August 2014

Draft Specifications for the Functional Status Quality Measures for Long-Term Care Hospitals (Version 3)

Prepared for

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RTI INTERNATIONAL

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DRAFT SPECIFICATIONS FOR THE FUNCTIONAL STATUS QUALITY MEASURES FOR LONG-TERM CARE HOSPITALS (VERSION 3)

RTI International

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Function Definition:

The World Health Organization's International Classification of Functioning, Disability and Health (ICF) describes the term "function" as an umbrella term that encompasses all body structures and functions, activities, and participation in daily life.[1] Examples of functioning within the components of body structures and functions include swallowing and bladder and bowel continence. Examples of functioning within the area of activities include eating, bathing, and dressing; in the area of participation, examples include working and participating in recreational activities. As noted above, functioning is a broad term that covers various components and several levels (e.g., body, person, society).

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SECTION 1
BACKGROUND

This document describes draft specifications for two functional status quality measures for long-term care hospitals (LTCHs). This work builds on previous work, including the Development and Testing of the Continuity Assessment Record and Evaluation (CARE),[2,3] the Post-Acute Care Payment Reform Demonstration (PAC PRD),[4-8] and the Analysis of Crosscutting Medicare Functional Status Quality Metrics Using the Continuity Assessment Record and Evaluation.[9] A Technical Expert Panel (TEP) convened by RTI International was consulted during the development of these measure specifications during one in-person meeting and several conference calls.[10]

Patients in LTCHs are clinically complex and are sometimes referred to as chronically critically ill. In addition to having complex medical care needs for an extended period of time, LTCH patients often have limitations in functioning because of the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (e.g., ventilator use). These patients are therefore at high risk for functional deterioration that is both condition-related and iatrogenic.

In describing the importance of functional status, the National Committee on Vital and Health Statistics, Subcommittee on Health[11] noted,

> "Information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations, in other words, their functional status."

The first LTCH function quality measure is a process measure, and focuses on assessment of LTCH patients' functional status and incorporating functional status into the care plan. The second function quality measure is an outcome measure, and focuses on improvement in mobility function among LTCH patients requiring ventilator support.

The functional assessment items included in the two LTCH function quality measures are from the CARE Item Set, which was designed to standardize assessment of patients' status across acute and post-acute settings (PAC), including LTCHs, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and home health agencies (HHAs). The CARE Item Set was developed and tested as part of the PAC PRD. The functional status items (also known as data elements) on the CARE Item Set include daily activities that clinicians typically assess at the time of admission and/or discharge to determine patient needs, evaluate patient progress, and prepare patients and families for a transition to home or another setting.

The development of the CARE Item Set and a description and rationale for each item are described in a report titled *The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set*: *Final Report on the Development of the CARE Item Set: Volume 1 of 3*.[2] Results of the reliability and validity testing conducted as part of the PAC PRD found the functional status items to have acceptable reliability and validity in the acute and post-acute patient populations. A description of the testing methodology and results is available in

several reports, including Volumes 2 (*Final Report on Reliability Testing*)[8] and 3 (*Final Report on CARE Item Set and Current Assessment Comparisons*) of the series.[3] The reports are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html. A summary of the reliability and validity testing of the CARE functional status items is provided in **Appendix A** of this document.

SECTION 2
QUALITY MEASURES

2.1 Quality Measure: Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function

2.1.1 Quality Measure Description

This quality measure reports the percentage of LTCH patients with an admission and discharge functional assessment and a care plan that addresses function. Many LTCH patients have functional limitations and are at high risk for functional decline during the hospital stay; therefore, this measure addresses the assessment of functional status and inclusion of function in care plans.

This process measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items (also known as data elements) that assess specific areas of function (i.e., self-care, mobility, cognition, communication, and bladder continence). The self-care and mobility items are coded based on a 6-level rating scale (for the list of items and the rating scale, see ***Section 2.1.6, Items Included in the Quality Measure***). The Centers for Medicare & Medicaid Services (CMS) intends to revise the LTCH CARE Data Set to include these functional assessment items. For this quality measure, inclusion of function in the patient's care plan is determined based on whether a functional goal is recorded at admission for at least one of the standardized self-care or mobility function items using the 6-level rating scale.

This quality measure addresses the importance of 1) conducting a comprehensive functional assessment at the time of admission addressing self-care, mobility, cognition and communication skills, and bladder continence; 2) incorporating the admission functional assessment findings into the patients' care plan and setting discharge functional status goals; and 3) conducting a comprehensive functional assessment at the time of discharge addressing self-care, mobility, cognition, communication, and bladder continence. An increasing body of evidence has reported on the safety and feasibility of early mobilization and rehabilitation of critically ill but stable patients, with minimal adverse events and risk to the patient.[12-17] Early mobility and rehabilitation in these settings have been associated with improved patient outcomes.

2.1.2 Purpose/Rationale for Quality Measure

Limitations in functioning after critical illness are becoming increasingly prevalent as a result of improving critical care medicine and survival rates.[12] Short- and long-term adverse consequences among critically and chronically ill patients in LTCH and Intensive Care Unit (ICU) settings include severe weakness,[12,18-20] muscle atrophy,[16] connective-tissue shortening,[16] loss of bone mass,[19] increased risk for blood clots,[19] increased risk for pressure ulcers,[19] deconditioning,[14,16] deficits in self-care and ambulation,[12] functional impairment,[20] fatigue,[18] and cognitive impairment including profound and persistent deficits in memory, attention/concentration, and executive function,[18,21,22] and the inability to return to work 1 year after hospital discharge.[19,23] Cognitive impairment in survivors of critical illness has been associated with anxiety and depression, inability to return to work, and the inability of older

persons to return home.[21] In recent years, to mitigate these adverse consequences, traditional practices of bed rest and immobility have been challenged and early mobility and rehabilitation have been increasingly recognized as important to improve patients' long-term functional outcomes,[17,19,24] with recovery of function being described as both desirable and possible.[25] The lack of early mobility initiation in ICU settings has also been described as a strong predictor of adverse patient outcomes.[19]

The clinical practice guideline *Rehabilitation after Critical Illness*[18] from the National Institute for Health and Clinical Excellence (NICE) recommends performing timely clinical assessments to identify current rehabilitation needs for patients at risk of morbidity, to determine the patient's risk of developing physical and non-physical morbidity during the critical-care phase, to establish short- and medium-term rehabilitation goals based on the clinical assessment, to initiate an individualized structured rehabilitation program, and to perform a clinical reassessment before discharge.

