Proposed Specifications for IRF QRP Quality Measures and Standardized Data Elements

PROPOSED SPECIFICATIONS FOR IRF QRP QUALITY MEASURES AND STANDARDIZED
DATA ELEMENTS

RTI International
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Introduction

In this document, we present specifications for the standardized patient assessment data elements and the following measure proposed for adoption for the IRF QRP through the FY 2018 IRF proposed rule:

1. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

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Chapter 2
IMPACT Act Measure Beginning with the FY 2020 IRF QRP

Section 1: Cross-Setting Measures Development Work: An Introduction

The Improving Medicare Post-Acute Care Transformation Act (IMPACT Act), enacted October 6, 2014, directs the Secretary of Health and Human Services to "specify quality measures on which Post-Acute Care (PAC) providers are required under the applicable reporting provisions to submit standardized patient assessment data" in several quality measure domains, including but not limited to incidence of major falls, skin integrity, and function. The IMPACT Act requires the implementation of quality measures to address these measure domains in Home Health Agencies (HHAs), Skilled Nursing Facilities (SNFs), Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs).

The IMPACT Act also requires, to the extent possible, the submission of such quality measure data through the use of a PAC assessment instrument and the modification of such instrument as necessary to enable such use. This requirement refers to the collection of such data by means of the Minimum Data Set (MDS) 3.0 for SNFs, the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set for LTCHs, and the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs.

For more information on the statutory history of the SNF, LTCH, or IRF QRP, please refer to the FY 2015 final rules. More information on the IMPACT Act is available at https://www.govtrack.us/congress/bills/113/hr4994.

In this document, we present specifications for the following quality measure proposed for the IRF QRP:

Outcome Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, Measure Steward: CMS

Section 2: Cross-Setting Pressure Ulcer Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

Measure Description

This quality measure reports the percent of patients/residents with Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that are new or worsened since admission. The measure is calculated using data from the MDS 3.0 assessment instrument for SNF residents, the LTCH CARE Data Set for LTCH patients, and the IRF-PAI for IRF patients. Data are collected separately in each of the three settings using standardized data elements. Data elements are referred to hereafter in this specification as items that have been harmonized across the MDS 3.0, LTCH CARE Data Set, and IRF-PAI. For residents or patients in SNFs, LTCHs and IRFs, this measure reports the percent of patient stays with reports of Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that were not present or were at a lesser stage on admission.

It is important to note that data collection and measure calculation for this measure are conducted separately for each of the three provider settings and will not be combined across settings.

For SNF residents, this measure is restricted to Medicare Part A residents. In IRFs, this measure is limited to Medicare (Part A and Medicare Advantage) patients. In LTCHs, this measure includes all patients.

Purpose/Rationale for the Quality Measure

This quality measure is proposed as a cross-setting quality measure to meet the requirements of the IMPACT Act of 2014 addressing the domain of skin integrity and changes in skin integrity. A pressure ulcer measure has previously been successfully implemented in NHs, SNFs, LTCHs and IRFs. The data for the pressure ulcer measure have been collected and submitted by LTCHs and IRFs (using the LTCH CARE Data Set and IRF-PAI, respectively) since October 1, 2012. Effective December 14, 2016, data for the pressure ulcer measure is publicly reported for LTCHs on CMS' Long-Term Care Hospital Compare at: https://www.medicare.gov/longtermcarehospitalcompare/ and for IRFs on CMS' Inpatient Rehabilitation Facility Compare at: https://www.medicare.gov/inpatientrehabilitationfacilitycompare/.

In order to improve the quality measure and address recommendations provided by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP), the quality measure has been modified in two ways. First, the measure has been modified to incorporate the addition of unstageable pressure ulcers due to slough or eschar, unstageable pressure ulcers due to non-removable dressing or device, and unstageable pressure ulcers presenting as deep tissue injuries in the numerator.

Second, the measure calculation has been amended to include M0300 items instead of M0800 items for the IRF QRP and LTCH QRP. This item calculation modification is intended to reduce redundancies in assessment items. To reflect these two changes, the measure is being proposed for FY 2018 federal rulemaking as: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.

This measure is intended to encourage SNFs, LTCHs, and IRFs to prevent pressure ulcer development or worsening, and to closely monitor and appropriately treat existing pressure ulcers.

Pressure ulcers are recognized as a serious medical condition. Considerable evidence exists regarding the seriousness of pressure ulcers, and the relationship between pressure ulcers and pain, decreased quality of life, and increased mortality in aging populations.[1,2,3,4] Pressure ulcers interfere with activities of daily living and functional gains made during rehabilitation, predispose patients to osteomyelitis and septicemia, and are strongly associated with longer hospital stays, longer IRF stays, and mortality.[5,6,7] Additionally, patients with acute care hospitalizations related to pressure ulcers are more

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[1] Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." Nurs N Z 19(10): 20-24.

[2] Gorzoni, M. L. and S. L. Pires (2011). "Deaths in nursing homes." Rev Assoc Med Bras 57(3): 327-331.

[3] Thomas, J. M., et al. (2013). "Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality." J Am Geriatr Soc 61(6): 902-911.

[4] White-Chu, E. F., et al. (2011). "Pressure ulcers in long-term care." Clin Geriatr Med 27(2): 241-258.

[5] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744-51.

[6] Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from http://www.cdc.gov/nchs/data/databriefs/db14.htm.

[7] Wang, H., et al. (2014). "Impact of pressure ulcers on outcomes in inpatient rehabilitation facilities." Am J Phys Med Rehabil 93(3): 207-216.

likely to be discharged to long-term care facilities (e.g., a nursing facility, an intermediate care facility, or a nursing home) than hospitalizations for all other conditions.[8,9]

Pressure ulcers typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, or bone.[10, 11,12] Elderly individuals in SNFs, LTCHs, and IRFs have a wide range of impairments or medical conditions that increase their risk of developing pressure ulcers, including but not limited to, impaired mobility or sensation, malnutrition or under-nutrition, obesity, stroke, diabetes, dementia, cognitive impairments, circulatory diseases, and dehydration. The use of wheelchairs and medical devices (e.g., hearing aids, feeding tubes, tracheostomies, percutaneous endoscopic gastrostomy tubes), a history of pressure ulcers, or presence of a pressure ulcer at admission are additional factors that increase pressure ulcer risk in elderly patients.[13,14,15,16,17,18,19,20,21]

Pressure ulcers are high-cost adverse events across the spectrum of health care settings, from acute hospitals to home health.[22, 23,24] Pressure ulcer incidence rates vary considerably by clinical setting, ranging from 0.4% to 38% in acute care, 2.2% to 23.9% in SNFs and NHs, and 0% to 17% in home care.[25] No national survey of pressure ulcer incidence or prevalence has been conducted in LTCHs or

[8] Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500-2005-000181 TO 0002. 2010.

[9] Institute for Healthcare Improvement (IHI). Relieve the pressure and reduce harm. May 21, 2007. Available from http://www.ihi.org/resources/pages/improvementstories/relievethepressureandreduceharm.aspx.

[10] Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006 (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available from http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf.

[11] Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.

[12] Advancing Excellence in America's Nursing Homes (AEANH).Explore our goals.. n.d. Available from https://www.nhqualitycampaign.org/goals.aspx

[13] Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.

[14] Agency for Healthcare Research and Quality (AHRQ). Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from https://archive.ahrq.gov/news/newsletters/research-activities/jan09/0109RA22.html

[15] Cai, S., et al. (2013). "Obesity and pressure ulcers among nursing home residents." Med Care 51(6): 478-486.

[16] DeJong, G., et al. (2014). "Factors Associated with Pressure Ulcer Risk in Spinal Cord Injury Rehabilitation." Am J Phys Med Rehabil. 2014 May 29. [Epub ahead of print]

[17] MacLean DS. Preventing & managing pressure sores. Caring for the Ages. March 2003;4(3):34-7.

[18] Michel, J. M., et al. (2012). "As of 2012, what are the key predictive risk factors for pressure ulcers? Developing French guidelines for clinical practice." Ann Phys Rehabil Med 55(7): 454-465.

[19] National Pressure Ulcer Advisory Panel (NPUAP) Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. Adv Skin Wound Care. 2001;14(4):208-15.

[20] Teno, J. M., et al. (2012). "Feeding tubes and the prevention or healing of pressure ulcers." Arch Intern Med 172(9): 697-701

[21] Centers for Medicare & Medicaid Services (CMS). Medicare program; changes to the hospital inpatient prospective payment system and fiscal year 2008 rates. Fed Register. August 22, 2007;72(162):47205.

[22] Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.

[23] Centers for Medicare & Medicaid Services (CMS). Medicare program; changes to the hospital inpatient prospective payment system and fiscal year 2008 rates. Fed Register. August 22, 2007;72(162):47205.

[24] Kandilov AMG, Coomer NM, Dalton K. (2014) The impact of hospital-acquired conditions on Medicare program payments. MMRR 4(4): E1-E23

[25] Institute for Healthcare Improvement (IHI). Relieve the pressure and reduce harm. May 21, 2007. Available from http://www.ihi.org/resources/pages/improvementstories/relievethepressureandreduceharm.aspx.

IRFs. However, a study evaluating 2009 Medicare FFS claims data from post-acute care facilities found 15,995 secondary diagnosis claims of Stage 3 or 4 pressure ulcers in LTCHs; 2,342 secondary diagnosis claims of Stage 3 or 4 pressure ulcers in IRFs; and 9,939 secondary diagnosis claims of Stage 3 or Stage 4 pressure ulcers in SNFs.[26] Additionally, analysis conducted by RTI International examined the national incidence of new or worsened Stage 2, 3, or 4 pressure ulcers in LTCHs, SNFs, or IRFs at discharge compared with admission using discharges from January through December 2015. In LTCHs, RTI found a national incidence of 0.95 percent of new or worsened Stage 2 pressure ulcers, 0.65 percent of Stage 3 pressure ulcers, and 0.48 percent of Stage 4 pressure ulcers. In SNFs, RTI found a national incidence of 1.28 percent of new or worsened Stage 2 pressure ulcers, 0.26 percent of new or worsened Stage 3 pressure ulcers, and 0.05 percent of new or worsened Stage 4 pressure ulcers. In IRFs, RTI found a national incidence of 0.56 percent of new or worsened Stage 2 pressure ulcers, 0.09 percent of new or worsened Stage 3 pressure ulcers, and 0.01 percent of new or worsened Stage 4 pressure ulcers.

Pressure ulcers that are unstageable due to slough or eschar, unstageable due to non-removable dressing or device, and unstageable presenting as deep tissue injuries (DTI) are also potentially avoidable and considered to be important indicators of quality of care. Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into Stage 3, or Stage 4 pressure ulcers.[27, 28]

The rate of unstageable pressure ulcers varies according to the type of unstageable pressure ulcer and setting. An analysis conducted by RTI International examined the national incidence of new or worsened unstageable pressure ulcers in LTCHs, IRFs, or SNFs at discharge compared with admission using discharges from January through December 2015. In LTCHs, RTI found a national incidence of 1.15 percent of new unstageable pressure ulcers due to slough/eschar, 0.05 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 1.01 percent of new DTIs. In SNFs, RTI found a national incidence of 0.40 percent of new unstageable pressure ulcers due to slough/eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.57 percent of new DTIs. In IRFs, RTI found a national incidence of 0.14 percent of new unstageable pressure ulcers due to slough/eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.26 percent of new DTIs. There is some evidence to suggest that the proportion of pressure ulcers identified as DTI has increased over time. An international study spanning the time 2006 to 2009 found DTIs increased by three-fold, to nine percent of all observed ulcers in 2009 and that DTIs were more prevalent than either Stage 3 or 4 ulcers. During the same time period, the proportion of Stage 1 and 2 ulcers decreased, and the proportion of Stage 3 and 4 ulcers remained constant.[29]

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[26] Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for Centers for Medicare & Medicaid Services. 2011.

[27] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9) http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien

[28] Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury

[29] VanGilder, C, MacFarlane, GD, Harrison, P, Lachenbruch, C, Meyer, S (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006-2009. Advances in Skin & Wound Care. 23(6): 254-261.

As reported in the Federal Register, in 2006 the average cost for a hospital stay related to pressure ulcers was $40,381.[30] As of 2010, the cost for treatment of Stage 4 hospital acquired pressure ulcers and complications averaged $129,248 per admission.[31] Using data from 2009 and 2010, severe (Stage 3 and Stage 4) pressure ulcers acquired during a hospital stay were estimated to have increased CMS payments across 90-day episodes of care by at least $18.8 million a year.[32]

The terminology and definitions developed by the National Pressure Ulcer Advisory Panel (NPUAP) for the care of pressure ulcers are often used to inform the PAC patient and resident assessment instruments and corresponding assessment manuals, specifically the IRF-PAI, the LTCH CARE Data Set, the MDS for SNFs, and the OASIS for HHAs. Considering the recent updates made by the NPUAP to their Pressure Ulcer Staging System, CMS intends to continue the adaptation of NPUAP terminology for coding the patient and resident assessment instruments. CMS will provide guidance which emphasizes that terminology related to these wounds may include injuries, as well as pressure ulcers, while retaining current holistic assessment instructions definitions and terminology. Further guidance and information on adaptation of the NPUAP guidelines, and definitions, and terminology, via assessment manuals and assessment instruments will be posted on the Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html

Denominator

Specific denominator definitions for each setting are provided below.

IRF Denominator

The denominator is the total number of Medicare* (Part A and Medicare Advantage) patient stays with an IRF-PAI assessment in the measure target period, except those that meet the exclusion criteria.

*IRF-PAI data are submitted for Medicare patients (Part A and Medicare Advantage) only.

LTCH Denominator

The denominator is the number of patient stays with both an admission and planned or unplanned discharge LTCH CARE Data Set assessment with the discharge date in the measure target period, except those that meet the exclusion criteria.

SNF Denominator

The denominator is the number of Medicare Part A SNF stays in the selected time window for SNF residents ending during the selected time window, except those who meet the exclusion criteria.

Denominator Exclusions

Specific denominator exclusions for each setting are provided below.

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[30] Centers for Medicare & Medicaid Services (CMS). Medicare program; changes to the hospital inpatient prospective payment system and fiscal year 2008 rates. Fed Register. August 22, 2007;72(162):47205.

[31] Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., … Vladeck, B. (2010). High Cost of Stage IV Pressure Ulcers. *American Journal of Surgery*, *200*(4), 473–477. http://doi.org/10.1016/j.amjsurg.2009.12.021

[32] Kandilov AMG, Coomer NM, Dalton K. (2014) The impact of hospital-acquired conditions on Medicare program payments. MMRR 4(4): E1-E23.

IRF Denominator Exclusions:

1. Patient stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries, are missing at discharge; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1= [-] or (M0300D2= [-]) and (M0300E1= [-] or M0300E2=[-]) and (M0300F1= [-] or M0300F2=[-]) and (M0300G1= [-] or M0300G2=[-]).

2. Patient stay is excluded if the patient died during the IRF stay; i.e., Item 44C = [0].

LTCH Denominator Exclusions:

1. Patient stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries, are missing on the planned or unplanned discharge assessment; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1= [-] or (M0300D2= [-]) and (M0300E1= [-] or M0300E2=[-]) and (M0300F1= [-] or M0300F2=[-]) and (M0300G1= [-] or M0300G2=[-]).

2. Patient stay is excluded if the patient died during the LTCH stay; i.e., A0250 = [12].

SNF Denominator Exclusions:

1. Resident stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries are missing at discharge; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1= [-] or (M0300D2= [-]) and (M0300E1= [-] or M0300E2=[-]) and (M0300F1= [-] or M0300F2=[-]) and (M0300G1= [-] or M0300G2=[-]).

2. Resident stay is excluded if the resident died during the SNF stay.

Numerator

Specific numerator definitions for each setting are provided below.

IRF Numerator

The numerator is the number of Medicare (Part A and Medicare Advantage) stays for which the IRF-PAI indicates one or more Stage 2-4 pressure ulcer(s), or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that are new or worsened at discharge compared to admission.

1) Stage 2 (M0300B1) **-** (M0300B2) > 0, OR

2) Stage 3 (M0300C1) **-** (M0300C2) > 0, OR

3) Stage 4 (M0300D1) **-** (M0300D2) > 0, OR

4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR

5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR

6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

LTCH Numerator

The numerator is the number of stays for which the discharge assessment indicates one or more new or worsened Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, compared to admission.

1) Stage 2 (M0300B1) **-** (M0300B2) > 0, OR

2) Stage 3 (M0300C1) **-** (M0300C2) > 0, OR

3) Stage 4 (M0300D1) **-** (M0300D2) > 0, OR

4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR

5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR

6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

SNF Numerator

The numerator is the number of complete resident Medicare Part A stays for which the discharge assessment indicates one or more new or worsened Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, compared to admission.

1) Stage 2 (M0300B1) **-** (M0300B2) > 0, OR

2) Stage 3 (M0300C1) **-** (M0300C2) > 0, OR

3) Stage 4 (M0300D1) **-** (M0300D2) > 0, OR

4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR

5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR

6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

Measure Time Window

Specific measure time window descriptions for each setting are provided below.

IRF Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All IRF records, except those that meet the exclusion criteria, during the 12 months will be included in the denominator and are eligible for inclusion in the numerator. For patients with multiple records during the 12-month time window, each record is eligible for inclusion in the measure.

LTCH Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All LTCH stays, except those that meet the exclusion criteria, during the 12 months are included in the denominator and are eligible for inclusion in the numerator. For patients with multiple stays during the 12-month time window, each stay is eligible for inclusion in the measure.

