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Ventilator Weaning (Liberation) Quality Measures Pilot Test for Long-Term Care Hospitals

A Summary of Findings

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RTI INTERNATIONAL

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EXECUTIVE SUMMARY

In accordance with Section 3004(a) of The Patient Protection and Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International to develop and pilot test potential quality measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program, including two new quality measures (one process measure and one outcome measure) related to the care of patients treated with mechanical ventilation. 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. The aim of these two quality measures, titled *Compliance with Spontaneous Breathing Trial (SBT) (Including Tracheostomy Collar Trial [TCT] or Continuous Positive Airway Pressure [CPAP] Breathing Trial) by Day 2 of LTCH Stay*, and *Ventilator Weaning (Liberation) Rate*, is to encourage adherence to weaning protocols and to reduce the negative impact of unnecessarily prolonged mechanical ventilation.

For these quality measures, Day 2 is defined as the day following admission to the LTCH. Patients who are considered fully weaned at discharge are those who did not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to discharge. The first measure informs whether the LTCH facility assessed patients admitted on invasive mechanical ventilation for readiness to wean in a timely manner, and whether patients who were sufficiently stable for weaning received a breathing trial. The second measure assesses the discharge liberation rate of patients who were admitted on invasive mechanical ventilation with the expectation or anticipation of weaning attempts during their stay.

CMS, with our measure contractor RTI, conducted a pilot test on the items used to calculate these draft measures. The pilot test was conducted in 10 LTCH facilities and used a mixed methods research design to collect data. Quantitative data on the ventilator weaning items was collected from May 27, 2016 through September 10, 2016, and qualitative data on these items was collected from June 6, 2016 through October 4, 2016.

The LTCHs who participated in the pilot test were selected to represent variation across several key facility-level characteristics: geographic location, size, and profit status. Each facility selected at least one data collector to complete pilot data collection forms, including ventilator liberation (weaning) items and other relevant information. The pilot sites participated in a pilot training conference call before pilot testing. Pilot participants from each facility also participated in multiple calls during data collection and one conference call at the conclusion of data collection. These calls were used to obtain qualitative information related to the ventilator weaning data collection process and item validity.

Key findings and conclusions from the RTI analyses included the following:

1. Different LTCHs use different methods for calculating self-reported facility-level liberation rates.
2. Data collection for the ventilator weaning (liberation) quality measures was feasible and not seen as burdensome by pilot sites.
3. Pilot participants were confident that the data they captured using the draft ventilator weaning items were valid, reliable, and adequately represented measure concepts.
4. Analyses of quantitative and qualitative data indicate the need for further clarification of item definitions and response options.

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SECTION 1
PILOT OVERVIEW

1.1 Legislative Authority and Purpose

The Long-Term Care Hospital (LTCH) Ventilator Weaning (Liberation) Quality Measures pilot test is part of the national effort mandated by The Patient Protection and Affordable Care Act to develop a quality reporting program for LTCHs. In accordance with Section 3004(a) of the Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International to develop and pilot test potential quality measures for the LTCH Quality Reporting Program, including two new quality measures (one process measure and one outcome measure) related to the care of patients treated with mechanical ventilation. Patients on invasive mechanical ventilation comprise a substantial proportion of LTCH patient admissions, and invasive mechanical ventilation care compliance was identified as a gap in the LTCH Quality Reporting Program measure set. The purpose of these measures, reducing the negative impact of unnecessarily prolonged mechanical ventilation, also aligns with the National Quality Setting Priority and the CMS Quality Strategy Goal of "making care safer by reducing the harm caused in the delivery of care."

During this pilot test, draft admission and discharge item sets for two ventilator weaning (liberation) quality measures were implemented in 10 LTCH pilot sites to test for feasibility and face validity. Pilot test site participants provided direct feedback to the research team on the utility and limitations of the data elements being tested, and about their experiences with the data collection and reporting processes.

RTI will use the findings from the pilot test to inform revisions to the quality measure specifications, the data elements, and the data collection process for each quality measure included in the pilot test.

1.2 Pilot Objective

The focus of the pilot test was to inform measure development, address issues raised by the technical expert panel (TEP) and public comments, and evaluate the feasibility of patient-level data collection and submission.

Quantitative and qualitative analyses of admission and discharge item sets included analysis of the data entry errors and outliers, the face validity of the measures, and the feasibility and burden of implementing the new data elements. The specific goals of the pilot were as follows:

1. **Capture provider experience.** Provider feedback was obtained through check-in calls during the data collection period and a final semi-structured debriefing call following the end of data collection. During these calls, RTI collected information about the providers' experience regarding integration of patient-level data collection into routine care processes for the ventilator weaning (liberation) quality measures.

2. **Refine the item set.** The item set for this pilot test was specifically developed to collect the necessary data elements for calculation of the process and outcome quality measures listed in Section 1.3.

3. **Assess provider burden.** Information on provider burden was obtained through time-estimate questions on the data submission forms, check-in calls, and a semi-structured debriefing interview.

4. **Respond to questions raised by the TEP.** In addition to the goals above, check-in and debriefing call discussion topics as well as analysis of patient-level data were designed to provide insight into questions raised by TEP member concerns. These issues included whether "undetermined" is needed as a category of weaning status on admission; the importance and impact of adding "partially weaned" categories as options for the outcome measure numerator; the importance and impact of including weaned patients who die in the numerator of the outcome measure; and characterization of the excluded patient population.

1.3 Ventilator Weaning (Liberation) Measures Overview

The two ventilator weaning (liberation) quality measures include one process measure and one outcome measure.

The process measure, *Compliance with Spontaneous Breathing Trial (SBT) (Including Tracheostomy Collar Trial [TCT] or Continuous Positive Airway Pressure [CPAP] Breathing Trial) by Day 2 of LTCH Stay,* assesses facility-level compliance with assessment for SBT. This measure is reported for patients on invasive mechanical ventilation support upon LTCH admission for whom weaning attempts were expected or anticipated at admission. This measure is calculated and reported for the following two components:

1. Percentage of patients assessed for SBT by Day 2 of LTCH stay, and

2. Percentage of patients ready for SBT who received SBT by Day 2 of LTCH stay.

The outcome measure, *Ventilator Weaning (Liberation) Rate,* reports the facility-level ventilator weaning (liberation) rate for patients on invasive mechanical ventilation support upon admission to the LTCH, for whom weaning attempts were expected or anticipated as reported on the admission assessment.

Patients who are considered non-weaning at admission are excluded from both measures.

1.4 Summary of Pilot Activities

1.4.1 Pilot Site Selection and Recruitment

Pilot Site Selection: To obtain a convenience sample of LTCHs that varied by hospital characteristics, including bed size, occupancy (i.e., average daily census), geographic region, and ownership type, RTI compiled a preliminary list of potential pilot testing sites based on analyses of the LTCH Prospective Payment System (PPS) Historical Impact files

(http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Historical-Impact-Files.html). These files also contain data pertaining to LTCH length of stay, case-mix, and urban/rural setting. RTI also used Medicare and Medicaid claims data to estimate the annual number of patients at each LTCH who were ventilated at any point during their stay. Because the analytic goals of the pilot test did not include a risk model assessment or calculation of quality measure variance, a large sample size was not required. On the basis of the size and projected number of ventilated patients, RTI anticipated that recruitment of 9 or 10 sites would provide a sufficient number of patients for analysis of the feasibility of data collection and face validity of the quality measures.

RTI compiled an initial list of 10 selected pilot sites and 10 comparable alternate sites. In addition to the hospital characteristic criteria, low staff turnover, available staff for data collection, and the presence of a "quality champion" were considered important criteria for pilot testing success. The lists of selected and alternate sites were submitted to TEP members for their feedback. TEP members were asked to respond to the recommendations and suggest additional alternative sites on the basis of the key criteria.

Pilot Site Recruitment: Following compilation of the final list of pilot sites for consideration, sites were contacted via telephone, presented with a brief description of the pilot test, and emailed more-detailed information. Ten pilot sites were recruited. Please refer to Section 2.2 and ***Table 1*** for a description of the 10 participating sites.

1.4.2 Pilot Site Training

Each pilot site participated in an in-depth, 90-minute training webinar, during which one or two providers per facility were trained on the purpose of the pilot, the proposed item sets, the pilot test data collection and submission processes, and maintenance of the patient crosswalk. Pilot site coordinators, one from each site, were required to participate in the training. Other facility staff who are normally involved in collecting ventilator quality data were also encouraged to attend.

Pilot sites received training materials for review before the first pilot test training call. Training materials included the following:

- Confidentiality Statement Form.
- LTCH Ventilator Weaning Quality Measures Pilot Testing Admission Item Set.
- LTCH Ventilator Weaning Quality Measures Pilot Testing Planned and Unplanned Discharge and Expired Item Set.
- LTCH Ventilator Weaning Quality Measures Pilot Testing Item Set Manual.
- LTCH Ventilator Weaning Quality Measures Pilot test data Entry Manual.
- LTCH Ventilator Weaning Quality Measures Pilot Testing Process Guide.

- LTCH Ventilator Weaning Quality Measures Pilot Testing Training Slides.
- Patient Crosswalk Form.
- RTI Institutional Review Board Approval Form.

The format of the Item Set Manual was based on the LTCH Quality Report Program Manual and contained instructions for coding responses to each of the pilot items. The Process Guide provided detailed information on the nature and timing of pilot activities. Training sessions occurred at least 3 days before the start of data collection at each pilot site. Please refer to ***Appendices A*** and ***B*** for the Pilot Testing Admission Item Set and the Pilot Testing Discharge and Expired Item Set.

1.4.3 Pilot Testing Patient Eligibility and Enrollment

Only patients admitted to the LTCHs on invasive mechanical ventilation were eligible for the pilot test. Each pilot test site enrolled all eligible patients admitted during the first 3 weeks of the pilot data collection period. Enrolled patients were followed from their admission date through either their discharge date or September 10, 2016, whichever occurred first. If a patient was admitted on mechanical ventilation and discharged more than once during the pilot, each patient stay was included (i.e., patients could have multiple stays). Data collection ended for each site when the last pilot patient in the target population was discharged or on September 10, 2016.

1.4.4 Patient-Level Data Collection and Submission

Participating LTCHs collected patient-level data using patient Admission Assessments and Planned Discharge, Unplanned Discharge, and Expired Assessments (***Appendices A*** and ***B***, respectively). Pilot test item sets for the Planned Discharge, Unplanned Discharge, and Expired Assessments were identical; thus, these assessments were collapsed into one discharge and expired assessment. Specifications for the draft ventilator weaning (liberation) quality measures suggest the use of the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set for collection and submission of data necessary for calculating the measure. Therefore, the pilot assessments were closely modeled after the version of the LTCH CARE Data Set in use at the time of the pilot test (Version 3.00).

Both the admission assessment and the discharge and expired assessment included items pertaining to site identification, key dates, reason for assessment, pilot case number, and age range of the patient. The Pilot Test Admission Assessment Item Set also included items related to potential risk adjustment factors for the ventilator weaning (liberation) outcome measure, a screening question for patient inclusion and exclusion criteria, and the processes assessed by the ventilator weaning process measure. The Pilot Test Discharge and Expired Assessment Item Set contained items pertaining to the patient liberation status at the time of discharge. Pilot sites completed pilot admission assessments for each enrolled patient; discharge assessments were completed for all patients discharged on or before September 10, 2016.

One of RTI's objectives was to gather information on the providers roles and activities necessary for implementation of the ventilator weaning quality measures; therefore, pilot sites

were asked to develop their own processes for the collection of patient-level pilot test data that were as consistent as possible with their usual processes of care and pre-existing workflow procedures. RTI did not prescribe data collection responsibilities or roles; these were left to the determination of individual sites based on staff availability, clinical practices, and any other appropriate factors.

RTI offered two methods for submitting patient-level pilot data: (1) Web-based data entry and electronic submission or (2) secure upload of scanned paper assessments. Sites that opted for electronic data submission entered data using the web-based RTI proprietary Hatteras data collection interface and submitted it via the RTI Electronic Secure Network. The Hatteras interface was designed to mirror the LTCH CARE Data Set admission assessment and discharge and expired assessment to the extent possible. Alternatively, sites could submit data by using a file transfer protocol (FTP) to upload scanned paper assessment forms to an RTI secured file share. Sites were encouraged to submit the pilot assessment forms within 5 days of the assessment reference date to align submission processes with the contemporary CMS LTCH CARE Data Set submission protocols.

Pilot assessment data submitted via the FTP site were downloaded and manually entered into the Hatteras data collection instrument by RTI staff within 1–2 days of receiving the data. Cumulative data were extracted from the pilot database weekly or twice weekly and reviewed for accuracy. RTI staff tracked which admission assessments had matched discharge assessments and which admission assessments were still pending discharge.

1.4.5 Qualitative Pilot Site Feedback

To learn more about the feasibility of implementing the draft Pilot Assessments and the perceived validity of the draft Pilot Item Sets, RTI solicited feedback from pilot site coordinators and other pilot site staff during a series of check-in calls and a final debriefing call. Questions asked during these calls were specifically designed to meet pilot test objectives and to respond to challenges raised by stakeholders during the ventilator weaning (liberation) quality measure public comment period. Probing was used during both types of calls to encourage participants to expand on their responses and to ensure all sites provided feedback. The semi-structured interview method also allowed the RTI team flexibility to tailor the questions to each site's responses, based on their feedback and on site-specific patient-level data analysis. Interview responses were recorded by RTI.