The importance of standardized functional assessment in LTCH settings is also supported by the high prevalence of therapy services provided in this setting, and the need for care coordination for patients returning home and receiving follow-up care in the community, as well as for those patients receiving additional institutional healthcare services after discharge from an LTCH. A study[26] of 1,419 ventilator-dependent patients from 23 LTCHs reported that physical, occupational, and speech therapy were the most commonly provided services among a comprehensive list of 34 procedures, services, and treatments provided during the LTCH stay. The authors concluded that the very high frequency of physical (84.8%), occupational (81.5%), and speech (79.7%) therapy reflects use of the rehabilitative model of care adopted by many post-ICU weaning programs, which is important in restoration of function. This high utilization of therapy services supports the need for standardized functional assessment at admission in order to document functional status, identify the need for therapy, set functional status goals, and assist with discharge planning and care coordination.

Whether an LTCH patient is discharged home or to another care setting for continuing healthcare, the patient's functional status is an important aspect of a person's health status to document at the time of transition. The study[26] of 23 LTCHs also reported that 28.8% of patients were discharged directly home or to assisted living, further supporting the importance of functional assessment and early rehabilitation to facilitate discharge planning and home discharge when possible. In another study of 101 LTCH patients, discharge functional status scores significantly discriminated across five different discharge destinations, including home, IRF, SNF, nursing facility /hospice/expired, and short-stay acute-care hospital transfer,[27] highlighting the association of functional status with discharge setting.

An increasing body of evidence has reported on the safety and feasibility of early mobilization and rehabilitation of critically ill but stable patients in LTCH and ICU settings with minimal adverse events and risk to the patient.[12-17] Early mobility and rehabilitation in these settings have been associated with several improved patient outcomes, such as (1) improved strength[14,19,24] and functional status;[12,14,24] (2) earlier achievement of mobilization milestones, such as out of bed mobilization;[12,28] (3) improvement in mobility and self-care function scores from admission to discharge;[24,26] (4) greater incidence of return to functional baseline in mobility and self-care, greater unassisted walking and walking distances, and improved self-reported

physical function scores at hospital discharge compared with persons not participating in early mobility and rehabilitation;[12] (5) enhanced recovery of functional exercise capacity;[19] (6) improved self-perceived functional status;[19] (7) reduced physiological and cognitive complications;[19] and (8) improved cognitive function.[24] Early mobility and rehabilitation have also been associated with (1) reduced ICU and hospital length of stay;[12-14,19,23,24] (2) reduced incidence of delirium and improved patient awareness;[12,14] (3) increased ventilator-free days and improved weaning outcomes;[12,19,24] (4) greater incidence of discharge home directly after hospitalization compared with patients not receiving early mobilization;[15,23] and (5) reduced hospital readmission or death in the year after hospitalization.[12,24]

Mobility activities that are feasible to assess in LTCH and ICU settings include bed mobility, sitting at the edge of the bed, transferring from bed to chair, sitting in a chair, out-of-bed mobility; standing, and ambulation.[12,15,28,29] In a sample of 103 patients with respiratory failure undergoing 1,449 activity events in a respiratory ICU, more than one-half of the activity events were reported to be ambulation, and 40% of the activity events occurred in intubated, mechanically ventilated patients at the end of the respiratory ICU stay. Moreover, 69.4% of survivors ambulated more than 100 feet, 8.2% ambulated less than 100 feet, 15.3% could sit in a chair, 4.7% could sit on the edge of the bed, and 2.4% did not accomplished any of these activities.[29] Self-care items that are feasible to assess in LTCH and ICU settings include bathing, dressing, eating, grooming, and using the toilet.[14-16] In a study of 19 medical ICU patients who received physical and/or occupational therapy services, 48% participated in grooming activities and 46% participated in bathing activities.[16]

Short- and long-term cognitive impairments are very frequent complications of critical illness and negatively influence survivors' ability to function independently.[21,22,30] Delirium during hospitalization is highly prevalent in critically ill patients and has been associated with longer lengths of stay, increased duration of mechanical ventilation, and higher risk of death.[21] A longer duration of delirium has been associated with worse short- and long-term cognition and executive function.[21,30] Given these adverse consequences, the importance of early assessment of cognitive function, including possible delirium, and early initiation of cognitive rehabilitation in critical care settings is being increasingly recognized.[22,31] Also, given the positive effects of physical exercise on cognitive function in other populations, the potential positive influence of exercise on cognitive function in the critically ill population is being examined by researchers.[22]

2.1.3 Numerator

The numerator for this quality measure is the number of patients with all three of the following:

1. a valid numeric score indicating the patient's status, or a valid code indicating the activity did not occur or could not be assessed for each of the functional assessment items on the admission assessment;

   AND

2. a valid numeric score, which is a discharge goal indicating the patient's expected level of independence for at least one self-care or mobility item on the admission assessment;

AND

3. a valid numeric score indicating the patient's status, or a valid code indicating the activity did not occur or could not be assessed for each of the functional assessment items on the discharge assessment.

