

March 2017

Proposed Specifications for LTCH QRP Quality Measures and Standardized Data Elements

Prepared for

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DATA ELEMENTS

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This report was prepared under a project funded by the Centers for Medicare & Medicaid Services under contract no. HHSM-500-2013-13015I and HHSM-500-2013-13014I.

Table of Contents

Chapter 1 Introduction	1
Chapter 2 IMPACT Act Measures Beginning with the FY 2020 LTCH QRP	3
Section 1: Cross-Setting Measures Development Work: An Introduction	3
Section 2: Cross-Setting Pressure Ulcer Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	3
Measure Description	3
Purpose/Rationale for the Quality Measure	4
Denominator	7
Denominator Exclusions	8
Numerator	8
Measure Time Window	9
Items Included in the Quality Measure	10
Risk Adjustment Covariates	12
Quality Measure Calculation Algorithm	14
Chapter 3 Ventilator Weaning (Liberation) Measures Beginning with the FY 2020 LTCH QRP	17
Section 1: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	17
Measure Description	17
Purpose/Rationale for the Quality Measure	18
Denominator	22
Denominator Exclusions	23
Numerator	23
Items Included in the Quality Measure	24
Risk Adjustment	24
Quality Measure Calculation Algorithm	24
Section 2: Ventilator Liberation Rate	26
Measure Description	26
Purpose/Rationale for the Quality Measure	27
Denominator	29
Denominator Exclusions	30
Numerator	30
Items Included in the Quality Measure	31
Risk Adjustment	31
Quality Measure Calculation Algorithm	33
Chapter 4 Standardized Data Elements	35
Section 1: Standardized Patient Assessment Data Element Work: An Introduction	35
Section 2: Functional Status	36
Section 3: Cognitive Function	37
Standardized Data Elements to Assess Cognitive Impairment	38
Brief Interview for Mental Status (BIMS)	38

Confusion Assessment Method (CAM©).....	40
Behavioral Signs and Symptoms	42
Mental Status (Depressed Mood).....	43
Standardized Data Elements to Assess Depressed Mood	44
Patient Health Questionnaire-2 (PHQ-2)	44
Section 4: Special Services, Treatments, and Interventions (Including Nutritional Approaches).....	47
Standardized Data Elements to Assess for Special Services, Treatments, and Interventions.....	47
Chemotherapy (IV, Oral, Other)	47
Radiation	49
Oxygen Therapy (Continuous, Intermittent).....	50
Suctioning (Scheduled, As Needed)	51
Tracheostomy Care	53
Invasive Mechanical Ventilation	54
Non-invasive Mechanical Ventilation (Continuous Positive Airway Pressure [CPAP], Bilevel Positive Airway Pressure [BiPAP])	56
IV Medications.....	58
Transfusions	59
Dialysis (Hemodialysis, Peritoneal dialysis)	60
IV Access	62
Parenteral/IV Feeding	63
Feeding Tube	64
Mechanically Altered Diet	65
Therapeutic Diet.....	66
Section 5: Medical Conditions and Co-Morbidities.....	68
Section 6: Impairments	69
Standardized Data Elements to Assess Hearing and Vision Impairments	69
Hearing.....	69
Vision.....	70
Appendix 1 Data Elements Used in Calculation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	73
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.....	77
Appendix 3 Reliability and Validity of Items used to Calculate Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	79

Chapter 1

Introduction

In this document, we present specifications for the standardized patient assessment data elements and the following three (3) measures proposed for adoption for the LTCH QRP through the FY 2018 IPPS/LTCH PPS proposed rule:

1. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
2. Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
3. Ventilator Weaning (Liberation) Rate

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Chapter 2

IMPACT Act Measures Beginning with the FY 2020 LTCH 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 QRPs:

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

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

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- 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.ihl.org/resources/pages/improvementstories/relievethethepressureandreduceharm.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.ihl.org/resources/pages/improvementstories/relievethethepressureandreduceharm.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

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-patient>

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/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-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.

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.

Denominator Exclusions

Specific denominator exclusions for each setting are provided below.

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: $BMI = (\text{weight} * 703 / \text{height}^2) = ([26A] * 703) / (25A^2)$ 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: $BMI = (\text{weight} * 703 / \text{height}^2) = ([K0200B] * 703) / (K0200A^2)$ 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 $BMI \geq [12.0]$ AND $BMI \leq [19.0]$

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

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

Where: $BMI = (\text{weight} * 703 / \text{height}^2) = ([K0200B] * 703) / (K0200A^2)$ 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:

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

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).

$$X = \beta_0 + \beta_1 * COVA + \beta_2 * COVB + \beta_3 * COVC + \beta_4 * COVD \quad (2)$$

Where β_0 is the logistic regression constant, β_1 is the logistic regression coefficient for the first covariate, $COVA$ is the patient/resident-level score for the first covariate, β_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:

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

where

Adj is the facility-level adjusted QM score, and
 $y = (\ln(\text{Obs}/(1-\text{Obs})) - \ln(\text{Exp}/(1-\text{Exp})) + \ln(\text{Nat}/(1-\text{Nat})))$
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

Ventilator Weaning (Liberation) Measures Beginning with the FY 2020 LTCH QRP

This section describes draft specifications for two ventilator weaning (liberation) quality measures for Long-Term Care Hospitals (LTCHs). The Centers for Medicare & Medicaid Services (CMS) solicits public comments on these quality measure specifications to inform ongoing quality measure development and implementation for the CMS LTCH Quality Reporting Program (QRP). The quality measures described in this section focus on ventilator weaning processes and outcomes.

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act required the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), to include quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures, such as alignment with the CMS Quality Strategy, which incorporates the three broad aims of the National Quality Strategy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

Invasive mechanical ventilation care was identified through technical expert panels and public comment periods as a gap in the LTCH QRP measure set and aligns with the National Quality Strategy Priority and the CMS Quality Strategy Goal of “promoting the most effective prevention and treatment practices” by reducing the risk of complications from unnecessarily prolonged mechanical ventilation.

Section 1: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay

Measure Description

This measure assesses facility-level compliance with Spontaneous Breathing Trial (SBT), including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) breathing trial, by Day 2 of the Long-Term Care Hospital (LTCH) stay for patients on invasive mechanical ventilation support upon admission, and for whom at admission weaning attempts were expected or anticipated. This measure is calculated and reported separately for the following two components:

Component 1, “Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay”: the percentage of patients who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

Component 2, “Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay”: the percentage of patients found ready for SBT (including TCT or CPAP breathing trial) for whom an SBT (including TCT or CPAP breathing trial) was performed by Day 2 of LTCH stay.

Patients included in Component 2 comprise a subset of the population in Component 1. While all patients admitted on invasive mechanical ventilation are included in the denominator for Component 1, only those patients who were found ready for SBT (including TCT and CPAP breathing trial) are included in the denominator for Component 2

Definitions

- **Invasive mechanical ventilation support** is defined as the use of a device to assist or control pulmonary ventilation, inclusive of the weaning period, either intermittently or continuously through a tracheostomy or by endotracheal intubation. Note: Lung expansion devices such as intermittent positive-pressure breathing (IPPB), nasal positive end-expiratory pressure (nasal PEEP), and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).
- **Day 1 of the LTCH stay** is the day of admission.
- **Day 2 of the LTCH stay** is defined as the second day of the patient's LTCH stay.
- **"Weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom weaning attempts are expected or anticipated at admission (e.g. patients admitted for the purpose of weaning).
- **"Non-weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom at admission weaning attempts are NOT expected or anticipated (e.g., patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning *must* be based on documentation found in the patient's medical record at admission.
- **SBT** is a trial of unassisted breathing during the day and full ventilator support at night, administered to patients with endotracheal tubes. This includes TCT or CPAP breathing trial.
- **TCT** is a trial of unassisted breathing via a tracheostomy collar (mask) with aerosol (mist), administered to patients with tracheostomy tubes. TCT would apply only to patients with tracheostomy tubes.
- **CPAP breathing trial** is a trial of unassisted breathing for a certain period of time administered while the patient is wearing any type of continuous positive airway pressure respiratory support device that prevents the airways from closing by delivering slightly pressurized air through a mask continuously or via electronic cycling throughout the breathing cycle.
- **"Documentation"** indicates explicit physician, registered nurses, or respiratory therapist documentation of the reason that a patient was not deemed ready for SBT (including TCT or CPAP breathing trial) within the given time frame. Documentation must be dated by Day 2 of the LTCH stay.

Purpose/Rationale for the Quality Measure

This ventilator-related process quality measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay, is important for encouraging implementation of evidence-based weaning guidelines as early during the LTCH patient stay as is beneficial to patients, in order to decrease LTCH patient exposure to adverse ventilator-associated morbidity and mortality.

Patients on invasive mechanical ventilation comprise a substantial proportion of LTCH patient admissions, and thus present a critical focus for assessment of high quality care. In 2012, about 22,000 or 15.8% of all LTCH discharges received PMV services during the LTCH stay.³³

Although often necessary for life support, invasive mechanical ventilation is not without risk of harm to patients, and these risks increase as duration of ventilation continues.^{34 35 36} Studies have shown that invasive mechanical ventilation of critically ill patients is associated with higher rates of mortality³⁷ and morbidity, including ventilator-associated pneumonia,^{40 41 42 43 44} ventilator-associated lung

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- ³³ MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.
- ³⁴ Boles, J. M., et al. (2007). "Weaning from mechanical ventilation." *Eur Respir J* **29**(5): 1033-1056.
- ³⁵ Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." *Crit Care* **11**(1): R9.
- ³⁶ Penuelas, O., Frutos-Vivar, F., Fernandez, C., Anzueto, A., Epstein, S. K., Apezteguia, C., . . . Esteban, A. (2011). Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation. *Am J Respir Crit Care Med*, 184(4), 430-437. doi:10.1164/rccm.201011-1887OC
- ³⁷ Cox, C. E., & Carson, S. S. (2012). Medical and economic implications of prolonged mechanical ventilation and expedited post-acute care. *Semin Respir Crit Care Med*, 33(4), 357-361. doi:10.1055/s-0032-1321985
- ³⁸ Esteban, A., Anzueto, A., Frutos, F., Alia, I., Brochard, L., Stewart, T. E., . . . Mechanical Ventilation International Study, G. (2002). Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. *JAMA*, 287(3), 345-355. Retrieved from <http://jama.jamanetwork.com/data/Journals/JAMA/4816/JCE10020.pdf>
- ³⁹ Kahn, J. M., Benson, N. M., Appleby, D., Carson, S. S., & Iwashyna, T. J. (2010). Long-term acute care hospital utilization after critical illness. *JAMA*, 303(22), 2253-2259. doi:10.1001/jama.2010.761
- ⁴⁰ Cook, D. J., et al. (1998). "Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients." *Ann Intern Med* **129**(6): 433-440.
- ⁴¹ Papazian, L., et al. (1996). "Effect of ventilator-associated pneumonia on mortality and morbidity." *Am J Respir Crit Care Med* **154**(1): 91-97.
- ⁴² Vincent, J. L., et al. (1995). "The prevalence of nosocomial infection in intensive care units in Europe. Results of the European Prevalence of Infection in Intensive Care (EPIC) Study. EPIC International Advisory Committee." *JAMA* **274**(8): 639-644
- ⁴³ Safdar, N., et al. (2005). "Clinical and economic consequences of ventilator-associated pneumonia: a systematic review." *Crit Care Med* **33**(10): 2184-2193.
- ⁴⁴ Buczko, W. (2010). "Ventilator-associated pneumonia among elderly Medicare beneficiaries in long-term care hospitals." *Health Care Financ Rev* **31**(1): 1-10.

