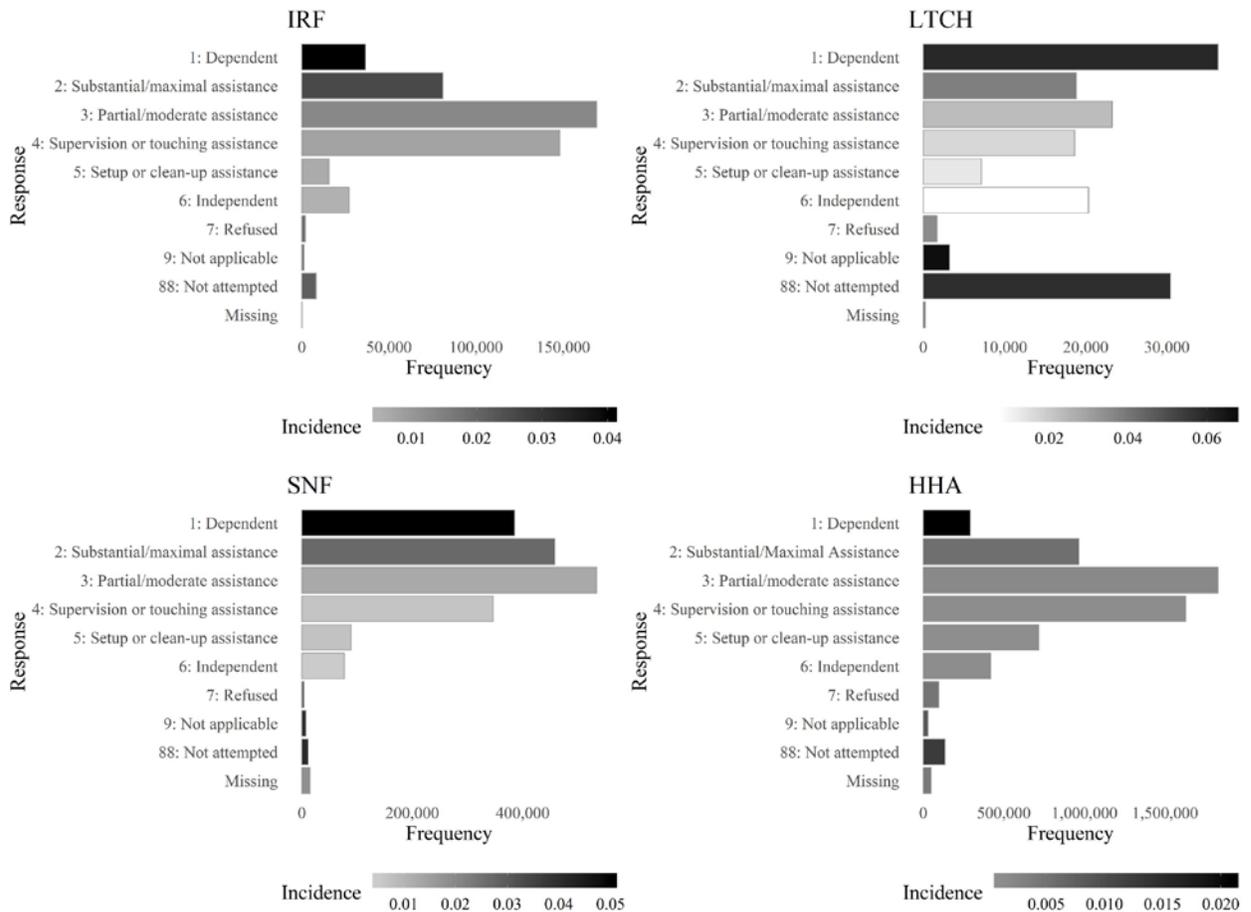
**APPENDIX D:
RISK ADJUSTMENT CODING RESULTS**

Recoding Functional Limitation (Bed Mobility)

RTI and Abt provided testing results to the TEP indicating that, across settings, dependence in bed mobility is strongly and directly associated with the incidence of new-or-worsened pressure ulcers. “Not applicable” and “not attempted” responses are also directly associated with incidence of new-or-worsened pressure ulcers across settings. Partial or moderate dependence in bed mobility is not associated with the incidence of new-or-worsened pressure ulcers. The frequencies of bed mobility item responses and their respective associations with new-or-worsened pressure ulcers are shown in *Figure D-1*.