SNF Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All Medicare Part A SNF stays, except those that meet the exclusion criteria, during the 12 months are included in the denominator and are eligible for inclusion in the numerator. For residents with multiple stays during the 12-month time window, each stay is eligible for inclusion in the measure.

Items Included in the Quality Measure

See **Appendix 1** for a summary of the M0300 items in instruments across settings.

IRF Items:

- Items from the time of discharge:
  - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission),
  - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission),
  - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission),
  - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission),
  - M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission),
  - M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure injuries that were present upon admission).
- In addition, items from the time of admission used to risk-adjust this quality measure:
  1. Functional Mobility Admission Performance:

     GG0170C (Functional Mobility Admission Performance; Lying to Sitting on Side of Bed);
  2. Bowel Continence:

     H0400 (Bowel Continence);
  3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

     I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or

     I2900 (Diabetes Mellitus);
  4. Low Body Mass Index, based on Height (25A) and Weight (26A) at admission:

     25A (Height); and

     26A (Weight).

LTCH Items:

- Items from the planned or unplanned discharge assessment:

  - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission),

  - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission),

  - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission),

  - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission),

  - M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission),

  - M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure injuries that were present upon admission).

- In addition, items from the admission assessment used to risk-adjust this quality measure:

  1. Functional Mobility Admission Performance:

     GG0170C (Functional Mobility; Lying to Sitting on Side of Bed);

  2. Bowel Continence:

     H0400 (Bowel Continence);

  3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

     I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or

     I2900 (Diabetes Mellitus);

  4. Low Body Mass Index, based on Height and Weight:

     K0200A (Height); and

     K0200B (Weight).

SNF Items:

- Items from the discharge assessment:

  - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission/entry or reentry),

  - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission/entry or reentry),

  - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission/entry or reentry),

  - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission/entry or reentry),

- M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission/entry or reentry),
- M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure injuries that were present upon admission/entry or reentry).

- In addition, items from the PPS 5-Day assessment used to risk-adjust this quality measure:
    1. Functional Mobility Admission Performance:

        GG0170C (Mobility; Lying to Sitting on Side of Bed);

    2. Bowel Continence:

        H0400 (Bowel Continence);

    3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

        I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or

        I2900 (Diabetes Mellitus);

    4. Low Body Mass Index, based on Height and Weight:

        K0200A (Height); and

        K0200B (Weight).

Risk Adjustment Covariates

Specific covariate definitions for each setting are provided below.

IRF Risk Adjustment Covariates

For each patient stay covariate values are assigned either '0' for covariate condition not present or '1' for covariate condition present as reported at admission.

1. Functional Mobility Admission Performance:

    Indicator of supervision/touching assistance or more assistance for the functional mobility item Lying to Sitting on Side of Bed at admission:

    Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] = Substantial/maximal assistance, [03] = Partial/moderate assistance, [04] = Supervision or touching assistance, [07] = Patient refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)

    Covariate = [0] (no) if GG0170C= [05, 06, -, ^] ([05] = Setup or clean-up assistance, [06] = Independent, [-] = No response available, [^] = Valid skip)

2. Bowel Continence

    Bowel Continence (H0400) at admission

    Covariate = [1] (yes) if H0400 = [1, 2, 3] ([1] = Occasionally incontinent, [2] = Frequently incontinent, [3] = Always incontinent)

    Covariate = [0] (no) if H0400 = [0, 9, - , ^] ([0] = Always continent, [9] = Not rated, [-]= No response available, [^] = Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

> Covariate = [1] (yes) if any of the following are true:
>
> > 1. I0900 = [1] (checked)
> > 2. I2900 = [1] (checked)
>
> Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -] ([0] = No, [-] = No response available)

4. Low Body Mass Index, based on Height and Weight:

> Covariate = [1] (yes) if BMI $\geq$ [12.0] AND $\leq$ [19.0]
>
> Covariate = [0] (no) if BMI < [12.0] OR > [19.0]
>
> Covariate = [0] (no) if 25A = [-] OR 26A = [-] ([-] = No response available)
>
> Where: BMI = (weight * 703 / height^2) = ([26A] * 703) / (25A^2) and the resulting value is rounded to one decimal place.

LTCH Risk Adjustment Covariates

For each patient stay covariate values are assigned, either '0' for covariate condition not present or '1' for covariate condition present, as reported on the admission assessment.

1. Functional Mobility Admission Performance:

> Supervision/touching assistance or more for the functional mobility item Lying to Sitting on Side of Bed
>
> Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] =Substantial/maximal assistance, [03] =Partial/moderate assistance, [04] =Supervision or touching assistance, [07] = Patient refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)
>
> Covariate = [0] (no) if GG0170C = [05, 06, -, ^] ([05] =Setup or clean-up assistance, [06] = Independent, [-]=No response available, [^] =Valid skip)

2. Bowel Continence:

> Covariate = [1] (yes) if H0400 = [1, 2, 3] ([1] = Occasionally incontinent, [2] = Frequently incontinent, [3] = Always incontinent)
>
> Covariate = [0] (no) if H0400 = [0, 9, - , ^] ([0] = Always continent, [9] = Not rated, [-]= No response available, [^] = Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

> Covariate = [1] (yes) if any of the following are true:
>
> > 1. I0900 = [1] (checked)
> > 2. I2900 = [1] (checked)
>
> Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -] ([0] = No, [-] = No response available)

4. Low Body Mass Index, based on Height and Weight on the Admission assessment:

> Covariate = [1] (yes) if BMI $\geq$ [12.0] AND $\leq$ [19.0]
>
> Covariate = [0] (no) if BMI < [12.0] OR BMI > [19.0]

Covariate = [0] (no) if K0200A = [-] OR K0200B = [-] ('-' = No response available)

Where: BMI = (weight * 703 / height^2) = ([K0200B] * 703) / (K0200A^2) and the resulting value is rounded to one decimal place.

SNF Risk Adjustment Covariates

For each resident covariate values are assigned, either '0' for covariate condition not present or '1' for covariate condition present, as reported on the PPS 5-Day assessment.

1. Functional Mobility Admission Performance:

   Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] =Substantial/maximal assistance, [03] =Partial/moderate assistance, [04] =Supervision or touching assistance, [07] = Resident refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)

   Covariate = [0] (no) if GG0170C = [05, 06, -, ^] ([05] =Setup or clean-up assistance, [06] = Independent, [-]=No response available, [^] =Valid skip)

2. Bowel Continence:

   Covariate = [1] (yes) if H0400 = [1, 2, 3] (1 – Occasionally incontinent, 2 – Frequently incontinent, 3 – Always incontinent)

   Covariate = [0] (no) if H0400 = [0, 9, - , ^] (0 – Always continent, 9 – Not rated, '[-]'– No response available, '[^]' – Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

   Covariate = [1] (yes) if any of the following are true:

   1. Active Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD) in the last 7 days (I0900 = [1] (checked))

   2. Active Diabetes Mellitus (DM) in the last 7 days (I2900 = [1] (checked))

   Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -]

4. Low Body Mass Index, based on Height and Weight:

   Covariate = [1] (yes) if BMI ≥ [12.0] AND ≤ [19.0]

   Covariate = [0] (no) if BMI < [12.0] OR BMI > [19.0]

   Covariate = [0] (no) if K0200A = [-] OR K0200B = [-] ('[-]' =No response available)

   Where: BMI = (weight * 703 / height^2) = ([K0200B] * 703) / (K0200A^2) and the resulting value is rounded to one decimal place.

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

A. Calculate the facility observed score (steps 1 through 3)

Step 1. Calculate the denominator count:
In the SNF setting, calculate the total number of complete Medicare Part A SNF stays ending in the measure time window, which do not meet the exclusion criteria.

In the LTCH setting, calculate the total number of stays with both an admission and discharge LTCH CARE Data Set assessment in the measure time window, which do not meet the exclusion criteria.

In the IRF setting, calculate the total number of stays with an IRF-PAI assessment in the measure time window, which do not meet the exclusion criteria.

Step 2. Calculate the numerator count:
In the SNF setting, calculate the total number of Medicare Part A SNF stays in the denominator with discharge assessment that indicates one or more new or worsened pressure ulcers.

In the LTCH setting, calculate the total number of patient stays whose discharge assessment indicates one or more new or worsened pressure ulcers compared to the admission assessment. In the IRF setting, calculate the total number of patient stays whose IRF-PAI assessment indicates one or more new or worsened pressure ulcers at discharge compared to admission.

Step 3. Calculate the facility's observed score:
Divide the facility's numerator count by its denominator count to obtain the facility's observed score; that is, divide the result of step 2 by the result of step 1.

B. Calculate the expected score for each patient/resident (steps 4 and 5)

Step 4. Determine presence or absence of the pressure ulcer covariates for each patient/resident:
Assign covariate values, either '0' for covariate condition not present or '1' for covariate condition present, for each patient/resident for each of the four covariates as reported on the PPS 5-Day assessment for the SNF setting or the assessment at admission for the LTCH and IRF settings, as described in the Risk Adjustment section above.

Step 5. Calculate the expected score for each patient/resident with the following formula:

$$\textit{Patient-/resident-level expected QM score} = 1/[1+e^{-x}] \qquad (1)$$

Where e is the base of natural logarithms and X is a linear combination of the constant and the logistic regression coefficients times the covariate scores (from Formula [2], below).

$$X = \beta 0 + \beta 1*COVA + \beta 2*COVB + \beta 3*COVC + \beta 4*COVD \qquad (2)$$

Where $\beta 0$ is the logistic regression constant, $\beta 1$ is the logistic regression coefficient for the first covariate, $COVA$ is the patient/resident-level score for the first covariate, $\beta 2$ is the logistic regression coefficient for the second covariate, and $COVB$ is the patient-/resident-level score for the second covariate, etc. The regression constant and regression coefficients* are numbers obtained through statistical logistic regression analysis.

* Regression coefficients and constants are calculated separately for each facility type (SNF, LTCH, and IRF) and are updated each reporting period.

C. Calculate the facility-level expected score (step 6)

Step 6. Once an expected QM score has been calculated for all resident or patient stays for the SNF, LTCH and IRF settings, calculate the facility-level expected QM score by averaging all resident-/patient-level expected scores.

D. Calculate National mean observed QM score (steps 7 through 9)

Step 7. Calculate the national denominator count:
Calculate the total number of resident or patient stays retained after exclusions and sum to derive the national denominator count.

Step 8. Calculate the national numerator count:

Calculate the total number of resident or patient stays that triggered the QM and sum to derive the national numerator count.

Step 9. Calculate National mean observed QM score:

Divide the numerator count by its denominator count to obtain the national mean observed score; that is, divide the result of step 8 by the result of step 7.

E.   Calculate the Facility-level adjusted score (step 10)

Step 10. Calculate the facility-level adjusted score based on the:

Facility-level observed QM score (step 3),
Facility-level expected QM score (step 6), and
National mean observed QM score (step 9).*

The national mean observed QM score is updated separately for each facility type (SNF, LTCH, and IRF) for each reporting period.

The calculation of the adjusted score uses the following equation:

$$Adj = 1/[1 + e^{-y}] \qquad\qquad (3)$$

where

Adj is the facility-level adjusted QM score, and
$y = (Ln(Obs/(1–Obs)) - Ln(Exp/(1–Exp)) + Ln(Nat/(1–Nat)))$
Obs is the facility-level observed QM score,
Exp is the facility-level expected QM score,
Nat is the national mean observed QM score,
Ln indicates a natural logarithm, and
e is the base of natural logarithm.

Chapter 3
Standardized Data Elements

Section 1: Standardized Patient Assessment Data Element Work: An Introduction

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires CMS to develop, implement, and maintain standardized patient assessment data elements for PAC settings. The goals of implementing cross-setting standardized patient assessment data elements are to facilitate care coordination, interoperability, and improve outcomes of Medicare beneficiaries and other patients receiving post-acute care. Existing PAC assessment instruments (i.e., Outcome and Assessment Information Set (OASIS) for HHAs, Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs, LTCH CARE Data Set (LCDS) for LTCHs, and the Minimum Data Set (MDS) for SNFs) often collect data items pertaining to similar concepts, but the individual data elements -- questions and response options -- vary by assessment instrument. With a few exceptions, the data elements collected in these assessment instruments are not currently standardized or interoperable, therefore, patient responses across the assessment instruments cannot be compared easily. The IMPACT Act further requires that the assessment instruments described above be modified to include core data elements on health assessment categories and that such data be standardized and interoperable. Implementation of a core set of standardized assessment items across PAC settings has important implications for Medicare beneficiaries and other patients receiving post-acute care, families, providers, and policymakers. CMS is proposing standardized patient assessment data elements for five categories specified in the IMPACT Act. These categories are:

1. Functional status, such as mobility and self-care

2. Cognitive function (e.g., able to express ideas and to understand normal speech) and mental status (e.g., depression and dementia)

3. Special services, treatments, and interventions (e.g., need for ventilator, dialysis, chemotherapy, and total parenteral nutrition)

4. Medical conditions and co-morbidities (e.g., diabetes, heart failure, and pressure ulcers)

5. Impairments (e.g., incontinence; impaired ability to hear, see, or swallow)

In the following sections, we present specifications and evidence of support for the standardized patient assessment data elements proposed in the IRF QRP.

Section 2: Functional Status

Beginning with the FY 2020 IRF QRP, we are proposing that the submission of the data used in the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), that we finalized in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111), also meets the requirement for the collection of standardized data in the area of Functional Status.

This cross-setting function process measure requires the collection of admission and discharge functional status data using standardized clinical assessment items, or data elements, which assess specific functional activities, that is, self-care and mobility activities. These activities are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. For more information about this quality measure, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47100 through 47111).

Section 3: Cognitive Function

Impairments in cognitive function can result from a number of underlying conditions, including dementia, Alzheimer's Disease, stroke, brain injury, side effects of medication, metabolic and/or endocrine imbalances, and delirium.[33] Cognitive impairments may affect a patient or resident's ability to recover from illness or injury, or they may be a sign of an acute condition (e.g., hypoxia) that requires immediate intervention. Cognitive impairment that manifests with behavioral symptoms—or that impairs a patient's ability to communicate, prompting behavioral disturbances—may put the patient or resident or others in the care setting at risk for injury or assault, or may signal unmet patient or resident needs (e.g. pain management). Screening for the presence of impairment can help ensure appropriate and timely intervention.

A substantial proportion of PAC patients and residents experience cognitive impairment, delirium, and behavioral distress. Testing from the PAC PRD found that about one-third of patients and residents in PAC settings were classified as having moderately or severely impaired cognitive function.[34,35] About one-third exhibited disorganized thinking and altered level of consciousness, and about one-half exhibited inattention. Fewer than 7 percent of patients and residents exhibited signs and symptoms of behavioral distress in the PAC PRD.

Therapeutic interventions can improve patient outcomes, and evidence suggests that treatment (e.g., drugs, physical activity) can stabilize or delay symptom progression in some patients, thereby improving quality of life.[36,37,38] In addition, assessments help PAC providers to better understand the needs of their patients by establishing a baseline for identifying changes in cognitive function and mental status (e.g., delirium), elucidating the patient's ability to understand and participate in treatments during their stay, highlighting safety needs (e.g., to prevent falls), and identifying appropriate support needs at the time of discharge. The standardized assessment of patient or resident cognition supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, enabling the transfer of accurate health information.

Standardized Data Elements to Assess Cognitive Impairment

CMS has identified several data elements as applicable for cross-setting use in standardized assessment of cognitive impairment. The proposed data elements comprise:

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[33] National Institute on Aging. (2013). Assessing Cognitive Impairment in Older Patients: A Quick Guide for Primary Care Physicians. Available at https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients

[34] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[35] This estimate is based on responses to the Brief Interview for Mental Status (BIMS) in a study of patient/residents in the Post-Acute Care Payment Reform Demonstration (Gage et al., 2012).

[36] Casey, D. A., Antimisiaris, D., & O'Brien, J. (2010). Drugs for Alzheimer's disease: are they effective? Pharmacy and Therapeutics 35(4): 208.

[37] Bherer, L., Erickson, K. I., & Liu-Ambrose, T. (2013). A review of the effects of physical activity and exercise on cognitive and brain functions in older adults. J of Aging Research. 2013.

[38] Langa, K. M., & Levine, D. A. (2014). The diagnosis and management of mild cognitive impairment: a clinical review. JAMA 312(23): 2551-2561.

1. The Brief Interview for Mental Status (BIMS);

2. The Confusion Assessment Method (CAM); and

3. Behavioral Signs & Symptoms

It should be noted that the data elements proposed involve different aspects of cognition (e.g., short term memory, executive function), types of data (e.g., interview, performance-based), and are collected by various modes (e.g., clinician assessed, patient reported).

Brief Interview for Mental Status (BIMS)

The Brief Interview for Mental Status (BIMS) is a performance-based cognitive assessment developed to be a brief cognition screener, with a focus on learning and memory. The BIMS evaluates repetition, recall with and without prompting, and temporal orientation.