injury,^{45 46 47} ventilator -induced diaphragm dysfunction,^{48 49} psychological distress^{50 51 52} and post-traumatic stress disorder,⁵³ disability⁵⁴ and decreased functional status,^{55 56} and chronic critical illness syndrome.⁵⁷ Mechanical ventilation is also associated with increased costs. Studies in the ICU setting indicate that patients who require mechanical ventilation can have up to 50% higher costs than patients who do not receive mechanical ventilation.⁵⁸ Patients on prolonged ventilation (≥ 21 days) incur even greater health care costs; the estimated cost per one-year survival for patients who are ventilated for ≥ 21 days is \$423,596.⁵⁹

Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is associated with improved patient health outcomes. In LTCHs, fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications/events, enhanced rehabilitation opportunities, and shorter LOS.⁶⁰ Ventilator liberation has been associated with lower post-discharge mortality, even among the elderly,^{61 62} and fewer days of mechanical ventilation may lead to decreased risk of ventilator-

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- 45 Meade, M. O. and D. J. Cook (1995). "The aetiology, consequences and prevention of barotrauma: a critical review of the literature." Clin Intensive Care **6**(4): 166-173.
- 46 Meade, M. O., et al. (1997). "How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury." Crit Care Med **25**(11): 1915-1922.
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- 51 Schou, L. and I. Egerod (2008). "A qualitative study into the lived experience of post-CABG patients during mechanical ventilator weaning." Intensive Crit Care Nurs **24**(3): 171-179.
- 52 Rotondi, A. J., et al. (2002). "Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit." Crit Care Med **30**(4): 746-752.
- 53 Jubran, A., et al. (2010). "Post-traumatic stress disorder after weaning from prolonged mechanical ventilation." Intensive Care Med **36**(12): 2030-2037.
- 54 Barnato, A. E., et al. (2011). "Disability among elderly survivors of mechanical ventilation." Am J Respir Crit Care Med **183**(8): 1037-1042.
- 55 Scheinhorn, D. J., et al. (2007). "Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study." Chest **131**(1): 85-93.
- 56 Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." Crit Care **11**(1): R9.
- 57 Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." Crit Care **11**(1): R9.
- 58 Dasta, J. F., et al. (2005). "Daily cost of an intensive care unit day: the contribution of mechanical ventilation." Crit Care Med **33**(6): 1266-1271.
- 59 Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." Crit Care **11**(1): R9.
- 60 Hassenpflug, M. S., et al. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific (TIPS?) Weaning Protocol. B44. Invasive And Non-Invasive Mechanical Ventilation, American Thoracic Society: A3166-A3166.
- 61 Frengley, J., et al. (2014). "Prolonged mechanical ventilation in 540 seriously ill older adults: effects of increasing age on clinical outcomes and survival." J Am Geriatr Soc **62**(1): 1-9.
- 62 Stearn-Hassenpflug, M., et al. (2013). "Post-ICU Mechanical Ventilation: Trends in Mortality and 12-month Post-discharge Survival." Critical Care Medicine **41**(12): A166.

associated complications/events, enhanced rehabilitation opportunities, and a shorter length of stay.⁶³ However, prior studies have shown that some physicians may underestimate the probability of weaning success.^{64 65} Based on studies and observations of implementation of regular assessment for SBTs and weaning protocols in ICUs, adherence to the recommended weaning processes, including prompt assessment of weaning readiness and initiation of SBTs, appears quite variable, likely due to differences in clinicians' intuitive thresholds for determination of patients' readiness to wean.^{66 67} Clinician delays in recognizing that weaning may be possible and in beginning assessment of weaning readiness are two common causes of weaning delays.⁶⁸

In 2005, an international task force convened and developed recommendations to address the entire weaning process. This task force recommended that weaning be considered as soon as possible,⁶⁹ because failure to assess the patient for readiness to wean may lead to undue prolonged mechanical ventilation,⁷⁰ thus exposing patients unnecessarily to adverse ventilator-associated morbidity and mortality.⁷¹ Evidence continues to support early patient assessment using weaning criteria and performance of a spontaneous breathing trial as soon as it medically appropriate for the patient.^{72 73 74}

In a study of ventilator weaning in an LTCH by Jubran and colleagues,⁷⁵ 32% of newly admitted LTCH patients on invasive mechanical ventilation were able to breathe unassisted during the first 5 days following admission⁷⁶, suggesting that many ICU patients sent to LTCHs for "failure to wean" from the ventilator may not have undergone ventilator weaning attempts during the latter part of their stay in an

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- ⁶³ Hassenpflug, M. S., et al. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific Weaning Protocol. [abstract] B44. Invasive And Non-Invasive Mechanical Ventilation, American Thoracic Society: A3166-A3166.
- ⁶⁴ MacIntyre, N. R. (2013). "The ventilator discontinuation process: an expanding evidence base." Respir Care **58**(6): 1074-1086.
- ⁶⁵ Strickland, J. H., Jr., & Hasson, J. H. (1993). A computer-controlled ventilator weaning system. A clinical trial. Chest, *103*(4), 1220-1226. Retrieved from <http://journal.publications.chestnet.org/data/Journals/CHEST/21669/1220.pdf>
- ⁶⁶ MacIntyre, N. R. (2013). "The ventilator discontinuation process: an expanding evidence base." Respir Care **58**(6): 1074-1086.
- ⁶⁷ Kollef, M. H., et al. (1997). "A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation." Crit Care Med **25**(4): 567-574.
- ⁶⁸ Boles, J. M., et al. (2007). "Weaning from mechanical ventilation." Eur Respir J **29**(5): 1033-1056.
- ⁶⁹ *Ibid.*
- ⁷⁰ MacIntyre, N. R., Epstein, S. K., Carson, S., Scheinhorn, D., Christopher, K., Muldoon, S., & National Association for Medical Direction of Respiratory, C. (2005). Management of patients requiring prolonged mechanical ventilation: report of a NAMDRC consensus conference. Chest, *128*(6), 3937-3954.
- ⁷¹ Hess, D. R., & MacIntyre, N. R. (2011). Ventilator discontinuation: why are we still weaning? Am J Respir Crit Care Med, *184*(4), 392-394
- ⁷² Frutos-Vivar, F., & Esteban, A. (2014). Our paper 20 years later: how has withdrawal from mechanical ventilation changed? Intensive Care Med, *40*(10), 1449-1459. doi:10.1007/s00134-014-3362-0
- ⁷³ MacIntyre, N. R. (2013). "The ventilator discontinuation process: an expanding evidence base." Respir Care **58**(6): 1074-1086.
- ⁷⁴ McConville, J. F., & Kress, J. P. (2012). Weaning patients from the ventilator. N Engl J Med, *367*(23), 2233-2239. doi:10.1056/NEJMra1203367
- ⁷⁵ Jubran, A., et al. (2013). "Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial." JAMA **309**(7): 671-677.
- ⁷⁶ *Ibid.*

ICU.⁷⁷ That a substantial portion of newly admitted LTCH patients could be weaned within 5 days underscores the need to assess patients' ability to breathe without assistance soon after admission, in order to identify individuals who are able to discontinue invasive mechanical ventilation.

Because invasive mechanical ventilation should be discontinued as soon as patients are capable of breathing independently,⁷⁸ unnecessarily prolonged mechanical ventilation can be an indicator of poor quality care.⁷⁹ This quality measure is designed to encourage adherence to evidence-based and consensus based guidelines through implementation of trials of unassisted breathing and early assessment of weaning criteria. The anticipated improvement in quality is an improvement in timeliness of weaning and ventilator liberation for patients admitted to LTCHs on invasive mechanical ventilation. Additionally, facilities can use results of this measure to improve early compliance with evidence-based weaning guidelines and develop ventilator weaning quality improvement programs.

Denominator

The target population for this measure is patients who were on invasive mechanical ventilation support upon admission to the LTCH, for whom weaning attempts were expected or anticipated at admission. If a patient has more than one LTCH stay during the reporting period, each discharge will be reported and included in the measure calculation. The denominator will be calculated separately according to each of the component groups below:

Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay

The denominator for Component 1 is patients who were on invasive mechanical ventilation upon admission to an LTCH, for whom weaning attempts are expected or anticipated at admission.

Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay

The denominator for Component 2 is the subset of patients in the denominator of Component 1, who were assessed and deemed ready for SBT by Day 2 of the LTCH stay.

For patients with more than one LTCH stay during the reporting period, each admission and discharge is reported and included in the measure calculation. For example, if an LTCH patient is transferred to a short-stay acute care hospital for a procedure, surgery, or some other reason(s), returns to the LTCH within three (3) calendar days, and is subsequently discharged from the LTCH, this is considered one "patient stay." However, if this patient's "stay" at the short-stay acute care hospital exceeds three (3) calendar days, whereby day one begins on the day of transfer from the LTCH to the short-stay acute care hospital, regardless of the hour of transfer, then a new LTCH CARE Data Set Admission Assessment is conducted upon return of the patient to the LTCH, and a second LTCH CARE Data Set Discharge Assessment accompanies the second discharge. Admission and Discharge (Planned or Unplanned) Assessments are completed for this patient for the first stay, and Admission and Discharge (Planned or Unplanned) Assessments are completed for the second stay. Both stays for this patient are included in the measure calculation and reporting.

⁷⁷ Kahn, J. M. and S. S. Carson (2013). "Generating evidence on best practice in long-term acute care hospitals." *JAMA* **309**(7): 719-720.

⁷⁸ Blackwood, B., et al. (2011). "Use of weaning protocols for reducing duration of mechanical ventilation in critically ill adult patients: Cochrane systematic review and meta-analysis." *BMJ* **342**: c7237.

⁷⁹ MacIntyre, N. R. (2013). "The ventilator discontinuation process: an expanding evidence base." *Respir Care* **58**(6): 1074-1086.