The functional assessment items on the admission and discharge assessment forms are listed in ***Section 2.1.6***.

2.1.4 Denominator

The denominator for this quality measure is the number of LTCH patients in the target population (see inclusion and exclusion criteria in ***Section 2.1.5, Target Population***).

2.1.5 Target Population

Inclusion Criteria

The population included in this measure is all LTCH patients, including patients of all ages.

Exclusion Criteria

The following three exclusion criteria apply to the collection of *discharge* functional status data:

1. Patients with incomplete stays because of a medical emergency: discharge functional status data are not required for these patients, because these data may be difficult to collect at the time of the medical emergency.
2. Patients who leave the LTCH against medical advice: discharge functional status data are not required because these patients may not participate in the assessment.
3. No discharge functional status data are required if a patient dies while in the LTCH.

2.1.6 Items Included in the Quality Measure

An important consideration when measuring functional status is that certain activities may not be relevant or feasible to assess for all patients in all types of settings. For example, dressing with street clothes may not occur on admission in LTCHs because patients are wearing hospital gowns because of their use of medical equipment and devices. Walking 10 feet may also be too challenging for these patients at the time of admission, but walking short distances may be goals for these patients by discharge. Therefore, clinicians may indicate that a functional activity did not occur because it was not safe or feasible for the patient to perform the activity.

The following functional status items were selected for inclusion in this measure. Item selection is based on published literature and discussion with the TEP members convened by RTI. The technical experts were asked to describe functional activities assessed in their own hospitals and hospitals that implement best practices.

Self-Care Items

Eating: The ability to use suitable utensils to bring food to the mouth and swallow food once the meal is presented on a table/tray. Includes modified food consistency.

Oral hygiene: The ability to use suitable items to clean teeth. [Dentures (if applicable): The ability to remove and replace dentures from and to the mouth, and manage equipment for soaking and rinsing them.]

Toileting hygiene: The ability to maintain perineal hygiene; ability to adjust clothes before and after using the toilet, commode, bedpan or urinal. If managing an ostomy, include wiping the opening but not managing equipment.

Wash upper body: The ability to wash, rinse, and dry the face, hands, chest, and arms while sitting in a chair or bed.

Mobility Items

Roll left and right: The ability to roll from lying on back to left and right side, and roll back to back.

Sit to lying: The ability to move from sitting on side of bed to lying flat on the bed.

Lying to sitting on side of bed: The ability to safely 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.

Sit to stand: The ability to safely come to a standing position from sitting in a chair or on the side of the bed.

Chair/bed-to-chair transfer: The ability to safely transfer to and from a chair (or wheelchair).

Toilet transfer: The ability to safely get on and off a toilet or commode.

For patients who are walking, complete the following items:

Walk 10 feet: Once standing, the ability to walk at least 10 feet (3 meters) in a room, corridor, or similar space.

Walk 50 feet with two turns: Once standing, the ability to walk 50 feet and make two turns.

Walk 150 feet: Once standing, the ability to walk at least 150 feet (45 meters) in a corridor or similar space.

For patients who use a wheelchair, complete the following items:

Wheel 50 feet with two turns: The ability to wheel 50 feet and make two turns once seated in wheelchair/scooter.

Indicate the type of wheelchair/scooter used.

0. Manual

1. Motorized wheelchair/scooter

Wheel 150 feet: Once seated, can wheel at least 150 feet (45 meters) in a corridor or similar space.

Indicate the type of wheelchair/scooter used.

0. Manual

1. Motorized wheelchair/scooter

Self-Care and Mobility Rating Scale: Codes and Code Definitions

6. **Independent**—Patient completes the activity by himself/herself with no assistance from a helper.
5. **Setup or clean-up assistance**—Helper SETS UP or CLEANS UP; patient completes activity. Helper assists only prior to or following the activity.
4. **Supervision or touching assistance**—Helper provides VERBAL CUES or TOUCHING/ STEADYING assistance as patient completes activity. Assistance may be provided throughout the activity or intermittently.
3. **Partial/moderate assistance**—Helper does LESS THAN HALF the effort of the activity. Helper lifts, holds, or supports patient's trunk or limbs, but provides less than half the effort.
2. **Substantial/maximal assistance**—Helper does MORE THAN HALF the effort of the activity. Helper lifts, holds or supports patient's trunk or limbs and provides more than half the effort.
1. **Dependent**—Helper does ALL of the effort. Patient does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the patient to complete the activity.

If activity was not attempted, code:

07. Patient refused

09. Not applicable

88. Not attempted due to **medical condition or safety concerns**

Cognitive Function

C1610. Signs and Symptoms of Delirium Confusion Assessment Method (CAM) Shortened Version Worksheet)		
		Enter Codes in Boxes
CODING: **0. No** 1. **Yes**	☐ ☐	**Acute Onset and Fluctuating Course** **A.** Is there evidence of an acute change in mental status from the patient's baseline? **B.** Did the (abnormal) behavior fluctuate during the day, that is tend to come and go or increase and decrease in severity?
	☐	**Inattention** **C.** Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?
	☐	**Disorganized Thinking** **D.** Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?
CODING: **0. No** **1. Yes**	☐ ☐	**Altered Level of Consciousness** **E.** Overall, how would you rate the patient's level of consciousness? **E1**. Alert (Normal) **E2.** Vigilant (hyperalert) or Lethargic (drowsy, easily aroused) or Stupor (difficult to arouse) or Coma (unarousable)

Adapted from: Inouye SK et al, Clarifying confusion: The Confusion Assessment Method. A new method for detection of delirium. Ann Intern Med. 1990; 113: 941-948. Confusion Assessment Method: Training Manual and Coding Guide, Copyright 2003, Hospital Elder Life Program, LLC. Not to be reproduced without permission.