Relevance to IRFs

The BIMS is currently included in the IRF-PAI assessment on admission. Assessing cognitive functioning is critical in IRF settings, as cognitive impairments are common among IRF patients. Although more comprehensive cognitive assessment is commonplace in IRFs (e.g., instruments incorporated in speech therapy or administered by neuropsychologists), standardized assessment tools can provide comparable baseline information if uniformly administered to all patients and standardized across provider types. An estimated 22.2 percent of IRF patients are moderately impaired, and 11.6 percent are severely impaired, as assessed by the BIMS in the PAC PRD.[39] Patients with brain injury and stroke are commonly transferred to IRFs for intensive post-acute care: approximately 21 percent of IRF patients have a primary diagnosis of stroke, and approximately 8 percent have primary diagnosis of brain injury.[40] In addition, cognitive impairments are associated with engagement in rehabilitation therapies,[41] and individuals with severe cognitive impairment as measured by BIMS at IRF admission are more likely to be readmitted after discharge.[42] Cognitive impairment has significant implications for patient resource utilization, ability to participate in rehabilitation therapies, and care planning in IRFs. The standardized assessment of cognitive function using the BIMS would provide important information for care planning, care transitions, patient safety, and resource use in IRFs.

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[39] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[40] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

[41] E.J. Lenze, M.C. Munin, M.A. Dew, et al. (2004). Adverse effects of depression and cognitive impairment on rehabilitation participation and recovery from hip fracture. Int J Geriatr Psychiatry 19: 472–478

[42] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

Section C	Cognitive Patterns

C0100. Should Brief Interview for Mental Status (C0200-C0500) be conducted? (3-day assessment period)
Attempt to conduct interview with all patients.

Enter Code [ ]
  0. **No** (patient is rarely/never understood) → *Skip to C0900. Memory/Recall Ability*
  1. **Yes** → *Continue to C0200. Repetition of Three Words*

Brief Interview for Mental Status (BIMS)

C0200. Repetition of Three Words

Ask patient: *"I am going to say three words for you to remember. Please repeat the words after I have said all three. The words are:* **sock, blue** *and* **bed.** *Now tell me the three words."*

Number of words repeated after first attempt

Enter Code [ ]
  3. **Three**
  2. **Two**
  1. **One**
  0. **None**

After the patient's first attempt, repeat the words using cues (*"sock, something to wear; blue, a color; bed, a piece of furniture"*). You may repeat the words up to two more times.

C0300. Temporal Orientation (orientation to year, month, and day)

Ask patient: *"Please tell me what year it is right now."*

Enter Code [ ]
A. Able to report correct year
  3. **Correct**
  2. **Missed by 1 year**
  1. **Missed by 2 - 5 years**
  0. **Missed by > 5 years** or no answer

Ask patient: *"What month are we in right now?"*

Enter Code [ ]
B. Able to report correct month
  2. **Accurate within 5 days**
  1. **Missed by 6 days to 1 month**
  0. **Missed by > 1 month** or no answer

Ask patient: *"What day of the week is today?"*

Enter Code [ ]
C. Able to report correct day of the week
  1. **Correct**
  0. **Incorrect** or no answer

C0400. Recall

Ask patient: *"Let's go back to an earlier question. What were those three words that I asked you to repeat?"* If unable to remember a word, give cue (something to wear; a color; a piece of furniture) for that word.

Enter Code [ ]
A. Able to recall "sock"
  2. **Yes, no cue required**
  1. **Yes, after cueing** (*"something to wear"*)
  0. **No - could not recall**

Enter Code [ ]
B. Able to recall "blue"
  2. **Yes, no cue required**
  1. **Yes, after cueing** (*"a color"*)
  0. **No - could not recall**

Enter Code [ ]
C. Able to recall "bed"
  2. **Yes, no cue required**
  1. **Yes, after cueing** (*"a piece of furniture"*)
  0. **No - could not recall**

C0500. BIMS Summary Score

Enter Score [ ][ ]
Add scores for questions C0200-C0400 and fill in total score (00-15)
Enter 99 if the patient was unable to complete the interview

Current use

The BIMS data elements are currently used in the MDS 3.0 and the IRF-PAI.

Evidence supporting use of the BIMS

The BIMS data elements were tested in the PAC PRD, where they showed substantial to almost perfect reliability of 0.71 to 0.91 (weighted kappas) when used across all four PAC settings. The lowest agreement was on the "repetition of three words" memory data element, with a kappa of 0.71, which still falls within the range of substantial agreement. PAC PRD testing found evidence of strong reliability of the BIMS data elements in the IRF setting. In addition, the BIMS data elements were also found to be

predictive of cost.[43] The BIMS data elements were also included in the national MDS 3.0 test in nursing homes and showed almost perfect reliability. [44] Agreement ranged from 0.862 to 0.994 (standard kappa). The BIMS data elements were found to be highly correlated (0.906) with a gold-standard measure of cognitive function, the Modified Mini-Mental Status (3MS) exam.[45]

Confusion Assessment Method (CAM©)

The Confusion Assessment Method (CAM) screens for certain types of cognitive impairment, including delirium and reversible confusion. Delirium, when undetected or untreated, can increase the likelihood of complications, rehospitalization, and death compared to patients/residents without delirium.[46] The CAM is available free of charge, for public use.

Although multiple versions of the CAM have been developed, CMS is proposing that the Short version be adopted for standardized patient assessment data elements. The Short CAM contains only four items (i.e., items 1 to 4) from the original Confusion Assessment Method (Long CAM). These items focus on an acute change in mental status, inattention, disorganized thinking, and altered level of consciousness.

Relevance to IRFs

The IRF-PAI does not include items to assess signs and symptoms of delirium, although delirium is common among IRF populations. In PAC PRD testing using the CAM, high proportions of IRF patients demonstrated signs and symptoms of delirium: 57.3 percent showed inattention, 44.1 percent showed disorganized thinking, and 21.4 percent showed altered level of consciousness.[47] Delirium may also interfere with functional recovery and a patient's ability to actively participate in intensive rehabilitation therapies,[48,49] which is required by IRFs. In addition, presence of delirium has implications for administering and interpreting cognitive assessments,[50,51] which has implications for assessing recovery and anticipated benefits of cognitive rehabilitation for IRF patients. As such, assessing IRF

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[43] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[44] Chodosh, J., Edelen, M. O., Buchanan, J. L., Yosef, J. A., Ouslander, J. G., Berlowitz, D. R., ... & Saliba, D. (2008). Nursing home assessment of cognitive impairment: development and testing of a brief instrument of mental status. J of the Am Geriatrics Society 56(11): 2069-2075.

[45] Saliba, D., Buchanan, J., Edelen, M. O., Streim, J., Ouslander, J., Berlowitz, D., & Chodosh, J. (2012). MDS 3.0: Brief interview for mental status. J of the Am Med Directors Association 13(7): 611-617.

[46] Marcantonio, E. R., Kiely, D. K., Simon, S. E., John Orav, E., Jones, R. N., Murphy, K. M., & Bergmann, M. A. (2005). Outcomes of older people admitted to postacute facilities with delirium. J of the Am Geriatrics Society 53(6): 963-969.

[47] Unpublished data from the PAC PRD Public Comments sample, 2008-2010.

[48] Marcantonio ER, Simon SE, Bergmann MA, et al. (2003). Delirium symptoms in postacute care: Prevalent, persistent, and associated with poor functional recovery. J Am Geriatr Soc 51:4e9.

[49] Kiely DK, Jones RN, Bergmann MA, et al. (2006). Association between delirium resolution and functional recovery among newly admitted postacute facility patients. J Gerontol A Biol Sci Med Sci. 61:204e208.

[50] Landi F, Liperoti R, Bernabei R. (2011). Postacute rehabilitation in cognitively impaired patients: comprehensive assessment and tailored interventions. JAMA 12:395e397.

[51] McCusker J, Cole M, Dendukuri N, et al. (2001). Delirium in older medical inpatients and subsequent cognitive and functional status: A prospective study. CMAJ 165:575e583.

patients for signs and symptoms of delirium is critical for care planning and decision making in IRF settings, and for ensuring that IRF patients can maximally benefit from rehabilitation therapies.

The standardized assessment of delirium and reversible confusion using the Short CAM would provide important information for care planning, care transitions, patient safety, and resource use in IRFs.

Proposed Data Elements for the Assessment of Cognitive Function: CAM

C1310. Signs and Symptoms of Delirium (from CAM©)
Code after completing Brief Interview for Mental Status, and reviewing medical record (3-day assessment period).

A. Acute Onset Mental Status Change

Enter Code	Is there evidence of an acute change in mental status from the patient's baseline?
☐	0. **No** 1. **Yes**

CODING:
0. **Behavior not present**
1. **Behavior continuously present, does not fluctuate**
2. **Behavior present, fluctuates** (comes and goes, changes in severity)

↓ **Enter Code in Boxes**

☐	**B. Inattention** - Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?
☐	**C. Disorganized Thinking** - Was the patient's thinking disorganized or incoherent (rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject)?
☐	**D. Altered Level of Consciousness** - Did the patient have altered level of consciousness, as indicated by any of the following criteria? ■ **vigilant** - startled easily to any sound or touch ■ **lethargic** - repeatedly dozed off when being asked questions, but responded to voice or touch ■ **stuporous** - very difficult to arouse and keep aroused for the interview ■ **comatose** - could not be aroused

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Current use

The Short CAM data elements are currently collected in the MDS 3.0 and the LCDS, and the scoring is based on staff observations of delirium. While the Short CAM data elements are used in both assessment tools, the response options currently differ. The current version of the LCDS includes two response options (yes/no, indicating that the behavior is present or not present), whereas the MDS 3.0 offers three response options (behavior continuously present, does not fluctuate; behavior present, fluctuates; behavior not present). The LCDS and MDS versions of the CAM also differ slightly in wording and criteria for the "Altered Level of Consciousness" item.

Evidence supporting use of the CAM

The four elements in the Short CAM have been shown to be effective in identifying delirium in validated research studies.[52] The Short CAM was tested in the PAC PRD and found to be reliable across all four settings.[53] The "Inattention" and "Disorganized Thinking" questions had substantial inter-rater reliability agreement (kappa range of 0.70 to 0.73) and the "Altered Level of Consciousness" question showed moderate agreement (kappa of 0.58).[54]

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[52] Waszynski, C. M. (2007). How to try this: Detecting delirium. AJN 107(12): 50-59.

[53] Smith, L., Gage, B., & Deutsch, A. (2012). Continuity Assessment Record and Evaluation (CARE) Item Set: additional provider-type specific interrater reliability analyses. Centers for Medicare & Medicaid Services Contract No. RTI International.

[54] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

A version of the CAM, with the addition of an item to assess psychomotor retardation, was tested in the national MDS 3.0 test in nursing homes. Reliabilities were substantial or almost perfect. Overall average kappa ranged from 0.893 to 0.850 and items ranged from 0.784 to 0.902 (standard kappa).[55]

Behavioral Signs and Symptoms

Behavioral disturbances can require additional resources from providers. They can disrupt care, result in poorer patient outcomes, and place the patient at risk for injury, isolation, and inactivity. Assessment and documentation of these disturbances can help inform care planning and patient transitions. For example, standardized assessment of behavioral symptoms would foster attention to the patient's needs and limitations early in the care planning process, and could trigger addition clinical assessment (e.g., for pain or depression) that could address underlying causes of behavioral disturbances.

The Behavioral Signs and Symptoms data elements assess whether the patient has exhibited any behavioral symptoms that may indicate cognitive impairment or other issues during the assessment period. These include physical, verbal, and other disruptive or dangerous behavioral symptoms, but exclude wandering. These assessed behavioral disturbances can indicate unrecognized needs and care preferences and are associated commonly with dementia and other cognitive impairment, but associated less commonly with adverse drug events, mood disorders, and other conditions.

Relevance to IRFs

The IRF-PAI does not currently assess signs and symptoms of behavioral disturbances. Disruptive behaviors are documented infrequently among IRF patients, but these behaviors can have a significant impact on care in IRF settings when they occur. In PAC PRD testing, percentages of IRF patients demonstrating behavioral signs and symptoms were low: 1.2 percent exhibited physical behaviors toward others, 1.7 percent exhibited verbal behaviors towards others, and 1.1 percent demonstrated some other disruptive behavior toward self.[56] Agitated or disruptive behaviors have implications for patient resource utilization and a patient's capacity to actively participate in intensive rehabilitation therapies.[57] Such behaviors may also have implications for the rehabilitation of other patients in an IRF setting (e.g., disruption of therapy provided in a group context may limit other patients' ability to maximally benefit from rehabilitation therapies). Given the capacity for these behaviors to interfere with rehabilitation,[58] and the implications that such disruptive behaviors may have for other patients in the IRF setting, it is important to assess these behaviors in IRFs. The standardized assessment of behavioral disturbances with the Behavioral Signs and Symptoms data elements would provide useful information for care planning, resource use, and patient and staff safety in IRFs.

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[55] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[56] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[57] Lequerica AH, Rapport LJ, Loeher K, Axelrod BN, Vangel Jr SJ, Hanks RA. (2007). Agitation in acquired brain injury: Impact on acute rehabilitation therapies. The Journal of head trauma rehabilitation 1;22(3):177-83.

[58] *Ibid*.

Proposed Data Elements for the Assessment of Cognitive Function:
Behavioral Signs and Symptoms

Section E	Behavioral Symptoms

E0200. Behavioral Symptom - Presence & Frequency
Note presence of symptoms and their frequency.

CODING:	↓ Enter Code in Boxes
0. **Behavior not exhibited** 1. **Behavior of this type occurred 1 to 3 days** 2. **Behavior of this type occurred 4 to 6 days, but less than daily** 3. **Behavior of this type occurred daily**	☐ A. **Physical behavioral symptoms directed toward others** (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)
	☐ B. **Verbal behavioral symptoms directed toward others** (e.g., threatening others, screaming at others, cursing at others)
	☐ C. **Other behavioral symptoms not directed toward others** (e.g., physical symptoms such as hitting or scratching self, pacing, rummaging, public sexual acts, disrobing in public, throwing or smearing food or bodily wastes, or verbal/vocal symptoms like screaming, disruptive sounds)

Current use

The Behavioral Signs and Symptoms data elements are currently in use in the MDS 3.0.

Evidence supporting use of Behavioral Signs and Symptoms

The Behavioral Signs and Symptoms data elements were tested in the PAC PRD with two response options per data element (yes/no to indicate that behavior is present/not present). Because of the low incidence of these behavioral disturbances, the PAC PRD did not report inter-rater reliability for these items.

The Behavioral Signs and Symptoms data elements were tested in the national MDS 3.0 test in nursing homes with three response options per data element (Not present in last 5 days, present 1-2 days, present 3 or more days). Reliabilities were almost perfect and ranged from 0.964 to 0.984 (standard kappa).[59] The Behavioral Signs and Symptoms data elements were also validated against a gold-standard measure of behavior disturbance, the Cohen Mansfield Agitation Inventory (CMAI), where kappas ranged from 0.532 to 0.856.

Mental Status (Depressed Mood)

Depression is the most common mental health condition in older adults, yet under-recognized and thus under-treated. Existing data show that depressed mood is relatively common in patients and residents receiving PAC services. The PAC PRD found that about 9 percent of individuals in PAC were classified as having likely depression.[60] The prevalence varied from a low of 7 percent of beneficiaries in SNFs to a high of 11 percent in IRFs.[61]

Diagnosis and treatment of depression can lead to significant improvement of symptoms, as measured on depression assessment scales. Depressive symptoms improve in 60 to 80 percent of elderly

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[59] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[60] This estimate is based on patient responses to a question about being sad in the two weeks prior to the assessment interview in a study of patient/residents in the PAC PRD (Gage et al., 2012). If they responded "often" or "always," they were considered to have depression.

[61] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

patients taking an antidepressant medication.[62] Psychosocial treatments of depression in older adults have been shown to be more effective than no treatment, based on self-rated and clinician-rated measures of depression.[63,64]

Assessments of the signs and symptoms of depression help PAC providers to better understand the needs of their patients and residents by prompting further evaluation (i.e., to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. The standardized assessment of depression among PAC patients and residents supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, further enabling the transfer of accurate health information.

Standardized Data Elements to Assess Depressed Mood

CMS has identified the Patient Health Questionnaire (PHQ-2) data elements for standardization for assessment of depressed mood.

Patient Health Questionnaire-2 (PHQ-2)

The Patient Health Questionnaire-2 (PHQ-2) data elements use a summed item scoring approach to screen for signs and symptoms of depressed mood in patients and residents by assessing the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure).[65] At least one of the two must be present for a determination of probable depression, which signals the need for additional clinical assessment to determine a depression diagnosis.

Relevance to IRFs

The PHQ-2 would provide valuable patient information for use in IRFs. The IRF-PAI does not currently assess the signs and symptoms of depression, though depression is common among IRF patients. In PAC PRD, 11.3 percent of IRF patients screened positive for depressive symptoms as assessed by the PHQ-2, more than the other three PAC settings.[66] This highlights the importance of screening for depressed mood among patients in IRF settings. Depressed mood may influence patient participation in rehabilitation therapies and may affect the validity of cognitive assessments,[67,68] and

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[62] Lebowitz, B. D., Pearson, J. L., Schneider, L. S., Reynolds, C. F., Alexopoulos, G. S., Bruce, M. L., ... & Mossey, J. (1997). Diagnosis and treatment of depression in late life: Consensus statement update. JAMA 278(14): 1186-1190.

[63] Scogin, F., & McElreath, L. (1994). Efficacy of psychosocial treatments for geriatric depression: a quantitative review. J Consult Clin Psychol 62(1):69-74.

[64] Wei, W., Sambamoorthi, U., Olfson, M., Walkup, J. T., & Crystal, S. (2005). Use of psychotherapy for depression in older adults. Am J of Psychiatry 162(4): 711-717.

[65] American Psychiatric Association. Diagnostic and Statistic Manual of Mental Disorders. 1980.