Denominator Exclusions

This measure (both Component 1 and Component 2) excludes patients with missing data and invasively mechanically ventilated patients identified as non-weaning at the time of admission to an LTCH. Patients who may be identified as non-weaning by LTCHs include patients who are considered chronically ventilated as defined by evidence-based guidelines for ventilator liberation⁸⁰ or patients with an acute or chronic condition that negates any expectation or anticipation of weaning attempts at admission (e.g., amyotrophic lateral sclerosis, or severe neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning must be based on documentation found in the patient's medical record.

After patient-level exclusions are applied, LTCHs with denominator counts of less than 20 in the sample during the reporting period will be excluded from public reporting, owing to small sample size.

Denominator exclusion details

Patients are excluded from the target population (i.e., denominator) if they meet either of the following criteria:

1. O0150A. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 0 (i.e., No, not on invasive mechanical ventilation support), OR:
2. O0150A. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 2, Yes, non-weaning (i.e., No weaning attempts are expected or anticipated at admission)

Numerator

The numerator represents patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay and, if deemed ready, who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

The numerator will be computed and reported separately according to each of the components below. Each component numerator is the number of patients in the following components:

Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of the LTCH Stay

The numerator represents the number of patients admitted on invasive mechanical ventilation during the reporting period who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay

For the purpose of this measure component, a patient is considered in the numerator if the LTCH reports, on the LTCH CARE Data Set Admission Assessment, either of the following combinations of items:

⁸⁰ MacIntyre, N. R., et al. (2001). "Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine." *Chest* **120**(6 Suppl): 375s-395s.

O0150B = 1 (Yes) AND O0150C = 1 (Yes). Assessed for readiness for SBT by day 2 of the LTCH stay and Deemed medically ready for a SBT by day 2 of the LTCH stay.

OR

O0150B = 1 (Yes) AND O0150D= 1 (Yes): Assessed for readiness for SBT by day 2 of the LTCH stay and documentation of reason(s) that patient was deemed medically unready for a SBT by day 2 of the LTCH stay.

The sum of the numbers of patients in these two groups represents the number of patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT by day 2 of the LTCH stay, as reported on the Admission Assessment.

Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay

The numerator represents the number of patients admitted on invasive mechanical ventilation during the reporting period who were ready for SBT and who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

For the purpose of this measure component, a patient is considered in the numerator if the LTCH reports on the LTCH CARE Data Set Admission Assessment item O0150E = 1 (Yes), SBT performed by day 2 of the LTCH stay.

Compliance with SBT (including TCT or CPAP breathing trial) by day 2 of LTCH stay is reported as a percentage and is calculated and reported for these two numerator components separately.

Items Included in the Quality Measure

For this quality measure, the following ventilator weaning items are assessed at the time of admission:

- O0150. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay
- O0150A Invasive Mechanical Ventilation Support upon Admission to the LTCH
- O0150B Assessed for readiness for SBT by day 2 of the LTCH stay
- O0150C Deemed medically ready for SBT by day 2 of the LTCH stay
- O0150D Is there documentation of reason(s) in the patient’s medical record that the patient was deemed medically unready for SBT by day 2 of the LTCH stay?
- O0150E SBT performed by day 2 of the LTCH stay

Risk Adjustment

This measure is not risk-adjusted or stratified.

Quality Measure Calculation Algorithm

Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay

$$= \frac{A + B}{C - D} \times 100$$

where

A = Number of patients who were deemed ready for SBT by Day 2 of the LTCH Stay

B = Number of patients with documentation that the patient was deemed medically unready for SBT by Day 2 of the LTCH stay

C = All patients admitted on invasive mechanical ventilator support for any duration during the reporting period

D = Patients for whom weaning attempts were NOT expected or anticipated at admission

Steps for Calculation

1. Of patients admitted to the LTCH during the reporting period, identify all patients who were on invasive mechanical ventilation support upon admission to the LTCH. This is the target population.
2. Of patients identified in (1) above, identify the subset of patients for whom weaning attempts are not expected or anticipated at admission. These patients are excluded from the measure.
3. Of the patients identified in (1) above, identify the subset of patients for whom weaning attempts were expected or anticipated at admission. This is the denominator for Component 1 of the measure.
4. Of the patients identified in (3) above, identify the subset of patients who were found ready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.
5. Of the patients identified in (3) above, identify the subset of patients who were assessed and documented as being unready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.
6. The numerator for Component 1 is the sum of the number of patients identified in (4) and (5) above.
7. Calculate the percentage of patients who were assessed for SBT by Day 2 of the LTCH stay by dividing the number of patients in (6) by the number of patients in (3).

Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay

$$= \frac{E}{F} \times 100$$

where

E = Number of patients who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH Stay

F = Number of patients who were deemed ready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH Stay

1. The group of patients identified in (4) above is the denominator for Component 2 of the measure.
2. Of the patients identified in (8) above, identify the number of patients who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay. This is the numerator for component 2 of the measure.
3. Divide the results of Step (9) by Step (8).

Section 2: Ventilator Liberation Rate

Measure Description

This measure reports facility-level Ventilator Liberation Rate for patients admitted to an LTCH requiring invasive mechanical ventilation support, *and* for whom weaning attempts were expected or anticipated as reported on the Admission Assessment. The Ventilator Liberation Rate is defined as the percentage of patients who are alive and fully weaned at discharge.

Data will be collected using items to be added to the LTCH CARE Data Set Admission, Planned Discharge and Unplanned Discharge Assessments. A patient is considered fully weaned if he or she does not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to the date of discharge.

Definitions

- **Invasive mechanical ventilation support** is defined as the use of a device to assist or control pulmonary ventilation, inclusive of the weaning period, either intermittently or continuously through a tracheostomy or by endotracheal intubation. Note: Lung expansion devices such as intermittent positive-pressure breathing (IPPB), nasal positive end-expiratory pressure (nasal PEEP), and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).
- **Day 1 of the LTCH stay** is the day of admission.
- **Day 2 of the LTCH stay** is defined as the second day of the patient's LTCH stay.
- **"Weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom weaning attempts are expected or anticipated at admission (e.g. patients admitted for the purpose of weaning).
- **"Non-weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom at admission weaning attempts are NOT expected or anticipated (e.g., patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning *must* be based on documentation found in the patient's medical record at admission.
- **A patient is considered fully weaned** if he or she is alive and does not require any invasive mechanical ventilation support for at least two consecutive calendar days immediately prior to the day of discharge from the LTCH.
- **A patient is considered not fully weaned** if he or she is not alive or requires invasive mechanical ventilation support for any duration of time during the two consecutive calendar days immediately prior to the day of discharge from the LTCH.

Purpose/Rationale for the Quality Measure

Patients on invasive mechanical ventilation comprise a substantial proportion of LTCH patient admissions, and thus present a critical focus for assessment of high quality care. In 2012, about 22,000 or 15.8% of all LTCH discharges received PMV services during the LTCH stay.⁸¹

Although often necessary for life support, invasive mechanical ventilation is not without risk of harm to patients, and these risks increase as duration of ventilation continues.^{82 83 84} Studies have shown that invasive mechanical ventilation of critically ill patients is associated with higher rates of mortality^{85 86 87} and morbidity, including ventilator-associated pneumonia,^{88 89 90 91 92} ventilator-associated lung

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- ⁸¹ MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.
- ⁸² Boles, J. M., et al. (2007). "Weaning from mechanical ventilation." *Eur Respir J* **29**(5): 1033-1056.
- ⁸³ Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." *Crit Care* **11**(1): R9.
- ⁸⁴ Penuelas, O., Frutos-Vivar, F., Fernandez, C., Anzueto, A., Epstein, S. K., Apezteguia, C., . . . Esteban, A. (2011). Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation. *Am J Respir Crit Care Med*, 184(4), 430-437. doi:10.1164/rccm.201011-1887OC
- ⁸⁵ Cox, C. E., & Carson, S. S. (2012). Medical and economic implications of prolonged mechanical ventilation and expedited post-acute care. *Semin Respir Crit Care Med*, 33(4), 357-361. doi:10.1055/s-0032-1321985
- ⁸⁶ Esteban, A., Anzueto, A., Frutos, F., Alia, I., Brochard, L., Stewart, T. E., . . . Mechanical Ventilation International Study, G. (2002). Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. *JAMA*, 287(3), 345-355. Retrieved from <http://jama.jamanetwork.com/data/Journals/JAMA/4816/JCE10020.pdf>
- ⁸⁷ Kahn, J. M., Benson, N. M., Appleby, D., Carson, S. S., & Iwashyna, T. J. (2010). Long-term acute care hospital utilization after critical illness. *JAMA*, 303(22), 2253-2259. doi:10.1001/jama.2010.761
- ⁸⁸ Cook, D. J., et al. (1998). "Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients." *Ann Intern Med* **129**(6): 433-440.
- ⁸⁹ Papazian, L., et al. (1996). "Effect of ventilator-associated pneumonia on mortality and morbidity." *Am J Respir Crit Care Med* **154**(1): 91-97.
- ⁹⁰ Vincent, J. L., et al. (1995). "The prevalence of nosocomial infection in intensive care units in Europe. Results of the European Prevalence of Infection in Intensive Care (EPIC) Study. EPIC International Advisory Committee." *JAMA* **274**(8): 639-644
- ⁹¹ Safdar, N., et al. (2005). "Clinical and economic consequences of ventilator-associated pneumonia: a systematic review." *Crit Care Med* **33**(10): 2184-2193.
- ⁹² Buczko, W. (2010). "Ventilator-associated pneumonia among elderly Medicare beneficiaries in long-term care hospitals." *Health Care Financ Rev* **31**(1): 1-10.

injury,^{93 94 95} ventilator induced diaphragm dysfunction,^{96 97} psychological distress^{98 99 100} and post-traumatic stress disorder,¹⁰¹ disability¹⁰² and decreased functional status,^{103 104} and chronic critical illness syndrome.¹⁰⁵ Mechanical ventilation is also associated with increased costs. Studies in the ICU setting indicate that patients who require mechanical ventilation can have up to 50% higher costs than patients who do not receive mechanical ventilation.¹⁰⁶ Patients on prolonged ventilation (≥ 21 days) incur even greater health care costs; the estimated cost per one-year survival for patients who are ventilated for ≥ 21 days is \$423,596.¹⁰⁷

Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is feasible for many ventilated patients, and is associated with improved health outcomes. Although attempts to liberate patients from invasive mechanical ventilation in LTCHs have variable success, expectations of successful ventilator liberation are high for many LTCH patients.^{108 109 110} A recent meta-analysis of weaning attempts in ICU patients with PMV found a pooled weaning rate in US ICUs of 47% (95% CI 42-51). The analysis included nine studies (4,769 patients); weaning rates reported for included studies