Communication: Understanding and Expression

BB0700. Expression of Ideas and Wants (consider both verbal and non-verbal expression)

4. Expresses complex messages **without difficulty** and with speech that is clear and easy to understand
3. Exhibits some **difficulty** with expressing needs and ideas (e.g., some words or finishing thoughts) or speech is not clear
2. **Frequently** exhibits difficulty with expressing needs and ideas
1. **Rarely/never** expresses self or speech is very difficult to understand.

BB0800. Understanding Verbal Content (with hearing aid or device if used and excluding language barriers)

4. **Understands:** Clear comprehension without cues or repetitions
3. **Usually Understands:** Understands most conversations, but misses some part/intent of message. Requires cues at times to understand.
2. **Sometimes Understands:** Understands only basic conversations or simple, direct phrases. Frequently requires cues to understand.
1. **Rarely/Never Understands**

Bladder Continence

H0350. Bladder Continence—Select the one category that best describes the patient.

0. Always continent (no documented incontinence)

1. Stress incontinence only

2. Incontinent less than daily (e.g., only once or twice during the 3-day assessment period)

3. Incontinent daily (at least once a day)

4. Always incontinent

5. No urine/bowel output (e.g., renal failure)

9. Not applicable (e.g., indwelling catheter)

2.2 Quality Measure: LTCH Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support

2.2.1 Summary Description

This measure estimates the risk-adjusted change in mobility score between admission and discharge among LTCH patients requiring ventilator support at admission. The change in mobility score is calculated as the difference between the discharge mobility score and the admission mobility score.

2.2.2 Purpose/Rationale for Quality Measure

Limitations in functioning after critical illness are becoming increasingly prevalent as a result of improving critical care medicine and survival rates.[12] Short- and long-term adverse consequences among critically ill and chronically critically ill patients in LTCH and ICU settings include severe weakness;[12,19,14,18,20] muscle atrophy;[16] connective-tissue shortening;[16] loss of bone mass;[19] increased risk for blood clots;[19] increased risk for skin and pressure ulcers;[19] deconditioning;[14,16] deficits in self-care and ambulation;[12] functional impairment;[20] fatigue;[18] cognitive impairment, including profound and persistent deficits in memory, attention/concentration, and executive function;[18,21,22] and inability to return to work 1 year after hospital discharge.[19,23]

To mitigate these adverse consequences, traditional practices of bed rest and immobility have been challenged in recent years, and early mobility and rehabilitation have been increasingly recognized as important to improve patients' long-term functional outcomes,[17,19,24] with recovery of function being described as both desirable and possible.[25] Functional improvement is particularly relevant for patients who require ventilator support because these patients traditionally have limited or no mobility because of cardiovascular and pulmonary instability, delirium, sedation, lack of rehabilitation therapy staff, and lack of physician referral.[16]

An increasing body of evidence has reported on the safety and feasibility of early mobilization and rehabilitation of critically ill, but stable, patients in LTCH and ICU settings, with minimal adverse events and risk to the patient.[12-17] Early mobility and rehabilitation in these settings have been associated with several improved patient outcomes. Reported benefits of early mobility and rehabilitation include (1) improved strength[14,19,24] and functional status;[12,14,24] (2) earlier achievement of mobilization milestones, such as out of bed mobilization;[12,28] (3) improvement in mobility and self-care function scores from admission to discharge;[24,26] (4) greater incidence of return to functional baseline in mobility and self-care, greater unassisted walking and walking distances, and improved self-reported physical function scores at hospital discharge compared with persons not participating in early mobility and rehabilitation;[12] (5) enhanced recovery of functional exercise capacity;[19] (6) improved self-perceived functional status;[19] (7) reduced physiological and cognitive complications;[19] and (8) improved cognitive function.[24] Early mobility and rehabilitation have also been associated with reduced ICU and hospital length of stay;[12-14,19,23,24] reduced incidence of delirium and improved patient awareness;[12,14] increased ventilator-free days and improved weaning outcomes;[12,19,24] greater incidence of discharge home directly after hospitalization compared with patients not receiving early mobilization;[15,23] and reduced hospital readmission or death in the year after hospitalization.[12,24]

Several studies have examined functional improvement among patients in the long-term care setting. In a sample of 101 patients in LTCH (three-quarters were ventilator-dependent), median functional status scores using the Functional Status Score for the ICU (FSS-ICU; rolling, supine-to-sit transfers, unsupported sitting, sit-to-stand transfers, and ambulation) improved significantly from admission to discharge, with significant change in all five functional items. Physical therapy interventions focused on early mobilization and consisted of functional tasks, therapeutic exercise, and balance activities that varied according to each patient's individual impairments and limitations. Occupational therapy interventions primarily included cognitive assessment and retraining, activities of daily living-related training, and group therapy sessions for social, behavioral, and physical interventions. Discharge functional status scores were significantly different across five different discharge destinations (i.e., home, IRF, SNF, nursing facility/hospice/expired, and short-stay acute care hospital transfer), highlighting the association of functional status with discharge disposition. A small effect size (0.25) for rehabilitation (physical therapy and occupational therapy) was noted for the entire LTCH sample, and large effect sizes (0.80–0.91) were noted for patients discharged to home, IRF, or SNF.[27]

In a sample of 103 patients with respiratory failure undergoing 1,449 activity events in a respiratory ICU, more than one-half of the activity events were reported to be ambulation, and 40% occurred in intubated, mechanically ventilated patients. At the end of the respiratory ICU stay, 69.4% of survivors ambulated more than 100 feet, 8.2% ambulated less than 100 feet,