[66] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[67] E.J. Lenze, M.C. Munin, M.A. Dew, et al. (2004). Adverse effects of depression and cognitive impairment on rehabilitation participation and recovery from hip fracture. Int J Geriatr Psychiatry 19: 472–478

[68] Lequerica AH, Kortte K. (2010). Therapeutic engagement: a proposed model of engagement in medical rehabilitation. American journal of physical medicine & rehabilitation 89(5):415-22.

therefore has significant implications for monitoring and supporting progress toward rehabilitation goals among IRF patients. The PHQ-2 demonstrated high reliability in IRF settings in PAC PRD testing.[69]

The standardized assessment of the signs and symptoms of depression using the PHQ-2 would provide important information for care planning, care transitions, and resource use in IRFs.

Proposed Data Elements for the Assessment of Cognitive Function: PHQ-2

Section D	Mood

D0150. Patient Health Questionnaire 2 (PHQ-2©)

Say to patient: *"Over the last 2 weeks, have you been bothered by any of the following problems?"*

If symptom is present, enter 1 (yes) in column 1, Symptom Presence.
If yes in column 1, then ask the patient: "About how often have you been bothered by this?"
Read and show the patient a card with the symptom frequency choices. Indicate response in column 2, Symptom Frequency.

1. Symptom Presence	2. Symptom Frequency	1. Symptom Presence	2. Symptom Frequency
0. **No** (enter 0 in column 2) 1. **Yes** (enter 0-3 in column 2) 9. **No response** (leave column 2 blank)	0. **Never or 1 day** 1. **2-6 days** (several days) 2. **7-11 days** (half or more of the days) 3. **12-14 days** (nearly every day)		
		↓ Enter Scores in Boxes ↓	
A. *Little interest or pleasure in doing things?*		☐	☐
B. *Feeling down, depressed, or hopeless?*		☐	☐

Current use

The PHQ-2 data elements are currently in use in the OASIS-C2. The PHQ-9 data elements, which include the two questions used in the PHQ-2 plus additional items, are in use in MDS 3.0.

Evidence supporting use of PHQ-2

The PHQ-2 is a brief, reliable screening tool for assessing signs and symptoms of depression. Among studies conducted in primary care centers with large samples of adults, the PHQ-2 has performed well as both a screening tool for identifying symptoms of depression and to assess depression severity.[70,71] It has also been shown to be sensitive to changes in a patient's mood. Across 15 studies that assessed the diagnostic accuracy of the PHQ-2 against a recognized gold-standard instrument for the diagnosis of major depression in adults, sensitivity estimates (based on the summed-item approach to scoring and a cutoff score of 3) have varied, ranging between 39 percent and 97 percent (median value = 77 percent); specificity estimates (based on the summed-item approach to scoring and a cutoff score of 3) have been higher and more stable, ranging between 74 percent and 97 percent (median value = 90

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[69] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[70] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people. J of the A Geriatrics Society 55(4): 596-602.

[71] Löwe, B., Kroenke, K., & Gräfe, K. (2005). Detecting and monitoring depression with a two-item questionnaire (PHQ-2). J of Psychosomatic Research 58(2): 163-171.

percent).[72,73,74,75,76,77,78,79,80,81,82,83,84,85,86] Thus, the specificity of the PHQ-2 appears to be comparable to that of the longer form PHQ-9, although the slightly lower sensitivity of the PHQ-2 means that more cases of depressive symptoms are likely to be missed using this brief instrument compared with the PHQ-9. The PHQ-2 was tested in the PAC PRD and found to be reliable in beta testing across the four PAC settings (kappas ranged from 0.74 to 0.91).[87] It is thus a viable option for standardization, with the benefits of the shorter assessment counterbalancing the limitation of the lower sensitivity.

[72] Arroll, B., Goodyear-Smith, F., Crengle, S., Gunn, J., Kerse, N., Fishman, T., ... & Hatcher, S. (2010). Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. Ann Fam Med 8(4): 348-353.

[73] Bhana, A., Rathod, S. D., Selohilwe, O., Kathree, T., & Petersen, I. (2015). The validity of the Patient Health Questionnaire for screening depression in chronic care patients in primary health care in South Africa. BMC Psych 15(1): 118.

[74] Boyle, L. L., Richardson, T. M., He, H., Xia, Y., Tu, X., Boustani, M., & Conwell, Y. (2011). How do the PHQ-2, the PHQ-9 perform in aging services clients with cognitive impairment? Int Jof Geriatric Psych 26(9): 952-960.

[75] Chagas, M. H., Crippa, J. A., Loureiro, S. R., Hallak, J. E., Meneses-Gaya, C. D., Machado-de-Sousa, J. P., ... & Tumas, V. (2011). Validity of the PHQ-2 for the screening of major depression in Parkinson's disease: two questions and one important answer. Aging & Mental Health 15(7): 838-843.

[76] Chen, S., Chiu, H., Xu, B., Ma, Y., Jin, T., Wu, M., & Conwell, Y. (2010). Reliability and validity of the PHQ-9 for screening late-life depression in Chinese primary care. Int J of Geriatric Psychiatry 25(11): 1127-1133.

[77] de Lima Osório, F., Vilela Mendes, A., Crippa, J. A., & Loureiro, S. R. (2009). Study of the discriminative validity of the PHQ-9 and PHQ-2 in a sample of Brazilian women in the context of primary health care. Perspectives in Psych Care 45(3): 216-227.

[78] Hanwella, R., Ekanayake, S., & de Silva, V. A. (2014). The validity and reliability of the Sinhala translation of the Patient Health Questionnaire (PHQ-9) and PHQ-2 Screener. Depression research and treatment.

[79] Inagaki, M., Ohtsuki, T., Yonemoto, N., Kawashima, Y., Saitoh, A., Oikawa, Y., ... & Yamada, M. (2013). Validity of the PHQ-9 and PHQ-2 in general internal medicine primary care at a Japanese rural hospital: a cross-sectional study. Gen Hosp Psychiatry 35(6): 592-597.

[80] Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9. J Gen Intern Med 16(9): 606-613.

[81] Anand, A., Li, Y., Wang, Y., Wu, J., Gao, S., Bukhari, L., ... & Lowe, M. J. (2005). Activity and connectivity of brain mood regulating circuit in depression: a functional magnetic resonance study. Biological Psychiatry 57(10): 1079-1088.

[82] Phelan, E., Williams, B., Meeker, K., Bonn, K., Frederick, J., LoGerfo, J., & Snowden, M. (2010). A study of the diagnostic accuracy of the PHQ-9 in primary care elderly. BMC Fam Practice 11(1): 63.

[83] Suzuki, K., Kumei, S., Ohhira, M., Nozu, T., & Okumura, T. (2015). Screening for major depressive disorder with the Patient Health Questionnaire (PHQ-9 and PHQ-2) in an outpatient clinic staffed by primary care physicians in Japan: a case control study. PloS One 10(3): e0119147.

[84] Thombs, B. D., Ziegelstein, R. C., & Whooley, M. A. (2008). Optimizing detection of major depression among patients with coronary artery disease using the patient health questionnaire: data from the heart and soul study. J of Gen Int Med 23(12): 2014-2017.

[85] Xiong, N., Fritzsche, K., Wei, J., Hong, X., Leonhart, R., Zhao, X., ... & Fischer, F. (2015). Validation of patient health questionnaire (PHQ) for major depression in Chinese outpatients with multiple somatic symptoms: a multicenter cross-sectional study. J of Affective Disorders 174: 636-643.

[86] Zuithoff, N. P., Vergouwe, Y., King, M., Nazareth, I., van Wezep, M. J., Moons, K. G., & Geerlings, M. I. (2010). The PHQ-9 for detection of major depressive disorder in primary care: consequences of current thresholds in a crosssectional study. BMC Fam Practice 11(1): 98.

[87] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

The PHQ-9 was also tested in the national MDS 3.0 test in nursing homes. For the two presence items in the PHQ-2 (little interest in doing things; feeling down, depressed or hopeless), kappa statistics were almost perfect and ranged from 0.981 to 0.988.[88] The PHQ-9 was also found to have agreement with Modified Schedule for Affective Disorders and Schizophrenia (m-SADS), a gold-standard measure for mood disorder, in residents without severe cognitive impairment (weighted kappa=0.685) and with the Cornell Depression Scale, a gold-standard measure for mood disorder, in residents with severe cognitive impairment (correlation=0.63).[89]

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[88] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[89] *Ibid.*

Section 4: Special Services, Treatments, and Interventions (Including Nutritional Approaches)

Some medical conditions require complex clinical care, consisting of special services, treatments, and interventions. The implementation of these interventions typically indicates conditions of a more serious nature and can be life-sustaining. Patients and residents who need them may have few clinical alternatives. Conditions requiring the use of special services, treatments, and interventions can have a profound effect on an individual's health status, self-image, and quality of life. Providers should be aware of the patient or resident's clinical needs in order to plan the provision of these important therapies and to ensure the continued appropriateness of care and support care transitions. The assessment of special services, treatments, and interventions may also help to identify resource use intensity by capturing the medical complexity of patients/residents.

Standardized Data Elements to Assess for Special Services, Treatments, and Interventions

CMS has identified data elements for cross-setting standardization of assessment for 15 special services, treatments, and interventions in the areas of cancer, respiratory, and other treatments, as well as nutritional approaches. The proposed data elements are:

1. Chemotherapy (IV, Oral, Other);
2. Radiation;
3. Oxygen therapy (Continuous, Intermittent);
4. Suctioning (Scheduled, As needed);
5. Tracheostomy Care
6. Invasive Mechanical Ventilator;
7. Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP]; Continuous Positive Airway Pressure [CPAP]);
8. Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other);
9. Transfusions;
10. Dialysis (Hemodialysis, Peritoneal dialysis);
11. Intravenous (IV) Access (Peripheral IV, Midline, Central line, Other);
12. Parenteral/IV Feeding;
13. Feeding Tube;
14. Mechanically Altered Diet; and
15. Therapeutic Diet.

Chemotherapy (IV, Oral, Other)

Chemotherapy is a type of cancer treatment that uses medications to destroy cancer cells. This treatment indicates that a patient has a malignancy (cancer) and therefore has a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection (due to a suppressed immune system), anemia, and an increased risk of bleeding (due to low platelet counts). Oral chemotherapy can be as potent as chemotherapy given by IV but can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling, and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations following specific protocols and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource

intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

Relevance to IRFs

Chemotherapy (either in general or specific routes of administration) is not assessed at present in the IRF-PAI. Patient in the rehabilitation setting with cancer and who are receiving chemotherapy may be different than other patients in terms of their rehabilitation stay requirements, their potential for rehabilitation functional gains, and their risk of return to the acute care setting. In addition, these patients may require more intensive medical care and monitoring than some other populations of patients (e.g., lab work, nursing care). Individuals impaired by cancer or chemotherapy treatments have been shown to make functional gains in the IRF Setting.[90,91] Some cancer patients can benefit from 3 hours of therapy per day and benefit from multi-modal types of therapy to address heterogeneous needs that can include neurologic issues, orthopedic problems, general conditioning, pain management, and lymphedema management.[92,93] However, cancer patients in an inpatient rehabilitation unit are at risk of transfer back to the acute care setting at rates ranging from 17 percent to of 35 percent.[94,95] Receipt of chemotherapy has implications for care planning, assessing functional gains, and estimating patient length of stay and resource utilization in IRF setting.

Given the resource intensity of administering chemotherapy and the side effects and potential complications of these highly-toxic medications, assessing whether the patient is receiving Chemotherapy would provide important information for care planning, clinical decision making, and resource use in IRFs.

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[90] Marciniak, C. M., Sliwa, J. A., Spill, G., Heinemann, A. W., & Semik, P. E. (1996). Functional outcome following rehabilitation of the cancer patient. Archives of physical medicine and rehabilitation, 77(1): 54-57. Available at http://www.sciencedirect.com/science/article/pii/S0003999396902208.

[91] McKinley, W. O., Huang, M. E., & Tewksbury, M. A. (2000). Neoplastic vs. traumatic spinal cord injury: an inpatient rehabilitation comparison. American journal of physical medicine & rehabilitation, 79(2): 138-144. Available at http://journals.lww.com/ajpmr/Abstract/2000/03000/Neoplastic_vs__Traumatic_Spinal_Cord_Injury__An.5.aspx

[92] Fialka-Moser, V., Crevenna, R., Korpan, M., & Quittan, M. (2003). CANCER REHABILITATION. Journal of rehabilitation medicine, 35(4): 153-162. Available at https://www.medicaljournals.se/jrm/content/abstract/10.1080/16501970306129.

[93] Hewitt, M., Maxwell, S., & Vargo, M. M. (2007). Policy issues related to the rehabilitation of the surgical cancer patient. Journal of surgical oncology, 95(5): 370-385.Available at http://onlinelibrary.wiley.com/doi/10.1002/jso.20777/pdf.

[94] Guo, Y., Persyn, L., Palmer, J. L., & Bruera, E. (2008). Incidence of and risk factors for transferring cancer patients from rehabilitation to acute care units. American Journal of Physical Medicine & Rehabilitation, 87(8): 647-653.Available at http://journals.lww.com/ajpmr/Abstract/2008/08000/Incidence_of_and_Risk_Factors_for_Transferring.6.aspx.

[95] Asher, A., Roberts, P. S., Bresee, C., Zabel, G., Riggs, R. V., & Rogatko, A. (2014). Transferring inpatient rehabilitation facility cancer patients back to acute care (TRIPBAC). PM&R, 6(9): 808-813.Available at http://www.sciencedirect.com/science/article/pii/S1934148214000240.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Chemotherapy

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. **Performed during the first 3 days of admission** **Check all that apply** ↓
Cancer Treatments		
	A. Chemotherapy (if checked, please specify below) A2a. IV A3a. Oral A10a. Other	☐ ☐ ☐ ☐

Current use

Chemotherapy data elements are currently used in the MDS 3.0. The items document whether the resident received chemotherapy in the past 14 days while not a resident of the assessing facility, and also if the resident has received chemotherapy in the past 14 days while a resident, but do not assess the route of chemotherapy.

Evidence supporting use of Chemotherapy (IV, Oral, Other)

An IV Chemotherapy data element was found to be feasible for cross-setting use in the PAC PRD.[96] A checkbox for chemotherapy during the last 14 days was shown to have reliabilities of 0.695 and 0.8 in studies of MDS 2.0 in nursing homes.[97]

Radiation

Radiation is a type of cancer treatment that uses high-energy radiation to shrink tumors and kill cancer cells by damaging their DNA. However, it can also damage normal cells, leading to side effects such as fatigue, skin irritation or damage, hair loss, nausea, and delayed side effects such as fibrosis (scar tissue formation), damage to the bowels if radiation was delivered to the abdominal region, memory loss, and infrequently, a second cancer due to radiation exposure. Radiation is a mainstay of cancer treatment; about half to two-thirds of all patients with cancer receive radiation therapy at some point in their treatment course.[98, 99] The indications range from early-stage cancer treated with curative intent to palliative radiation therapy, such as to treat metastatic cancer; tumors that are pressing on the spine or growing within bones, causing severe pain; or shrinking a tumor near the esophagus, which can inhibit swallowing. There are many types of radiation, such as external-beam radiation therapy and internal

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[96] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[97] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[98] Yamada, Y. Principles of Radiotherapy. (2009). In Cancer rehabilitation: principles and practice. Eds. Stubblefield Michael D. and O'dell Michael W.

[99] National Cancer Institute. (2010). Radiation Therapy for Cancer. Available at https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet

radiation therapy (brachytherapy that is delivered from sources placed inside or on the body), and systemic radiation therapy (in which the patient swallows or receives an injection of a radioactive substance).

Relevance to IRFs

As noted above, individuals impaired by cancer, or its treatments, including chemotherapy or radiation, have been shown to make functional gains in the IRF setting, and cancer patients can benefit from intensive rehabilitation therapies. In particular, patients with brain tumors who are receiving concurrent radiation during an IRF stay make greater functional gains compared to those who are not.[100,101] However, cancer patients in an inpatient rehabilitation unit are at risk of transfer back to the acute care setting, at rates ranging from 17 percent to of 35 percent.[102,103] Receipt of radiation therapy has implications for care planning, assessing functional gains, and estimating patient length of stay and resource utilization in IRF setting.

Therefore, assessing whether the patient is receiving Radiation would provide important information for care planning, clinical decision making, and resource use in IRFs.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Radiation

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. Performed during the first 3 days of admission Check all that apply ↓
	B. Radiation	☐

Current use

A version of this data element, Radiation, is currently collected in the MDS 3.0. The items document whether the resident received radiation in the past 14 days while not a resident of the assessing facility, and also if the resident has received radiation in the past 14 days while a resident.

[100] Marciniak, C. M., Sliwa, J. A., Heinemann, A. W., & Semik, P. E. (2001). Functional outcomes of persons with brain tumors after inpatient rehabilitation. Archives of physical medicine and rehabilitation, 82(4): 457-463. Available at http://www.sciencedirect.com/science/article/pii/S0003999301948294.

[101] McKinley, W. O., Huang, M. E., & Tewksbury, M. A. (2000). Neoplastic vs. traumatic spinal cord injury: an inpatient rehabilitation comparison. American journal of physical medicine & rehabilitation, 79(2): 138-144. Available at http://journals.lww.com/ajpmr/Abstract/2000/03000/Neoplastic_vs__Traumatic_Spinal_Cord_Injury__An.5.aspx

[102] Guo, Y., Persyn, L., Palmer, J. L., & Bruera, E. (2008). Incidence of and risk factors for transferring cancer patients from rehabilitation to acute care units. American Journal of Physical Medicine & Rehabilitation, 87(8): 647-653.Available at http://journals.lww.com/ajpmr/Abstract/2008/08000/Incidence_of_and_Risk_Factors_for_Transferring.6.aspx.