Check-In Calls: Weekly 20-60 minute check-in calls were scheduled with all pilot sites during the first 3 weeks of data collection, and then again following the first discharge of enrolled patients at each site. The purpose of the check-in calls was to answer any questions that LTCHs had about the pilot testing process, patient eligibility, and identification of the target population. RTI also gathered providers' perspectives on the data collection and submission processes, data sources, interpretation and clarity of the Pilot Assessment wording and definitions, skip patterns, importance and utility of patient liberation outcomes, and feasibility of implementation of the draft item sets. Check-in calls were semi-structured and consisted of a set of open-ended questions and topics for discussion. The duration of the check-in calls varied depending on the number of participants and the nature of the topics discussed. For a guide to questions discussed during the check-in calls, please refer to ***Appendix C***.

Debriefing Calls: Debriefing calls were scheduled after all or nearly all enrolled patients were discharged from the pilot sites. All pilot sites were required to participate in a debriefing call. Questions posed during debriefing calls focused on any changes made by pilot sites to data collection processes (e.g., timing, personnel), the extent to which participants felt that their pilot data collection process reflected realistic data collection practices, the face validity of the item sets, reasons for long patient lengths of stay, and overall impressions of the burden of data collection. Additional questions about skip patterns and risk adjustment factors were based on preliminary analysis of patient-level assessment data (e.g., Pilot Admission Assessment Sections I and O0200). For a guide to questions discussed during the debriefing calls, please refer to ***Appendix D***.

1.4.5 Patient-Level Data Monitoring and Verification

During manual entry of paper-based assessment data into Hatteras by RTI staff, RTI noted any questions about the data (e.g., if a date or entry was illegible, there were unanswered time burden items, or there were ineligible responses to Pilot Item O0200A). RTI staff also reviewed electronically entered data on a weekly basis to identify similar issues, and followed up on any questions related to patient eligibility for the pilot, illegible data entry, or missing discharge assessments.

1.4.6 Data Analysis

Pilot findings were analyzed using both quantitative and qualitative methods. For the quantitative analysis of patient-level assessment data, RTI staff performed simple analysis of frequencies and correlations to assess item completeness and validity, including the use of skip patterns and the extent of missing data (see ***Section 2***).

For the qualitative analysis of check-in and debriefing calls, two RTI staff conducted a review of detailed notes and check-in call transcripts to identify key themes pertaining to the utility and feasibility of the measures and item sets (see ***Section 3***).

Findings from the quantitative and qualitative data analyses were compared to evaluate consistency of themes across the two sources of data, and to support, explain, and expand upon themes identified during the analyses.

SECTION 2
ANALYSIS OF PATIENT ASSESSMENT DATA

2.1 Data Source

The findings presented in this chapter are based on quantitative data gathered using Pilot Data Collection Item Sets. Pilot site employees completed pilot item set admission assessments within the 3-day CMS admission period for all enrolled patients. The employees also completed pilot item set discharge assessments (including planned discharges, unplanned discharges, and expired assessments) for the same patients at the time of discharge. Admission assessments were matched with patient discharge assessments using the pilot case ID number; 93 percent of admission assessments were matched with a discharge assessment. Most "missing" discharge assessments were related to delays in patient discharge beyond the end of the pilot period.

2.2 Pilot Sites

Ten sites were enrolled in the pilot test of the ventilator liberation quality measures. Six of the 10 participating sites represented three LTCH corporations. The number of enrolled patients, and thus the number of admission assessments and discharge and expired assessments, varied by site. The number of patients at each site ranged from 2 to 43 (mean 15), with an average length of stay of 31.3 days. Mean hospital bed size ranged from 40 to 225+ beds (mean 99 beds); 70 percent of hospitals were proprietary facilities; and all facilities were located in urban areas, with 8 of 10 located in large urban areas. LTCHs submitted pilot data for 7 to 14 weeks, depending on the length of stays of patients enrolled at each site. Four out of the 10 sites opted to use paper-based data submission.

The selected LTCHs represented variation across the key criteria, including geographic region, bed size, and ownership type. However, none of the LTCHs who agreed to participate were located in rural areas. Key characteristics of the final 10 pilot sites are provided in ***Table 1***.

2.3 Patient-Level Data

As of September 14, 2016, the 10 pilot sites had submitted 151 admission assessments and 139 discharge assessments.

Of the 151 admission assessments, 5 assessments were excluded from the analytic file because the case did not meet pilot eligibility criteria or was a duplicate, leaving 146 admission assessments for inclusion in the analytic file. Of the 139 discharge assessments, 3 were excluded because the case did not meet pilot eligibility criteria. Also, at the conclusion of the pilot data collection period, 10 admission assessments did not have a matching discharge assessment. According to pilot sites, most of these were patients who had not been discharged because of challenges in transferring the patients to another post-acute care setting. The final analytic file thus includes records from **146 admission assessments**, of which **136 (93.2%) had a matching discharge assessment** as of September 14, 2016.

Table 1
Pilot site characteristics

Site identifier	Pilot admission assessments (N)	Pilot discharge assessments* (N [%])	Mean pilot LOS (days)	Hospital bed size category	Ownership type	Geography
1	21	21 (100.0)	30.3	75 to 124	Voluntary	Large urban
2	5	4 (80.0)	22.8	200+	Voluntary	Large urban
3	6	4 (66.7)	25.3	75 to 124	Proprietary	Large urban
4	24	21 (87.5)	33.1	50 to 74	Proprietary	Large urban
5	21	20 (95.2)	24.4	25 to 49	Proprietary	Large urban
6	13	12 (92.3)	32.6	75 to 124	Proprietary	Large urban
7	2	2 (100.0)	20.5	50 to 74	Proprietary	Large urban
8	8	8 (100.0)	31.6	25 to 49	Proprietary	Other urban
9	3	3 (100.0)	39.7	50 to 74	Government	Other urban
10	43	41 (95.3)	35.2	125 to 199	Proprietary	Large urban
Total	146	136 (93.1)	31.3	—	—	—

NOTES: * = as of September 14, 2016. N = number of assessments. % = percentage compared to admission assessments. LOS = length of stay among 136 matched discharged assessments. Hospital bed size category is measured by number of licensed beds.

SOURCE: RTI analysis of pilot test data and Fiscal Year 2015 Long-Term Care Hospital Prospective Payment System Final Rule Impact File data. (Program reference: NMJ001)

Patient characteristics (age range), and type of discharge assessment are provided in ***Table 2***. Most patients were between 45 and 80 years old, and 65 percent had a planned discharge assessment. ***Table 3*** shows the distribution of patients' weaning status upon admission to the LTCH and at discharge from the facility; the majority of patients (83%) were classified as weaning on the admission assessment. More than half (53.4%) of all patients admitted on mechanical ventilation were fully weaned at discharge. With respect to outcome measure risk factors (those that affect weaning), 14 percent were classified as dependent for prior functional status; 16 percent were classified as having irreversible neurological injury, disease, or dysfunction (including due to cerebral palsy); and over 14 percent were on dialysis (***Table 4 and Figure 1***).

Table 2
Age and discharge characteristics of pilot test patient stays

Characteristic	N	Percentage
Age category		
≤ 44 years	13	8.9
45–54 years	23	15.8
55–64 years	32	21.9
65–69 years	16	11.0
70–74 years	20	13.7
75–79 years	21	14.4
80–84 years	11	7.5
85–89 years	3	2.1
≥ 90 years	7	4.8
Total	146	100.0
Discharge type		
No matched discharge assessment*	10	6.9
Planned discharge	95	65.1
Unplanned discharge	28	19.2
Expired	13	8.9
Total*	146	100.0

NOTE: * Includes 10 missing discharge assessments. N = number of assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: NMJ001)

Table 3
Distribution of weaning status on admission and discharge

Characteristic	N	Percentage
O0200A, Invasive mechanical ventilation support upon admission to LTCH		
Weaning	121	82.9
Non-weaning	19	13.0
Weaning status cannot be determined by Day 2	6	4.1
Total	146	100.0
O0350A, Invasive Mechanical Ventilator: Weaning Status at Discharge		
Fully weaned	78	53.4
< 12 hours invasive mechanical ventilation	11	7.5
12–24 hours invasive mechanical ventilation	4	2.7
24 hours invasive mechanical ventilation	40	27.4
Not applicable	3	2.1
Missing*	10	6.9
Total	146	100.0

NOTES: *Missing data is a result of missing discharge assessments. N = number of assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: NMJ001)

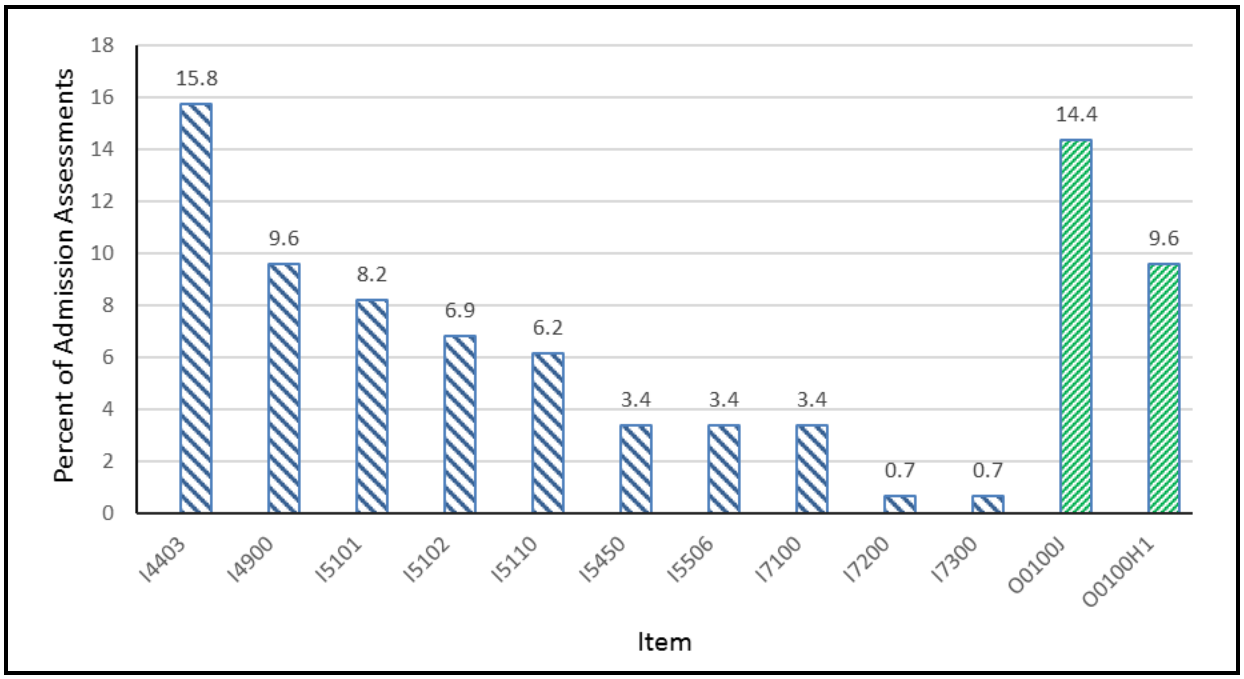
Table 4
Distribution of patient prior functional status

Characteristic	N	Percentage
Prior functional status, GG0100B		
Dependent	20	13.7
Needed some help	23	15.8
Independent	90	61.6
Unknown	4	2.7
Not applicable	9	6.2
Total	146	100.0

NOTES: Patient prior functional status is a risk factor for weaning (liberation) outcome. N = number of admission assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: NMJ001)

Figure 1
Percentage of patient active diagnoses and special treatments



NOTES: These items are risk factors for weaning (liberation) outcome. Pilot Item I5000, Paraplegia, was not present on any assessment. Frequency is presented as percentage of 146 admission assessments.

I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I7300: Severe Left Systolic/Ventricular Dysfunction
I7200: Metastatic Cancer
I4900: Hemiplegia or Hemiparesis
I7100: Lung, Heart, Liver, Kidney, or Bone Marrow Transplant
I5101: Complete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5506: Progressive Neuromuscular Disease
I5102: Incomplete Tetraplegia
I5450: Amyotrophic Lateral Sclerosis
O0100J: Dialysis
O0100H1: Vasoactive Medications

SOURCE: RTI analysis of pilot test data. (Program reference: NMJ001)

2.4 Response Distribution in Section O0200 of Admission Assessment

This section reports the responses and skip patterns in Pilot Section O0200, Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay. Ninety-six percent (95.9%) of admission assessments classified patients as either weaning or non-weaning by Day 2 of LTCH stay; Pilot Item O0200A = 3 (yes, weaning status cannot be determined) was selected for only 4.1 percent of admission assessments (n = 6) (***Table 5***). Three of those six assessments occurred at the same

facility. With respect to classification of weaning status at the facility level, 4 of 10 facilities selected response "1 = yes, weaning" on 100 percent of their admission assessments. Two of 10 facilities reported "1 = yes, weaning" on 91–92 percent of their admission assessments, and one facility selected "1 = yes, weaning" on 88 percent of their admission assessments.