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- ⁹³ Meade, M. O. and D. J. Cook (1995). "The aetiology, consequences and prevention of barotrauma: a critical review of the literature." Clin Intensive Care **6**(4): 166-173.
- ⁹⁴ Meade, M. O., et al. (1997). "How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury." Crit Care Med **25**(11): 1915-1922.
- ⁹⁵ Slutsky, A. S. and L. N. Tremblay (1998). "Multiple system organ failure. Is mechanical ventilation a contributing factor?" Am J Respir Crit Care Med **157**(6 Pt 1): 1721-1725.
- ⁹⁶ Levine, S., et al. (2008). "Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans." N Engl J Med **358**(13): 1327-1335
- ⁹⁷ Demoule, A., et al. (2016). "Patterns of diaphragm function in critically ill patients receiving prolonged mechanical ventilation: a prospective longitudinal study." Ann Intensive Care **6**(1): 75.
- ⁹⁸ Rose, L., et al. (2014). "Psychological wellbeing, health related quality of life and memories of intensive care and a specialised weaning centre reported by survivors of prolonged mechanical ventilation." Intensive Crit Care Nurs **30**(3): 145-151.
- ⁹⁹ Schou, L. and I. Egerod (2008). "A qualitative study into the lived experience of post-CABG patients during mechanical ventilator weaning." Intensive Crit Care Nurs **24**(3): 171-179.
- ¹⁰⁰ Rotondi, A. J., et al. (2002). "Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit." Crit Care Med **30**(4): 746-752.
- ¹⁰¹ Jubran, A., et al. (2010). "Post-traumatic stress disorder after weaning from prolonged mechanical ventilation." Intensive Care Med **36**(12): 2030-2037.
- ¹⁰² Barnato, A. E., et al. (2011). "Disability among elderly survivors of mechanical ventilation." Am J Respir Crit Care Med **183**(8): 1037-1042.
- ¹⁰³ Scheinhorn, D. J., et al. (2007). "Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study." Chest **131**(1): 85-93.
- ¹⁰⁴ Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." Crit Care **11**(1): R9.
- ¹⁰⁵ *Ibid.*
- ¹⁰⁶ Dasta, J. F., et al. (2005). "Daily cost of an intensive care unit day: the contribution of mechanical ventilation." Crit Care Med **33**(6): 1266-1271.
- ¹⁰⁷ Cox, C. E., et al. (2007). "Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study." Crit Care **11**(1): R9.
- ¹⁰⁸ Scheinhorn, D. J., et al. (2007). "Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study." Chest **131**(1): 85-93.
- ¹⁰⁹ Rose, L. and I. M. Fraser (2012). "Patient characteristics and outcomes of a provincial prolonged-ventilation weaning centre: a retrospective cohort study." Can Respir J **19**(3): 216-220.
- ¹¹⁰ Hassenpflug, M. S., et al. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific (TIPS?) Weaning Protocol. B44. Invasive And Non-Invasive Mechanical Ventilation, American Thoracic Society: A3166-A3166.

varied from 13% to 56%.¹¹¹ These findings have also been observed in LTCHs, where higher weaning rates have been associated with lower post-discharge mortality.^{112 113} In LTCHs, fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications, enhanced rehabilitation opportunities, and shorter LOS.¹¹⁴

Unnecessarily prolonged mechanical ventilation increases the risk of negative patient outcomes and can be an indicator of poor quality care or of persistent illness.¹¹⁵ Based on the evidence, improving weaning processes and increasing weaning rates are expected to mitigate the risk of harm associated with invasive mechanical ventilation, thus contributing to more favorable clinical outcomes for patients^{116 117} and decreased costs.¹¹⁸

This quality measure, Ventilator Liberation Rate, will assess the proportion of patients discharged alive from an LTCH who are fully weaned, thereby promoting weaning efforts and encouraging quality management of LTCH patients on invasive mechanical ventilation. Kahn et al. noted that inclusion of a liberation outcome measure is key to providing a truly patient-centered measure related to invasive mechanical ventilation weaning among LTCH patients.¹¹⁹

Denominator

The target population is patients discharged from an LTCH AND who were on invasive mechanical ventilation support upon admission to the LTCH, for whom at admission weaning attempts were expected or anticipated.

For patients with more than one LTCH stay during the reporting period, each admission and discharge is included in the measure calculation and reporting. For example, if an LTCH patient is

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- ¹¹¹ Damuth, E., Mitchell, J. A., Bartock, J. L., Roberts, B. W., & Trzeciak, S. (2015). Long-term survival of critically ill patients treated with prolonged mechanical ventilation: a systematic review and meta-analysis. *Lancet Respir Med*. doi:10.1016/S2213-2600(15)00150-2
- ¹¹² Frengley, J. D., Sansone, G. R., Shakya, K., & Kaner, R. J. (2014). Prolonged mechanical ventilation in 540 seriously ill older adults: effects of increasing age on clinical outcomes and survival. *J Am Geriatr Soc*, 62(1), 1-9. doi:10.1111/jgs.12597
- ¹¹³ Stearn-Hassenpflug, M., Steckart, M., & Nelson, D. (2013). 678: Post-ICU Mechanical Ventilation: Trends in Mortality and 12-month Post-discharge Survival. *Critical Care Medicine*, 41(12), A166. doi:10.1097/01.ccm.0000439916.52441.12
- ¹¹⁴ Hassenpflug, M. S., Douglas, V., Rafael, S., David, R. N., Scott, A. S., & Steckart, M. J. (2015). Post-ICU Mechanical Ventilation: Outcomes of the Revised Therapist-Implemented Patient-Specific (TIPS?) Weaning Protocol B44. *Invasive And Non-Invasive Mechanical Ventilation* (pp. A3166-A3166): American Thoracic Society.
- ¹¹⁵ MacIntyre, N. R. (2013). "The ventilator discontinuation process: an expanding evidence base." *Respir Care* 58(6): 1074-1086.
- ¹¹⁶ Blackwood, B., Burns, K. E., Cardwell, C. R., & O'Halloran, P. (2014). Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients. *Cochrane Database Syst Rev*, 11, Cd006904. doi:10.1002/14651858.CD006904.pub3
- ¹¹⁷ Jubran, A., Grant, B. J., Duffner, L. A., Collins, E. G., Lanuza, D. M., Hoffman, L. A., & Tobin, M. J. (2013). Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial. *JAMA*, 309(7), 671-677. doi:10.1001/jama.2013.159
- ¹¹⁸ Dasta, J. F., McLaughlin, T. P., Mody, S. H., & Piech, C. T. (2005). Daily cost of an intensive care unit day: the contribution of mechanical ventilation. *Crit Care Med*, 33(6), 1266-1271.
- ¹¹⁹ Kahn, J. M., & Carson, S. S. (2013). Generating evidence on best practice in long-term acute care hospitals. *JAMA*, 309(7), 719-720. doi:10.1001/jama.2013.848.

transferred to a short-stay acute care hospital for a procedure, surgery, or some other reason(s), returns to the LTCH within three (3) calendar days, and is subsequently discharged from the LTCH, this is considered one “patient stay.” However, if this patient’s “stay” at the short-stay acute care hospital exceeds three (3) calendar days, whereby day one begins on the day of transfer from the LTCH to the short-stay acute care hospital, regardless of the hour of transfer, then a new LTCH CARE Data Set Admission Assessment is conducted upon return of the patient to the LTCH, and a second LTCH CARE Data Set Discharge Assessment accompanies the second discharge. Admission and Discharge (Planned or Unplanned) Assessments are completed for this patient for the first stay, and Admission and Discharge (Planned or Unplanned) Assessments are completed for the second stay. Both stays for this patient are included in the measure calculation and reporting.

Denominator Exclusions

This measure excludes patients with missing data and invasively mechanically ventilated patients identified as non-weaning at the time of admission to an LTCH. Patients who may be considered non-weaning include patients who are considered chronically ventilated as defined by evidence-based guidelines for ventilator liberation¹²⁰ or patients with an acute or chronic condition that may negate any expectation or anticipation of weaning attempts at admission (e.g., amyotrophic lateral sclerosis, or severe neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning must be based on documentation found in the patient’s medical record by Day 2 of LTCH stay.

After patient-level exclusions are applied, LTCHs with denominator counts of less than 20 patient stays during the reporting period will be excluded from public reporting, owing to a small sample size.

Denominator exclusion details

Patients are excluded from the target population (i.e., denominator) if they meet either of the following criteria:

1. O0150A. Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 0 (i.e., No, not on invasive mechanical ventilation support), OR:
2. O0150A. Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 2, Yes, non-weaning (i.e., No weaning attempts are expected or anticipated at admission)

Numerator

The numerator represents the number of patients who were reported as fully weaned at discharge on the Planned or Unplanned Discharge Assessments.

A patient is included in the numerator if the LTCH reports that Item O0250A (Invasive Mechanical Ventilator: Weaning Status at Discharge) = 1 (Fully weaned) on the LTCH CARE Data Set Planned or Unplanned Discharge Assessments.

¹²⁰ MacIntyre, N. R., et al. (2001). "Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine." *Chest* **120**(6 Suppl): 375s-395s.

Items Included in the Quality Measure

For this quality measure, the following items are assessed at the time of admission:

A0900	Birth Date
GG0100B	Prior Functioning: Everyday Activities. Indoor Mobility (Ambulation)
I0103	Metastatic Cancer
I0104	Severe Cancer
I0605	Severe Left Systolic/Ventricular Dysfunction (known ejection fraction \leq 30%).
I5200	Multiple Sclerosis (MS)
I5450	Amyotrophic Lateral Sclerosis
I5455	Other Progressive Neuromuscular Disease
I4900	Hemiplegia or Hemiparesis
I5000	Paraplegia
I5101	Complete Tetraplegia
I5102	Incomplete Tetraplegia
I5470	Severe Anoxic Brain Damage, Cerebral Edema, or Compression of Brain
I5110	Other Spinal Cord Disorder/Injury
I5480	Other Severe Neurological Injury, Disease, or Dysfunction
I7100	Lung Transplant
I7101	Heart Transplant
I7102	Liver Transplant
I7103	Kidney Transplant
I7104	Bone Marrow Transplant
O0100H	IV Medications
O0100H2a	Vasoactive Medications (e. g. continuous vasopressors or inotropes)
O0100J	Dialysis
O0100J2a	Hemodialysis
O0100J3a	Peritoneal dialysis
O0150A	Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH

The following item is assessed at the time of discharge for patients with Planned or Unplanned Discharge Assessments:

O0200A	Ventilator Liberation Rate: Invasive Mechanical Ventilator: Liberation Status at Discharge
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Risk Adjustment

This measure is risk-adjusted to account for various risk factors using a statistical risk model.