Recodes for All Settings (IRF/LTCH/SNF/HHA):
 Risk adjuster = 1 if GG0170C (Lying to sitting on side of bed) = 01 (dependent), 02 (substantial/maximal assistance), 07 (patient refused), 09 (not applicable), 88 (not attempted)

Figure D-1. Bed mobility and pressure ulcer/injury incidence in IRFs, LTCHs, SNFs, and HHAs



Coding Bowel Incontinence

RTI and Abt showed the TEP testing results indicating that frequent (daily or more-frequent) bowel incontinence is positively associated with the incidence of new-or-worsened pressure ulcers. The frequencies of bowel incontinence item responses and their respective associations with new-or-worsened pressure ulcers are shown in *Figure D-2*.

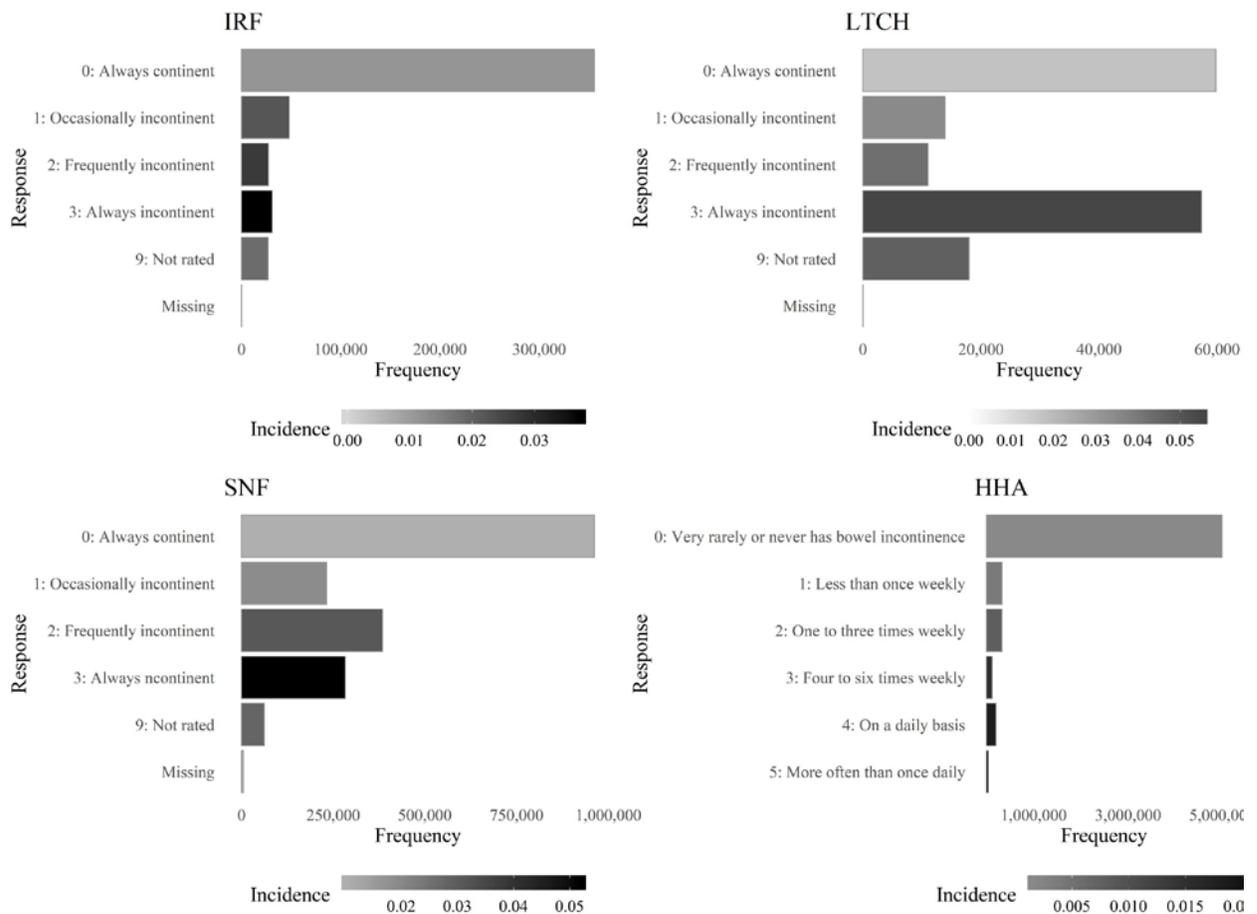
Recodes for IRF/LTCH/SNF:

Risk adjuster = 1 if H0400 (Bowel Continence) = 2 (frequently incontinent), 3 (always incontinent), 9 (not rated)

Recodes for HHA:

1 = Any problems (M1620 = 1, 2, 3, 4, 5);
0 = otherwise (includes NA and UK)

Figure D-2. Bowel incontinence and pressure ulcer/injury incidence in IRFs, LTCHs, SNFs, and HHAs



Coding Urinary Incontinence

RTI showed that, across IRF, LTCH, and SNF settings, frequent bladder incontinence was directly associated with incidence of new-or-worsened pressure ulcers. “Not rated” (for SNF), “no urine output,” and “not applicable” (IRF and LTCH) were directly associated with incidence of new-or-worsened pressure ulcers. HHA data were not available. The frequencies of urinary incontinence item responses and their respective associations with new-or-worsened pressure ulcers are shown in *Figure D-3*.