Table 5
Distribution of item-level responses in Section O0200, Spontaneous Breathing Trial (SBT) (Including Tracheostomy Collar [TCT] or Continuous Positive Airway Pressure [CPAP] Breathing Trial) by Day 2 of long-term care hospital (LTCH) stay

O0200 items	Description	N	%
O0200A	Invasive mechanical ventilation support upon admission to LTCH		
1	Yes, weaning	121	82.9
2	No, non-weaning	19	13.0
3	Yes, weaning status can't be determined	6	4.1
	Total	146	100.0
O0200B	Assessed for readiness for SBT by Day 2 of stay		
—	Missing (error) or intentionally skipped	18	12.3
0	No	9	6.2
1	Yes	119	81.5
	Total	146	100.0
O0200C	Deemed medically ready for SBT by Day 2 of the LTCH stay		
—	Missing (skip error) or intentionally skipped	27	18.5
0	No	16	11.0
1	Yes	103	70.6
	Total	146	100.0
O0200D	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?		
—	Missing (skip error) or intentionally skipped	109	74.7
0	No	21	14.4
1	Yes	16	11.0
	Total	146	100.0

(continued)

Table 5 (continued)
Distribution of item-level responses in Section O0200, Spontaneous Breathing Trial (SBT) (Including Tracheostomy Collar [TCT] or Continuous Positive Airway Pressure [CPAP] Breathing Trial) by Day 2 of long-term care hospital (LTCH) stay

O0200 items	Description	N	%
O0200E	SBT performed by Day 2 of stay		
—	Missing (skip error) or intentionally skipped	38	26.0
0	No	7	4.8
1	Yes	101	69.1
	Total	146	100.0

NOTE: N = number of admission assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: RL_02)

2.4.1 Skip Patterns

The frequency and location of skip pattern errors in Pilot Section O0200, SBT (including Tracheostomy Collar or CPAP Breathing Trial) by Day 2 of LTCH Stay, speaks to the clarity and logical progression of the items used to calculate the process measure. We first present a description of appropriate skip patterns, followed by findings from the analysis of skip pattern errors.

Appropriate Skip Patterns

The skip patterns in Pilot Section O0200 are based on the response to Pilot Item O0200A, Invasive Mechanical Ventilation Support upon Admission to LTCH. Correct skip patterns are:

- If Pilot Item O200A = 0 (no, patient was not on invasive mechanical ventilation support upon admission), data collection for Pilot Section O0200 ended, and the respondent would proceed to item T03 (Time Estimate for Pilot Section O0200).
- If Pilot Item O0200A = 1 (yes, weaning), the respondent must complete Pilot Item O0200B (assessed for readiness for SBT by Day 2 of the LTCH Stay).
- If Pilot Item O2000A = 2 (yes, non-weaning), the respondent must end data collection for Pilot Section O0200 and go to item T03.
- If Pilot Item O0200A = 3 (yes, weaning status can't be determined), the respondent must proceed to Pilot Item O0200B.
  - If Pilot Item O0200B = 0 (no), the respondent must end data collection for Pilot Section O0200 and proceed to item T03.

- If Pilot Item O0200B = 1 (yes), the respondent must proceed to Pilot Item O0200C (deemed medically ready for SBT by Day 2 of the LTCH Stay).

    - If Pilot Item O0200C = 0 (no), the respondent must proceed to Pilot Item O0200D (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?).

    - If Pilot Item O0200C = 1 (yes), the respondent must proceed to Pilot Item O0200E (SBT performed by Day 2 of the LTCH stay).

    - If Pilot Item O0200D or Pilot Item O0200E = 0 (no) or 1 (yes), the respondent must proceed to T03.

Skip Pattern Error Findings

Twenty-eight out of 146 admission assessments (19.2%, not shown) in the analytic file had at least one skip pattern error in Pilot Section O0200 of the admission assessment. ***Table 6*** shows skip patterns recorded among patients who were categorized as weaning by Day 2 of the LTCH stay. ***Tables 7 and 8*** show the skip patterns recorded among patients categorized as non-weaning on admission (***Table 7***) and weaning status undetermined on admission (***Table 8***). Over 60 percent of skip pattern errors were due to a specific error at a single site (N= 18, Pattern 8); providers involved in data collection at this site had the misconception, based on participation in other pilot projects, that even "skipped" items required responses, and therefore filled these in using "0" on paper-based data submission forms. Thus, this error did not appear to be due to the wording or order of the items. The next most common error occurred when the patient was deemed not medically ready for SBT by Day 1 (Pilot Item O0200C = 1), but staff still indicated that an SBT was not performed (N=3, Pattern 4).

Table 6
Skip patterns for patients who were categorized as "weaning" by Day 2 (Pilot Item O0200A = 1)

Pattern ID	O0200B	O0200C	O0200D	O0200E	N (%)	Comment
1	0	—	—	—	5 (3.4)	No error
2	1	0	0	—	2 (1.4)	No error
3	1	0	1	—	8 (5.5)	No error
4	1	0	1	0	3 (2.1)	E should be blank if D is 1
5	1	1	—	0	1 (0.7)	No error
6	1	1	—	1	81 (55.5)	No error
7	1	1	0	0	1 (0.7)	D should be blank if C is 1
8	1	1	0	1	18 (12.3)	D should be blank if C is 1
9	1	1	1	1	2 (1.4)	D should be blank if C is 1

NOTES: N = number of admission assessments; % = percentage of 146 admission assessments; — = skipped.

SOURCE: RTI analysis of pilot test data. (Program reference: RL_02)

Of the 19 patients who were categorized as "non-weaning" on admission, 16 assessments showed no coding errors in Pilot Section O0200 (***Table 7***). Of the six patients for whom weaning status could not be determined by Day 2 of the LTCH stay, one patient received an assessment for SBT and was deemed not medically ready for weaning attempts by Day 2, but subsequently underwent weaning and was coded as fully weaned at discharge (***Table 8***). Of the five remaining discharged patients for whom weaning status could not be determined, three were not assessed for SBT by Day 2 of the LTCH stay (***Table 8***). For two of the five, the question "Assessed for Readiness for SBT by Day 2 of the LTCH Stay" was not completed.

Table 7
Skip patterns for patients who were categorized as "non-weaning" by Day 2 (Pilot Item O0200A = 2)

Pattern ID	O0200B	O0200C	O0200D	O0200E	N (%)	Comment
10	—	—	—	—	16 (11.0)	No error
11	0	—	—	—	1 (0.7)	B should be blank if A = 2
12	1	0	1	—	1 (0.7)	B–D should be blank if A = 2
13	1	0	1	0	1 (0.7)	B–E should be blank if A = 2

NOTE: N = number of admission assessments; % = percentage of 146 admission assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: RL_02)

Table 8
Skip patterns for patients who were categorized as "weaning status cannot be determined" by Day 2 (Pilot Item O0200A = 3)

Pattern ID	O0200B	O0200C	O0200D	O0200E	N (%)	Comment
14	—	—	—	—	2 (1.4)	If A = 3, then B should be complete
15	0	—	—	—	3 (2.1)	No error
16	1	0	1	0	1 (0.7)	If C = 0, then E should be blank

NOTE: N = number of admission assessments; % = percentage of 146 admission assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: RL_02)

Excluding Pattern 8, no single skip error pattern occurred more than 3 times, which suggests that no single skip pattern was particularly difficult to follow. However, the presence of skip errors in Pilot Section O0200 indicates that training should emphasize the progression and response patterns of the items in this section.

2.5 Process Measure Performance and Variability

The facility-level score for the two process measure components is shown by pilot site in ***Table 9***. These scores are calculated based on responses provided in Pilot Section O0200 of the Admission Assessment. Component 1 evaluated the percentage of mechanically ventilated patients admitted to an LTCH for weaning who were assessed for medical readiness for SBT by Day 2. The minimum score on Component 1 was 55.6 percent; the maximum was 100 percent. Seven out of ten sites had perfect scores (100%) on Component 1. Component 2 evaluated the percentage of mechanically ventilated patients deemed medically ready for SBT by Day 2 who received an SBT by Day 2 of the LTCH stay. The minimum score for Component 2 was higher,

at 88.9 percent; the maximum was 100 percent. Nine out of 10 sites had perfect scores on Component 2.

Table 9
Process measure component scores by LTCH

Pilot Site	Admission assessments	Component 1 score (%)	Component 2 score (%)
1	21	55.6	88.9
2	5	100.0	100.0
3	6	100.0	100.0
4	24	75.0	100.0
5	21	100.0	100.0
6	13	100.0	100.0
7	2	100.0	100.0
8	8	100.0	100.0
9	3	100.0	100.0
10	43	97.7	100.0
Mean	—	92.8	98.9

NOTES: Scores are expressed as a percentage of admission assessments. Data based on 146 admission assessments.

Component 1: Of mechanically ventilated patients admitted to a long-term care hospital for weaning, the percentage of patients who are assessed for medical readiness for a spontaneous breathing trial (SBT) by Day 2.
Component 2: Of mechanically ventilated patients deemed medically ready for SBT by Day 2 of the LTCH stay, the percentage of patients for whom SBT was performed by Day 2.

SOURCE: RTI analysis of pilot test data. (Program reference: RL04_201609016)

2.6 Weaning Status at Admission and Discharge

Table 10 shows the distribution of patients' liberation status at discharge, stratified by weaning status as categorized on admission. Among the 113 patients who were admitted to pilot sites for weaning (Pilot Item O0200A = 1), 68 (60.2%) were reported as fully liberated on discharge, and response option 09, "not applicable," was checked for 1 patient with an expired assessment. There were 17 mechanically ventilated patients who were admitted without the expectation on arrival of weaning attempts (Pilot Item O0200A = 2); of these, 8 (47.1%) were reported as fully liberated on discharge. There were 6 patients with an undetermined weaning status on admission. (Pilot Item O0200A = 3). Of the 6 patients, 2 patients were fully liberated at discharge and four patients were not fully liberated at discharge.

This table suggests a misunderstanding of the use of response option "09. Not applicable" for Pilot Item O0350A. Instructions for completing this item were documented on the pilot test item set and emphasized during the pilot training. Providers were asked to select response option "09" for those patients for whom on admission no weaning attempts are expected.; Therefore, this option should have selected for all 17 discharge assessments for "non-weaning" patients (Pilot Item O0200A=2).

Table 10
Distribution of weaning (liberation) status at discharge (O0350A) by weaning status on admission (O0200A)

Weaning status on admission (O0200A)	Fully liberated (01)	Liberated < 12 hours (02)	Liberated > 12 hours but < 24 hours (03)	Not liberated (04)	Not applicable (09)	All
Weaning	68 (60.2)	11 (9.7)	4 (3.5)	29 (25.7)	1 (0.9)	113 (100.0)
Non-weaning	8 (47.1)	0 (0.0)	0 (0.0)	7 (41.2)	2 (11.8)	17 (100.0)
Undetermined	2 (33.3)	0 (0.0)	0 (0.0)	4 (66.7)	0 (0.0)	6 (100.0)
Any	78 (57.4)	11 (8.1)	4 (2.9)	40 (29.4)	3 (2.2)	136 (100.0)

NOTES: Values are reported as frequency (row percentage). Data based on 136 matched discharge assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

Table 11 shows the liberation status at discharge by type of discharge assessment (Planned, Unplanned, or Expired). The percentage of fully liberated patients was higher among planned discharges than unplanned discharges (72.6% and 25.0%, respectively). The finding that some fully liberated patients had unplanned discharges, underscores the need to capture liberation status on this type of assessment; it cannot be assumed that all patients with unplanned discharges are on mechanical ventilation at the time of discharge.

Among the 10 patients who died (expired discharge assessment), only two were fully liberated before the date of death. Of the 8 who were not fully liberated, 2 were reported as partially liberated on the expired discharge assessment.

Table 11
Comparison of O0350A responses between patients with type of discharge assessment

Item description (O0350A Responses)	Planned*	Unplanned*	Expired
Fully liberated (01)	69 (72.6)	7 (25.0)	2 (15.4)
Not fully liberated (02, 03, 04)	24 (25.3)	21 (75.0)	10 (76.9)
Liberated < 12 hours (02)	6 (6.3)	3 (10.7)	2 (15.4)
Liberated > 12 hours but < 24 hours (03)	1 (1.1)	3 (10.7)	0 (0.0)
Not liberated (04)	17 (17.9)	15 (53.6)	8 (61.5)
Not applicable (09)	2 (2.1)	0 (0.0)	1 (7.7)
Total	95 (100.0)	28 (100.0)	13 (100.0)

NOTES: *Planned and unplanned assessments together represent all patients discharged alive. Values are reported as frequency (column percentage). Data based on analysis of 136 matched discharge assessments, including patients for whom no weaning attempts were anticipated on admission.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

Note that unless otherwise stated, patients who were reported as non-weaning on admission or as weaning status undetermined are excluded from analyses in the remainder of this report because they meet measure exclusion criteria.

2.7 Outcome Measure

2.7.1 Numerator Inclusion Criteria: Impact of Including "Partially Liberated"

TEP members raised questions about the utility and impact of including the of partial weaning (liberation) category in the numerator of the outcome measure. In the first conceptualization, the outcome measure would be based on a binary categorical outcome variable: whether the patient was fully liberated or not fully liberated at discharge. In the second conceptualization the outcome measure "not fully liberated" would be stratified by patients who were fully liberated, partially liberated, or not liberated at discharge. In this model, patients who are partially liberated at discharge and patients who were fully weaned at discharge would be included in the measure numerator, yielding a higher numerator count.