[103] Asher, A., Roberts, P. S., Bresee, C., Zabel, G., Riggs, R. V., & Rogatko, A. (2014). Transferring inpatient rehabilitation facility cancer patients back to acute care (TRIPBAC). PM&R 6(9): 808-813.Available at http://www.sciencedirect.com/science/article/pii/S1934148214000240

Evidence supporting use of Radiation

In studies of the MDS 2.0, a checkbox for radiation during the last 14 days was shown to have reliabilities of 1 and 0.66.[104]

Oxygen Therapy (Continuous, Intermittent)

Oxygen therapy provides a patient/resident with supplemental oxygen when medical conditions (e.g., chronic obstructive pulmonary disease [COPD], pneumonia, severe asthma) prevent the patient or resident from adequately oxygenating their bloodstream. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment: a reliable source of oxygen, various delivery systems (e.g., oxygen concentrator, liquid oxygen containers, and high-pressure systems), and the patient interface (e.g., nasal cannula, various types of masks). Accessories are also required (e.g., regulators, filters, tubing, etc.). While the equipment is generally the same for both sub-elements of this data element (continuous vs. intermittent), the main differences between delivering oxygen intermittently versus continuously are the severity of the underlying illness (which often requires more hours per day of oxygen therapy), and the bedside nursing care to set up the oxygen delivery system if the patient is unable (whether physically or cognitively) to do so independently.

The proposed Oxygen (Continuous, Intermittent) data elements assess if the patient received oxygen therapy and whether the oxygen was delivered continuously (typically defined as >=14 hours per day) or intermittently.

Relevance to IRFs

There are currently no items in IRF-PAI addressing oxygen use in the IRF setting. Use of oxygen is a marker of clinical complexity and medical risk, potential for functional gains, and resource use in the IRF setting. Stroke, spinal cord injury, brain injury, and other neurologic conditions are commonly addressed conditions in the IRFs; a subset of patients with these conditions are at risk of dysphagia and inability to handle oral secretions which could result in aspiration pneumonia and may require supplemental oxygen use. When pneumonia is present as a comorbidity among IRF patients, it can be associated with longer length of stay, lower discharge functional status ratings, and lower odds of home discharge.[105] In addition, patients with cardiac conditions (some of whom may require oxygen therapy) represent approximately 5 percent of IRF cases.[106] Patients' use of oxygen therapy has important implications for ability to participate in intensive rehabilitation therapies (3 hours per day, 5 days per week), and ability to make functional gains over the course of rehabilitation, which may affect length of stay. Assessing whether a patient is receiving Oxygen Therapy would provide important information for care planning, clinical decision making, care transitions, and resource use in IRFs.

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[104] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[105] Ahmed, I., Graham, J. E., Karmarkar, A. M., Granger, C. V., & Ottenbacher, K. J. (2013). In-patient rehabilitation outcomes following lower extremity fracture in patients with pneumonia. Respiratory care 58(4): 601-606. Available at http://rc.rcjournal.com/content/58/4/601.short

[106] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Available at http://www.medpac.gov/-documents-/reports

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Oxygen Therapy

Section O	Special Treatments, Procedures, and Programs
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.	

	3. Performed during the first 3 days of admission Check all that apply ↓
Respiratory Treatments	
C. Oxygen Therapy (if checked, please specify below)	☐
C2a. Continuous	☐
C3a. Intermittent	☐

Current use

Related data elements are collected in the OASIS-C2 and the MDS 3.0. In the MDS, the items document whether the resident received oxygen therapy in the past 14 days while not a resident of the assessing facility, and also if the resident has received oxygen therapy in the past 14 days while a resident.

Evidence supporting use of Oxygen Therapy (Continuous, Intermittent)

A related data element on high concentration oxygen use (FiO2>40%) was used and found feasible for cross-setting use in the PAC PRD.[107] In nursing homes, a checkbox for oxygen therapy during the last 5 days was shown to have reliability ranging from 0.925 to 0.955 in the national MDS 3.0 test.[108] Oxygen therapy data elements during the last 14 days were shown to have reliabilities ranging from of 0.81 to 0.87 in studies of MDS 2.0.[109]

Suctioning (Scheduled, As Needed)

Suctioning is used to clear secretions from the airway when a person cannot clear those secretions on his or her own due to a variety of reasons, including excess production of secretions from a pulmonary infectious process or neurological deficits that inhibit the ability to cough, swallow, etc. It is done by aspirating secretions through a catheter connected to a suction source.

Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions that can lead to aspiration pneumonias (a common condition in patients with inadequate gag reflexes) and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as

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[107] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[108] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[109] *Ibid.*

needed, such as when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents patients from clearing their secretions effectively, which also means they are in need of increased nursing care more generally (such as after a stroke or during an acute respiratory infection).

Relevance to IRFs

Pneumonia and dysphagia are two conditions that may occur in the IRF setting that may necessitate the use of suctioning of secretions. Stroke, spinal cord injury, brain injury, and other neurologic conditions are commonly addressed conditions and qualifying conditions for IRFs; a subset of patients with these conditions are at risk of dysphagia and inability to handle oral secretions, which could result in aspiration pneumonia and may require suctioning. As mentioned above, pneumonia, which in many cases could require suctioning of respiratory secretions, and when present as a comorbidity among IRF lower extremity fracture patients, is associated with longer length of stay, lower discharge functional status ratings, and lower odds of home discharge.[110] Additionally, pneumonia (which in some cases could require suctioning) is a common reason for interruptions in rehabilitation programs and for short stay transfers to an acute care setting among several classes of IRF Patients (e.g., bacterial pneumonia caused 26.4 percent of preventable short-stay transfers to an acute care setting among IRF patients with traumatic brain injury and 66.7 percent of preventable short-stay transfers to an acute setting among IRF patients with spinal cord injury).[111] The need for suctioning may affect patients' ability to full participate in the intensive rehabilitation program (3 hours per day, 5 days per week) in the IRF setting. Assessing whether Suctioning is being performed for a patient would provide important information for care planning, clinical decision making, care transitions, and resource use in IRFs.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Suctioning

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. Performed during the first 3 days of admission **Check all that apply** ↓
	D. Suctioning (if checked, please specify below)	☐
	D2a. Scheduled	☐
	D3a. As needed	☐

110 Ahmed, I., Graham, J. E., Karmarkar, A. M., Granger, C. V., & Ottenbacher, K. J. (2013). In-patient rehabilitation outcomes following lower extremity fracture in patients with pneumonia. Respiratory care 58(4): 601-606.Available at http://rc.rcjournal.com/content/58/4/601.short

111 Middleton, A., Graham, J. E., Krishnan, S., & Ottenbacher, K. J. (2016). Program Interruptions and Short-Stay Transfers Represent Potential Targets for Inpatient Rehabilitation Care-Improvement Efforts. American Journal of Physical Medicine & Rehabilitation 95(11): 850-861. Available at http://journals.lww.com/ajpmr/Fulltext/2016/11000/Program_Interruptions_and_Short_Stay_Transfers.9.aspx

Current use

Related Suctioning data elements are collected in the MDS 3.0. The items document whether the resident received Suctioning in the past 14 days while not a resident of the assessing facility, and also if the resident has received Suctioning in the past 14 days while a resident.

Evidence supporting use of Suctioning (Scheduled, As Needed)

In the PAC PRD, suctioning was assessed as part of Trach Tube with Suctioning data element, which evaluated whether patients or residents had a tracheostomy tube or needed suctioning. This related data element was found feasible for cross-setting use in the PAC PRD.[112] A checkbox for suctioning during the last 14 days was shown to have reliabilities of 0.89 and 0.775 in studies of MDS 2.0.[113]

Tracheostomy Care

A tracheotomy is a surgical procedure that consists of making a direct airway opening (tracheostomy) into the trachea (windpipe). Tracheostomies are created primarily for reasons such as to bypass an obstructed upper airway; in chronic cases, to enable the removal of secretions from the airway; and to deliver oxygen to the patient's lungs. For example, patients with a need for long-term ventilation (such as those in a persistent vegetative state or those who require long-term ventilator weaning but are alert and oriented); patients with tumors of the upper airway; patients with severe neck, mouth, or chest wall injuries; patients with degenerative neuromuscular diseases such as amyotrophic lateral sclerosis (ALS); patients with spinal cord injuries; and patients with airway burns are just some of the examples of the indications for a tracheostomy. Generally, in all of these cases we note that suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, permanent or temporary, warrants careful monitoring and immediate intervention should the tracheostomy become occluded, or in the case of a temporary tracheostomy, the devices used become dislodged.

For patients with a tracheostomy, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of their care plans. Regular cleansing is important to prevent infection, such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the tracheostomy is performed by the patient) in general the presence of such a device is associated with increased patient risk, and clinical care services will necessarily include close monitoring since to ensure that no life threatening events occur as a result of the tracheostomy, often considered part of the patient's life line.

The data element, Tracheostomy Care, assesses whether a patient/resident received tracheostomy care during the assessment period.

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[112] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[113] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

Relevance to IRFs

Patients with deficits in respiratory drive or in respiratory muscle strength may require prolonged mechanical ventilation that would require a tracheostomy; such deficits may be present in patients with stroke, traumatic brain injury, spinal cord injury, or other neurologic conditions that serve as IRF qualifying conditions. In addition, the presence of a tracheostomy tube itself may be a marker of resource use and functional gains among key populations of IRF patients. For example, stroke patients admitted to IRFs with medical tubes, including tracheostomies, have been found to have longer lengths of stay, lower admission and discharge FIM scores, and more medical complications.[114] Tracheostomy care may also affect a patient's capacity to participate in intensive rehabilitation therapies. As such, it is important to assess tracheostomy care in IRF settings for purposes of care planning and determining resource use. Assessing whether Tracheostomy Care is being performed for a patient would provide important information for care planning, clinical decision making, care transitions, and resource use in IRFs.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Tracheostomy Care

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. **Performed** **during the first** **3 days of admission** **Check all that apply** ↓
	E. Tracheostomy Care	☐

Current use

A version of this data element currently exists in the MDS 3.0. The items document whether the resident received Tracheostomy Care in the past 14 days while not a resident of the assessing facility, and also if the resident has received Tracheostomy Care in the past 14 days while a resident.

Evidence supporting use of Tracheostomy Care

In two studies of the MDS 2.0, a checkbox for tracheostomy care during the last 14 days was shown to have reliability of 1.[115]

Invasive Mechanical Ventilation

Invasive mechanical ventilation includes any type of electrically or pneumatically powered closed-system mechanical support devices, to ensure adequate ventilation of the patient who is unable to support his or her own respiration. Patients receiving closed-system ventilation include those receiving ventilation via a tracheostomy, as well as those patients with an endotracheal tube (e.g., nasally or orally intubated). Depending on the patient's underlying diagnosis, clinical condition, and prognosis, he or she may or may not be a candidate for weaning off the ventilator. For instance, certain medical conditions such as lung infections are expected to improve or resolve to a point where the patient can support his or

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[114] Roth, E. J., Lovell, L., Harvey, R. L., Bode, R. K., & Heinemann, A. W. (2002). Stroke rehabilitation. Stroke 33(7): 1845-1850. Available at http://stroke.ahajournals.org/content/33/7/1845.short

[115] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

her own respiration, whereas chronic neurodegenerative diseases are likely to progress over time and therefore preclude the patient from weaning and eventually having the tube removed.

Ventilation in this manner is a resource-intensive therapy associated with life threatening conditions without which the patient would not survive. However, ventilator use has inherent risks requiring close monitoring and failure to adequately care for the patient who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical and/or surgical condition.

Relevance to IRFs

Although the frequency of patients receiving invasive mechanical ventilation varies widely across IRF settings, IRF patients who are ventilator dependent can participate and benefit from intensive rehabilitation programs,[116] and early initiation of rehabilitation for such patients may be associated with improved outcomes. Invasive mechanical ventilation is associated with high daily and aggregate costs. In a national study of mechanical ventilation use in the United States, the estimated aggregated costs were $27 billion, 12 percent of all hospital costs.[117] The daily incremental cost of mechanical ventilation for intensive care unit (ICU) patients was estimated at between $600 and $1500 per day. While this study was of acute care hospitals, the costliness of this intervention can be extrapolated to IRFs as well. Assessment of whether the patient is on Invasive Mechanical Ventilation would provide important information for care planning, clinical decision making, care transitions, and resource use in IRFs.[118]

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Invasive Mechanical ventilation

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. **Performed during the first 3 days of admission** **Check all that apply** ↓
F. Invasive Mechanical Ventilator		☐

Current use

Invasive mechanical ventilation is currently assessed in the MDS 3.0, the OASIS-C2, and the LCDS. In the MDS, the items document whether the resident used a ventilator or respirator in the past 14 days while not a resident of the assessing facility, and also if the resident used a ventilator or respirator in the past 14 days while a resident. The OASIS-C2 assessment data element includes a checkbox item for respiratory treatments used at home, in which "ventilator (continually or at night)" is included. The LCDS has two items that specify whether the invasive mechanical ventilator is weaning or non-weaning.

[116] Make B, Gilmartin M, Brody JS, Snider GL. (1984). Rehabilitation of ventilator-dependent subjects with lung disease. The concept and initial experience. Chest 86:358-65.

[117] Wunsch, H., Linde-Zwirble, W. T., Angus, D. C., Hartman, M. E., Milbrandt, E. B., & Kahn, J. M. (2010). The epidemiology of mechanical ventilation use in the United States. Critical Care Med 38(10): 1947-1953.

[118] Foster S, Lopez D, Thomas HM III. (1988). Pulmonary rehabilitation in COPD patients with elevated PaCO2. Am Rev Respir Dis 138: 1519-23.

Evidence supporting use of Invasive Mechanical Ventilation

Checkbox items for ventilator (weaning and non-weaning) were tested in the PAC PRD and were found to be feasible for cross-setting use.[119] A version of the item was tested in the MDS 3.0 National Evaluation Study and had perfect reliability (1.0).[120]

Non-invasive Mechanical Ventilation (Continuous Positive Airway Pressure [CPAP], Bilevel Positive Airway Pressure [BiPAP])

CPAP and BiPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air through a mask continuously or via electronic cycling throughout the breathing cycle. A BiPAP/CPAP mask provides breathing support through the provision of positive airway pressure that prevents airways from collapsing down during the respiratory cycle. Non-invasive mechanical ventilation differs from invasive mechanical ventilation because the interface with the patient is a mask rather than an endotracheal tube that is passed into the windpipe. CPAP and BiPAP have a variety of clinical indications, from obstructive sleep apnea, to acute respiratory infections, to progressive neuromuscular decline leading to respiratory failure. The key difference between CPAP and BiPAP is that CPAP delivers the same amount of positive airway pressure throughout the breathing cycle while BiPAP, as the name implies, delivers two different pressure levels, a higher pressure to support inhalation and a lower pressure to prevent the airways from collapsing during exhalation. These interventions signify underlying medical conditions in the patient who requires their use.

Relevance to IRFs

BiPAP and CPAP use are not currently assessed in IRF-PAI. Many populations of patients admitted to IRFs are at increased risk of sleep-disordered breathing that could require use of CPAP or BIPAP, including stroke patients (about 21 percent of IRF patients), individuals with neurological conditions (about 20 percent of IRF patients), and cardiac patients (about 5 percent of IRF patients).[121] For example, sleep disordered breathing has been identified as common in stroke patients, and is a risk-factor for stroke itself and stroke recurrence; treatment of stroke patients with OSA with CPAP has been

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[119] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[120] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[121] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

associated with improved functional motor outcomes.[122,123,124,125] In addition, neurological conditions and spinal cord injuries, which are qualifying conditions for admission to an IRF, can be associated with respiratory muscle weakness, which could require non-invasive mechanical ventilation (i.e., CPAP, BiPAP). Noninvasive mechanical ventilation may improve outcomes in patients admitted to IRFs for cardiac or pulmonary rehabilitation, and may improve pulmonary rehab outcome in patients with interstitial lung disease and COPD patients.[126 127] Use of noninvasive mechanical ventilation may also have implications for daytime energy, and patient motivation to actively participate in intensive rehabilitation therapies in the IRF setting, as well as being a marker of clinical complexity and resource use. As such, use of noninvasive mechanical ventilation is important to assess in IRF settings for purposes of care planning and resource use.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Non-invasive Mechanical Ventilation

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. **Performed during the first 3 days of admission** **Check all that apply** ↓
G. Non-invasive Mechanical Ventilator (BiPAP/CPAP) (if checked, please specify below) G2a. BiPAP G3a. CPAP		☐ ☐ ☐

Current use

The *BiPAP/CPAP* data elements assess if the patient received bilevel positive airway pressure or continuous positive airway pressure during the assessment period. They are currently collected in the OASIS-C2, LCDS, and the MDS 3.0. The OASIS-C2 assessment data elements include a checkbox item for respiratory treatments, in which continuous/bi-level positive airway pressure is included. The LCDS uses a checklist format, including an item asking if a non-invasive ventilator (BIPAP, CPAP) is part of the patient's treatment plan. In the MDS, the items document whether the resident used BiPAP/CPAP in

[122] Brooks, D., Davis, L., Vujovic-Zotovic, N., Boulias, C., Ismail, F., Richardson, D., & Goldstein, R. S. (2010). Sleep-disordered breathing in patients enrolled in an inpatient stroke rehabilitation program. Archives of physical medicine and rehabilitation 91(4): 659-662. Available at http://www.sciencedirect.com/science/article/pii/S0003999310000298

[123] Brown, D. L. (2006). Sleep disorders and stroke. Copyright© 2006 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Seminars in neurology 26(1): 117-122 Available at https://www.thieme-connect.com/products/ejournals/html/10.1055/s-2006-933315

[124] Davis, A. P., Billings, M. E., Longstreth, W. T., & Khot, S. P. (2013). Early diagnosis and treatment of obstructive sleep apnea after stroke Are we neglecting a modifiable stroke risk factor? Neurology: Clinical Practice 3(3): 192-201. Available at http://cp.neurology.org/content/3/3/192.short

[125] Ryan, C. M., Bayley, M., Green, R., Murray, B. J., & Bradley, T. D. (2011). Influence of continuous positive airway pressure on outcomes of rehabilitation in stroke patients with obstructive sleep apnea. Stroke, STROKEAHA-110. Available at http://stroke.ahajournals.org/content/42/4/1062.short

[126] Köhnlein, T., Schönheit-Kenn, U., Winterkamp, S., Welte, T., & Kenn, K. (2009). Noninvasive ventilation in pulmonary rehabilitation of COPD patients. Respiratory medicine 103(9): 1329-1336. Available at http://www.sciencedirect.com/science/article/pii/S0954611109000997

[127] Dreher, M., Ekkernkamp, E., Schmoor, C., Schoenheit-Kenn, U., Winterkamp, S., & Kenn, K. (2015). Pulmonary rehabilitation and noninvasive ventilation in patients with hypercapnic interstitial lung disease. Respiration 89(3): 208-213. Available at https://www.ncbi.nlm.nih.gov/pubmed/25677159

the past 14 days while not a resident of the assessing facility, and also if the resident used BiPAP/CPAP in the past 14 days while a resident.