We are developing, subsequent to measure testing and data analysis, a statistical risk model based on hierarchical logistic regression to predict the probability of full ventilator liberation at discharge for patients discharged from the LTCH alive. Patient characteristics related to admission and a marker for the specific discharging LTCH are included in the equation.

The equation is hierarchical in that both individual patient characteristics are accounted for, as well as the clustering of patient characteristics by LTCH. The statistical model estimates both the average predictive effect of the patient characteristics across all facilities, and the degree to which each LTCH has an effect on ventilator weaning (liberation) that differs from that of the average LTCH. The LTCH effects are assumed to be randomly distributed around the average (according to a normal distribution). When computing the LTCH effect, hierarchical modeling accounts for the potential predictors of ventilator weaning (liberation) in LTCHs, on average, such as patient characteristics, the observed LTCH rate, and the number of LTCH stays eligible for inclusion in the measure. The estimated LTCH effect is determined mostly by the LTCH's own data if the number of patient discharges is relatively large (as the estimate would be relatively precise), but is adjusted toward the average if the number of patient discharges is small (as that would yield a less precise estimate).

We are testing the following risk adjustment model:

Let Y_{ij} , denote the outcome (equal to 1 if patient i is alive and fully liberated at LTCH discharge, 0 otherwise) for a patient i at LTCH j ; Z_{ij} denotes a set of risk adjustment variables. We assume the outcome is related to the risk adjusters via a logit function with dispersion:

$$\begin{aligned} \text{logit}(\text{Prob}(Y_{ij}=1)) &= \alpha_j + \beta_i * Z_{ij} + \varepsilon_{ij} \\ \alpha_j &= \mu + \omega_j; \omega_j \sim N(0, \tau^2) \end{aligned} \tag{1}$$

where $Z_{ij} = (Z_1, Z_2, \dots, Z_k)$ is a set of k patient-level risk adjustment variables; α_j represents the LTCH-specific intercept; μ is the adjusted average outcome across all LTCHs; τ^2 is the between-LTCH variance component; and $\varepsilon \sim N(0, \sigma^2)$ is the error term.

The hierarchical logistic regression model is estimated using SAS software (PROC GLIMMIX: SAS/STAT User's Guide, SAS Institute Inc.).

The estimated equation is used twice in the measure. The sum of the probabilities of ventilator weaning (liberation) of all patients in the LTCH measure, including both the effects of patient characteristics and the LTCH, is the "predicted number" of liberated patients after adjusting for the LTCH's case mix. The same equation is used without the LTCH effect to compute the "expected number" of liberated patients for the same patients at the average LTCH. This is shown in equation 2.

$$\text{logit}(\text{Prob}(Y_{ij}=1)) = \beta_0 + \beta_i * Z_{ij} + \varepsilon_{ij} \tag{2}$$

The ratio of the predicted-to-expected number of fully liberated patients is a measure of the degree to which ventilator weaning (liberation) rates are higher or lower than what would otherwise be expected. This standardized risk ratio is then multiplied by the mean observed ventilator liberation rate for all LTCH stays included in the measure. As a result, this yields the risk-adjusted ventilator weaning (liberation) rate for each LTCH. Please note that the estimation procedure is recalculated for each measurement period. Re-estimating the models for each measurement period allows the estimated effects of the patient characteristics to vary over time as patient case-mix and medical treatment patterns change.

Proposed risk adjustment variables include variables for age; prior functional status; selected conditions and comorbidities; special treatments and programs; and medications from the LTCH CARE Data Set V4.00 as provided below.

The following variables will be used as risk adjusters for initial measure testing:

1. Age

2. Prior Functioning: Everyday Activities
3. Metastatic cancer
4. Severe cancer
5. Left ventricular assistive device with known ejection fraction $\leq 30\%$
6. Progressive Neuromuscular Disease
7. Severe Neurological Injury, Disease, or Dysfunction
8. Post-transplant (lung, heart, liver, kidney, and bone marrow)
9. Vasoactive medication (i.e. continuous vasopressors or inotropes)
10. Dialysis

Quality Measure Calculation Algorithm

Risk-adjusted ventilator weaning (liberation) rate:

1. Identify all patients discharged (alive or expired) during the reporting period from an LTCH.
2. Of patients discharged (alive or expired) from the LTCH during the reporting period, identify all patients who were admitted on invasive mechanical ventilation support upon admission to an LTCH. This is the target population.
3. Of patients identified in (2), identify the subset of patients for whom weaning attempts are not expected or anticipated at admission. These patients are excluded from the measure.
4. Of the patients identified in (2), identify the subset of patients for whom weaning attempts were expected or anticipated at admission. This is the denominator.
5. Of patients identified in (4), identify the subset of patients who are reported as alive and fully weaned at discharge on the Planned or Unplanned Discharge Assessments. This is the numerator.
6. Identify presence or absence of risk factors for each patient identified in (4).
7. Calculate the predicted number of patients ($pred_j$) who are reported as alive and fully weaned at discharge for each LTCH using the hierarchical logistic regression model specified in 3.4.7.
8. Calculate the expected number of patients (exp_j) who are reported as alive and fully weaned at discharge for each LTCH using the logistic regression model specified in 3.4.7.
9. Calculate the LTCH standardized risk ratio (SRR_j) using the following equation: $SRR_j = pred_j/exp_j$.
10. Calculate the risk-adjusted LTCH ventilator (liberation) rate by multiplying the standardized risk ratio by the overall national observed ventilator (liberation) rate times 100.

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Chapter 4

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 LTCH QRP.

Section 2: Functional Status

Beginning with the FY 2020 LTCH 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 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), 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 IPPS/LTCH PPS final rule (80 FR 49739 through 49747).

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.¹²¹ 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.¹²² ¹²³ 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.¹²⁴ ¹²⁵ ¹²⁶ 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.

¹²¹ 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>

¹²² Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹²³ 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).

¹²⁴ Casey, D. A., Antimisiaris, D., & O’Brien, J. (2010). “Drugs for Alzheimer’s disease: are they effective?” *Pharmacy and Therapeutics* 35(4): 208.

¹²⁵ 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.

¹²⁶ Langa, K. M., & Levine, D. A. (2014). “The diagnosis and management of mild cognitive impairment: a clinical review.” *JAMA* 312(23): 2551-2561.

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:

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 LTCHs

The BIMS data elements comprehensively assess cognitive functioning in greater detail than existing data elements in the LCDS. In older adults, dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.¹²⁷ Therefore, assessment of mental status and early detection of cognitive decline or impairment is critical in the LTCH setting. The PAC PRD found that 16.8 percent of LTCH patients are moderately cognitively impaired and 15.5 percent are severely cognitively impaired, as assessed by the BIMS.¹²⁸ The burden of cognitive impairment in LTCHs is high. The intensity of routine nursing care is higher for LTCH patients with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from LTCHs.¹²⁹ Assessing cognitive function using the BIMS would provide important information for care planning, care transitions, patient safety, and resource use in LTCHs.

¹²⁷ Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). "Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study." *Am J of Public Health* 88(10): 1452-1456.

¹²⁸ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. RTI International. Research Triangle Park, NC. 2012. 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.

¹²⁹ RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM. Research Triangle Park, NC. 2016.

Proposed Data Elements for the Assessment of Cognitive Function: The BIMS

Section C		Cognitive Patterns
C0100. Should Brief Interview for Mental Status (C0200-C0500) be Conducted?		
Attempt to conduct interview with all patients.		
Enter Code <input type="checkbox"/>	0. No (patient is rarely/never understood) → Skip to C1310. Signs and Symptoms of Delirium (from CAM®) 1. Yes → Continue to C0200. Repetition of Three Words	
Brief Interview for Mental Status (BIMS) (3-day assessment period)		
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."		
Enter Code <input type="checkbox"/>	Number of words repeated after first attempt 0. None 1. One 2. Two 3. Three	
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)		
Enter Code <input type="checkbox"/>	Ask patient: "Please tell me what year it is right now." A. Able to report correct year 0. Missed by > 5 years or no answer 1. Missed by 2-5 years 2. Missed by 1 year 3. Correct	
Enter Code <input type="checkbox"/>	Ask patient: "What month are we in right now?" B. Able to report correct month 0. Missed by > 1 month or no answer 1. Missed by 6 days to 1 month 2. Accurate within 5 days	
Enter Code <input type="checkbox"/>	Ask patient: "What day of the week is today?" C. Able to report correct day of the week 0. Incorrect or no answer 1. Correct	
C0400. Recall		
Enter Code <input type="checkbox"/>	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. A. Able to recall "sock" 0. No - could not recall 1. Yes, after cueing ("something to wear") 2. Yes, no cue required	
Enter Code <input type="checkbox"/>	B. Able to recall "blue" 0. No - could not recall 1. Yes, after cueing ("a color") 2. Yes, no cue required	
Enter Code <input type="checkbox"/>	C. Able to recall "bed" 0. No - could not recall 1. Yes, after cueing ("a piece of furniture") 2. Yes, no cue required	
C0500. BIMS Summary Score		
Enter Score <input type="text"/>	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 also demonstrated feasibility of the BIMS for use in LTCHs and found evidence of strong reliability of the BIMS data elements in the LTCH

setting. In addition, the BIMS data elements were also found to be predictive of cost.¹³⁰ The BIMS data elements were also included in the national MDS 3.0 test in nursing homes and showed almost perfect reliability.¹³¹ 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.¹³²

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.¹³³ 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 LTCHs

The CAM data elements would provide important information for the LTCH setting if added to the LCDS. Because patients with multiple comorbidities are hospitalized in LTCHs for long periods of time, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.¹³⁴ The prevalence of signs and symptoms of delirium in LTCH patients is high. As assessed in the PAC PRD using the CAM, the following proportions of LTCH patients showed the following signs or symptoms of delirium: 48 percent of patients in LTCHs exhibited inattention; 35.6 percent had disorganized thinking; and 31.7 percent had an altered level of consciousness.¹³⁵ Assessing certain types of cognitive impairment, including delirium and reversible confusion, using the Short CAM would provide important information for care planning, care transitions, patient safety, and resource use in LTCHs.

¹³⁰ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹³¹ 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.

¹³² 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.

¹³³ 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.

¹³⁴ Fick, D. M., Steis, M. R., Waller, J. L., & Inouye, S. K. (2013). "Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults." *J of Hospital Med* 8(9): 500-505.

¹³⁵ Unpublished data from the PAC PRD Public Comments sample, 2008-2010.