Table 12 displays the one-way distribution of Pilot Item O0350A (Weaning (Liberation) Status on Discharge) responses among patients reported as "weaning" on admission (i.e. those for whom weaning attempts were anticipated or expected). As shown in the table, providers indicated that 68 (60.2%) of discharged patients were fully liberated at discharge and 15 (13.2%) were "partially liberated" at discharge. Thus, including partially liberated patients in the measure's numerator would add 13.3% of patients to the 60.2% of patients who were fully liberated at discharge. It is important to note that, depending on the patient's weaning status at admission, a discharge goal of partial liberation may or may not represent an improved patient

outcome. (Refer to Section 3.3.4 for a discussion of the utility of reporting partial weaning at discharge.)

Table 12
O0350A response distribution

Item description (O0350A responses)	N (%)
Fully liberated (01)	68 (60.2)
Not fully liberated (02, 03, 04)	44 (38.9)
Liberated < 12 hours (02)	11 (9.7)
Liberated > 12 hours but < 24 hours (03)	4 (3.5)
Not liberated (04)	29 (25.7)
Not applicable (09)	1 (0.9)
Total	113 (100.0)

NOTES: Data based on 113 matched discharge assessments for patients reported as weaning on admission. Values are reported as frequency (percentage). Liberation includes 2 patients who died in the facility. N = number of matched discharge assessments; % = percentage of matched discharge assessments.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

2.7.2 Outcome Measure Performance and Variability

Table 13 displays the facility-level liberation rates for the 10 pilot sites. Liberation rate is defined as the percentage of patients fully weaned at discharge, among patients who were mechanically ventilated on admission and for whom weaning attempts are expected or anticipated. The mean liberation rate across all sites was 75 percent, with a standard deviation of 19 percent.

Table 13 shows that liberation rates varied widely by site, with a minimum of 46 percent and a maximum of 100 percent. Variability among facilities cannot be accurately determined because of the low numbers of stays at some of the test sites. For example, the site with a liberation rate of 100% admitted 3 patients on mechanical ventilation during the pilot period, of whom only 1 was admitted with the expectation of weaning attempts.

Table 13
Liberation rate by LTCH

Pilot Site	Patients fully liberated at discharge
1	12 (80.0)
2	2 (50.0)
3	2 (50.0)
4	5 (62.5)
5	10 (55.6)
6	10 (83.3)
7	1 (100.0)
8	5 (71.4)
9	2 (66.7)
10	19 (46.3)

NOTES: Data based on 113 matched discharge assessments for patients reported as weaning on admission. N = number of patients reported as fully liberated on discharge. Rate is reported as a percentage. "Fully liberated" includes 2 patients who died in the facility.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

Table 14
Patient-level liberation rate by age group

Age group (years)	N	Patients fully liberated at discharge
≤ 54	29	18 (62.1)
55–64	28	15 (53.6)
65–74	29	16 (55.2)
≥ 74	27	19 (70.4)
All ages	113	68 (60.2)

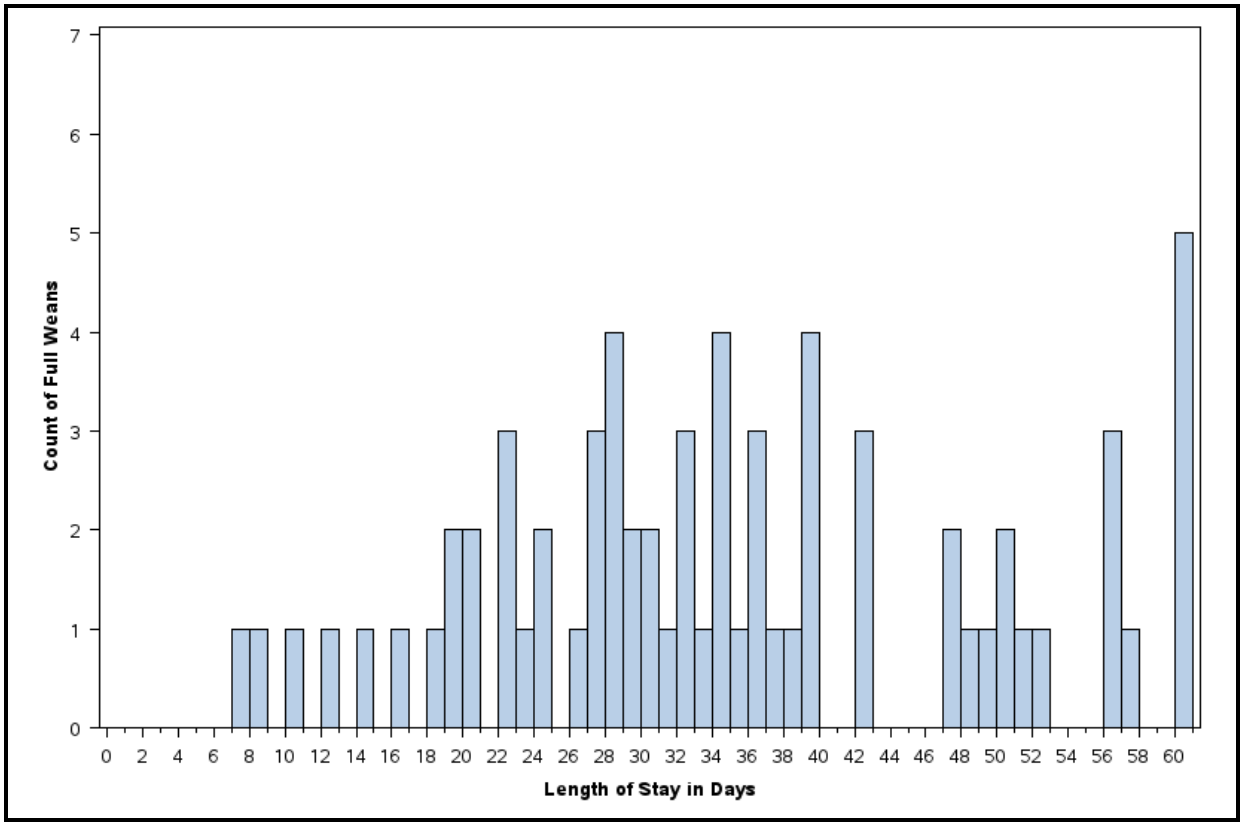
NOTES: Data based on 113 matched discharge assessments for patients reported as weaning on admission. N = number of assessments. Values are reported as frequency (percentage). "Fully liberated" includes 2 patients who died in the facility.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

Table 14 shows patients' liberation rate by age group. ***Figure 2*** shows the number of fully liberated patients by length of stay. The results indicate some variability by age group and length of stay, respectively. The patients in the oldest age category had the highest weaning rate (70.4%) followed by those in the youngest age category (62.1%). The average length of stay for

the 68 fully weaned patients was 35 days (maximum 66 days), which is slightly longer than the average length of stay (31 days) for all patients discharged during the pilot period (***Table 1***).

Figure 2
Distribution of fully liberated patients by length of stay



NOTE: Data based on 68 matched discharge assessments for fully liberated patients admitted with the expectation of weaning, including 2 patients who died in the facility

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

2.7.3 Impact of Counting Patients Who Die in the Liberation Rate Numerator

TEP members debated whether to include fully liberated patients who die in the outcome measure numerator or to count them as not liberated. ***Table 15*** shows the impact of counting patients with expired assessments as "not liberated" on discharge, which affects 2 fully liberated patients, 2 partially liberated patients, and one patient reported as "NA." The fully liberated rate would drop slightly, from 60 percent to 58 percent.

Table 15
Impact of removing patients who die from the outcome measure numerator

Item description (O0350A responses)	Liberation status as reported on all assessments	Distribution if expired assessments are counted as "not liberated" (04)
Fully liberated (01)	68 (60.2)	66 (58.4)
Not fully liberated (02, 03, 04)	44 (38.9)	47 (41.6)
Liberated < 12 hours (02)	11 (9.7)	9 (8.0)
Liberated > 12 hours but < 24 hours (03)	4 (3.5)	4 (3.5)
Not liberated (04)	29 (25.7)	34 (30.1)
Not applicable (09)	1 (0.9)	0 (0.0)
Total	113 (100.0)	113 (100.0)

NOTES: Data based on 113 matched discharge assessments for patients reported as weaning anticipated on admission. Values are reported as frequency (column percentage).

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

2.7.4 Interpretation of the Definition of "Fully Weaned"

This section reports the number of days patients are fully weaned prior to being discharged from the LTCH for the outcome quality measure, *Ventilator Weaning (Liberation) Rate.* Fully weaned patients are defined as patients with no mechanical ventilator support for 2 or more calendar days prior to the date of discharge.

The Ventilation-discharge date interval is calculated by subtracting the last date of ventilator support (Pilot Item O0350B) from the discharge date (Pilot Item A0270). Because fully liberated patients are defined as patients with no mechanical ventilator support for 2 calendar days prior to the h discharge date, the interval between the discharge date and the last date of mechanical ventilator support must equal 3 or more days to allow the discharge date to be preceded by 2 ventilator-free days. An interval of less than 3 days indicates either a data entry error or a misinterpretation of the definition of "fully weaned" on the part of pilot site participants.

Table 16 shows frequencies of liberation status at discharge by ventilator-discharge interval in days for all 136 matched discharge assessments. Providers correctly identified liberation status (e.g., ventilation-discharge date interval ≥ 3 days) for the majority (96.1%) of fully weaned patients. The two exceptions are the fully weaned patients with 1 and 2 ventilator-free calendar days prior to the date of discharge. In addition, one fully weaned patient had a negative wean discharge time, which is not possible; this value is likely because of inputting the incorrect last date of ventilator support.

Table 16
Frequencies of weaning statuses at discharge (O0350A) by ventilator-free days prior to the date of discharge

Ventilation-discharge date interval	Fully liberated (01)	Not fully liberated (02, 03, 04)	Not applicable (09)
−1*	1 (100.0)	0 (0.0)	0 (0.0)
0	0 (0.0)	21 (91.3)	2 (8.7)
1	1 (100.0)	0 (0.0)	0 (0.0)
2	1 (50.0)	1 (50.0)	0 (0.0)
3	2 (100.0)	0 (0.0)	0 (0.0)
4+	73 (100.0)	0 (0.0)	0 (0.0)
Missing	0 (0.0)	33 (97.1)	1 (2.9)
Total	78 (57.4)	55 (40.4)	3 (2.2)

NOTES: *Negative intervals indicate data entry errors. Data based on 136 matched discharge assessments. Values are reported as frequency (row percentage). The Ventilation-discharge date interval is calculated as A0270 (discharge date) - O0350B (last date of ventilator support). Liberation of any length includes patients who died in the facility.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_02)

2.8 Proposed Risk Factors

2.8.1 Distribution of Potential Risk Factors by Facility

Table 17shows the distribution by facility of categories of prior function. Over 61 percent of LTCH patients in the pilot were classified as functionally independent prior to the illness, exacerbation, or injury that led to the hospitalization before LTCH admission (i.e., acute hospitalization)**.** Site 1 selected “not applicable” for a sizeable proportion of admitted patients, indicating that a patient was not walking prior to the acute care hospitalization.

Table 17
Frequencies for Prior Functioning: Everyday Activities, Indoor Mobility (GG0100B) by LTCH

Pilot Site	1 (Dependent)	2 (Needed some help)	3 (Independent)	8 (Unknown)	9 (Not applicable)
1	0 (0.0)	2 (9.5)	11 (52.4)	0 (0.0)	8 (38.1)
2	2 (40.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)
3	3 (50.0)	1 (16.7)	2 (33.3)	0 (0.0)	0 (0.0)

(continued)

Table 17 (continued)
Frequencies for Prior Functioning: Everyday Activities, Indoor Mobility (GG0100B) by LTCH

Pilot Site	1 (Dependent)	2 (Needed some help)	3 (Independent)	8 (Unknown)	9 (Not applicable)
4	7 (29.2)	9 (37.5)	8 (33.3)	0 (0.0)	0 (0.0)
5	2 (9.5)	1 (4.8)	18 (85.7)	0 (0.0)	0 (0.0)
6	1 (7.7)	3 (23.1)	9 (69.2)	0 (0.0)	0 (0.0)
7	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)
8	0 (0.0)	1 (12.5)	6 (75.0)	1 (12.5)	0 (0.0)
9	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)
10	4 (9.3)	6 (14.0)	29 (67.4)	3 (7.0)	1 (2.3)
Total	20 (13.7)	23 (15.8)	90 (61.6)	4 (2.7)	9 (6.2)

NOTES: Values are reported as frequency (row percentage). Data based on 146 admission assessments. Includes patients who died in the facility.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

Table 18 shows the distribution by facility of risk factors related to active diagnoses and special treatment, found in Pilot Sections I and O0100 respectively of the Pilot Admission Assessment. The number of risk factors reported within each facility ranged from 1 to 10.