15.3% could sit in a chair, 4.7% could sit on the edge of the bed, and 2.4% did not accomplish any of these activities.[29]

The importance of monitoring improvement in mobility skills among LTCH patients who require ventilator support at the time of admission is also supported by the high prevalence of therapy service provision as part of the treatment plan and the percentage of patients discharged home after an LTCH stay. In a study of 1,419 ventilator-dependent patients from 23 LTCHs with weaning programs,[26] physical therapy, occupational therapy, and speech therapy were the three most commonly provided services among 34 procedures, services, and treatments provided during the LTCH admission. The very high frequency of physical (84.8%), occupational (81.5%), and speech (79.7%) therapy reflects use of the rehabilitative model of care adopted by many post-ICU weaning programs, which is important in restoration of function. Improvement in functional status, including mobility and self-care, was noted from admission to discharge. Nearly 30% of all patients discharged alive returned directly home or to assisted living.[26]

2.2.3 Population

Inclusion

The population for this quality measure is LTCH patients requiring ventilator support at the time of admission to the LTCH.

Exclusions

The following exclusion criteria apply to this quality measure:

1. Patients with incomplete stays: It can be challenging to gather accurate discharge functional status data for patients who experience incomplete stays. Patients with incomplete stays include patients who are unexpectedly discharged to an acute-care setting (Inpatient Prospective Payment System or Inpatient Psychiatric Hospital) because of a medical emergency or psychiatric condition; patients transferred to another LTCH facility; patients who leave the LTCH against medical advice; patients who die; and patients with a length of stay less than 3 days.
2. Patients discharged to hospice are excluded because functional improvement may not be a goal for these patients.
3. Patients with progressive neurological conditions, including amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, and Huntington's chorea are excluded because these patients may have functional decline or less predictable function trajectories.
4. Patients in coma, persistent vegetative state, complete tetraplegia, and locked-in syndrome are excluded, because they may have limited or less predictable mobility recovery.
5. Patients younger than age 21.
6. Patients who are coded as independent on all the CARE mobility items at admission are excluded because no improvement in mobility skills can be measured with the mobility items used in this quality measure.

2.2.4 Items for Quality Measure Calculation

For this quality measure, the following mobility items are collected at admission and discharge.

Mobility Items

Roll left and right: The ability to roll from lying on back to left and right side, and roll back to back.
Sit to lying: The ability to move from sitting on side of bed to lying flat on the bed.
Lying to sitting on side of bed: The ability to safely move from lying on the back to sitting on the side of the bed with feet flat on the floor, no back support.
Sit to stand: The ability to safely come to a standing position from sitting in a chair or on the side of the bed.
Chair/bed-to-chair transfer: The ability to safely transfer to and from a chair (or wheelchair).
Toilet transfer: The ability to safely get on and off a toilet or commode.
Walk 50 feet with two turns: Once standing, the ability to walk 50 feet and make two turns.
Walk 150 feet: Once standing, the ability to walk at least 150 feet (45 meters) in a corridor or similar space.

Mobility Rating Scale: Codes and Code Definitions

6. **Independent**—Patient completes the activity by himself/herself with no assistance from a helper.
5. **Setup or clean-up assistance**—Helper SETS UP or CLEANS UP; patient completes activity. Helper assists only prior to or following the activity.
4. **Supervision or touching assistance**—Helper provides VERBAL CUES or TOUCHING/ STEADYING assistance as patient completes activity. Assistance may be provided throughout the activity or intermittently.
3. **Partial/moderate assistance**—Helper does LESS THAN HALF the effort. Helper lifts, holds or supports patient's trunk or limbs, but provides less than half the effort.
2. **Substantial/maximal assistance**—Helper does MORE THAN HALF the effort. Helper lifts or holds patient's trunk or limbs and provides more than half the effort.
1. **Dependent**—Helper does ALL of the effort. Patient does none of the effort to complete the task. Or, the assistance of 2 or more helpers is required for the patient to complete the activity.

If activity was not attempted, code one of the following:

07. Patient refused

09. Not applicable

88. Not attempted due to **medical condition or safety concerns**

2.2.5 Quality Measure Calculation

The following steps are used to calculate the measure:

1. Sum the scores of the admission mobility items to create an admission mobility score for each patient after 'activity did not occur' values are recoded.
2. Sum the scores of the discharge mobility items to create a discharge mobility score for each patient after 'activity did not occur' values are recoded.
3. Calculate the difference between the admission mobility score and the discharge mobility score for each patient to create a change in mobility score for each patient.
4. Calculate an expected change in mobility score for each patient using regression coefficients from national data and each patient's admission characteristics (risk adjustors).
5. Calculate an average change in mobility score for each LTCH. This is the facility-level observed change in mobility score.
6. Calculate an average expected change in mobility score for each LTCH. This is the facility-level expected change in mobility score.
7. Divide the facility-level observed change score by the facility-level expected change score to create an observed to expected ratio. A ratio value that is 1 indicates the observed and expected scores are equal. A ratio value that is higher than 1 indicates that the observed change scores are higher (better) than expected. A ratio value that is less than 1 indicates that the observed change scores less (worse) than expected.
8. Multiply each LTCH ratio by the national average change in mobility score.