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?
<input type="checkbox"/>	0. No 1. Yes
CODING:	Enter Code in Boxes
0. Behavior not present	<input type="checkbox"/> B. Inattention - Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?
1. Behavior continuously present, does not fluctuate	<input type="checkbox"/> 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)?
2. Behavior present, fluctuates (comes and goes, changes in severity)	<input type="checkbox"/> D. Altered Level of Consciousness - Did the patient have altered level of consciousness, as indicated by any of the following criteria? <ul style="list-style-type: none"> ■ 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

Confusion Assessment Method. © 1988, 2003, Hospital Elder Life Program. All rights reserved. Adapted from: Inouye SK et al. Ann Intern Med. 1990; 113:941-8. Used with permission.

© 1988, 2003, Hospital Elder Life Program

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.¹³⁶ The Short CAM was tested in the PAC PRD and found to be reliable across all four settings.¹³⁷ 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).¹³⁸

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).¹³⁹

¹³⁶ Waszynski, C. M. (2007). “How to try this: Detecting delirium.” AJN 107(12): 50-59.

¹³⁷ 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.

¹³⁸ 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.

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>.

Behavioral Signs and Symptoms

Behavior 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 additional 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 LTCHs

The Behavioral Signs and Symptoms data elements would provide important information about resource use in LTCHs. As has been documented in LTCHs, patients displaying behavioral disturbances require more case management time,²³ and these symptoms may also disrupt the institutional or home environment and impact the safety and privacy of other patients and residents, caregivers, and staff. For LTCH staff, exposure to aggressive behavior has a negative effect on job satisfaction.¹⁴⁰ Among LTCHs studied in the PAC PRD, 1.6 percent of LTCH patients were physically aggressive towards others; 1.7 percent were verbally aggressive towards others; and 6.6 percent exhibited another concerning behavior towards themselves.¹⁴¹ Assessing 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 LTCHs.

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.	
↓ Enter Code in Boxes	
CODING: 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	<input type="checkbox"/> A. Physical behavioral symptoms directed toward others (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)
	<input type="checkbox"/> B. Verbal behavioral symptoms directed toward others (e.g., threatening others, screaming at others, cursing at others)
	<input type="checkbox"/> 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.

¹⁴⁰ Dougherty, L. M., Bolger, J. P., Preston, D. G., Jones, S. S., & Payne, H. C. (1992). “Effects of exposure to aggressive behavior on job satisfaction of health care staff.” *J of Applied Gerontology* 11(2): 160-172.

¹⁴¹ Unpublished data from the PAC PRD Public Comments sample, 2008-2010.

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)¹⁴². 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.¹⁴³ The prevalence varied from a low of 7 percent of beneficiaries in SNFs to a high of 11 percent in IRFs.¹⁴⁴

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 patients taking an antidepressant medication.¹⁴⁵ 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.^{146 147}

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

¹⁴² 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>.

¹⁴³ 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.

¹⁴⁴ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁴⁵ 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.

¹⁴⁶ Scogin, F., & McElreath, L. (1994). "Efficacy of psychosocial treatments for geriatric depression: a quantitative review." *J Consult Clin Psychol* 62(1):69-74.

¹⁴⁷ 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.

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).¹⁴⁸ 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 LTCHs

Major depressive disorder is common in LTCH patients, with a prevalence of 8.2 percent for LTCHs, as assessed in the PAC PRD.¹⁴⁹ Screening for the signs and symptoms of depression using the PHQ-2 would provide important information for care planning, care transitions, and resource use in LTCHs.

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

Section D		Mood	
D0150. Patient Health Questionnaire 2 (PHQ-2)			
<p>Say to patient: "Over the last 2 weeks, have you been bothered by any of the following problems?"</p> <p>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.</p>			
<p>1. Symptom Presence</p> <p>0. No (enter 0 in column 2) 1. Yes (enter 0-3 in column 2) 9. No response (leave column 2 blank)</p>	<p>2. Symptom Frequency</p> <p>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)</p>	<p>1. Symptom Presence</p>	<p>2. Symptom Frequency</p>
		↓ Enter Scores in Boxes ↓	
A. Little interest or pleasure in doing things?		<input type="checkbox"/>	<input type="checkbox"/>
B. Feeling down, depressed, or hopeless?		<input type="checkbox"/>	<input type="checkbox"/>
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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

¹⁴⁸ American Psychiatric Association. Diagnostic and Statistic Manual of Mental Disorders. 1980.

¹⁴⁹ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

well as both a screening tool for identifying depression and to assess depression severity.^{150 151} 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 percent).^{152 153 154 155 156 157 158 159 160 161 162 163 164 165 166} Thus, the specificity of the PHQ-2 appears to be comparable to

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- ¹⁵⁰ 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.
- ¹⁵¹ 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.
- ¹⁵² 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.
- ¹⁵³ 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.
- ¹⁵⁴ 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.
- ¹⁵⁵ 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.
- ¹⁵⁶ 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.
- ¹⁵⁷ 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.
- ¹⁵⁸ 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*, 2014.
- ¹⁵⁹ 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.
- ¹⁶⁰ Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9. *J Gen Intern Med* 16(9): 606-613.
- ¹⁶¹ 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.
- ¹⁶² 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.
- ¹⁶³ 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.
- ¹⁶⁴ 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.
- ¹⁶⁵ 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.
- ¹⁶⁶ 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.

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).¹⁶⁷ It is thus a viable option for standardization, with the benefits of the shorter assessment counterbalancing the limitation of the lower sensitivity.

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 0.988.¹⁶⁸ 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).¹⁶⁹

¹⁶⁷ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁶⁸ 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>.

¹⁶⁹ *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 LTCHs

In one study of inpatient survival in four LTCH settings, which reviewed approximately 300 medical records, the prevalence of malignancy was 16 percent.¹⁷⁰ Given the significant burden of malignancy in LTCH patients, 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 LTCHs.

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)		<input type="checkbox"/>
A2a. IV		<input type="checkbox"/>
A3a. Oral		<input type="checkbox"/>
A10a. Other		<input type="checkbox"/>

Current use

Chemotherapy data elements are currently used in the MDS 3.0. They ask first if the resident received chemotherapy in the past 14 days while not a resident of the assessing facility, and then ask 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.¹⁷¹ 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.¹⁷²

¹⁷⁰ D'Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). "Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness." CHEST Journal 124(3): 1039-1045.

¹⁷¹ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁷² 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>.

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.^{173 174} 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 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 LTCHs

As mentioned in the discussion of Chemotherapy, one study of inpatient survival in four LTCH settings found that the prevalence of malignancy was 16 percent.¹⁷⁵ Radiation is an important therapy for particular types of cancer and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient is receiving radiation therapy is important to determine resource utilization because LTCH patients will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing whether the patient is receiving Radiation would provide important information for care planning, clinical decision making, and resource use in LTCHs.

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

Section O Special Treatments, Procedures, and Programs	
00100. 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	<input type="checkbox"/>

Current use

A version of this data element, Radiation, is currently collected in the MDS 3.0. It uses a 14-day look-back period to assess whether a patient received radiation while a resident or before admission to the facility.

¹⁷³ Yamada, Y. Principles of Radiotherapy. In Cancer rehabilitation: principles and practice. Eds. Stubblefield Michael D. and O'dell Michael W. 2009.

¹⁷⁴ National Cancer Institute. Radiation Therapy for Cancer. 2010 Available at <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet>

¹⁷⁵ D'Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). "Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness." CHEST Journal 124(3): 1039-1045.

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 0.66.¹⁷⁶

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 LTCHs

In a small study of LTCH patients, the prevalence of respiratory failure was 45 percent, so continuous oxygen therapy is likely a part of the treatment plan for many LTCH patients.¹⁷⁷ While continuous and intermittent oxygen therapy both require resources, in terms of medical equipment, clinical monitoring, and staff resources, distinguishing between oxygen delivered intermittently and continuously provides information on the severity of the underlying illness (which is related to the number of hours of oxygen therapy per day), and the level of monitoring and bedside care required. Assessing whether a patient is receiving Oxygen Therapy would provide important information for care planning, clinical decision making, care transitions, and resource use in LTCHs.

¹⁷⁶ 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>.

¹⁷⁷ D'Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). "Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness." CHEST Journal, 124(3), 1039-1045.

*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	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

Current use

Related data elements are collected in the OASIS-C2 and the MDS 3.0. In the MDS, the data elements use a 14-day look-back period to assess whether a patient received oxygen therapy while a resident or before admission to the facility.

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.¹⁷⁸ 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.¹⁷⁹ Oxygen therapy data elements during the last 14 days were shown to have reliabilities ranging from 0.81 to 0.87 in studies of MDS 2.0.¹⁸⁰

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 needed, such as when secretions become so prominent that gurgling or choking is noted, or a sudden

¹⁷⁸ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁷⁹ 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>.

¹⁸⁰ *Ibid.*

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 LTCHs

Suctioning clears excessive airway secretions in LTCH patients, which not only improves patient comfort but it also improves oxygenation and also serves a preventive purpose, in that excess secretions can be aspirated and cause aspiration pneumonia. Pneumonia itself is also a cause of excess secretions and is particularly common in the LTCH setting. The reported annual incidence of pneumonia in long-term care residents ranges from 99 to 912 per 1,000 persons, with a median reported incidence of 365 per 1,000 persons. Furthermore, between 9 percent and 51 percent of patients acquiring pneumonia in long-term care facilities are transferred to acute hospitals, representing worsening in clinical status.¹⁸¹ Pneumonia is one of several reasons patients may not be able to handle their secretions. In a small study of inpatient survival in LTCHs, the prevalence of pneumonia among LTCH patients was 13 percent; the prevalence of chronic obstructive pulmonary disease (COPD) was 13 percent; and the prevalence of a primary cerebral insult was 8 percent.¹⁸² Each of these conditions may require frequent suctioning as part of the patient care routine, while taking care to minimize airway trauma and thereby increase the production of secretions. Finally, suctioning of excess secretions is important in patients with tracheostomies to ensure the tracheostomy remains unobstructed and the patient can adequately oxygenate. 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 LTCHs.

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)		<input type="checkbox"/>
D2a. Scheduled		<input type="checkbox"/>
D3a. As needed		<input type="checkbox"/>

Current use

Related Suctioning data elements are collected in the MDS 3.0. These data elements use a 14-day look-back period to assess whether a patient received suctioning while a resident or before admission to the facility.

¹⁸¹ Muder, R. R. (1998). "Pneumonia in residents of long-term care facilities: epidemiology, etiology, management, and prevention." *Am J of Med* 105(4): 319-330.

¹⁸² D'Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). "Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness." *CHEST Journal* 124(3): 1039-1045.

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.¹⁸³ A checkbox for suctioning during the last 14 days was shown to have reliabilities of 0.89 and 0.775 in studies of MDS 2.0.¹⁸⁴

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.