2.8.2 Correlation Among Potential Risk Factors Related to Active Neurological or Neuromuscular Diagnoses

Table 19 reports the percent overlap between general and specific types of neurological and neuromuscular disease or injury. Providers marked patients with irreversible neurological injury, disease, or dysfunction (Pilot Item I4403) and hemiplegia or hemiparesis (Pilot Item I4900) together. ***Table 20*** shows the Pearson correlation between general and specific types of neurological and neuromuscular disease or injury. Note that the small cell sizes yield less-accurate correlation statistics. The correlation between Pilot Item I4403, Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy), and Item I4900, Hemiplegia or Hemiparesis, was significant but weak (0.18, $p =< 0.05$), as was the correlation between Pilot Item I5506, Progressive Neuromuscular Disease and Pilot Item I5110, Other Spinal Cord Disorder/Injury (0.17, $p= <0.05$).

Table 18
Frequencies for potential risk factors by LTCH

Pilot Site	I4403	I4900	I5000	I5101	I5102	I5110	I5450	I5506	I7100	I7200	I7300	O0100J	O0100H1	# of risk factors within each LTCH
1	4 (19.0)	0 (0.0)	0 (0.0)	2 (9.5)	0 (0.0)	1 (4.8)	0 (0.0)	1 (4.8)	0 (0.0)	0 (0.0)	1 (4.8)	1 (4.8)	2 (9.5)	7
2	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4
3	2 (33.0)	1 (17.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (17.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	6
4	8 (33.0)	1 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	6 (25.0)	5 (21.0)	5 (20.8)	8 (33.3)	7
5	1 (4.8)	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)	0 (0.0)	1 (4.8)	0 (0.0)	1 (4.8)	1 (4.8)	2 (9.5)	0 (0.0)	7
6	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (31.0)	0 (0.0)	3 (23.0)	4 (30.8)	1 (7.7)	4
7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3
8	1 (13.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1
9	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.0)	0 (0.0)	1 (33.3)	2
10	7 (16.0)	6 (14.0)	0 (0.0)	3 (7.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	3 (7.0)	5 (12.0)	3 (7.0)	7 (16.3)	2 (4.7)	10
Total patients	23	10	0	5	1	5	1	5	9	12	14	31	14	
# of LTCHs reporting diagnoses	6	5	0	2	1	5	1	5	4	3	6	6	5	

NOTES: Values are reported as frequency (percentage of patients within each site). Data based on 146 admission assessments. LTCH = long-term care hospital.
Item Key:
I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I4900: Hemiplegia or Hemiparesis; I5000: Paraplegia;
I5101: Complete Tetraplegia; I5102: Incomplete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5450: Amyotrophic Lateral Sclerosis
I5506: Progressive Neuromuscular Disease
I7100: Lung, Heart, Liver, Kidney, or Bone Marrow Transplant
I7200: Metastatic Cancer
I7300: Severe Left Systolic/Ventricular Dysfunction
O0100J: Dialysis
O0100H1: Vasoactive Medications

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

Table 19
Percent overlap between general and specific types of neurological and neuromuscular disease or injury

Diagnoses	I4900	I5101	I5102	I5110	I5450
I4403	4 (19.0)	2 (9.5)	0 (0.0)	1 (4.8)	0 (0.0)
I5506	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)

NOTES: Values are reported as frequency (row percentage). Data based on 146 admission assessments.

Item Key:
I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I4900: Hemiplegia or Hemiparesis
I5101: Complete Tetraplegia
I5102: Incomplete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5450: Amyotrophic Lateral Sclerosis
I5506: Progressive Neuromuscular Disease

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

Table 20
Correlation between general and specific types of neurological and neuromuscular disease or injury

Diagnoses	I4900	I5101	I5102	I5110	I5450
I4403	0.18*	0.13	−0.04	0.02	−0.04
I5506	−0.05	−0.04	−0.02	0.17*	−0.02

NOTES: * = Significant with $p < 0.05$. Data based on 146 admission assessments.

Item Key:
I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I4900: Hemiplegia or Hemiparesis
I5101: Complete Tetraplegia
I5102: Incomplete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5450: Amyotrophic Lateral Sclerosis
I5506: Progressive Neuromuscular Disease

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

2.8.3 Association of Potential Risk Factors with Weaning Outcome Among All Discharge Types

Table 21 shows the cross tabulation between liberation status at discharge and prior functioning among all 136 matched discharge assessments. Most patients who were fully

liberated at discharge were independent prior to the illness, exacerbation, or injury (66%, or 57 of 87). Only 3.8 percent of fully liberated patients were dependent prior to the illness, compared to 27.5 percent of those who were not liberated.

Table 21
Cross-tabulation of Weaning Status at Discharge (Pilot Item O0350A) and Prior Functioning: Everyday Activities, Indoor Mobility (Pilot Item GG0100B) among all discharge types

Weaning status at discharge	1 (Dependent)	2 (Needed some help)	3 (Independent)	8 (Unknown)	9 (Not applicable)
Fully liberated (01)	3 (3.8)	11 (14.1)	57 (73.1)	3 (3.8)	4 (5.1)
Liberated < 12 hours (02)	1 (9.1)	1 (9.1)	9 (81.8)	0 (0.0)	0 (0.0)
Liberated > 12 hours but < 24 hours (03)	1 (25.0)	1 (25.0)	2 (50.0)	0 (0.0)	0 (0.0)
Not liberated (04)	11 (27.5)	6 (15.0)	17 (42.5)	1 (2.5)	5 (12.5)
Not applicable (09)	1 (33.3)	0 (0.0)	2 (66.7)	0 (0.0)	0 (0.0)

NOTES: Values are reported as frequency (row percentage). Data based on 136 discharged patients. IMV = invasive mechanical ventilation.

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

Table 22 presents the cross-tabulation between weaning status at discharge and active diagnosis items among patients who were categorized as weaning on admission, based on data from 136 matched discharge assessments. (All discharged patients are included regardless of whether patients were weaning or non-weaning on admission.) This table shows that many patients were fully liberated, despite the presence of comorbidities or treatments that are considered more difficult to wean. Of the 21 patients reported as having irreversible neurological injury, disease, or dysfunction on admission, nearly half were fully liberated at discharge. One patient with complete tetraplegia was fully liberated, as was the sole patient with ALS.

Table 22
Cross-tabulation of Weaning Status at Discharge (Pilot Item O0350A) and active diagnosis and treatment items

Weaning status at discharge	I4403	I4900	I5000	I5101	I5102	I5110	I5450	I5506	I7100	I7200	I7300	O0100J	O0100H1
Fully liberated (01)	10 (47.6)	7 (70.0)	0 (0.0)	2 (40.0)	0 (0.0)	1 (25.0)	1 (100)	2 (40.0)	6 (66.6)	4 (33.3)	8 (66.7)	8 (44.4)	7 (53.8)
Liberated < 12 hours (02)	1 (4.8)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	1 (20.0)	1 (11.1)	0 (0.0)	2 (16.7)	2 (11.1)	0 (0.0)
Liberated > 12 hours but < 24 hours (03)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	0 (0.0)	2 (11.1)	1 (7.7)
Not liberated (04)	9 (42.9)	1 (10.0)	0 (0.0)	2 (40.0)	0 (0.0)	2 (50.0)	0 (0.0)	2 (40.0)	2 (22.2)	6 (58.3)	2 (16.7)	6 (33.3)	5 (38.5)
Not applicable (09)	1 (4.8)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	21	10	0	5	0	4	1	5	9	11	12	18	13

NOTES: Values are reported as frequency (column percent). Data based on 136 matched discharge assessments, regardless of whether patients were weaning or non-weaning on admission.

Item Key:
I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I4900: Hemiplegia or Hemiparesis
I5000: Paraplegia
I5101: Complete Tetraplegia
I5102: Incomplete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5450: Amyotrophic Lateral Sclerosis
I5506: Progressive Neuromuscular Disease
I7100: Lung, Heart, Liver, or Bone Marrow Transplant
I7200: Metastatic Cancer
I7300: Severe Left Systolic/Ventricular Dysfunction
O0100J: Dialysis
O0100H1: Vasoactive Medications

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

2.9 Utility of Potential Risk Factors as Exclusion Criteria

The Ventilator Weaning TEP identified mechanically ventilated patients for whom no weaning attempts were anticipated during the LTCH stay as the appropriate population to exclude from both measures; the TEP stated that these patients are usually chronically ventilated patients admitted to LTCHs with treatment goals that do not include weaning. TEP members discussed two different options for operationalizing this definition. The first option was to exclude mechanically ventilated patients based on a list of diagnoses that often result in chronic ventilation (e.g. amyotrophic lateral sclerosis). The second option was to exclude patients admitted on mechanical ventilation but for whom providers anticipated no weaning attempts during the patients' stays. For the purpose of pilot testing, the excluded population is based on the second option.

RTI analyzed the frequency of selected neurological conditions, which may represent reasons for chronic ventilation (and thus measure exclusion), among the non-weaning population. We also included Pilot Item I7200. Metastatic Cancer as a proxy for end-of-life status. ***Table 23*** shows the active diagnosis items for all patients who were non-weaning on admission, including those without matched discharge assessments. Nearly 30 percent of patients reported as non-weaning on admission had an irreversible neurological injury, disease, or dysfunction and 18 percent had metastatic cancer. Of the 19 mechanically ventilated patients who were classified as non-weaning on admission, 5 had none of the selected conditions and are not represented in the table below, indicating that this list is insufficient in capturing all patients for whom no weaning attempts are anticipated (data not shown). The prevalence of these factors among patients who were fully weaned at discharge (***Table 22***) indicates that these factors should not be used to define the non-weaning population; during check-in calls, pilot site participants described undertaking weaning efforts for patients with some of these conditions.

Table 23
Cross-tabulation of non-weaning status on admission (Pilot Item O0200A = 2), with items for active diagnoses, and special treatment, procedures and programs

Weaning status on admission	I4403	I4900	I5000	I5101	I5102	I5110	I5450	I5506	I7200
02 (Yes, non-weaning)	5 (29.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	2 (12.0)	0 (0.0)	1 (5.9)	3 (18.0)

NOTES: Values are reported as frequency (percentage of patients with weaning status of "yes, non-weaning" on admission).
Item Key:
I4403: Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy)
I4900: Hemiplegia or Hemiparesis; I5000: Paraplegia
I5101: Complete Tetraplegia; I5102: Incomplete Tetraplegia
I5110: Other Spinal Cord Disorder/Injury
I5450: Amyotrophic Lateral Sclerosis
I5506: Progressive Neuromuscular Disease
I7200: Metastatic Cancer

SOURCE: RTI analysis of pilot test data. (Program reference: TL_01)

2.10 Time Estimates

Responders were asked to estimate the time it took to complete new assessment items in Pilot Sections I, Active Diagnoses; O0100 (T01), Special Treatments, Procedures, and Programs; O0200 (T02) , SBT (including Tracheostomy Collar or CPAP Breathing Trial) by Day 2 of LTCH Stay(T03) ; and O0350, Ventilator Weaning (Liberation) Rate (T04). These items were added to the admission and discharge assessments to evaluate the burden of completing the draft items for collection of ventilation weaning data.

The average time to complete new assessment items for Pilot Sections I, O0100, O0200, and O0350 is shown in ***Table 24***. The mean time was 4.1 minutes (standard deviation [SD] 5.0), 2.8 (SD 4.0) minutes, 5.0 (SD 5.1) minutes, and 5.3 (SD 4.7) minutes, respectively, for items T01, T02, T03, and T04. We identified two admission assessments that both had high outlying time estimates of 30 minutes for Pilot Section O0200 and 45 minutes for Pilot Section O0350. The same pilot site completed both assessments. During the check-in calls, this site noted that staff had to go to another area of the facility to obtain the medical records necessary for data collection, and that manual review of physician notes took time. The data collector for this site also did not have access to electronic records of the existing LTCH CARE Data Set v. 3.00 items.

Table 24
Patient-level distribution of time estimates in minutes

Time item	Assessment section	N	Mean time	SD	Min	Max
T01	I	146	4.1	5.0	1	45
T02	O0100	146	2.8	4.0	1	30
T03	O0200	146	5.0	5.0	1	45
T04	O0350	136	5.3	4.7	1	30

NOTES: Data for T01, T02, and T03 are based on 146 admission assessments. Data for T04 are based on 136 discharge assessments. N = number of assessments. SD = standard deviation.

SOURCE: RTI analysis of pilot test data. (Program reference: RL_02)

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SECTION 3
PILOT TESTING QUALITATIVE FINDINGS

This section presents the results of the qualitative analysis for the two ventilator weaning (liberation) quality measures. Section 1.4.5 describes the intent of the qualitative analysis and the research methodology.

3.1 Check-In Calls

Each of the 10 pilot sites participated in at least two check-in calls, with an average of four check-in calls per site. There were 20 check-in calls, and 1 to 4 sites participated on each call. Check-in calls averaged 45 minutes in length.

Check-in calls that occurred during the first few weeks of pilot test data collection focused on the admission assessment. The discharge patient assessments were discussed during check-in calls that occurred after pilot patients began to be discharged. Each site participated in at least two calls focused on discharge-related questions.

3.2 Semi-Structured Debriefing Calls

Each of the 10 pilot sites participated in one semi-structured debriefing call. In total, 4 debriefing calls were held. The number of sites participating in each call varied from 1 to 5. Debriefing calls were scheduled after pilot sites had discharged all or nearly all pilot patients. These calls, which lasted approximately 1 hour, focused on an overall discussion of the pilot process and the item sets, including questions about changes in processes during the pilot, face validity and reliability of the item sets in practice, and views on the success of item implementation.