Evidence supporting use of Non-invasive Mechanical Ventilation (CPAP, BiPAP)

A checkbox item for Non-invasive Ventilation (CPAP) was tested in the PAC PRD and was found to be feasible for cross-setting use.[128]

IV Medications

Intravenous (IV) medications are drugs or biologics that are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a tube placed into the vein, including one that allows the fluids to enter the circulation through one of the larger heart vessels or more peripherally through a vein, e.g., commonly referred to as central midline, or peripheral ports.

This data element is important to collect, as IV medications are more resource intensive to administer than oral medications and signify a higher patient complexity (and often higher severity of illness). The clinical indications for each of the sub-types of IV medications proposed (antibiotics, anticoagulants, and other) are very different. IV antibiotics are used for severe infections when a) the bioavailability of the oral form of the medication would be inadequate to kill the pathogen; b) an oral form of the medication does not exist; or c) the patient is unable to take the medication by mouth. Due to growing concern about antimicrobial resistance, antibiotic stewardship initiatives are aimed at increasing evidence-based antibiotic prescribing and decreasing antibiotic overuse. While the particular antibiotic(s) would not be collected, collecting data on the use of IV antibiotics overall in the four PAC settings would assist with monitoring the implementation of evidence-based prescribing guidelines moving forward.

IV anticoagulants refers to anti-clotting medications ("blood thinners") often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are therefore at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. When a patient is on an IV anticoagulant, they require frequent monitoring of laboratory values to ensure appropriate anticoagulation status.

Relevance to IRFs

IRF-PAI does not currently assess delivery of IV Medications nor subtypes thereof. Several classes of patients with IRF-Qualifying Conditions are at risk of infections that could require intravenous antibiotics (e.g., post-operative infections in patients admitted after a lower extremity fracture or joint replacement; urinary tract infections among catheterized patients or those with urinary retention, which is common among those with neurological conditions, stroke, debility, brain injury or spinal cord injury; aspiration pneumonia among the same population of patients with neurological or debility related conditions that could impair ability to swallow). Several groups of patients with IRF qualifying conditions are at increased risk of venous thromboembolism (i.e., deep venous thrombosis or pulmonary embolism) that could require initiation of intravenous anticoagulation, including those admitted after lower extremity fracture, lower extremity joint replacement, major multiple trauma, spinal cord injury, traumatic brain injury patients, stroke patients, and other patients whose mobility has been limited due to other neurologic conditions. For example, incidence of DVT varies from 16.4 percent to 100 percent among stroke, spinal

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[128] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

cord injury, or traumatic brain injury patients not receiving prophylaxis, and incidents remains high when prophylactic measures (e.g., pneumatic compression, compression stockings, mobilization, medication) are used.[129] In addition, use of IV antibiotics could represent a medical complication or comorbidity that places key classes of IRF patients at risk of a program interruption or transfer to an acute care setting. Of preventable program interruptions among IRF patients, among the most frequent included urinary tract infections among patients with stroke and traumatic brain injury (28.2 percent and 42.9 percent of preventable program interruptions, respectively). Infection is among the most common admitting diagnosis for short-stay transfers from IRFs to acute care setting for patients with stroke, traumatic brain injury, and spinal cord injury. Thus, given the increased risk for IV medication use among patients with IRF-qualifying conditions and its association with the interruption of rehabilitation therapies, and the fact that it is a marker of clinical complexity and resource use, it is important to assess IV medication use in IRFs. The standardized assessment of IV Medications, including the type of medications, would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: IV Medications

ADMISSION	
Section O	**Special Treatments, Procedures, and Programs**

O0110. Special Treatments, Procedures, and Programs
Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.

	3. Performed during the first 3 days of admission **Check all that apply** ↓
Other Treatments	
H. IV Medications (if checked, please specify below)	☐
H3a. Antibiotics	☐
H4a. Anticoagulation	☐
H10a. Other	☐

Current use

An IV Medications data element is currently in use in the MDS 3.0 but without the sub-elements specifying types of IV Medication. The items document whether the resident received IV Medication in the past 14 days while not a resident of the assessing facility, and also if the resident has received IV Medication in the past 14 days while a resident.

Evidence supporting use of IV Medications

A similar data element, IV Vasoactive Medications, was tested in the PAC PRD and found to be feasible across PAC settings. This data element was specific to the IV administration of vasoactive drugs (e.g., pressors, dilators, continuous medication for pulmonary edema) that increase or decrease blood pressure and/or heart rate.

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[129] Akman, M. N., Cetin, N., Bayramoglu, M., Isiklar, I., & Kilinc, S. (2004). Value of the D-dimer test in diagnosing deep vein thrombosis in rehabilitation inpatients. Archives of physical medicine and rehabilitation 85(7): 1091-1094. Available at http://www.sciencedirect.com/science/article/pii/S0003999304000255

In nursing homes, a checkbox for IV medications during the last 5 days was shown to have reliability of 0.952 in the national MDS 3.0 test and IV medications during the last 14 days was shown to have reliabilities of 0.92 and 0.564 in studies of MDS 2.0.[130]

<u>Transfusions</u>

Transfusions are the administration of blood or blood products (e.g. platelets, synthetic blood products) into the bloodstream. Blood transfusions are highly protocolized, with multiple safety checks and monitoring required during and after the infusion to avoid adverse events. Coordination with the facility's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require additional nursing staff and care coordination, and impacts planning for transitions of care, as transfusions are not performed in all PAC settings.

Relevance to IRFs

Data regarding blood transfusions are not currently collected in the IRF-PAI. Key populations of IRF patients may benefit from blood transfusions during their rehabilitation stay. For example, patients with fractures of the lower extremity and major joint replacements of the lower extremity are IRF qualifying conditions and represent approximately 12 percent and approximately 8 percent of IRF cases annually, respectively.[131] As in other settings, blood transfusions are resource-intensive, requiring laboratory testing, coordination with the blood bank, intensive bedside nursing care and monitoring, and can be associated with adverse reactions. Because need for and receipt of a blood transfusion can be a marker of clinical complexity and resource use, assessment of receipt of transfusions is warranted in the IRF setting. The standardized assessment of patients' receipt of transfusions would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Transfusions

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. Performed during the first 3 days of admission Check all that apply ↓
	I. Transfusions	☐

Current use

The Transfusions data element is currently collected in the MDS 3.0, using a checkbox format. The items document whether the resident received Transfusions in the past 14 days while not a resident of

[130] Saliba, D., & Buchanan, J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. 2008. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf

[131] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

the assessing facility, and also if the resident has received Transfusions in the past 14 days while a resident.

Evidence supporting use of Transfusions

In nursing homes, a checkbox for transfusions in the past 5 days was shown to have reliability of 0.666 in the national MDS 3.0 test.[132] A checkbox for transfusions in the last 14 days was shown to have reliabilities of 0.57 and 0.304 when tested in two studies of MDS 2.0.[133]

Dialysis (Hemodialysis, Peritoneal dialysis)

Dialysis is used primarily in the case of end stage kidney failure. It is a process by which waste, salt, and excess water are removed from the body and key electrolytes such as sodium, potassium, and bicarbonate are maintained at a safe level. Hemodialysis is conducted using an artificial kidney, an external hemodialyzer, which filters the blood. During peritoneal dialysis, the dialysate is injected into the peritoneal (abdominal) cavity, excess fluid and waste products are drawn out of the blood and into the dialysate, and the fluid is then drained. Hemodialysis sessions are typically performed three times a week and last up to four hours each. Peritoneal dialysis can be performed continuously overnight or intermittently during the day.

Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients receiving hemodialysis are often transported to a different facility, or, at a minimum, to a different part of the hospital if the IRF is adjacent to a dialysis center. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and, as with hemodialysis, close monitoring is required.

Relevance to IRFs

IRF-PAI does not presently collect data regarding receipt of dialysis, or the type thereof. In PAC PRD 2.1 percent of IRF patients received hemodialysis.[134] There is a paucity of information about the impact of end-stage renal disease (ESRD) and receipt of dialysis in the IRF setting. However, some studies have found dialysis patients in IRFs to have longer lengths of stay[135] and poorer function performance outcomes.[136] ESRD and receipt of dialysis has been found to be related to functional outcomes in geriatric patients. For example, routine dialysis can lead to fatigue on non-dialysis days,

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[132] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[133] *Ibid.*

[134] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[135] Forrest, G. P. (2004). Inpatient rehabilitation of patients requiring hemodialysis. Archives of physical medicine and rehabilitation 85(1): 51-53. Available at http://www.sciencedirect.com/science/article/pii/S0003999303003666

[136] Cowen, T. D., Huang, C. T., Lebow, J., Devivo, M. J., & Hawkins, L. N. (1995). Functional outcomes after inpatient rehabilitation of patients with end-stage renal disease. Archives of physical medicine and rehabilitation 76(4): 355-359. Available at http://www.sciencedirect.com/science/article/pii/S000399939580661X

which may result in decreased physical activity and impede participation in therapies for some patients.[137] Finally, ESRD patients are at increased risk of amputations, which is a qualifying condition among Medicare IRF patients (3 to 4 percent of IRF cases).[138] Dialysis is a time intensive service that requires coordination with specialists and close monitoring of vital signs and laboratory studies and carries with it risks of complications and infections. Accordingly, dialysis may impact patients' ability to participate in an intensive rehabilitation program, resource use, and functional gains, and assessment of receipt of dialysis services in the IRF setting is warranted for resource use and care planning purposes. Assessing Dialysis (Hemodialysis, Peritoneal dialysis) would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Dialysis

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. Performed during the first 3 days of admission Check all that apply ↓
J. **Dialysis** (if checked, please specify below) J2a. Hemodialysis J3a. Peritoneal dialysis		☐ ☐ ☐

Current use

A Dialysis data element is currently collected in the MDS 3.0. The items document whether the resident received Dialysis in the past 14 days while not a resident of the assessing facility, and also if the resident has received Dialysis in the past 14 days while a resident. These data elements use a checkbox format to indicate peritoneal or renal dialysis including hemofiltration treatments, Slow Continuous Ultrafiltration (SCUF), Continuous Arteriovenous Hemofiltration (CAVH), and Continuous Ambulatory Peritoneal Dialysis (CAPD).

Evidence supporting use of Dialysis (Hemodialysis, Peritoneal dialysis)

In nursing homes, a data element assessing dialysis in the past 5 days was tested in the national MDS 3.0 test and shown to have almost perfect reliability (0.908 to 0.927).[139] Dialysis in the last 14 days was also shown to have almost perfect reliability (0.92 to 0.965) in studies of MDS 2.0.[140]

IV Access

Intravenous (IV) access refers to a catheter inserted into a vein for a variety of clinical reasons, including long-term medication treatment, hemodialysis, large volumes of blood or fluid, frequent access

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[137] Farragher, J., & Jassal, S. V. (2012). Rehabilitation of the geriatric dialysis patient. Blackwell Publishing Ltd. In Seminars in dialysis 25(6): 649-656. Available at http://onlinelibrary.wiley.com/doi/10.1111/sdi.12014/full

[138] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

[139] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[140] *Ibid.*

for blood samples, intravenous fluid administration, total parenteral nutrition (TPN), or in some instances the measurement of central venous pressure.

The data elements associated with IV Access distinguish between peripheral access and central access. Further, different types of central access are specified. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life threatening events such as pulmonary embolism, infection and bleeding. Patients with central lines, including those peripherally inserted or who have subcutaneous central line "port" access, always require vigilant nursing care to ensure patency of the lines and importantly to ensure that such invasive lines are free from any potentially life-threatening events such as infection, air embolism, as well as bleeding from an open lumen.

Relevance to IRFs

The presence of intravenous access is not currently assessed in IRF-PAI, nor are specific subtypes of intravenous access. The need for IV access in IRFs is common: in PAC PRD, 7.2 percent of IRF patients received central line management.[141] Presence of IV access and type is a marker of clinical complexity (i.e., need for a medication that can be administered through the IV route and nursing care need), and accordingly represents a marker of resource use and an important consideration for care planning. Assessing IV Access would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: IV Access

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures, and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days of admission. For chemotherapy and dialysis, check if it is part of the patient's treatment plan.		
		3. **Performed during the first 3 days of admission** **Check all that apply** ↓
O. IV Access (if checked, please specify below) O2a. Peripheral IV O3a. Midline O4a. Central line (e.g., PICC, tunneled, port) O10a. Other		☐ ☐ ☐ ☐ ☐

Current use

The IV Access data elements as proposed are not currently included in any of the PAC assessments.

Evidence supporting use of IV Access

The IV Access data elements were not tested in the PAC PRD but that study did test a related data element, Central Line Management, which was found feasible for cross-setting use.

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[141] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

Parenteral/IV Feeding

Patients can be fed parenterally (i.e. intravenously) to bypass the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. Parenteral/IV feeding is often used following surgery, when feeding by mouth or digestive system is not possible, when a patient's digestive system cannot absorb nutrients due to chronic disease, or if a patient's nutritional requirement cannot be met by tube feeding and supplementation.

The need for parenteral/IV feeding indicates a clinical complexity that prevents the patient from meeting his/her nutritional needs enterally and is more resource intensive than other forms of nutrition, as it often involves monitoring of blood chemistries and maintenance of a central line. Therefore, assessing a patient's need for parenteral feeding is important for resource use and care planning. In addition to the risks associated with central and peripheral intravenous access, parenteral/IV feeding is associated with significant risks such as embolism and sepsis.

Relevance to IRFs

Parenteral feeding is jointly assessed with tube feeding at present in the IRF-PAI and is also assessed separately. As in other settings, parenteral nutrition indicates clinical complexity and resource use requiring frequent blood work, central venous access, risk of infection, and more intensive nursing care; these are important in the IRF setting for resource use and care planning. Need for parenteral or IV feed also indicates the nutritional status of the patient, and accordingly could be an important marker for potential resource use and functional gains, particularly among key classes of IRF patients. For example, patients with severe malnutrition are at higher risk for a variety of complications.[142] Among IRF patients with stroke, an IRF qualifying condition, malnutrition (which may or may not require parenteral/IV feeding) has been associated with poorer rehabilitation outcomes and has been found to be associated with length of stay and functional outcomes among stroke patients in some IRFs.[143] As Parenteral/IV Feeding and nutritional state can be indicative of clinical complexity, resource use, potential ability to participate in an intensive rehabilitation program, and potential for functional gains, the standardized assessment Parenteral/IV Feeding would provide important information for IRFs.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Parenteral/IV Feeding

K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days of admission.	1. Performed during the first 3 days of admission Check all that apply ↓
A. Parenteral/IV feeding	☐

Current use

Versions of the Parenteral/IV Feeding data element are currently collected in the OASIS-C2, IRF-PAI, LCDS, and the MDS 3.0. The OASIS-C2 data element assesses whether the patient is receiving parenteral nutrition at home. Section O of the IRF-PAI includes a check box data element to assess total

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[142] Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). "The link between nutritional status and clinical outcome: can nutritional intervention modify it?" Am J of Clinical Nutrition 47(2): 352-356.

[143] Finestone, H. M., Greene-Finestone, L. S., Wilson, E. S., & Teasell, R. W. (1996). Prolonged length of stay and reduced functional improvement rate in malnourished stroke rehabilitation patients. Archives of physical medicine and rehabilitation 77(4): 340-345. Available at https://www.ncbi.nlm.nih.gov/pubmed/8607756

parenteral nutrition (TPN) with a 3-day look-back period. The LCDS includes a checklist with a question asking whether TPN is part of the patient's treatment plan at admission. In the MDS, the items document whether the resident received Parenteral/IV Feeding in the past 7 days while not a resident of the assessing facility, and also if the resident has received Parenteral/IV Feeding in the past 7 days while a resident.