Relevance to LTCHs

While individuals with tracheostomies represent only 3 percent of LTCH patients overall, having a tracheostomy is the clinical characteristic most strongly associated with discharge to an LTCH among Medicare beneficiaries being discharged from acute care settings.¹⁸⁵ Further, patients with tracheostomies are at relatively high risk of hospital acquired infections or other complications, and require close

¹⁸³ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁸⁴ 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>.

¹⁸⁵ Medicare Payment Advisory Commission (US). (2004). Report to the Congress: new approaches in Medicare. Medicare Payment Advisory Commission.

monitoring to ensure that their tracheostomy is patent, enabling the patient to breathe or be mechanically ventilated through the tracheostomy. Among patients with tracheostomies, total episode spending was lower for those who used an LTCH compared to those who did not, making assessment of this clinical characteristic very important in the LTCH setting in order to facilitate cross-setting comparisons of case mix, resource intensity, and total Medicare spending per episode of care.^{186 187} 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 LTCHs.

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	<input type="checkbox"/>

Current use

A version of this data element currently exists in the MDS 3.0.

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 1.¹⁸⁸

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 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

¹⁸⁶ *Ibid.*

¹⁸⁷ Hill, N. S. (2009). Where should noninvasive ventilation be delivered? *Respiratory Care*, 54(1), 62-70.

¹⁸⁸ 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>.

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.

Assessment of this item will be accomplished by a new quality measure, “Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay,” which will be included in the Admission assessment only and will replace the assessment of invasive mechanical ventilation (weaning versus non-weaning) in the extant LCDS. The quality measure will allow a more accurate and nuanced assessment of the patient’s candidacy for weaning from the ventilator, as well as document the steps taken to allow the patient a trial of spontaneous breathing, if appropriate. Specifically, the first subquestion of the item asks if the patient is on invasive mechanical ventilation support and, if yes, whether it is weaning or non-weaning support. If it is weaning, the next part of the item asks if the patient was assessed for readiness for SBT by day 2 of the LTCH stay. If deemed medically ready, the assessor documents if SBT was performed by day 2 of the LTCH stay and, if deemed medically unready for SBT by day 2, the item asks for documentation of the reason.

Relevance to LTCHs

Invasive mechanical ventilation is common in the LTCH setting. About 22 percent of LTCH patients used an invasive mechanical ventilator, compared with less than 1 percent of patients and residents in home health and SNFs.¹⁸⁹ Of note, 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.¹⁹⁰ 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 LTCHs 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 LTCHs.

¹⁸⁹ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁹⁰ 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.

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

O0150. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay	
Enter Code <input type="checkbox"/>	A. Invasive Mechanical Ventilation Support upon Admission to the LTCH 0. No, not on invasive mechanical ventilation support → Skip to O0250, Influenza Vaccine 1. Yes, weaning → Continue to O0150B, Assessed for readiness for SBT by day 2 of the LTCH stay 2. Yes, non-weaning → Skip to O0250, Influenza Vaccine
Enter Code <input type="checkbox"/>	B. Assessed for readiness for SBT by day 2 of the LTCH stay (Note: Day 2 = Date of Admission to the LTCH (Day 1) + 1 calendar day) 0. No → Skip to O0250, Influenza Vaccine 1. Yes → Continue to O0150C, Deemed medically ready for SBT by day 2 of the LTCH stay
Enter Code <input type="checkbox"/>	C. Deemed medically ready for SBT by day 2 of the LTCH stay 0. No → Continue to O0150D, Is there documentation of reason(s) in the patient's medical record that the patient was deemed medically unready for SBT by day 2 of the LTCH stay? 1. Yes → Continue to O0150E, SBT performed by day 2 of the LTCH stay
Enter Code <input type="checkbox"/>	D. Is there documentation of reason(s) in the patient's medical record that the patient was deemed medically unready for SBT by day 2 of the LTCH stay? 0. No → Skip to O0250, Influenza Vaccine 1. Yes → Skip to O0250, Influenza Vaccine
Enter Code <input type="checkbox"/>	E. SBT performed by day 2 of the LTCH stay 0. No 1. Yes

Current use

Invasive mechanical ventilation is currently assessed in the MDS 3.0, the OASIS-C2, and the LCDS. The MDS uses a 14-day look-back period to assess whether a patient received mechanical ventilation on a ventilator or respirator while a resident or before admission to the facility. 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.

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.¹⁹¹ A version of the item was tested in the MDS 3.0 National Evaluation Study and had perfect reliability (1.0).¹⁹²

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

¹⁹¹ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

¹⁹² 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>.

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 LTCHs

LTCH patients have a high prevalence of respiratory insufficiency, which may be managed by invasive or non-invasive mechanical ventilation. In a survey of respiratory care directors at 17 long-term acute-care hospitals in Massachusetts and Rhode Island with over 2,000 beds (unpublished data), of 180 patients who were receiving mechanical ventilation at the time (2003), 24 percent received non-invasive ventilation. Of those, 74 percent had COPD, 20 percent had restrictive processes (including neuromuscular diseases), and 6 percent had other conditions.¹⁹³ Assessment of Non-Invasive Mechanical Ventilation, including CPAP and BiPAP, would provide important information for care planning, care transitions, and resource use in LTCHs. Particularly when used in the context of acute illness or progressive respiratory decline, additional staff (e.g., respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient may require more nursing resources.

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		<input type="checkbox"/>
G3a. CPAP		<input type="checkbox"/>

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. The MDS 3.0 uses a 14-day look-back period to assess (checklist format) whether a patient needed treatment with BiPAP/CPCP while a resident or before admission to the facility.

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.¹⁹⁴

¹⁹³ Hill, N. S. (2009). "Where should noninvasive ventilation be delivered?" *Resp Care* 54(1): 62-70.

¹⁹⁴ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

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 LTCHs

Intravenous medications are a common and important part of clinical care for patients in LTCHs. For instance, in a study of LTCHs, 41 percent of patients had an active infection, defined by receiving antibiotics and having a high white blood cell count and/or fever, or sepsis, with a mortality of 78 percent.¹⁹⁵ Furthermore, in the same study, 18 percent of LTCH patients were requiring vasopressors or had a left ventricular ejection fraction <35 percent or NYHA class III/IV, with a mortality of 80.4 percent. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC; knowing not only whether or not patients are receiving IV medication but also the type of medication will be helpful in the LTCH setting.

Given the clinical complexity of patients in LTCHs, it is likely that they are receiving one or more medications using the IV route. Assessing 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 LTCHs.

¹⁹⁵ D’Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). “Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness.” CHEST Journal 124(3): 1039-1045.

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

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 ↓
Other Treatments		
H. IV Medications (if checked, please specify below)		<input type="checkbox"/>
H2a. Vasoactive medications (i.e., continuous infusions of vasopressors or inotropes)		<input type="checkbox"/>
H3a. Antibiotics		<input type="checkbox"/>
H4a. Anticoagulation		<input type="checkbox"/>
H10a. Other		<input type="checkbox"/>

Note: The response category H2a. Vasoactive medications is not being proposed for standardized assessment of Special Services, Treatments, and Interventions: IV Medications. This response option is being proposed to support the quality measure, Ventilator Liberation Rate, described elsewhere in this document.

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.

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.

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 2.0.¹⁹⁶

Transfusions

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. Receipt of transfusions is also important to assess for case mix adjustment due to the need for added resources and to the extent that receipt of transfusions indicates a more medically complex patient.

¹⁹⁶ 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>

Relevance to LTCHs

In the clinically-complex LTCH population, there may be many underlying reasons that a patient requires a transfusion of blood or blood products. In fact, unpublished data show that transfusions are the second most-common LTCH procedure, occurring in 18.4 percent of LTCH admissions from 2007 to 2012.¹⁹⁷ Transfusions are resource-intensive, requiring coordination among the blood bank and bedside care staff, and close monitoring is necessary given the incidence of adverse reactions, which may range from mild to severe. Assessing whether the patient requires Transfusions would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in LTCHs.

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	<input type="checkbox"/>

Current use

The Transfusions data element is currently collected in the MDS 3.0, using a checkbox format.

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.¹⁹⁸ 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 2.0.¹⁹⁹

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

¹⁹⁷ Einav, L., Finkelstein, A., & Mahoney, N. Provider Incentives and Healthcare Costs: Evidence from Long-Term Care Hospitals (No. w23100). National Bureau of Economic Research. 2017.

¹⁹⁸ 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>

¹⁹⁹ *Ibid.*

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 LTCH 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 LTCHs

In the LTCH setting, 15 percent of patients in one study were hemodialysis-dependent, with a mortality of 77.8 percent.²⁰⁰ Importantly, receipt of dialysis has implications for discharge destination of LTCH patients. In a study of dialysis patients admitted to an LTCH, 63 of 206 (31 percent) were discharged to home, 11 of 206 (5.4 percent) died or transferred to hospice, 81 of 206 (40 percent) went to a nursing home, and 49 of 206 (24 percent) were re-admitted to an acute hospital. Mortality after re-admission to this latter setting was high, at 32 percent.²⁰¹ Furthermore, 12.2 percent of LTCH patients have hemodialysis indicated on their admission assessment and 10.4 percent have hemodialysis indicated on their discharge assessment.²⁰² Given how common this resource-intensive service is in the LTCH setting, it is important to assess for care planning and case mix adjustment. Assessing Dialysis (Hemodialysis, Peritoneal dialysis) would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in LTCHs.

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)		<input type="checkbox"/>
J2a. Hemodialysis		<input type="checkbox"/>
J3a. Peritoneal dialysis		<input type="checkbox"/>

Current use

A Dialysis data element is currently collected in the MDS 3.0, using a 14-day look-back period to assess whether a patient received dialysis while a resident or before admission to the facility. 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).

²⁰⁰ D'Amico, J. E. D., Donnelly, H. K., Mutlu, G. M., Feinglass, J., Jovanovic, B. D., & Ndukwu, I. M. (2003). "Risk assessment for inpatient survival in the long-term acute care setting after prolonged critical illness." CHEST Journal 124(3): 1039-1045.

²⁰¹ Thakar, C. V., Quate-Operacz, M., Leonard, A. C., & Eckman, M. H. (2010). "Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study." Am J of Kidney Diseases 55(2): 300-306.

²⁰² Dalton, K, Kandilov, AA, Kennell, D, Wright, A. Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals (LTCHs) Final Report. Kennell and Associates Inc, RTI. 2012. Available at <http://www.aha.org/content/12/kennellltchreportdetmednec.pdf>

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).²⁰³ Dialysis in the last 14 days was also shown to have almost perfect reliability (0.92 to 0.965) in studies of MDS 2.0.²⁰⁴

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 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 LTCHs

Clinically complex patients in the LTCH setting are likely to be receiving medications or nutrition intravenously. Assessing IV Access would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in LTCHs. See also “IV Medications” and “Parenteral/IV Feeding” sections of this document.