2.2.6 Risk Adjustment and Statistical Methods

Functional improvement varies based on patients' demographic characteristics and medical conditions. Risk adjustment methods control for specific patient characteristics and conditions (e.g., age or diagnosis) that may influence outcomes so that data can be compared across facilities. An initial, extensive set of risk adjustment variables were selected for this quality measure based on a review of literature and empirical findings from the PAC PRD analyses[7] as well as input from the TEP convened by RTI.[10] Using this initial set of risk adjustment variables, we have been conducting regression analyses using the PAC PRD data to help identify the best set of risk adjustors based on regression coefficients, statistical significance, sample sizes, and other indicators. We also requested input on suggested risk adjustors as part of the public comment process and are incorporating suggestions we received as we refine our risk adjustment models. Data on reliability of CARE variables used for risk adjustment can be found in the report titled *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing: Volume 2 of 3.*[3]

The current list of risk adjustment variables is outlined below, and will be updated, as appropriate, based on further analyses. CMS intends to revise the LTCH CARE Data Set to include the following risk adjustment items:

- **Age**
  - Younger than 55 years
  - 55 to less than 65 years
  - 65 to less than 75 years
  - 75 to less than 85 years
  - 85 years and older (reference category)
- **Medical diagnosis**
  - Chronic respiratory condition
  - Acute onset respiratory condition (reference category)
  - Acute onset and chronic respiratory conditions
  - Chronic cardiac condition
  - Other medical condition
- **Prior functioning: indoor ambulation (before current illness, exacerbation, or injury)**
  - Dependent
  - Some help
  - Independent (reference category)
- **Major treatments during assessment period**
  - Total parenteral nutrition
- **Communication: Understanding Verbal Content, *and* Expression of Ideas and Wants**
  - Moderate to severe communication limitations: Rarely/never understands, or sometimes understands, or rarely/never expresses self or speech is very difficult to understand, or frequently exhibits difficulty with expression
  - Mild to no communication limitations: Usually understands or understands, or some difficulty with expression, or expression without difficulty (reference category)
- **Admission mobility function score**
- **Comorbidities (hierarchical condition categories)**, e.g., chronic kidney disease or dialysis; acute renal failure; septicemia or other severe infections; metastatic, lung, colorectal, bladder or other severe cancers; diabetes; paraplegia; stroke or hemiplegia and other spinal cord injury; protein calorie malnutrition; dementia; limb amputation)

- **Use of a wheelchair or scooter prior to current illness, exacerbation, or injury**
  - Yes
  - No (reference category)
- **Use of a mechanical lift prior to current illness, exacerbation, or injury**
  - Yes
  - No (reference category)

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APPENDIX A:
RELIABILITY AND VALIDITY TESTING

A.1 Overview of Reliability and Validity Testing

The functional assessment items used in the two long-term care hospitals (LTCHs) functional status quality measures are from the Continuity Assessment Record and Evaluation (CARE) Item Set. The CARE Item Set was designed to standardize assessment of patients' status across acute and post-acute settings, including inpatient rehabilitation facilities (IRFs), LTCHs, skilled nursing facilities (SNFs), and home health agencies (HHAs). The functional status items on the CARE Item Set are daily activities that clinicians assess at the time of admission and/or at discharge to determine patients' needs, evaluate progress, and prepare for a transition home or another setting.

The goal of reliability testing is to ensure that items on an assessment obtain consistent results when administered or used by different clinicians. Validity testing examines whether an item or scale measures what it is intended to measure. The CARE functional status items underwent reliability testing at the item- and scale-level in multiple types of providers in conjunction with the Post-Acute Care Payment Reform Demonstration. Item-level testing included inter-rater reliability testing within facilities and the use of videotaped standardized patients for inter-rater reliability testing across facilities/care settings. Additional testing focused on the items and scales and included internal consistency, factor analysis, and Rasch analysis. A brief summary of this testing is provided below; full reports describing the testing are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

A.2 Traditional Inter-rater Reliability Study

The reliability of the functional items was tested in a subset of 34 providers from each of the five levels of care (acute hospitals, HHAs, IRFs, LTCHs, and SNFs) distributed across 11 geographic areas. Each provider completed a duplicate CARE Item Set (admission or discharge assessment) on 15–20 patients included in the Post-Acute Care Payment Reform Demonstration (10–15 patients in the home health setting), in accordance with the guidelines and protocols.

Providers were asked to enroll a convenience sample of a set number of Medicare patients each month, representing a range of function and acuity. The overall patient sample size for each of the functional items was 450 for self-care items and 449 for mobility items (448 for transfers). After exclusions for missing data (unknown/not attempted/inapplicable), the effective sample sizes for the reliability testing were as follows:

- Eating: 401
- Oral hygiene: 414
- Toilet hygiene: 416
- Upper body dressing: 420
- Lower body dressing: 413
- Lying to sitting on the side of the bed: 412

- Sitting to standing: 387
- Chair/bed to chair transfer: 392
- Toilet transfer: 361
- Walk 150 feet: 68
- Walk once standing: 52
- Wheel in room: 46

The inter-rater reliability study included patients who were assessed by two different clinicians (raters), and the agreement of the clinicians' rating was calculated. Clinicians were instructed to have pairs of raters complete both patient assessments at the same time. Responses to items were obtained by direct observation of the patient by the clinician, and occasionally, supplemented by one or more of the following predetermined, matched methods: patient interviews (with each team member taking turns conducting and observing patient interviews); interviews with relatives/caregivers of the patient for certain items; and/or interviews with staff caring for the patient and/or chart review. Rater pairs were instructed to determine in advance which methods would be used to score the particular CARE items and to have both raters use the same methods. Raters were encouraged to divide hands-on assistance to the patient as evenly as possible for items that required hands-on assistance. Raters were instructed not to discuss item scoring during the assessment, nor to share item scores until the data were entered into the study database and finalized. Providers submitted data via the online CARE application for both assessments in each pair.

For categorical items, kappa statistics (kappa) indicate the level of agreement between raters using ordinal data, taking into account the role of chance agreement. The ranges commonly used to judge reliability based on kappa are as follows: ≤ 0 = poor; 0.01–0.20 = slight; 0.21–0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = substantial; and 0.81–1.00 = almost perfect.