Recodes for IRF/LTCH:

Risk adjuster = 1 if H0350 (Bladder continence) = 3 (incontinent daily), 4 (always incontinent), 5 (no urine output), or 9 (not applicable)

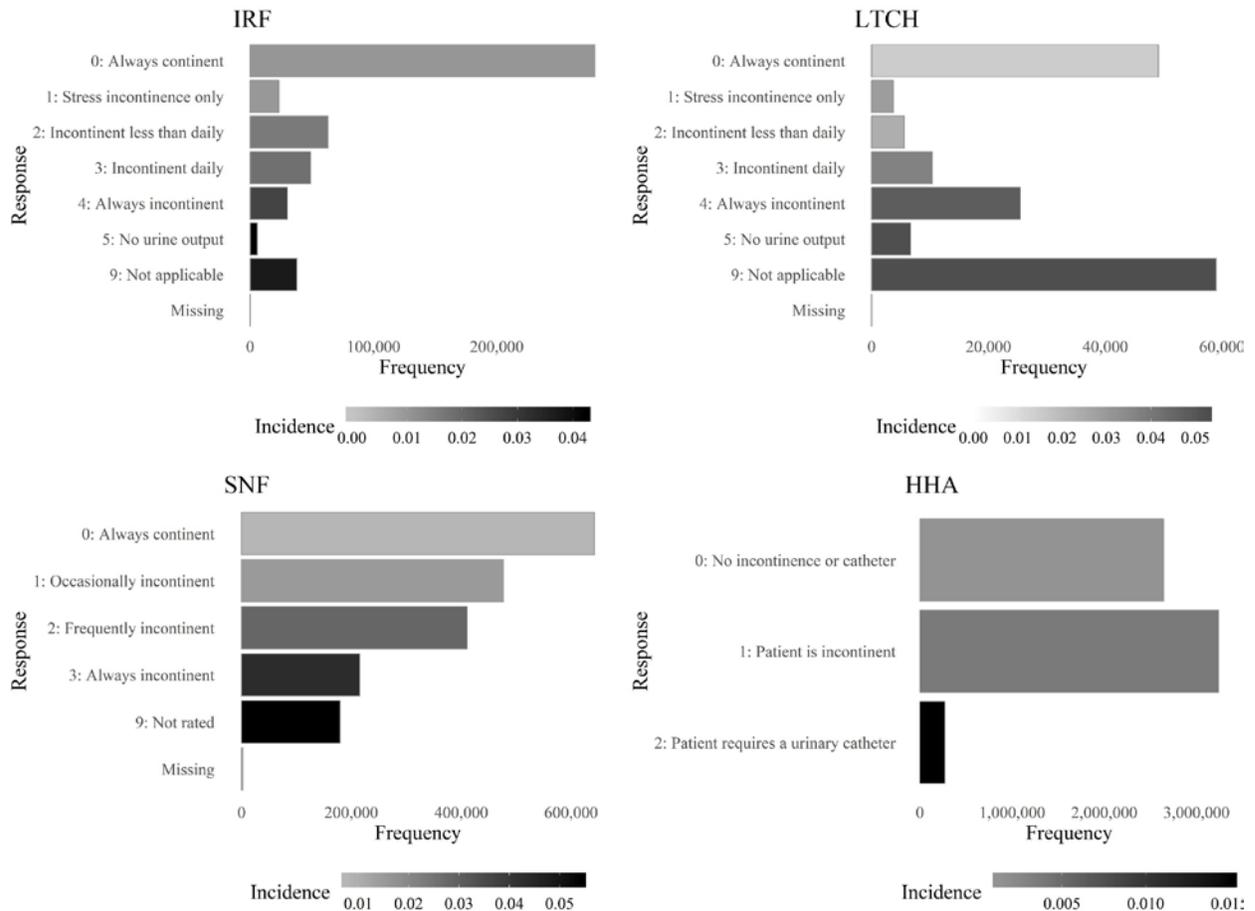
Recodes for SNF:

Risk adjuster = 1 if H0300 = 2, 3, 9

Recodes for HHA:

1 = Any problems (M1610 = 1, 2 [catheter]);
0 = otherwise

Figure D-3. Urinary incontinence and pressure ulcer/injury incidence in IRFs, LTCHs, and SNFs