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		<input type="checkbox"/>	
O3a. Midline		<input type="checkbox"/>	
O4a. Central line (e.g., PICC, tunneled, port)		<input type="checkbox"/>	
O10a. Other		<input type="checkbox"/>	

²⁰³ 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>

²⁰⁴ *Ibid.*

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.

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 care planning and case mix adjustment. 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 LTCHs

The need for parenteral/IV feeding in LTCHs is common: 8.5 percent of LTCH patients have total parenteral nutrition (TPN) indicated on their admission assessment and 5.2 percent have TPN indicated on their discharge assessment.²⁰⁵ As mentioned above, the need for TPN indicates a level of clinical complexity that prevents the patient from meeting his/her nutritional needs enterally.²⁰⁶ Assessing Parenteral/IV Feeding would provide important information for care planning, care transitions, and resource use in LTCHs.

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	<input type="checkbox"/>

²⁰⁵ Dalton, K, Kandilov, AA, Kennell, D, Wright, A. Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals (LTCHs) Final Report. Kennell and Associates Inc, RTI. 2012. Available at <http://www.aha.org/content/12/kennellltchreportdetmednec.pdf>

²⁰⁶ 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.

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 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. The MDS 3.0 uses a 7-day look-back period to assess, via a checklist, whether a patient received parenteral/IV feeding while a resident or before admission to the facility.

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.²⁰⁷ 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 2.0.²⁰⁸

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 LTCHs

Patients with severe malnutrition are at higher risk for a variety of complications.²⁰⁹ In the LTCH setting, there are a variety of reasons why patients may not be able to eat orally (including clinical or cognitive status). The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in the LTCH setting.²¹⁰ Additionally, this information is useful for the purposes of care planning, care transitions, and resource use in LTCHs, as enteral nutrition is most often used in medically complex patients and is a relatively resource-intensive feeding method, requiring frequent monitoring and administration.

²⁰⁷ 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>

²⁰⁸ *Ibid.*

²⁰⁹ 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.

²¹⁰ McWhirter, J. P., & Pennington, C. R. (1994). Incidence and recognition of malnutrition in hospital. *Bmj*, 308(6934), 945-948.

*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 ↓ <input type="checkbox"/>
B. Feeding tube - nasogastric or abdominal (e.g., PEG)	<input type="checkbox"/>

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 3.0, the data element, Feeding tube – Nasogastric Or Abdominal (PEG), uses a 7-day look-back period to assess whether a patient used a feeding while not a resident or before admission to the facility. 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).²¹¹

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 LTCHs

Patients with severe malnutrition are at higher risk for a variety of complications.²¹² In the LTCH setting, there are a variety of reasons why patients may have impairments related to oral feedings, including clinical or cognitive status. Specifically, 15 percent to 26 percent of residents in LTCHs require

²¹¹ 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>

²¹² 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.

a pureed diet.^{213 214} The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay,²¹⁵ making assessment of nutritional status and method of feeding if unable to eat a regular diet very important in the LTCH setting. In a Canadian study involving 93 LTCH patients, a diversified texture modified food diet improved patients' nutritional status and slowed weight loss in older adults with dysphagia.²¹⁶ Low interest in, and reduced consumption of, pureed food may increase the risk of malnutrition and dehydration and decrease the quality of life for older adults with dysphagia.²¹⁷ Assessing whether an LTCH patient requires a mechanically altered diet would provide important information for care planning, care transitions, patient safety, and resource use in LTCHs.

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)	<input type="checkbox"/>

Current use

The Mechanically Altered Diet data element is currently collected in the MDS 3.0. It uses a 7-day look-back period to assess if a patient received a mechanically altered diet while a resident or before admission to the facility.

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).²¹⁸

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).

²¹³ Hotaling, D. L. (1992). "Nutritional considerations for the pureed diet texture in dysphagic elderly." *Dysphagia* 7(2): 81-85.

²¹⁴ Cormier, D., Harper, D. W., O'Hara, P. A., Brilliant, C., Caissie, D., Dubeau, J., & Mitalas, J. (1993). "Pur ed diet: prevalence and reported reasons for use in a long-term care hospital. *Journal of the Canadian Dietetic Association*" 55(3): 121-124.

²¹⁵ McWhirter, J. P., & Pennington, C. R. (1994). "Incidence and recognition of malnutrition in hospital." *BMJ* 308(6934): 945-948.

²¹⁶ Germain, I., Dufresne, T., & Gray-Donald, K. (2006). "A novel dysphagia diet improves the nutrient intake of institutionalized elders." *J Am Dietetic Assc* 106(10): 1614-1623.

²¹⁷ College of Audiologists & Speech-Language Pathologists of Ontario. Practice Standards & Guidelines for Dysphagia; 2007: 2-35. Available at http://www.caslpo.com/portals/0/ppg/dysphagia_psg.pdf

²¹⁸ 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>.

The Therapeutic Diet data element is important to collect in the LTCH 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 LTCHs

Data are lacking on the prevalence of therapeutic diets among patients in LTCHs. However, given the clinical complexity of these patients and the multiple comorbidities, it is likely that therapeutic diets are common. Assessing whether a patient requires a Therapeutic Diet would provide important information for care planning, clinical decision making, care transitions, and resource use in LTCHs.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Therapeutic 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 ↓
D. Therapeutic diet (e.g., low salt, diabetic, low cholesterol)	<input type="checkbox"/>

Current use

This Therapeutic Diet data element is currently collected in the MDS 3.0. It uses a 7-day look-back period to assess whether a patient received a therapeutic diet while a resident or before admission to the facility.

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).²¹⁹

²¹⁹ 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>

Section 5: Medical Conditions and Co-Morbidities

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 LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule, and 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.²²⁰ About 51 percent of nursing facility patients and residents are estimated to have moderate to severe hearing impairment.²²¹ 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.^{222 223}

²²⁰ 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.

²²¹ 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.

²²² 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).

²²³ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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 LTCHs

In LTCHs, 1.7 percent of patients have severe hearing impairment.²²⁴ Assessing LTCH patients' ability to hear is not only important for patient quality of life while hospitalized and post-discharge but also facilitates care planning for the inpatient stay as well as post-discharge care. Assessing Hearing in a patient would provide important information for communication, ensuring safety, care planning, care transitions, and resource use in LTCHs.

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)
<input type="checkbox"/>	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).²²⁵ In MDS 2.0 testing, the Hearing data element showed moderate to good reliability (0.575 – 0.88).²²⁶

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.²²⁷ In addition to conditions affecting the eye itself, visual deficits can also be caused by other conditions such as stroke and traumatic 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.”²²⁸

²²⁴ *Ibid.*

²²⁵ 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>.

²²⁶ *Ibid.*

²²⁷ 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.

²²⁸ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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 LTCHs

In LTCHs studied in the PAC PRD, 2.8 percent of patients had severe vision impairment.²²⁹ Assessing visual impairment in LTCHs is important for patient quality of life and care planning for eventual discharge from this setting. Additionally, assessment of this information is useful for ensuring safety in the LTCH setting, as impaired vision increases the risk of falls.^{230 231} Assessing Vision in a patient would provide important information for patient safety, communication, care planning, care transitions, and resource use in LTCHs.

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)
<input type="checkbox"/>	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 homes²³². 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 found substantial agreement for inter-rater reliability across settings for this data element (kappa of 0.74).²³³

²²⁹ *Ibid.*

²³⁰ 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.

²³¹ 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.

²³² 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>.

²³³ Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. 2012. 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.

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Appendix 1

Data Elements Used in Calculation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

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 <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3
Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4
Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device

(continued)

SNF		IRF		LTCH	
Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission	Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> unstageable pressure ulcers/injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1030, Number of Venous and Arterial Ulcers	Enter number <input type="text"/>	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention	Enter number <input type="text"/>	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention
Enter number <input type="text"/>	2. Number of <u>these</u> 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 <input type="text"/>	2. Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> 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		
<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Resident refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>	<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>	<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>
Bowel Continence		
<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent) 9. Not rated</p>	<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated</p>	<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated</p>
Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) or Diabetes		
<p>I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)</p> <p>0. Did not have PVD or PAD in the last 7 days 1. Had PVD or PAD in the last 7 days</p> <p>I2900 Diabetes Mellitus (DM)</p> <p>0. Did not have DM in the last 7 days 1. Had DM in the last 7 days</p>	<p>I0900. Peripheral Vascular Disease (PVD) /Peripheral Arterial Disease (PAD)</p> <p>0. Does not have PVD or PAD 1. Have PVD or PAD</p> <p>I2900 Diabetes Mellitus (DM)</p> <p>0. Does not have DM 1. Has DM</p>	<p>I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)</p> <p>0. Does not have PVD or PAD 1. Have PVD or PAD</p> <p>I2900. Diabetes Mellitus (DM)</p> <p>0. Does not have DM 1. Has DM</p>
Height and Weight (Low Body Mass Index)		
<p>K0200A (Height); and K0200B (Weight).</p>	<p>25A (Height); and 26A (Weight).</p>	<p>K0200A (Height); and K0200B (Weight).</p>

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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			
<i>A</i>	Number of Stage 1 pressure ulcers	X	X	X
<i>B1</i>	Number of Stage 2 pressure ulcers	X	X	X
<i>B2</i>	Number of these Stage 2 pressure ulcers that were present upon admission	X	X	X
<i>C1</i>	Number of Stage 3 pressure ulcers	X	X	X
<i>C2</i>	Number of these Stage 3 pressure ulcers that were present upon admission	X	X	X
<i>D1</i>	Number of Stage 4 pressure ulcers	X	X	X
<i>D2</i>	Number of these Stage 4 pressure ulcers that were present upon admission	X	X	X
<i>E1</i>	Number of unstageable pressure ulcers/injuries due to non-removable dressing/device	X	X	X
<i>E2</i>	Number of these unstageable pressure ulcers/injuries that were present upon admission	X	X	X
<i>F1</i>	Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar	X	X	X
<i>F2</i>	Number of these unstageable pressure ulcers that were present upon admission	X	X	X
<i>G1</i>	Number of unstageable pressure injuries presenting as deep tissue injury	X	X	X
<i>G2</i>	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.²³⁴ 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.²³⁵ 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.

²³⁴ 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>.

²³⁵ 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 results²³⁶:

- 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.²³⁷ 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.²³⁸ Testing of the proposed measure, including adding unstageable pressure ulcers to the quality measure, increased performance scores in all settings (with scores increasing by 0.1% in IRF settings and 1.7% in NH/SNF settings) and increased the

²³⁶ 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

²³⁷ 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

²³⁸ 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.

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.²³⁹

²³⁹ 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), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs). Contract No. HHSM-500-2013-13015I. Research Triangle Park, NC: RTI International.

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.