3.3 Findings from Check-In and Debriefing Calls by Topic

3.3.1 Feedback on Pilot and Pilot Process

Initial Challenges with the Pilot Testing Processes: During the initial check-in calls, all 10 pilot sites reported no challenges with the pilot data collection and submission process. All sites stated that the materials and training were straightforward. One site said that the training materials were somewhat repetitive, and indicated that the training was more complex than it needed to be given the straightforward nature of the pilot process. Additionally, no sites reported challenges with the weaning item skip patterns.

Data Collection Process: The pilot sites used different data collection methods. Seven of the 10 pilot sites assigned all data collection responsibilities to a single person. Three of the 10 pilot sites relied on more than one person to collect and submit data. At 2 of these 3 sites, one LTCH staff member collected data only for the new items related to weaning processes and outcomes, and a separate staff member culled data from the existing LTCH CARE Data Set Version 3.00. The third site began data collection using three data collectors, but modified their processes mid-way through the pilot, largely to address inefficiencies in data entry and submission. After the modification, only one person collected data. All 10 pilot sites reported that they followed their normal clinical processes and standards for collecting this pilot data,

which included referencing the patient's history and physical, physician and respiratory therapist notes, and existing LTCH CARE Data Set v 3.00 items.

Determining Pilot Eligibility: To determine patient eligibility for enrollment in the pilot, the pilot sites reported that they relied on the history and physical, physician notes, and previous medical history to determine whether a patient was on mechanical ventilation upon LTCH admission. All sites reported use of a standard facility-level protocol for assessment of the weaning status of all patients admitted on a mechanical ventilator. These site-specific protocols also guided their pilot processes.

Questions from participating sites regarding patient pilot eligibility were related to a few special cases. These cases were discussed during early pilot check-in calls, and any uncertainty over patient eligibility in each case was resolved. These cases fell into three categories:

- Patients who were previously on mechanical ventilation and weaned at the prior facility, but placed back onto mechanical ventilation within 24 hours of their transfer to the LTCH.

- Patients readmitted to the LTCH after transfer out to another facility who were still on mechanical ventilator support.

- Patients who were put on a ventilator beginning more than 24 hours after admission (e.g., placed on a ventilator a few days into the LTCH stay).

3.3.2 Feedback on Pilot Section O0200 of the Admission Item Set

Determining Invasive Mechanical Ventilation Support upon Admission to LTCH, Pilot Item O0200A: During check-in calls, the majority of facilities (n = 8) reported that they were able to determine weaning status by Day 2. The other two sites reported that they found determination of weaning status by Day 2 somewhat challenging because of their particular staffing and facility process procedures. Of note, many sites reported that their staff involved in pilot data collection interpreted Pilot Item O0200A as, "was the patient admitted for weaning?"

When asked whether weaning attempts were expected or anticipated during the patient stay, 3 of 10 sites reported that they selected "weaning" for 100 percent of enrolled pilot patients. When prompted for further explanation on the high proportion of "weaning" patients, many pilot sites (n = 6) attributed the high proportions to standard facility weaning orders or protocols already implemented as part of their usual LTCH admission process. Three sites explicitly stated that they have a facility-level protocol to attempt weaning on all patients admitted on ventilator support; one of these sites reported that chronically ventilated (non-weaning) patients were treated in a nearby Title 19 long-term care unit.

Regardless of whether data collectors reported any pilot patients as non-weaning, all sites were asked to provide examples of patients who might be considered non-weaning by LTCH staff. The sites highlighted chronically ventilated patients, patients being admitted on a home ventilator for reasons other than weaning, amyotrophic lateral sclerosis (ALS) patients, and patients who were on intravenous medications during the first few days in the LTCH. However,

it became clear during these conversations that standard facility patient assessment practices and weaning protocols guided decisions to report these patients as weaning or non-weaning. Standing orders at some sites involve attempts to wean, or partially wean, all patients; these orders included patient assessment of readiness to begin SBT.

When asked to provide feedback on coding the items, some sites reported uncertainty about coding weaning status if a patient was not medically ready for SBT by Day 2. Some sites coded these patients as weaning, because weaning attempts were anticipated for the future, whereas some sites coded these patients as non-weaning because they had not yet begun weaning attempts. One site that begins a weaning protocol for all ventilated patients, regardless of comorbidities, and performs an SBT if appropriate, stated that many of their patients are chronically ventilated with a goal of partial weaning/ventilator setting support reduction. This site felt that these patients were not accurately reflected in the pilot because although the site's weaning protocol aligns with the process measure—all patients are assessed for readiness for SBT—the goal of full liberation, as specified by the outcome measure, is not appropriate for all of their patients. This feedback revealed a need for additional clarification of the definitions and distinction between patient classification as weaning or non-weaning upon LTCH admission (Pilot Item O0200A).

Challenges Regarding the 2-Day Time Window: One of the reported challenges with the Day 2 time frame arose because of variation in the usual timing during Day 1 of patient admission. The most common admission time varies by site, but over half of the pilot sites (n = 6) reported that their patients are generally admitted during the late afternoon or evening. Though all facilities had a high proportion of patients admitted late in the day, only two pilot sites stated that the determination of weaning status by Day 2 may be difficult due to late-in-the-day admissions. Quantitative analysis showed that weaning status by Day 2 was determined for 95 percent of eligible patients.

When alternative time frames were proposed, 8 sites felt that a shift to determining weaning status "by Day 3" would not make a difference in feasibility of data collection or measure scores. These 8 facilities preferred the current "Day 2" determination time frame because this criteria is consistent with their normal facility-level protocol for determining weaning status. Two sites said shifting to "by Day 3" would fit better with their current admission and weaning processes. One of those two sites, however, stated that their weaning protocols were outdated and that they were in the process of changing to a protocol for implementing a Rapid Shallow Breathing Index by the end of Day 2.

Six of the 10 pilot sites reported that, per their facility-level protocols, weaning attempts start as soon as possible for all patients admitted on mechanical ventilation. Therefore, determining weaning status by Day 2 was not challenging for these sites.

All pilot sites reported that weaning assessments are almost always begun within 48 hours of admission. However, when presented with the option to change the determination of weaning status from "by Day 2" to "within 48 hours," most pilot sites were not in favor of this change because they felt it would be more burdensome for providers to count hours as opposed to calendar days.

Challenges Related to the Wording of "Deemed Medically Ready" for SBT: During check-in conversations, one site suggested that the wording "deemed medically ready for SBT by Day 2" used in pilot item O0200C was "too soft" and could be interpreted differently by LTCH facilities; they suggested editing this item to reflect whether a patient passed screening for SBT. This was discussed with the other pilot sites. All other sites (n = 9) disagreed that "medically ready" was problematic. These sites stated that the wording "deemed medically ready" better aligns with their current processes of care, in that it allows for a multidiscipline approach to patient assessment (e.g., respiratory therapist, pulmonologist, nurses). These sites also appreciated that the item sets do not prescribe a standardized screening process for all patients; rather, patient assessment of readiness is left to the clinical judgement of LTCH staff.

Challenges Pertaining to Documentation in the Patient's Medical Record of Reason(s) That the Patient Was Deemed Medically Unready for SBT: Pilot Item O0200D asks, "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?" Although six sites had no difficulty with this item, four sites said that LTCHs may face challenges in gathering documentation to support patient classification as non-weaning.

Two sites cited varying physician preferences and documentation practices within their facilities as challenges to determination of "medically" ready based on medical record documentation. One pilot site expressed concern regarding the accuracy and consistency of documentation between LTCHs. This site also stated that gathering documentation could be difficult if the information is located across multiple places within the patient's records, and suggested removal of Pilot Item O0200D.

Another pilot site suggested that Pilot Item O0200C is captured within Pilot Item O0200D, because completion of Pilot Item O0200D inherently flags the patient as medically unready. This site therefore suggested removal of Pilot Item O0200C from the admission assessment. However, Pilot Item O0200C is a gateway question that determines subsequent skip patterns and therefore cannot be removed.

3.3.3 Items Related to Risk Adjustment of the Outcome Measure (Pilot Sections I and O0100 of the Admission Assessment)

Prior to the pilot, RTI developed five new items pertaining to five risk adjustment factors for the ventilator weaning (liberation) outcome measure. These risk factors were (1) irreversible neurological injury, disease, or dysfunction; (2) progressive neuromuscular disease; (3) lung, heart, liver, kidney, or bone marrow transplant; (4) severe left systolic/ventricular dysfunction; and (5) vasoactive medications. Most sites agreed that risk adjustment of the outcome measure is important. With respect to risk factors (1) and (2) above, several facilities provided "real-world" examples of patients who had difficult weaning trajectories because of existing medical comorbidities.

Pilot Item I4403. Irreversible Neurological Injury, Disease, or Dysfunction (Including Due to Cerebral Palsy): During the check-in call conversations, 6 of the 10 sites stated that they found the word "irreversible" confusing for Pilot Item I4403, Irreversible Neurological Injury, Disease, or Dysfunction. Three sites suggested removing the word

"irreversible," because they felt that it is often difficult to determine whether a disease is irreversible. They also noted that providers may not use this specific word in their documentation, so it may be unclear to the person collecting the data. Some relevant conditions (e.g., Guillain-Barré) were seen as cyclical rather than irreversible, and sites felt that providers may not always know whether a condition is irreversible (e.g., spinal cord injury). One site suggested replacing the word "irreversible" with "severe"; however, other sites argued that "severe" could be just as confusing to providers as "irreversible." They further noted "severe" makes the item even broader. As one site mentioned, interpreting a severe condition is likely to be even more dependent on the person collecting the data and could result in inconsistencies in coding across and within facilities.

One site mentioned that this item is too broad and includes some conditions already on the LTCH CARE Data Set (e.g., severe anoxic brain damage).

Pilot Item I5506. Progressive Neuromuscular Disease: Two sites suggested combining Pilot Item I5506 with Pilot Item I4403 above, and one of these sites asked that CMS and RTI conduct further testing to evaluate the degree to which combining these items could affect risk adjustment of the measure scores. However, five sites felt that these two items (I4403 and I5506) should remain distinct. Some sites expressed difficulty determining which pilot items to check for certain conditions (e.g., West Nile virus, hemorrhagic stroke, spinal cord injury, severe anoxic damage). One site suggested aligning the risk factor data elements with ICD-10 codes rather than using the data elements from Section I of the draft Ventilator Weaning Pilot.

Pilot Item I7100. Lung, Heart, Liver, Kidney, or Bone Marrow Transplant: Four sites interpreted this item as including both pre- and post-transplant patients, and six sites said they would code this item for post-transplant patients only. The varying interpretation of this item among pilot sites indicated that the intent and definition of this item requires additional clarification.

Pilot Item I7300. Severe Left Systolic/Ventricular Dysfunction: Only three sites commented on this risk adjustment item, and one of these sites stated that this was the most challenging of all the new items. This site noted that some LTCHs have Left Ventricular Assist Device (LVAD) units; facilities with these units would likely approach these patients differently than facilities without these units. The other two sites commented that use of the word "severe" could result in coding inconsistencies similar to those that might be anticipated for Pilot Item I4403.

Pilot Item O0100H1. Vasoactive Medications (e.g., pressors, dilators, continuous medication for pulmonary edema): Multiple sites reported challenges in interpreting this item. The wording of this item as piloted included examples of vasoactive medications: "pressors, dilators, and continuous medication for pulmonary edema." Three sites felt the wording was too subjective; they were unsure which vasoactive medications to include on this item. In response, RTI queried other sites during subsequent calls and found that at least two sites marked "Yes" (checked box) on this risk adjustor for any type of IV or oral vasoactive medication. Another site stated they only marked this item "Yes" if the patient was on a high dose of vasoactive medications, but "high dose" was not clearly defined.

Several sites reported that this item took the most time to complete. One site stated that an extremely thorough review of all medications was required to answer this question, which resulted in an increased time burden compared with other items in Pilot Section I.

3.3.4 Feedback on the Discharge Assessment Item Set

Findings from Discussion of Pilot Item O0350A, Determination of Weaning Status at Discharge: When asked for feedback on the discharge item sets, 9 out of 10 pilot sites reported that determination of weaning status at discharge was not problematic. However, one site did note that the providers have to manually look back to the Admission Assessment to code Pilot Item O0350A appropriately, which may increase both burden and coding errors. This provider requested confirmation that non-weaning patients who may be fully weaned at discharge should still be coded as "09. Not applicable" on Pilot Item O0350A, even if the patient was ventilated after admission.

Findings Related to Measurement of Weaning Outcome: When asked about their usual internal practice for tracking the weaning outcome, all sites reported that they record the patient's weaning status. However, sites differed in their methods for tracking and calculating their facility-level weaning rate. While some sites defined liberation status as the patient status at the time of discharge, other sites assessed weaning status at one or more points during patient stay. These sites recorded patient liberation status at the end of each "episode of ventilation"; patients could have multiple episodes of mechanical ventilation per stay, with episodes separated by a period of time during which the patient was considered fully weaned. When asked about their facility-specific definition of "fully weaned," several sites reported that their facility definition is based on a 72-hour window with no mechanical ventilation support.