Evidence supporting use of Parenteral/IV Feeding

A similar data element, the Total Parenteral Nutrition, was tested in the PAC PRD and found to be feasible across PAC settings. Parental/IV feeding in the last 5 days was shown to have almost perfect reliability (0.946 to 0.951) in the national MDS 3.0 test in nursing homes. [144] Parental/IV in the last 7 days was shown to have fair (0.213) and almost perfect (0.83) reliabilities in studies of the MDS 2.0.[145]

Feeding Tube

The Feeding Tube data element refers to enteral nutrition, which is the delivery of a nutritionally complete diet containing protein, carbohydrate, fat, water, minerals, and vitamins, directly into the stomach, duodenum, or jejunum. It is typically used for patients/residents who have a functional gastrointestinal tract but are unable to maintain an adequate or safe oral intake. This data element assesses if the patient/resident received enteral nutrition during the assessment period.

Relevance to IRFs

At present, tube feeding is jointly assessed in a single item with parenteral nutrition in IRF-PAI. Administration of tube feeding implies nutritional needs that cannot be met by standard oral feeds, either due to poor oral intake and inability to meet nutritional goals or due to aspiration risk. For IRF patients, tube feeding can imply risk of aspiration and aspiration-related complications such as pneumonia, as well as additional equipment and nursing resources. There are specific groups of IRF patient for whom tube feeding can serve as a proxy for risk of dysphagia, ability to fully participate in an intensive rehabilitation program, clinical complexity, and nutritional status. As mentioned above, malnutrition, which may or may not require tube feeding, has been associated with poorer rehabilitation outcomes among geriatric stroke patients and has been found to be associated with length of stay and functional outcomes among stroke patients in some IRF Settings.[146,147] Feeding tubes themselves also appear to have important implications: Stroke patients admitted to IRFs with medical tubes, including feeding tubes, have been found to have longer lengths of stay, lower admission and discharge FIM scores, and more medical complications and feeding tubes have been associated with greater functional improvements over the course of IRF stays for severe stroke patients.[148,149] Because it can be indicative of clinical complexity,

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[144] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[145] *Ibid.*

[146] Finestone, H. M., Greene-Finestone, L. S., Wilson, E. S., & Teasell, R. W. (1996). Prolonged length of stay and reduced functional improvement rate in malnourished stroke rehabilitation patients. Archives of physical medicine and rehabilitation 77(4): 340-345. Available at https://www.ncbi.nlm.nih.gov/pubmed/8607756

[147] Aptaker, R. L., Roth, E. J., Reichhardt, G., Duerden, M. E., & Levy, C. E. (1994). Serum albumin level as a predictor of geriatric stroke rehabilitation outcome. Archives of physical medicine and rehabilitation 75(1): 80-84. Available at https://www.ncbi.nlm.nih.gov/pubmed/8291969

[148] James, R., Gines, D., Menlove, A., Horn, S. D., Gassaway, J., & Smout, R. J. (2005). Nutrition support (tube feeding) as a rehabilitation intervention. Archives of physical medicine and rehabilitation 86(12): 82-92. Available at http://www.sciencedirect.com/science/article/pii/S0003999305011421

[149] Roth, E. J., Lovell, L., Harvey, R. L., Bode, R. K., & Heinemann, A. W. (2002). Stroke rehabilitation. Stroke 33(7): 1845-1850. Available at http://stroke.ahajournals.org/content/33/7/1845.short

resource use, and potential functional gains, assessment of tube feeding in the IRF setting would provide important information for care planning, care transitions, and resource use in IRFs.[150]

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Feeding Tube

K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days of admission.	1. Performed during the first 3 days of admission Check all that apply ↓
B. **Feeding tube** - nasogastric or abdominal (e.g., PEG)	☐

Current use

A version of the Feeding Tube data element is currently used in three existing PAC assessments. The data element Enteral Nutrition is currently collected in the OASIS-C2, with a question asking if the patient is receiving enteral nutrition at home. In the MDS, the items document whether the resident used a Feeding tube in the past 7 days while not a resident of the assessing facility, and also if the resident has used a Feeding tube in the past 7 days while a resident. In the IRF-PAI, a Swallowing Status data element captures some information related to enteral nutrition through the response option "Tube/Parenteral Feeding."

Evidence supporting use of Feeding Tube

In the national MDS 3.0 test in nursing homes, the Feeding Tube data element, collected for the last 5 days, was shown to have almost perfect reliability (0.886). In studies of the MDS 2.0, the Feeding Tube data element, collected in the last 7 days, was also shown to have almost perfect reliability (0.98).[151]

Mechanically Altered Diet

A mechanically altered diet is one that is specifically prepared to alter the texture or consistency of food to facilitate oral intake. Examples include soft solids, puréed foods, ground meat, and thickened liquids. A mechanically altered diet should not automatically be considered a therapeutic diet.

The provision of a mechanically altered diet is resource intensive, as it signifies difficulty swallowing/eating safety (dysphagia). Often, nurses are required to slowly feed patients meals consisting of a mechanically altered diet rather than having them eat independently.

Relevance to IRFs

Patients with severe malnutrition are at higher risk for a variety of complications.[152] Use of a mechanically altered diet or supervision is currently assessed in the IRF-PAI. Mechanically altered diets are particularly relevant for many common populations of IRF patients including those with strokes,

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[150] Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). "The link between nutritional status and clinical outcome: can nutritional intervention modify it?" Am J of Clinical Nutrition 47(2): 352-356.

[151] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[152] Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). "The link between nutritional status and clinical outcome: can nutritional intervention modify it?" Am J of Clinical Nutrition 47(2): 352-356.

neurologic conditions, and brain injuries, which account for 19.5 percent, 13.1 percent and 8.7 percent of patients in IRFs in 2014 and are IRF qualifying conditions.[153] Owing to neurological changes, these patients may be at risk of aspiration and related complications, and as such many benefit from the use of a mechanically altered diet with thickened liquids or pureed solids. As mechanically altered diets are a marker of dysphagia, they are a marker both of clinical complexity, complication risk, and resource use among key groups of IRF patients. Dysphagia commonly affects stroke patients, with incidents rates varying widely in the literature from 37 percent to 78 percent depending upon the setting and screening instrument used.[154] This is a risk for malnutrition, which has been found to be common among stroke patients and associated with worse functional outcomes and more complications.[155] Dysphagia is also common among patients with traumatic brain injury, with an incidence as high as 93 percent among traumatic brain injury patients admitted to rehabilitation.[156] Many other neurologic disorders, for which patients may be admitted to an IRF, may feature dysphagia that may benefit from a mechanically altered diet.[157] Because it can be a marker of clinical complexity, resource use, and can be related to potential for functional rehabilitation gains, assessing whether an IRF patient requires a mechanically altered diet would provide important information for care planning, care transitions, patient safety, and resource use in IRF.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Mechanically Altered Diet

K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days of admission.	1. Performed during the first 3 days of admission Check all that apply ↓
C. **Mechanically altered diet** - require change in texture of food or liquids (e.g., pureed food, thickened liquids)	☐

Current use

The Mechanically Altered Diet data element is currently collected in the MDS 3.0. The items document whether the resident received a Mechanically Altered Diet in the past 7 days while not a resident of the assessing facility, and also if the resident has received a Mechanically Altered Diet in the past 7 days while a resident.

[153] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

[154] Martino, R., Foley, N., Bhogal, S., Diamant, N., Speechley, M., & Teasell, R. (2005). Dysphagia after stroke. stroke 36(12): 2756-2763. Available at http://stroke.ahajournals.org/content/36/12/2756.

[155] Finestone, H. M., & Greene-Finestone, L. S. (2003). Rehabilitation medicine: 2. Diagnosis of dysphagia and its nutritional management for stroke patients. Canadian Medical Association Journal 169(10): 1041-1044. Available at http://www.cmaj.ca/content/169/10/1041.full

[156] Hansen, T. S., Engberg, A. W., & Larsen, K. (2008). Functional oral intake and time to reach unrestricted dieting for patients with traumatic brain injury. Archives of physical medicine and rehabilitation 89(8): 1556-1562. Available at http://www.sciencedirect.com/science/article/pii/S0003999308003237

[157] Buchholz, D. W. (1993). Dysphagia associated with neurological disorders. Acta oto-rhino-laryngologica belgica 48(2): 143-155. Available at https://www.ncbi.nlm.nih.gov/pubmed/8209677

Evidence supporting use of Mechanically Altered Diet

In the national MDS 3.0 test and studies of MDS 2.0 in nursing homes, the Mechanically Altered Diet data element was shown to have almost perfect reliability (0.82 to 0.960).[158]

Therapeutic Diet

A therapeutic diet is a diet intervention ordered by a health care practitioner as part of the treatment for a disease or clinical condition manifesting an altered nutritional status, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium).

The Therapeutic Diet data element is important to collect in the IRF setting in order to distinguish therapeutic diet from various other nutritional approaches. It is less resource intensive from the bedside nursing perspective but does signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC settings of whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

Relevance to IRFs

Therapeutic diets are not currently assessed in IRF-PAI and data are lacking regarding the prevalence of therapeutic diets in the IRF setting. However, therapeutic diets are part of the treatment and lifestyle changes required for patients with chronic conditions, which are common in IRF populations. In 2013 and 2014, more than 5 percent of IRF cases were for cardiac conditions,[159] many of which require therapeutic diets (e.g., fluid restriction, low-fat, low sodium) for successful management of that condition while the patient undergoes rehabilitation services. Similarly, diabetes, a condition which requires a carbohydrate controlled therapeutic diet, has been found to affect 23 percent of patients in IRFs after hip fracture and result in longer lengths of stay, lower functional status ratings, and reduced odds of discharge home.[160] Diabetes has also been shown to affect 20 to 22 percent of IRF knee replacement patients and 28% of stroke patients.[161,162] Fractures of the lower extremity, major joint replacements of the lower extremity, and stroke accounted for 12.2 percent, 7.8 percent, and 19.5 percent of IRF cases in 2014, respectively.[163] As therapeutic diets may be a common requirement of many key IRF populations and may be a marker of clinical complexity, the standardized assessment of Therapeutic Diets is warranted in the IRF setting.

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[158] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[159] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Retrieved from http://www.medpac.gov/-documents-/reports

[160] Reistetter, T. A., Graham, J. E., Deutsch, A., Markello, S. J., Granger, C. V., & Ottenbacher, K. J. (2011). Diabetes comorbidity and age influence rehabilitation outcomes after hip fracture. Diabetes care 34(6): 1375-1377. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114361

[161] DeJong, G., Hsieh, C. H., Gassaway, J., Horn, S. D., Smout, R. J., Putman, K., ... & Foley, M. P. (2009). Characterizing rehabilitation services for patients with knee and hip replacement in skilled nursing facilities and inpatient rehabilitation facilities. Archives of physical medicine and rehabilitation 90(8): 1269-1283. Available at http://www.sciencedirect.com/science/article/pii/S0003999309003025

[162] Roth, E. J., Lovell, L., Harvey, R. L., Heinemann, A. W., Semik, P., & Diaz, S. (2001). Incidence of and risk factors for medical complications during stroke rehabilitation. Stroke 32(2): 523-529. Available at http://stroke.ahajournals.org/content/32/2/523.short

[163] Medicare Payment Advisory Commission. (2016). Report to the Congress: Medicare Payment Policy. Chapter 9 Inpatient rehabilitation facility services. Available at http://www.medpac.gov/-documents-/reports

K0520. Nutritional Approaches	1. Performed during the first 3 days of admission
Check all of the following nutritional approaches that were performed during the first 3 days of admission.	Check all that apply ↓
D. Therapeutic diet (e.g., low salt, diabetic, low cholesterol)	☐

Current use

This Therapeutic Diet data element is currently collected in the MDS 3.0. The items document whether the resident received a Therapeutic Diet in the past 7 days while not a resident of the assessing facility, and also if the resident has received a Therapeutic Diet in the past 7 days while a resident.

Evidence supporting use of Therapeutic Diet

In the national MDS 3.0 test and studies of MDS 2.0 in nursing homes, the Therapeutic Diet data element was shown to have substantial to almost perfect reliability (0.797 to 0.931).[164]

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[164] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

Section 5: Medical Condition and Comorbidity Data

Standardized data elements to satisfy the IMPACT Act category of Medical conditions and comorbidities are already submitted for calculation of the measure the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), which was finalized for adoption into the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), adopted as a non-risk-adjusted application of the NQF-endorsed version in the CY 2013 OPPS/ASC Final Rule (77 FR 68500 through 68507), adopted as the risk adjusted, NQF-endorsed version in FY 2014 IRF PPS Final Rule (78 FR 47911 through 47912), and adopted in the FY 2016 IRF PPS final rule (80 FR 47089 through 47096) to fulfill IMPACT Act requirements. It was also adopted for the other PAC quality reporting programs in the FY 2016 SNF PPS final rule, the FY 2014 IRF PPS final rule, and the CY 2016 HH PPS final rule. The standardized data elements used to calculate and risk adjust this measure fall under the IMPACT Act category "medical conditions and comorbidities," listed in section 1899B(b)(1)(B) of the Act, which includes pressure ulcers and diabetes. The data elements proposed for use in the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, are also related to the category of medical conditions and comorbidities, are described in Chapter 2, Section 2 of this document.

Section 6: Impairments

Hearing and vision impairments are common conditions that, if unaddressed, affect patients' and residents' activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions such as cognition. Hearing impairments may cause difficulty in communication of important information concerning the patient's or resident's condition, preferences, and care transitions; vision impairments have been associated with increased risk of falls. Both types of impairment can also interfere with comprehension of and adherence to discharge plans. Onset of hearing and vision impairments can be gradual, so accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices, and to ensuring that person-directed care plans are developed to accommodate a patient or resident's needs during post-acute care and at discharge.

Assessments pertaining to sensory status aids PAC providers in better understanding the needs of their patients and residents by establishing a diagnosis of hearing or vision impairment, elucidating the patient or resident's ability and willingness to participate in treatments or use assistive devices during their stay, and identifying appropriate ongoing therapy and support needs at the time of discharge. The standardized assessment of vision impairment among PAC patients and residents supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, further enabling the transfer of accurate health information.

Standardized Data Elements to Assess Hearing and Vision Impairments

CMS has identified two data elements for cross-setting standardized assessment of hearing and vision impairment. The proposed data elements are:

1. Hearing (Ability to Hear)
2. Vision (Ability to See in Adequate Light)

Hearing

Hearing impairment is one of the most common complaints in adults over the age of 60 and is a major contributor to difficulties in speech comprehension.[165] About 51 percent of nursing facility patients and residents are estimated to have moderate to severe hearing impairment.[166] Data from the PAC PRD suggest that severe hearing impairment affects 1 to 2 percent of Medicare FFS beneficiaries in the four types of PAC.[167,168]

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[165] Peelle, J. E., Troiani, V., Grossman, M., & Wingfield, A. (2011). Hearing loss in older adults affects neural systems supporting speech comprehension. J of Neuroscience 31(35): 12638-12643.

[166] Garahan, M. B., Waller, J. A., Houghton, M., Tisdale, W. A., & Runge, C. F. (1992). Hearing loss prevalence and management in nursing home residents. J Am Geriatrics Society 40(2): 130-134.

[167] Hearing impairments were classified into categories from mildly impaired to severely impaired. The percentages reported here refer to severe impairment of hearing, defined as "Absence of useful hearing" (Gage et al., 2012).

[168] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

Relevance to IRFs

The IRF-PAI does not currently include Hearing or any comparable hearing impairment assessment items. In PAC PRD testing, 1.1 percent of IRF patients demonstrated severely impaired hearing.[169] Hearing impairments can impact the effectiveness of patient communication with providers, which has implications for patient understanding of and adherence to treatment plans and rehabilitation goals. Hearing impairments are also correlated with lower functional status and lower performance on measures of cognitive functioning in older adults,[170,171] which has implications for monitoring patient progress toward goals for some IRF patients and may also affect participation in some intensive rehabilitation therapies (e.g., speech and language therapies, cognitive rehabilitation). Assessing Hearing would provide important information for communication, ensuring safety, care planning, care transitions, and resource use in IRFs.

Proposed Data Element for the Assessment of Impairments: HEARING

B0200. Hearing (3-day assessment period)

Enter Code	**Ability to Hear** (with hearing aid or hearing appliances if normally used)
	0. **Adequate:** No difficulty in normal conversation, social interaction, listening to TV
	1. **Minimal difficulty:** Difficulty in some environments (e.g., when person speaks softly or setting is noisy)
	2. **Moderate difficulty:** Speaker has to increase volume and speak distinctly
	3. **Highly impaired:** Absence of useful hearing

Current use

The Hearing data element (Ability to Hear) is currently collected in the MDS 3.0.

Evidence supporting use of Hearing

The Hearing data element tested in the PAC PRD includes one question regarding hearing ability, which showed high reliability across PAC settings (unweighted kappa = 0.78). The MDS 3.0 version of the Hearing data element also had almost perfect agreement in the MDS 3.0 national test in nursing homes (weighted kappa = 0.938 and 0.894).[172] In MDS 2.0 testing, the Hearing data element showed moderate to good reliability (0.575 – 0.88).[173]

Vision

Visual impairment can be caused not only by age-related diseases (e.g., age-related macular degeneration [AMD], cataract, glaucoma, and diabetic retinopathy) but also due to nearsightedness, farsightedness, loss of near vision with age, and/or untreated disease.[174] In addition to conditions affecting the eye itself, visual deficits can also be caused by other conditions such as stroke and traumatic

[169] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[170] Lin FR, Ferrucci L, Metter EJ, An Y, Zonderman AB, Resnick SM. (2011). Hearing loss and cognition in the Baltimore Longitudinal Study of Aging. Neuropsychology 25(6):763.