For categorical items with only two responses available, RTI International calculated only unweighted kappas. For items with more than two responses, RTI calculated both weighted and unweighted kappas. Unweighted kappa assumes the same "distance" between every one-unit difference in response across an ordinal scale. RTI used Fleiss-Cohen weights, or quadratic weights, which approximate the intra-class correlation coefficient and are commonly used for calculating weighted kappas. This choice of weighting is consistent with prior analyses of assessment reliability, where the method for developing weights was specified.[1,2] Fleiss-Cohen weights put lower emphasis on disagreements between responses that fall near each other on an item scale. It should also be noted that the value of kappa can be influenced by the prevalence of the outcome or characteristic being measured. If the outcome or characteristic is rare, the kappa will be low because kappa attributes the majority of agreement among raters to chance. Kappa is also influenced by bias, and if the effective sample size is small, variation may play a role in the results. Hence, we report both weighted and unweighted kappas to give the range of agreement found under the two sets of assumptions.

Additionally, RTI calculated a separate set of kappa statistics (unweighted and weighted, where applicable) for items where additional responses outside of an ordinal scale were available (letter codes) and were set to missing.

For the traditional reliability study, kappa statistics indicated substantial agreement among raters. The weighted kappa values for the self-care items range between 0.798 for eating to 0.869 for upper-body dressing. Unweighted kappas ranged from 0.598 for oral hygiene to 0.634 for upper-body dressing. Provider-specific analyses of core self-care items show similar agreement to the overall estimates. The lower-body dressing item had the highest overall weighted kappa (0.855), whereas the eating item had the lowest (0.798). Unweighted overall kappas ranged from 0.636 (toileting) to 0.598 (oral hygiene). Acute hospitals had the highest weighted kappas across all self-care items.

The weighted kappa values for the mobility items ranged between 0.558 for walk 150 feet to 0.901 for sitting to standing and chair/bed to chair transfer. Unweighted kappas ranged from 0.667 for walk once standing to 0.762 for sit to stand. Provider-specific analyses of core mobility items show similar agreement to the overall estimates. The sit-to-stand and chair transfer items both had a weighted kappa of 0.901, whereas the lying to sitting item had a weighted kappa of 0.855. Unweighted overall kappas ranged from 0.693 (lying to sitting) to 0.762 (sitting to standing).

A.3 Videotaped Standardized Patients Reliability Study

For the video reliability study, which was designed to examine the level of clinician agreement across care settings, clinicians in each setting were asked to assess "standardized" patients presented through a videotape of a patient assessment. This ensured that the same information was presented to each clinician and allowed examination of differences in scoring effects among different clinicians examining the "same" patient.

The patient "case studies" in each of the videos varied in terms of medical complexity, functional abilities, and cognitive impairments. The nine videos included patients classified as high, medium, or low ability/complexity for each of these three areas. Each facility or agency received three videos, one of which demonstrated one of the following elements: cognitive impairments, skin integrity problems, a wheelchair-dependent patient, and a variety of mid-level functional activities. The mid-level functional activities were considered to be the most challenging for clinicians to score and are thus of particular interest in establishing reliability. Each clinician involved in the video study watched three videos and assessed the patients according to the study guidelines and protocols. Each video was approximately 20 minutes long and had a corresponding item set arranged in the sequence in which the items appeared in the video.

The sample included 28 providers (550 assessments), which included 3 acute hospitals (15 assessments [3%]); 9 HHAs (118 assessments [22%]); 8 IRFs (237 assessments [43%]); 3 LTCHs (114 assessments [21%]); and 5 SNFs (66 assessments [12%]). Participating providers included case managers (6% of assessments), occupational therapists (14% of assessments), physical therapists (21% of assessments), registered nurses (47% of assessments), speech therapists (5% of assessments), and others, mostly licensed practical nurses (LPNs; 8% of assessments).

Two main analytic approaches were used for assessing the video reliability of the CARE items, adhering closely to the methods used by Fricke et al.[3] in their video reliability study of the

FIM® instrument.[3] First, percent agreement with the mode response was calculated for each CARE item included in at least one of the nine videos. Unlike the approach used by Fricke et al., RTI did not consider agreement at one response level above and below the mode, and instead used a stricter approach looking at direct modal agreement only. In the second approach, percent agreement with the internal clinical team's consensus response was also calculated. This second measure not only gives an indication of item reliability, but also reflects training consistency for the providers.

The video reliability study indicated substantial agreement with the mode and clinical team among all items, typically upwards of 70%. The notable exception to this trend exists among the clinicians in the "Other" category (mostly LPNs); they consistently had the lowest levels of agreement among all core self-care items, ranging from 50 to 72%. For the toileting and dressing items, the agreement with the clinical team was lower than with the mode. This occurred because the clinical team response differed from the mode for these three items in either one or two videos. Nonetheless, because the clinical team response and mode were identical on most of the videos, agreement was still quite high for these items. In general, study clinicians had responses on average that agreed with the expert clinical team or were slightly lower.

The video reliability study indicated substantial agreement with the mode and clinical team for the lying-to-sitting, sit-to-stand, chair/bed to chair transfer, and toilet transfer items (greater than 76%). Although rates of agreement with the mode and clinical team response were generally identical, for the toilet transfer item, the clinical team agreement is slightly lower. The items for walking and wheeling distances showed more variable levels of agreement across disciplines, with overall agreement generally in the moderate range (50–78%). For the Walk In Room item, there was a notable decrease in the agreement with the clinical team compared to agreement with the mode. This occurred because in two of the four videos where this item was assessed, the clinical team response differed from the mode.