Findings Related to the Importance of Partial Weaning as a Liberation Outcome: During the discussion of partial weaning, sites were divided in their views. Five sites felt that partial weaning was not an important outcome because full liberation represents the chief goal of care for ventilated patients. One site noted that the criteria for establishing "partial weaning" are so ambiguous that it would be difficult to define successful partial weaning such that it was consistent and reflected a clinically significant outcome. Another site proposed reducing the level of ventilation support as an alternate outcome to partial weaning among chronically ventilated patients, whose treatment goals do not typically include full ventilator liberation. This suggestion was discussed during subsequent check-in calls with other sites; feedback received from these sites indicated that implementation would be overly burdensome, and that use of "partial weaning" as an outcome category could leave more room for intentional or inadvertent misclassification.

The five sites who did not feel that partial weaning status was useful or clinically important did not believe that partial weaning reflected a significant improvement in patient quality of life. Data collectors reported that the standard practice at their respective facilities is to define "weaning success" as full liberation. Additionally, some sites had observed that partial weaning does not impact patient discharge disposition or cost to CMS.

The remaining five sites provided varying reasons for collecting partial weaning as an outcome. Some sites asserted that including partial weaning status in the measure outcome

followed the patient-centered approach to care, citing partial weaning as the goal for many chronically ventilated patients admitted for exacerbation of other conditions (e.g., pneumonia). Additionally, partial weaning leads to an improved quality of life for patients, as it allows patients to freely move around the facility during the day. Partial weaning could also have a positive impact on patients' discharge disposition. Three sites suggested including nocturnal ventilation as a possible "partial weaning" outcome.

Though several sites confirmed the clinical importance of partial weaning, all 10 sites agreed that this outcome would be difficult to implement and may constitute unnecessary burden on providers. Assessment of baseline partial weaning status, necessary for determining an outcome measure, may be problematic because of (1) a lack of sufficient information or difficulty in accessing documentation from admitting facility, (2) a lack of reliability of documentation from the admitting facility, and (3) the timing of baseline measurement. Specifically, several sites reported an increased number of hours on ventilation because of transport to the LTCH.

Findings Related to Importance of Assessing Weaning Status for Patients Who Die: All nine pilot sites who responded to this question viewed the weaning status for patients who die as irrelevant. Several sites stated that weaning status of patients who die is not useful because many possible causes of death are unrelated to mechanical ventilation; other sites; sites also stated that feedback relating to this outcome would not affect their processes of care. However, several sites said that they do track this information. Two sites felt that patients who die after complete ventilator liberation could reflect poor quality care, medical errors, or both. They strongly discouraged counting these patients in the outcome measure numerator.

Findings Related to Terminal Weaning: Terminal weaning is the practice of planned withdrawal of invasive mechanical ventilation support at the request of patients or family members. All sites agreed that terminal weaning constitutes good quality of care for patients at the end of life. During check-in calls, many pilot sites said they were interested in tracking terminal weaning patients, but three sites said that these patients should not count against facilities' weaning rate score on the outcome measure. At least two sites supported reporting the percentage of fully weaned (alive), percentage of not fully weaned (alive), and percentage of terminal weaning patients as numerator components for the outcome measure. Most facilities reported that they already track this information; several internally report the number of patients with planned withdrawal of ventilator support. Furthermore, one site stated that it calculates terminal weaning patients separately but reports them alongside the percentage of patients who are not fully weaned to aid interpretation of the latter metric. Some sites already incorporate a specific field for the number of terminal weaning patient on their internal tracking sheets. For these sites, tracking terminal weaning patient would not involve additional data collection burden. Furthermore, the percentage of terminal weaning patients could be recorded in the expired discharge assessment item set as the number of patients with documentation of physician and family discussion of goals of care, similar to the documentation for SBT (and hospice measures).

Two sites felt that separate reporting of terminal weaning patient was not important information, and that only by understanding a patient's weaning history before entering the facility could outcomes for terminal and partial weaning patients be meaningful. One site

mentioned that "terminal weans" would not be admitted to or confessed publicly by some facilities because of negative connotations. Sites that do not currently use a specific field to record terminal weaning patient reported that counting terminal weaning patient would involve additional burden on data collectors. Several sites reported that terminal weaning patient are labeled as an unsuccessful weaning outcome in their current quality improvement programs, and felt that it would be inaccurate to represent terminal weaning as successful ventilator liberation.

The outcome measure currently includes patients who die in the measure denominator, but does not include them in the numerator. Pilot sites suggested that this could have two potential negative impacts on care practices surrounding planned withdrawal of ventilator support. At least one site said that implementation of the outcome measure may be seen as negatively affecting a facility's score. One site suggested that staff may be less willing to have conversations with patients and family on withdrawal of ventilator support. This may occur in facilities with a higher proportion of patients who elect withdrawal. One site said that these consequences would not begin until outcomes are tied to payment.

3.3.5 Feedback on the Validity of Item Sets and Feasibility of Implementation

Data Collection Burden: During the debriefing calls, all 10 sites reported that the additional data collection needed to calculate the two ventilator weaning (liberation) quality measures was not burdensome.

The amount of time required to complete the new items depended heavily on the sites' existing ventilator weaning assessment and data collection protocols. Sites with paper charts reported that data collection took them longer than sites using electronic medical records, largely because of challenges gaining chart access and reading physician notes; one site reported that Pilot Section O0200 was the most time consuming because it required review of written respiratory flow sheets and physician notes. Six sites reported that Section I took them the longest to complete, and two sites identified the Vasoactive Medications item as the most time consuming. Two sites mentioned that data collection was more difficult and burdensome for patients with longer lengths of stay. One site, which employed a dedicated data collector and submitter for all LTCH CARE Data Set related work, felt that no particular section took longer than the others.

When asked to compare the pilot process and the facility's actual data collection practices, 9 out of the 10 pilot sites stated that they developed an initial plan for pilot data collection and submission and adhered to this plan throughout the process. These sites generally followed existing protocols and processes at their institutions; very few adjustments were required to implement pilot data collection. One site initially employed three data collectors, but later transitioned to a single data collector midway through the pilot for the sake of efficiency.

All 10 sites agreed that the processes they implemented for pilot data collection reflected their actual data collection processes, and stated that they would continue with the same processes if the items were implemented on the LTCH CARE Data Set. Two data collectors felt that any respiratory employee at their facilities could accurately complete the data collection, given the clear and straightforward instructions provided during the pilot training.

Validity and Reliability of the Item Sets: Pilot sites unanimously agreed that the admission and discharge assessment items they completed during the pilot accurately reflect actual processes of care and the quality of care received. Most sites felt that the items would be interpreted the same way by different providers, but agreed that the training was critical for their understanding. As mentioned above, pilot sites felt that data elements for some risk factors, such as Vasoactive Medications and Irreversible Neurological Injury, Disease, or Dysfunction, were more likely to be interpreted differently by different providers. Two sites reported that their pilot data collectors had varying interpretations of the items in Pilot Section O0200; additional training/explanation was provided for these staff by the pilot site coordinators. One site felt that the draft pilot item set did not adequately capture weaning processes and outcomes for chronically ventilated patients, for whom partial weaning or reduction in ventilator support settings is a key goal of care.

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SECTION 4
LESSONS LEARNED BY CMS/RTI

4.1 Liberation Rate Measurement Gap

- Discussion of the ventilator liberation rate measure revealed that LTCH facilities use different definitions and methods for calculating and reporting facility-level weaning rates.

- Self-reported liberation rates are not standardized and therefore cannot be compared across facilities.

4.2 Feasibility

- Data collection was not seen as overly burdensome.

  – The Pilot Section I items (risk adjustors) were seen as more time consuming than the items for Pilot Sections O0200 and O0350 (ventilator process and outcome measure items).

  – Coding weaning items (Pilot Sections O0200 and O0350) took more time for sites with paper charts or weaning information in physician notes.

- Determining weaning status by Day 2 for most patients was feasible, and "by Day 2" aligned with current weaning protocols for most pilot sites.

  – Several sites operate under the expectation that weaning attempts will be made for all ventilated patients, and therefore did not classify any patients as "non-weaning."

- Partial weaning is viewed as clinically important by some providers, but nearly all providers agreed that it would be prohibitively difficult to capture the baseline information needed to confirm that partial weaning represents an improvement in patient weaning status since LTCH admission.

- The pilot reflected actual data collection processes, and almost all sites said that they would continue with their current pilot-based processes if the draft items were implemented.

4.3 Face Validity

- Pilot participants were confident that the data they captured in response to the assessments were valid, reliable, and adequately represented measure concepts.

4.4 Item Set Refinements

- The items used to calculate the process measure (Pilot Section O0200) progressed in a logical order; skip patterns in this section make sense and are not too difficult to follow given sufficient training.

- The definitions of weaning and non-weaning on admission (Pilot Item O0200A) need clarification.

- Instructions for use of response option 09 "Not applicable" for Pilot Item O0350A need to be clarified, and should be emphasized during training. Alternatively, a screening question may be added to the discharge item set in order to provide a suitable skip pattern in place of "not applicable."

- Challenges related to coding Section I: Active Diagnoses.

    - "Vasoactive medications" needs clarification.

    - Transplant item needs clarification.

    - "Severe left ventricular/systolic dysfunction" needs clarification.

    - The wording of Pilot Item I4403 should be reconsidered; some relevant conditions (e.g., Guillain-Barré) do not currently fall under I4403 or I5506.

4.5 Quality Measure Performance

- Process measure component scores had little variation; most sites had perfect scores for one or both components. However, the pilot sites represent a small sample size and were chosen as part of a convenience sample. Furthermore, during debrief calls, some sites said that they would expect more variation among other sites.

- The outcome measure score had some variation. The mean facility-level liberation rate was 75 percent.

SECTION 5
SUMMARY

5.1 Conclusion

The exploratory pilot testing revealed several significant findings. The qualitative data from the pilot test of the ventilator weaning (liberation) quality measures supported the importance of these two measures; results from qualitative and quantitative analysis also supported the feasibility of data collection. However, clarification of some of the items is needed to ensure the validity, accuracy, and reliability of the data elements. Pilot sites highlighted training as a key aspect of ensuring data validity and accuracy

Several pilot test participants stated that the ventilator-related measures will drive process improvement. Many providers said that their facilities currently have processes in place that facilitate data collection for weaning efforts. In addition, several providers indicated that their current system for collecting data to code this measure would benefit from further development to facilitate coding the ventilator-related measures.

5.2 Post-Pilot Test Actions by CMS

Findings from the pilot testing will be used during the final TEP meeting and subsequent activities to inform refinement of the draft measure specifications and item sets.

5.3 Future CMS Actions

CMS plans to implement this measure through future rulemaking. Further, during the measure development process, CMS will continue analysis of the measures to identify whether additional clarification or modification of the items or measures is necessary, and to evaluate risk factors and risk adjustment models.

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APPENDIX A:
DRAFT PILOT VENTILATOR WEANING (LIBERATION) QUALITY MEASURES ITEM SET:
ADMISSION ASSESSMENT

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Pilot Case ID

Section A. Administrative Information		
A0100B.	**CMS Certification Number (CCN)**	
A0210.	**Assessment Reference Date**	- - **MM DD YEAR**
A0220.	**Admission Date**	- - **MM DD YEAR**
A0250.	**Reason for Assessment**	Enter Code 01. **Admission** 10. **Planned Discharge** 11. **Unplanned Discharge** 12. **Expired**
A0X00.	**Age Range**	Enter Code in Boxes 01. ≤ **44 years** 02. **45 to 54 years** 03. **55 to 64 years** 04. **65 to 69 years** 05. **70 to 74 years** 06. **75 to 79 years** 07. **80 to 84 years** 08. **85 to 89 years** 09. ≥ **90 years**

Highlighted items = "new" data elements for ventilator weaning quality measures pilot test

Pilot Case ID

Section GG. Functional Abilities and Goals		
GG0100B.	**Prior Functioning: Everyday Activities.** **Indoor Mobility (Ambulation): Code the patient's need for assistance with walking from room to room (with or without a device such as cane, crutch, or walker) prior to the current illness, exacerbation, or injury.**	Enter Code ☐ 3. **Independent—**Patient completed the activities by him/herself, with or without an assistive device, with no assistance from a helper. 2. **Needed Some Help—**Patient needed partial assistance from another person to complete activities. 1. **Dependent—**A helper completed the activities for the patient 8. **Unknown** 9. **Not Applicable**

Pilot Case ID

Section I. Active Diagnoses		
Comorbidities and Co-existing Conditions. Check all that apply.		
I4403.	**Irreversible Neurological Injury, Disease, or Dysfunction** (Including Due to Cerebral Palsy)	☐
I4900.	**Hemiplegia or Hemiparesis**	☐
I5000.	**Paraplegia**	☐
I5101.	**Complete Tetraplegia**	☐
I5102.	**Incomplete Tetraplegia**	☐
I5110.	**Other Spinal Cord Disorder/Injury** (e.g., myelitis, cauda equina syndrome)	☐
I5450.	**Amyotrophic Lateral Sclerosis**	☐
I5506.	**Progressive Neuromuscular Disease**	☐
I7100.	**Lung, Heart, Liver, Kidney, or Bone Marrow Transplant**	☐
I7200.	**Metastatic Cancer**	☐
I7300.	**Severe Left Systolic/Ventricular Dysfunction**	☐
T-01	**Time Estimate** (Include only the time it took to complete the five new items in Section I.) **How long did it take you to assess the patient on I4403, I5506, I7100, I7200, and I7300 (including the time it took for you to refer to the patient's medical record, physically asses the patient, and determine the patient's status in reference to the five new items in Section I)?**	☐☐☐ minutes

Pilot Case ID

Section O. Special Treatments, Procedures, and Programs

O0100. Special Treatments, Procedures, and Programs Check all the treatments at admission. For dialysis, check if it is part of the patient's treatment plan.