[171] Keller BK, Morton JL, Thomas VS, Potter JF. (1999). The effect of visual and hearing impairments on functional status. Journal of the American Geriatrics Society 1;47(11):1319-25.

[172] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[173] *Ibid.*

[174] Cimarolli, V. R., Boerner, K., Brennan-Ing, M., Reinhardt, J. P., & Horowitz, A. (2012). Challenges faced by older adults with vision loss: a qualitative study with implications for rehabilitation. Clin Rehab 26(8): 748-757.

brain injury. The PAC PRD study found that between 1 and 3 percent of Medicare FFS beneficiaries among the four types of PAC providers had the most extreme category of visual impairment assessed, having "No vision or object identification questionable." [175]

Relevance to IRFs

The IRF-PAI does not currently assess vision impairment. In PAC PRD testing, 1.7 percent of IRF patients demonstrated severely impaired vision,[176] and this was associated with poorer outcomes with respect to change in self-care and mobility.[177] Additionally, assessment of this information is useful for ensuring safety in the IRF setting, as impaired vision increases the risk of falls.[178,179] Visual impairments are also associated with poorer rehabilitation outcomes among older IRF patients.[180] Visual impairments may also affect patients' participation in some rehabilitation therapies and/or ability to complete cognitive assessment tools (e.g., performance on visual-motor tasks). Assessing Vision would provide important information for patient safety, communication, care planning, care transitions, and resource use in IRFs.

Proposed Data Element for the Assessment of Impairments: VISION

B1000. Vision (3-day assessment period)	
Enter Code ☐	**Ability to See in Adequate Light** (with glasses or other visual appliances)
	0. **Adequate:** Sees fine detail, such as regular print in newspapers/books
	1. **Impaired:** Sees large print, but not regular print in newspapers/books
	2. **Moderately impaired:** Limited vision; not able to see newspaper headlines but can identify objects
	3. **Highly impaired:** Object identification in question, but eyes appear to follow objects
	4. **Severely impaired:** No vision or sees only light, colors or shapes; eyes do not appear to follow objects

Current use

The Vision data element (Ability to See in Adequate Light) is currently collected in the MDS 3.0. The data element contains five response options ranging from 0 (adequate) to 4 (severely impaired).

Evidence supporting use of Vision

The MDS 3.0 Vision data element has been shown to perform reliably in screening for vision impairment (weighted kappa = 0.917) in the national MDS 3.0 test in nursing homes.[181] In studies of MDS 2.0, the Vision data element was shown to have moderate to almost perfect reliability ranging from 0.581 to 0.85. The Vision data element is also linked to performance with readily available materials (i.e., newspaper). Finally, the Vision data element was tested in the PAC PRD assessment. The PAC PRD

[175] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[176] *Ibid*

[177] *Ibid*

[178] Ivers, R. Q., Norton, R., Cumming, R. G., Butler, M., & Campbell, A. J. (2000). Visual impairment and risk of hip fracture. Am J Epidemiol 152(7): 633-639.

[179] Freeman, E. E., Munoz, B., Rubin, G., West, S. K. (2007). Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. Invest Ophthalmol Vis Sci 48(10): 4445-4450.

[180] Lieberman, D., Friger, M., Lieberman, D. (2004). Visual and hearing impairment in elderly patients hospitalized for rehabilitation following hip fracture. J Rehabil Res Dev 41:669–674.

[181] Saliba, D., & Buchanan, J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. 2008. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

found substantial agreement for inter-rater reliability across settings for this data element (kappa of 0.74).[182]

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[182] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

SNF	IRF	LTCH
M0300 – Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage		
B. Stage 2: Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.	**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.	**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.
Enter number ☐ — 1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐ — 1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐ — 1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3
Enter number ☐ — 2: Number of these Stage 2 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission/ entry or reentry.	Enter number ☐ — 2: Number of these Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐ — 2: Number of these Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
C. Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.	**C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.	**C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
Enter number ☐ — 1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number ☐ — 1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number ☐ — 1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4
Enter number ☐ — 2: Number of these Stage 3 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry	Enter number ☐ — 2: Number of these Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐ — 2: Number of these Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
D. Stage 4: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.	**D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.	**D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.
Enter number ☐ — 1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number ☐ — 1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number ☐ — 1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device

(continued)

SNF		IRF		LTCH	
Enter number ☐	2: Number of these Stage 4 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of these Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission	Enter number ☐	2: Number of these Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
E. Unstageable - Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.		**E. Unstageable -** Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.		**E. Unstageable -** Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.	
Enter number ☐	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar	Enter number ☐	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar	Enter number ☐	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar
Enter number ☐	2: Number of these unstageable pressure ulcers/injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of these unstageable pressure ulcers/injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these unstageable pressure ulcers/injuries that were present upon admission. Enter how many were noted at the time of admission.
F. Unstageable - slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.		**F. Unstageable -** slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.		**F. Unstageable -** slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.	
Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury
Enter number ☐	2: Number of these unstageable pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of these unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
G. Unstageable - Deep tissue injury		**G. Unstageable -** Deep tissue injury		**G. Unstageable -** Deep tissue injury	
Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1030, Number of Venous and Arterial Ulcers	Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention	Enter number ☐	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention
Enter number ☐	2. Number of these unstageable pressure injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2. Number of these unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.

(continued)

SNF Risk Adjustment Covariates	IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates
Functional Mobility Admission Performance		
GG0170C. Mobility: Lying to Sitting on Side of Bed: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Resident refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed:** The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed**: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns
Bowel Continence		

H0400. Bowel Continence
  0. Always continent
  1. Occasionally incontinent
  2. Frequently incontinent
  3. Always incontinent)
  9. Not rated
	H0400. Bowel Continence
	  0. Always continent
	  1. Occasionally incontinent
	  2. Frequently incontinent
	  3. Always incontinent
	  9. Not rated
		H0400. Bowel Continence
		  0. Always continent
		  1. Occasionally incontinent
		  2. Frequently incontinent
		  3. Always incontinent
		  9. Not rated

Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) or Diabetes		

I0900. Peripheral Vascular Disease (PVD) /
Peripheral Arterial Disease (PAD)
  0. Did not have PVD or PAD in the last 7 days
  1. Had PVD or PAD in the last 7 days
 	
I2900 Diabetes Mellitus (DM)
  0. Did not have DM in the last 7 days
  1. Had DM in the last 7 days
	I0900. Peripheral Vascular Disease (PVD) /Peripheral Arterial Disease (PAD)
	  0. Does not have PVD or PAD
	  1. Have PVD or PAD
	
	I2900 Diabetes Mellitus (DM)
	  0. Does not have DM
	  1. Has DM
		I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)
		  0. Does not have PVD or PAD
		  1. Have PVD or PAD
		
		I2900. Diabetes Mellitus (DM)
		  0. Does not have DM
		  1. Has DM

Height and Weight (Low Body Mass Index)		
K0200A (Height); and K0200B (Weight).	**25A (Height); and 26A (Weight).**	**K0200A (Height); and K0200B (Weight).**

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Appendix 2
Pressure Ulcer Quality Measure Item Standardization: Data Elements Collected for Calculation of Quality Measures used in SNF, LTCH, and IRF Quality Reporting Programs

		SNF, LTCH, and IRF PAC Settings: Items Collected at Discharge		
Item	Item Description	Proposed MDS 3.0 (effective 10/1/2018)	Proposed LTCH CARE Data Set v4.00 (effective 4/1/2018)	Proposed IRF-PAI v2.0 (effective 10/1/2018)
M0300	Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage			
A	Number of Stage 1 pressure ulcers	X	X	X
B1	Number of Stage 2 pressure ulcers	X	X	X
B2	Number of these Stage 2 pressure ulcers that were present upon admission	X	X	X
C1	Number of Stage 3 pressure ulcers	X	X	X
C2	Number of these Stage 3 pressure ulcers that were present upon admission	X	X	X
D1	Number of Stage 4 pressure ulcers	X	X	X
D2	Number of these Stage 4 pressure ulcers that were present upon admission	X	X	X
E1	Number of unstageable pressure ulcers/injuries due to non-removable dressing/device	X	X	X
E2	Number of these unstageable pressure ulcers/injuries that were present upon admission	X	X	X
F1	Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar	X	X	X
F2	Number of these unstageable pressure ulcers that were present upon admission	X	X	X
G1	Number of unstageable pressure injuries presenting as deep tissue injury	X	X	X
G2	Number of these unstageable pressure injuries that were present upon admission	X	X	X

X = Item is present

Appendix 3
Reliability and Validity of Items used to Calculate Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

The assessment items used in the quality measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury have undergone rigorous reliability and validity testing. The goal of reliability testing is to ensure that items on an assessment obtain consistent results when assessed by different individuals. Validity testing determines if an item measures what it intends to measure. Testing of pressure ulcer assessment items conducted across post-acute care settings indicated high inter-rater reliability of the items. In addition, testing showed that inclusion of unstageable pressure ulcers in the measure increased variability of scores in IRFs, LTCHs, and SNFs and may improve the ability of the measure to distinguish between high and low performing facilities. Also, support from Technical Expert Panels (TEP), the National Pressure Ulcer Advisory Panel (NPUAP), and public commenters offer construct validity. A brief summary of testing conducted on the pressure ulcer assessment items is provided below.

Item-Level Reliability Testing (MDS 3.0)

Item reliability for data elements assessing pressure ulcers, including unstageable pressure ulcers, was tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[183] The project consisted of a representative sample of for-profit and not-for-profit facilities, and hospital-based and freestanding facilities, which included 71 community nursing facilities in 8 states and 19 Veterans Affairs (VA) nursing homes. The sample included 3,822 residents from community nursing homes and 764 residents from VA nursing homes. The RAND pilot test of the MDS 3.0 items showed good reliability and are applicable to the IRF-PAI as well as the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set because the items tested are the same as those used in the IRF-PAI and LTCH CARE Data Set. Furthermore, the MDS 3.0 testing results are appropriate to apply to the evaluation of the LTCH and IRF items because the items are identical across assessments, and there is significant overlap in the populations cared for by these providers. The short stay nursing home NQF endorsed measure, Percent of Residents or patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), was endorsed by NQF to include the IRF and LTCH settings using this MDS data as evidence of reliability and validity.

Across the pressure ulcer items, average gold-standard to gold standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate "almost perfect" agreement using the Landis and Koch standard for strength of agreement.[184] We believe that the kappa statistics comparing gold-standard nurse to facility nurse responses should be sufficient for evaluation of the validity of these items as well. The results of this study are publicly available on the CMS website.

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[183] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0.* Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[184] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159-174.

More specifically, the RAND project found a high level of inter-rater reliability for assessment items used to calculate the pressure ulcer quality measure, including assessment items for unstageable pressure ulcers. The study included the following results[185]:

- Number of existing stage 2 pressure ulcers: Kappa statistic = 0.993 (weighted)
- Number of stage 2 ulcers present on admission: Kappa statistic= 0.966 (weighted)
- Percent agreement for number of stage 3, stage 4, and nonstageable ulcers existing and present on admission was 100%

Item-Level Reliability Testing (CARE/PAC PRD)

Additional inter-rater reliability testing of pressure ulcer items similar to those used to calculate the quality measure in the IRF, LTCH and SNF settings was conducted as a part of the PAC PRD.[186] For the pressure ulcer item "Does this patient have one or more unhealed pressure ulcer(s) at stage 2 or higher or unstageable?" The kappa score across all settings (acute, IRF, LTCH, SNF and HHA) was 0.845, indicating almost perfect agreement. Setting specific scores are presented below. Kappa statistics for IRF, LTCH, SNF and HHA ranged from 0.58 to 0.92 indicating "moderate" to "almost perfect" agreement.

For the pressure ulcer items collecting number of pressure ulcers present at assessment by stage, the kappa scores across all settings (acute, HHA, IRF, LTCH, SNF) were:

- Stage 2 Pressure Ulcers = 0.815
- Stage 3 Pressure Ulcers = 0.852
- Stage 4 Pressure Ulcers = 0.780

For the pressure ulcer item "Number of pressure ulcers present at admission by stage-Unstageable", the kappa score across settings was 0.652, indicating substantial agreement. A setting specific score was only provided for the LTCH setting (kappa= 0.417, moderate agreement) as the sample size for most individual settings was too small to report (< 15).

Results of the PAC PRD study are publicly available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html

Additional Testing

RTI performed additional testing of the measure to compare the performance of the measure with proposed changes to the measure as currently specified.[187] Testing of the proposed measure, including adding unstageable pressure ulcers to the quality measure, increased performance scores in all settings

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[185] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0. Appendices*. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from http://www.geronet.med.ucla.edu/centers/borun/Appendix_A-G.pdf

[186] Smith, L., Deutsch, A., Hand, L., Etlinger, A., Ross, J., Abbate, J., Gage-Croll, Z., Barch, D., Gage, B. (2012, September). Continuity Assessment Record and Evaluation (CARE) Item Set: Additional Provider-Type Specific Interrater Reliability Analyses. Contract No. HHSM-500-2005-00291. Research Triangle Park, NC: RTI

[187] Schwartz, M., Barch, D. H., Kaur, R., Pardasaney, P. K., Seibert, J. H., Kandilov, A. M., Frank, J. M., et al. (2016, January). The development of a cross-setting pressure ulcer measure: Addition of unstageable pressure ulcers and transition to M0300 items. Prepared for Centers for Medicare & Medicaid Services.

(with scores increasing by 0.1% in IRF settings and 1.7% in NH/SNF settings) and increased the variability of measures scores. This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing facilities. RTI presented the results of their findings during the July 18, 2016 TEP. Information regarding this study are also included in the TEP Summary Report.

Testing results by setting are as follows:

- In NH/SNFs for reporting period Q1 2012, the mean risk-adjusted score increased from the original measure of 1.8% to 3.5% when we transitioned to M0300 items and added unstageable pressure ulcer items to the measure.
- LTCH: In the mean LTCH risk-adjusted score increased from the original measure of 2.6% to 2.8% for reporting period Q2 2014 when we transition to M0300 items and add unstageable pressure ulcer items.
- IRF: The mean IRF risk-adjusted score increased from the original measure of 0.9% to 1.0% for reporting period Q1 2015 when we transition to M0300 items and add unstageable pressure ulcer items.

Construct Validity

A TEP meeting was held on July 18, 2016 to discuss potential changes to the measure, including changes in the data elements used to calculate the measure. During the TEP meeting, RTI presented analyses to show the impact of a transition to calculation of the measure using M0300/M1313 items and inclusion of unstageable pressure ulcers in the measure calculation. Overall, the TEP was supportive of the data element changes as well as inclusion of unstageable pressure ulcers in the measure calculation, indicating construct validity.

Specific feedback from TEP members regarding the potential transition to M0300/M1313 items is excerpted here:

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.

None of the TEP members stated preference of the use of M0800 items instead of M0300 items in calculation of the proposed quality measure and none of the members expressed objections to the modification. However, the TEP requested that consistent training across all post-acute care settings be made available to providers to support the proposed measure if implemented. The TEP summary report is publicly available and is soon to be available on CMS' website.[188]

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[188] Seibert, J., Frank, J., Free, L., Waldron, D. (2016, December). 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),

Also, prior cross-setting TEP meetings held in June and November 2013 yielded support for the inclusion of unstageable pressure ulcers in the quality measure. During these meetings, TEP members concurred that newly-acquired unstageable pressure ulcers, including suspected deep tissue injuries, should be captured in the quality measure for pressure ulcers. The TEP also advised 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. CMS and the measure development contractor received additional feedback from technical and clinical advisors and the National Pressure Ulcer Advisory Panel (NPUAP) in January 2014 supporting inclusion of unstageable pressure ulcers in the measure numerator.

Functional Mobility Risk Adjustment in SNF

Since the IMPACT Act requires submission of standardized assessment data, there is a need to standardize risk adjustment for the measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury across settings. In the SNF setting, G0110A1 is used to measure limitations in bed mobility in the pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). However, in the proposed measure, the risk adjuster item G0110A1. Activities of Daily Living (ADL) Assistance: Bed Mobility Self-Performance will be replaced with the item GG0170C. Mobility: Lying to Sitting on Side of Bed for the SNF setting measure in order to align with the risk adjuster items used in the LTCH and IRF setting measures. Using data from SNF discharges between October 1, 2016 through December 15, 2016, RTI conducted testing on the comparability of assessment items G0110A1 and GG0170C. Testing results indicate high concordance for those coded as high risk for limitations in bed mobility using both items at 93.85 percent. Overall concordance for high and low risk for limitations in bed mobility using both items was 89.45 percent. The correlation between the G0110A1 and GG0170C assessment items in the SNF population was found to be of medium effect, according to Cohen's standard (Spearman coefficient=0.324).

Additional testing was conducted to provide a comparison of incidence of new or worsened pressure ulcers according to how residents are characterized using the different bed mobility items: G0110A1 and GG0170C. The percent of individuals who had a new or worsened pressure ulcer and were coded as high risk for limitations in bed mobility using the item G0110A1 was 3.28, while the percent of individuals who had a new or worsened pressure ulcer and were coded as high risk for limitations in bed mobility using the item GG0170C was 3.35. Similar rates of new or worsened pressure ulcers among both groups indicates support for the replacement of G0110A1 with GG0170C to increase harmonization across settings.