A.4 Scale-level Reliability Results: Internal Consistency

In addition to item-level reliability testing, we examined internal consistency, which provides a general assessment of how well the items interrelate within a domain or subscale. Internal consistency is assessed using the Cronbach's alpha coefficient, which is the average correlation of all possible half-scale divisions. Cronbach's alpha is a statistic frequently assessed when instrument or scale psychometrics are published. The Cronbach's alpha reliability estimate ranges from zero to one, with an estimate of zero indicating that there is no consistency of measurement among the items, and one indicating perfect consistency. Many cutoff criteria exist to determine whether or not a scale shows good consistency or whether the items "hang together" well. General consensus is that Cronbach's alpha should be at least 0.70 for an adequate scale for group-level decisions, and alphas closer to 1 indicate a good scale.[4]

Assessments of individual self-care and mobility subscales at both admission and discharge tend to show good reliability statistics (Cronbach's Alpha of at least 0.80) within their specified subscales. Reliability estimates by provider type show that the functional status items maintain a very high internal consistency. In addition, no one provider type appears to have

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reliability estimates higher or lower than the rest, indicating similarity of CARE usage with respect to internal consistency.

The following table shows the findings from the Cronbach's alpha internal consistency evaluation mentioned above.

Table A-1
CARE functional status internal consistency reliability summary by provider type

CARE analytic set	Overall alpha	HHA alpha	SNF alpha	IRF alpha	LTCH alpha
Self-Care	0.96	0.94	0.95	0.95	0.96
Mobility	0.96	0.94	0.95	0.96	0.97

A.5 Scale-level Reliability and Validity Testing: Rasch Analysis

Because we are measuring a latent trait—a concept that is not measured directly, but that relies on activities that can be directly observed—we used the one-parameter Rasch model to gain a better understanding of the functional status activities. More specifically, we examined the order of functional status items (from least challenging to most challenging) that characterize the concepts of the self-care and mobility.

Rasch analysis uses the scores from the functional assessment items to create the equivalent of a functional status "ruler" (i.e., scale). Rasch analysis uses the available data to estimate a person's location along the "ruler;" therefore, analyses can be conducted if some data are missing. Rasch analysis can also inform the optimal selection of key items in order to construct functional status scales that sufficiently span an entire range of patient functioning, so that both the least able and most able (lowest- and highest-functioning) patients are adequately measured. In addition, Rasch analysis can indicate where items overlap or are redundant in terms of the level of function they capture.

Rasch analysis has been used to examine the FIM® instrument,[5-8] the Minimum Data Set (MDS),[9] and the Outcome and Assessment Information Set (OASIS).[10] Rasch analysis has also been used to examine the extent to which existing functional assessment instruments (e.g., the FIM® instrument, MDS 2.0) capture the same construct.[11]

Rasch measurement is based on a probabilistic model that describes the association between a person's underlying ability level and probability of a particular item response, and summarizes a patient's position along a "ruler" that represents a latent trait or concept (e.g., self-care or mobility).[12] In essence, the Rasch analysis creates a ruler based on the domain measured (e.g., mobility) that can be used to assess the abilities of the patients. The analysis also provides information on the hierarchy of item difficulty (from easy to hard) that can be used to evaluate the construct validity of a set of items. In addition, the Rasch analysis provides information about the level of challenge associated with each item rating scale ("dependent" through "independent"). For example, an item with a low difficulty estimate (e.g., eating) would be more

likely to be completed with little or no help by patients items that are more challenging (e.g., 12 steps), where most patients would find completing this activity challenging. Finally, the Rasch analysis can provide information on items that do not fit into the single theorized concept through "item misfit" statistics, which may indicate that the item needs further evaluation before it is included on future administrations of the subscale. The infit mean square is an indicator of the degree to which patient responses are similar to what would be expected (i.e., predicted) by the measurement model. The acceptable range is generally 0.6 to 1.4. If the item values are above this range, it reflects that person response patterns are erratic, generally suggesting that the item is not measuring the same construct as other items. Infit mean squares above 1.4 are considered to be unacceptably unexpected[13] and indicate that the item most likely does not reflect the same construct as the other items included in the scale; for example, a need for assistance with self-care.

RTI used Rasch analysis to examine the extent to which the items worked together to define a coherent concept. This was conducted separately for the self-care and mobility items. Item fit statistics were examined as an indication of how well all items work together to describe the overall construct (self-care or mobility). The Rasch analysis provides insight into how the items work together as a subscale, including the hierarchy of item difficulty (ordering from easy to difficult) and item fit to the model.

Examinations of these Rasch analysis results reveal that the mobility and self-care item hierarchies make sense clinically and that the operational definitions of the constructs maintain general stability from admission to discharge. Some items have fit statistics outside the acceptable range (e.g., pick up object from floor), but the Technical Expert Panel members notes that this is an important assessment given the risk of falls.

RTI examined how well the items selected measure the persons in the data set for both self-care and mobility items. RTI examined the extent to which person response patterns fit the assumptions of the measurement model using the same range of infit statistics identified above. RTI examined the extent to which persons are effectively measured (ceiling and floor effects) in each setting overall and for admission and discharge time points. The mobility and self-care items were found to be well targeted to the range of patient ability sampled within this post-acute care population.

RTI established that the six steps of the CARE rating scale are operating as intended, both overall and for individual items on the self-care and mobility subscales. The probability that a person will be scored on a particular rating scale step varies depending on the functional ability of the person. That is, very able people will be more likely to be scored as "5" and "6" than as "1" and "2." Looking empirically at these distributions, we should see the transitions from one step to the next (called thresholds) proceed monotonically and distinctly across the range of person abilities. In other words, there should always be some point along the range at which each rating-scale step is more probable than another step. When a rating-scale step is not more probable at any point, it suggests that raters are not able to use that step to consistently distinguish patient ability at that level.

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