Other Treatments

☐	**O0100J. Dialysis (Hemodialysis, Continuous Renal Replacement Therapy, Peritoneal Dialysis)**	
☐	**O0100H1. Vasoactive Medications** (e.g., pressors, dilators, continuous medication for pulmonary edema)	
T-02	**Time Estimate** (Include only the time it took to complete O0100H1, and not the time it took you to provide information for other items or to complete any data collection notes.) **Time it took to complete O0100H1 (including the time it took for you to refer to the patient's medical record and determine the patient's status in reference to O0100H1).**	☐☐☐ minutes

Pilot Case ID		

O0200. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) **by Day 2 of LTCH Stay**		
O0200A.	**Invasive Mechanical Ventilation Support upon admission to LTCH**	Enter Code ☐ 0. **No** → *end data collection for O0200; go to T-03* 1. **Yes, Weaning** → *go to O0200B* 2. **Yes, Non-Weaning** → *end data collection for O0200, go to T-03* 3. **Yes, Weaning Status Can't Be Determined** → *go to O0200B*
O0200B.	**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	Enter Code ☐ 0. **No** → *end data collection for O0200* 1. **Yes** → *go to O0200C*
O0200C.	**Deemed medically ready for SBT by Day 2 of the LTCH Stay**	Enter Code ☐ 0. **No** → *go to O0200D* 1. **Yes** → *go to O0200E*
O0200D.	**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?**	Enter Code ☐ 0. **No** → go to T-03 1. **Yes** → go to T-03
O0200E.	**SBT performed by Day 2 of the LTCH Stay**	Enter Code ☐ 0. **No** → go to T-03 1. **Yes** → go to T-03
T-03	**Time Estimate** (Include only the time it took to complete the items in O0200, and not the time it took you to provide information for other items or to complete any data collection notes.) **Time it took to complete O0200A-E (including the time it took for you to refer to the patient's medical record and determine the patient's status in reference to items O0200A-E).**	☐☐☐ minutes

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APPENDIX B:
VENTILATOR WEANING QUALITY (LIBERATION) MEASURES PILOT DRAFT ITEM SET:
PLANNED DISCHARGE, UNPLANNED DISCHARGE, AND EXPIRED ASSESSMENTS

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Pilot Case ID

Section A. Administrative Information		
A0100B.	**CMS Certification Number (CCN)**	
A0210.	**Assessment Reference Date**	- - **MM** **DD** **YEAR**
A0250.	**Reason for Assessment**	Enter Code 01. **Admission** 10. **Planned Discharge** 11. **Unplanned Discharge** 12. **Expired**
A0270.	**Discharge Date** [Date of Death on Expired Assessment]	- - **MM** **DD** **YEAR**
A0X00.	**Age Range**	Enter Code in Boxes 01. ≤ **44 years** 02. **45 to 54 years** 03. **55 to 64 years** 04. **65 to 69 years** 05. **70 to 74 years** 06. **75 to 79 years** 07. **80 to 84 years** 08. **85 to 89 years** 09. ≥ **90 years**

Highlighted items = "new" data elements for ventilator weaning quality measures

Pilot Case ID

Section O. Special Treatments, Procedures, and Programs

O0350. Ventilator Weaning (Liberation) Rate

O0350A.	**Invasive Mechanical Ventilator: Weaning Status at Discharge**	Enter Code in Boxes 01. **Fully weaned at discharge** (i.e., patient did not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to discharge) ➔ *go to O0350B* 02. **Patient was on invasive mechanical ventilation support for < 12 hours/day immediately prior to discharge** ➔ *go to T-04* 03. **Patient was on invasive mechanical ventilation support for < 12 but < 24 hours/day immediately prior to discharge** ➔ *go to T-04* 04. **Patient on invasive mechanical ventilation support for 24 hours/day at the time of discharge** ➔ *go to T-04* 09. **Not applicable** (Code only if the patient was non-weaning or not ventilated on admission [O0200A = 2 or 0 on Admission Assessment]) ➔ *go to T-04*
O0350B	**Last date of ventilation**	__ - __ - ____ **MM** **DD** **YEAR** ➔ ***go to T-04***

T-04	**Time Estimate** (Include only the time it took to complete O0350A, and not the time it took you to provide information for O0350B or to complete any data collection notes.) **Time it took to complete O0350A (including the time it took for you to refer to the patient's medical record and determine the patient's status in reference to O0350A).**	___ minutes

Highlighted items = "new" data elements for ventilator weaning quality measures

APPENDIX C:
CHECK-IN CALL DISCUSSION GUIDE

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Questions for First Check-in Call

1. How are things going? How was your first week?

2. Have you run into any issues during the Vent QM Pilot?

3. Are you having any problems maintaining the patient crosswalk?

    a. Are you having any problems submitting your data?

4. What is your process for determining patient eligibility for the pilot test? About how many patients have you included thus far?

    a. Are they generally on full-time ventilation or part-time when they're admitted?

5. Can you share with us your initial impressions of the Vent QM data elements and the process for collecting this data?

    a. What sources of information did you use to determine responses for the different sections?

    b. Who collected the data for the different sections, and when?

6. Do you have any questions about the Pilot materials?

    a. Do you refer to the Vent QM Pilot Manual as you are completing your Data Submission Forms?

    b. Are the definitions/instructions in the Vent QM Pilot Manual clear?

7. Are there any additional training/resources/definitions you would recommend to make the data collection process easier?

Additional Check-In Questions Pertaining to the Admission Assessment

Pilot Section I and O0100

8. Is the three-day assessment window for these sections clear?

9. The TEP was concerned that some of the items in Pilot Section I contain overlapping conditions. Do you see this as a problem? What kinds of conditions cause you to check Pilot Item I4403 and Pilot Item I5506?

10. Do you have any problems with any of these items in Sections I or O0100? If so, which ones, and why? If the wording is confusing, how could the item be clarified?

Pilot Section O0200

11. Do you feel like you have a clear understanding of the timeframe "by the end of Day 2" for question O0200A on Admission?

12. Coding language: Did you understand the three options available to you under the combined Assessment item O0200A, "Invasive Mechanical Ventilation Support upon admission to LTCH?"

    a. What sources of information did you use to determine responses to O0200A?

    b. Who collected the data?

13. Was it clear to you that for item O0200A code 3—"Yes, Weaning Status Cannot be Determined" meant: The patient was on invasive mechanical ventilation support upon admission but *you could not determine weaning status on admission* ***by the end of day 2***?

14. What processes did you use for determining Weaning vs. Non-Weaning on Admission by the end of Day 2?

    a. What sources of information did you use to determine responses to O0200A?

    b. Who collected the data?

15. Describe any challenges you faced in determining Weaning on Admission vs. Non-Weaning on Admission by the end of Day 2.

16. What conditions/comorbidities generally lend to patients being marked as "non-weaning?"

17. Were there any time of day or weekend factors that made determining weaning versus non-weaning on admission by the end of day 2 easier or more difficult?

    a. E.g., was there less information for patients admitted at night/on a weekend?

18. If you coded O0200A as 3—**Yes, Weaning Status Cannot be Determined**, can you share why you were unable to determine weaning status and used this code?

19. Are the skip patterns for Section O0200 clear to you?

    a. If you experienced issues identifying when to skip certain items, can you share which items were most challenging?

20. Does the use of "deemed medically ready" in Item O0200C make sense? Can you suggest more appropriate wording?

Check-In Questions Pertaining to the Discharge Assessment

1. Where did you actually find the information you needed to complete the Pilot Data Submission Form at Discharge? E.g., specific area in patient's chart; nurses progress notes; MD orders, etc.?

    a. Would you have to change access to these records for a more comprehensive review of weaning status in order to complete these measure items in the future?

2. Did your facility already have a system of documentation in place for documenting weaning activities that made this type of retrospective chart abstraction easy?

    a. If yes, please describe those systems now in place.

    b. If not, what type of system or processes would your facility have to implement in order to make data collection for Vent QM items feasible, if this measure were rolled out on the national level?

3. Describe any challenges you faced in collecting partial weaning data for O0350A. Weaning Status at Discharge.

4. What do you think of the definition of fully weaned—is it appropriate/applicable? Would it be better to replace "2 calendar days" with 72 hours?

5. How important is partial weaning as an outcome? Should it be retained?

    a. If we were to retain partial weaning as an outcome, we would need to establish baseline weaning on admission. How would you determine weaning status (# hours) on admission?

6. Were there any time of day or weekend factors that made determining weaning status at discharge easier or more difficult?

    a. E.g., was there less information for patients discharged at night/ on a weekend?

7. How important is it to capture weaning status on discharge of patients who die?

    a. How do you represent terminal weans in your internal quality reporting program?

    b. Is it possible to capture the % with documentation of ventilator withdrawal at patient/family request?

    c. What unintended consequences, if any, might be associated with including or excluding liberated patients who die from the measure numerator?

8. How many patients started as non-weaning on admission, and then subsequently underwent weaning attempts during the stay? (e.g. after 2 days?)

9. How are you Section O0200 for patients who come to the LTCH on SBT?

10. One pilot site suggested a measure for chronically ventilated patients that would assess decreases in certain ventilator settings between admission and discharge. What do you think of this suggestion?

11. Do you have anything else you'd like to share about your experience collecting and submitting data during the Vent QM Pilot?

APPENDIX D:
DEBRIEFING CALL DISCUSSION GUIDE

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Debriefing: Data Collection

1. If you used the web-based data submission during the pilot, would you have used paper-based data collection with scanned upload in hindsight?

2. What changes, if any, did you make to your data collection processes (timing, personnel, etc.) along the way? Why?

3. We would like to hear any additional thoughts you have regarding the time burden of data collection. Did you find data collection to be burdensome?

4. What contributed to longer vs. shorter data collection times? (i.e., any reasons for within-facility variation? Are some patients harder to collect data for?) We are asking because we would like to understand why the time burden estimates are what they are.

5. How well do you think the pilot process reflects actual data collection practices? What do you think the differences would be if these item sets are implemented (*i.e.*, who would actually be doing the data collection? What implication might this have for wording changes or time burden estimates?)?

6. In terms of data collection during this pilot, what was helpful to you? What could have been done differently? Do you have additional feedback on this topic?

Debriefing: Face Validity and Reliability of Item Sets

7. Based on your experience with the admission and discharge assessments, do you feel confident that the data captured in response to the questions is accurate and consistent (valid/reliable)? Why or why not? If not, which questions do you feel could be misinterpreted?

8. Would you feel confident that different people would interpret the questions the same way? In what ways could responses be influenced by individual interpretation?

9. Do you feel that RTI successfully captured what we'd intended to capture in order to calculate the measures? Why or why not?

   Process Measure: 2 components:

   i. the percentage of mechanically ventilated patients admitted to an LTCH for weaning that are assessed, by Day 2, for medical readiness to begin an SBT, and

   ii. the percentage of patients ready for SBT by day 2 who actually *begin* an SBT by day 2. Patients who do not receive an SBT by day 2 should have documentation of the reasons that they were not ready for an SBT.

   Outcome measure: the percentage of mechanically ventilated patients admitted to an LTCH for weaning who are fully weaned at discharge.

10. Do you think that these measures would be able/useful for distinguishing between high- and low-performing facilities?

Debriefing: Admission Assessment

11. Can you tell us about the patients who were admitted for weaning, but were not assessed for SBT readiness by the end of Day 2? *(O0200A = 1 and O0200B = 0)*

12. Regarding Item O0200C, why were some patients who were admitted for weaning deemed medically unready for SBT by Day 2? *(O0200B = 1 and O0200C = 0)*

13. Regarding Item O0200D, we found there were some patients who were deemed not ready for SBT by Day 2, and didn't have documentation for the reason they deemed not ready. *(O0200C = 0 and O0200D = 0)* Can you tell us more about these patients? How were you able to determine that they were not ready for SBT?

14. Regarding Item O0200E, there were a few patients who were assessed and deemed ready for SBT by Day 2, but who did not receive an SBT by 2. *(O0200C = 1 and O0200E = 0)* Would you please tell us more about these patients? For example, was there a change in patient readiness following the assessment?

15. Can you describe your "non-weaning" patients in more detail? (O0200A = 2) Who were they? Can you elaborate on why you categorized them as "non-weaning?"

16. For Section I, Active Diagnoses, what specific conditions did you include when you checked I4403 or I5506, aside from ALS, degrees of paralysis (e.g., tetraplegia), or other spinal cord injury? For example, some sites checked I4403 for patients with *Guillain-Barré*, which is not mentioned elsewhere in Section I.

    - I4403. Irreversible Neurological Injury, Disease, or Dysfunction (including due to Cerebral Palsy)

    - I5506. Progressive Neuromuscular Disease

Debriefing: Discharge Assessment

17. What would you say is the average LOS for ventilated patients at your site?

18. We would like to learn more about patients who took longer than average to discharge. Why do you think they had longer LOS?

    a. Is discharge placement a problem?

19. Did you face any additional challenges capturing data for unplanned discharge assessments or expired discharge assessments? If so, what were they?

Debriefing: General Feedback

20. Do you have anything else you would like to share about your experience collecting and submitting data during the Vent QM Pilot?