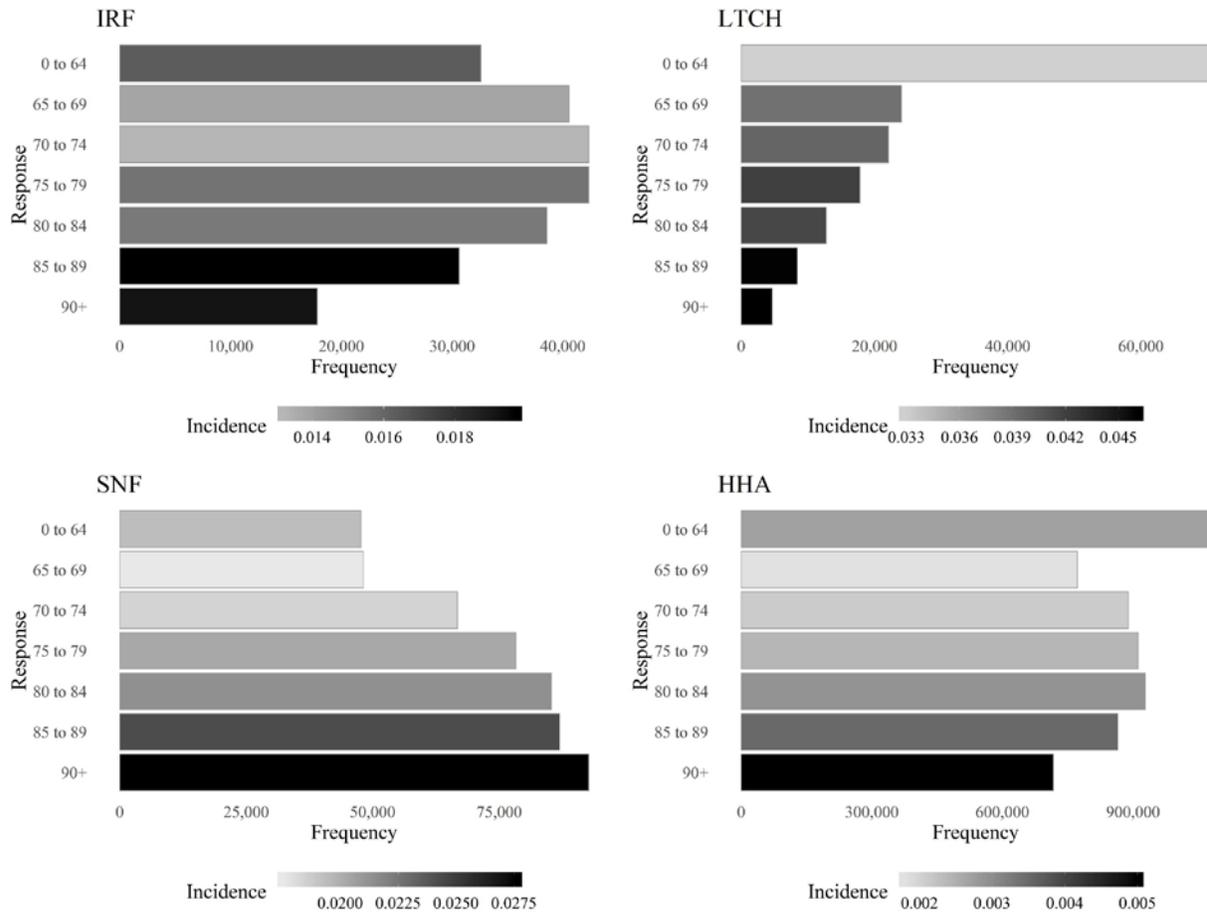


Coding Age Group

RTI showed that advanced age ($\geq 85+$ years) was directly associated with incidence of new-or-worsened pressure ulcers across IRF, LTCH, and SNF settings. HHA data were not available. The frequencies of age groups and their respective associations with new-or-worsened pressure ulcers are shown in *Figure D-4*.

Recodes for All Settings (IRF/LTCH/SNF/HHA):
Risk adjuster = 1 if age ≥ 90

Figure D-4. Age group and pressure ulcer/injury incidence in IRFs, LTCHs, and SNFs



**APPENDIX E:
CRITERIA FOR RISK ADJUSTMENT MODELS**

Criteria	Strict Cross— Setting Model	Relaxed Cross- Setting Model	Setting—Specific Model
The coefficient of the individual risk factors should be statistically significant ($p < 0.05$).	Across all four settings	In two or three of the four settings	In the specific setting
The coefficient should have a positive value.	Across all four settings	In two or three of the four settings	In the specific setting
The risk factor should have a non-zero or substantial effect (defined as a coefficient of 0.2 or greater).	Across all four settings	In two or three of the four settings	In the specific setting
Clinical practice and policies would be positively impacted by inclusion of the risk factor.	✓	✓	✓