

January 2017

Technical Expert Panel Summary Report: Development of Long-Term Care Hospital (LTCH) Ventilator Weaning Quality Measures, 2014-2016

Deliverable 14

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CMS Contract No. HHSM-500-2013-13015I



TECHNICAL EXPERT PANEL SUMMARY REPORT: DEVELOPMENT OF LONG-TERM
CARE HOSPITAL (LTCH) VENTILATOR WEANING QUALITY MEASURES, 2014-2016

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CMS Contract No. HHSM-500-2013-13015I

January 2017

This project was funded by the Centers for Medicare & Medicaid Services under contract no. 500-00-1234. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI assumes responsibility for the accuracy and completeness of the information contained in this report.

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EXECUTIVE SUMMARY

ES.1 Measure Development Activities and Themes

The Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International to develop ventilator care-associated process and outcome quality measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) under the contract, the Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractors during measure development and maintenance. CMS also asks contractors to engage persons and family representatives during measure development to ensure that resulting measures are understandable, important, and meaningful to public consumers. A technical expert panel (TEP) was convened by RTI to gain critical insight and feedback from clinicians, researchers, and experienced LTCH administrators with respect to LTCH ventilator care-associated quality measures and data collection instruments. Two TEP in-person meetings were convened, in addition to seven webinar meetings and two patient advocate telephone interviews between April 2014 and October 2016. The TEP consisted of twelve members; the patient advocates consisted of two former patients who had undergone weaning from mechanical ventilation in LTCHs and one patient caregiver. TEP members provided recommendations for appropriate measure specifications, identified potential risk factors for ventilator weaning¹ quality measures, and provided feedback on draft data collection items. Key discussions concerned identification of the target population, process measure focus and numerator categories, inclusion of patients who die during an LTCH stay in the outcome measure denominator, inclusion of patients who die in the outcome measure numerator, and selection of patient-level exclusion criteria and risk factors for ventilator weaning quality measures. The patient advocates provided insight into their experiences in the LTCH and the meaningfulness of the ventilator weaning measures. They also provided feedback on both measures.

ES.2 Results

Through ongoing deliberations during in-person and webinar TEP meetings, RTI identified several measure development priorities. As of September 2016, RTI recommended one ventilator weaning-related outcome measure and one ventilator-weaning related process measure as candidates for measure and instrument development and implementation for the LTCH QRP. These measures are:

- Compliance with Spontaneous Breathing Trial (SBT)(including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay (Process Measure)
- Ventilator Weaning (Liberation) Rate (Outcome Measure)

¹ RTI would like to note that the terms “weaning” and “liberation” are used interchangeably throughout this report.

Draft measure specifications and data collection elements were developed for both measures. Data will be collected for these measures using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set Admission Assessment, and Planned and Unplanned Discharge Assessments.

SECTION 1

INTRODUCTION AND OVERVIEW

1.1 Introduction

On behalf of the Centers for Medicare & Medicaid Services (CMS), RTI International convened a Technical Expert Panel (TEP) to seek expert input on the development of ventilator care-associated quality measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP). Two in-person TEP meetings, seven webinar TEP meetings, and two patient advocate interviews were held between April 2014 and October 2016.

This report provides a summary of the TEP proceedings, detailing the key issues of measure development and TEP discussion around those issues. In this section, we provide a summary of the background, process for the TEP meetings, and organization of the TEP report.

RTI would like to note that the terms “weaning” and “liberation” are used interchangeably throughout this report. Previous iterations of these measures used the term “weaning,” but more recent TEP discussions have prompted a shift to “liberation” to replace the term “weaning.” For the purposes of this document and preserving the intent of these measures, this document will use the two terms interchangeably.

1.2 Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International (RTI) to develop ventilator care-associated quality measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) under the contract, the Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance (HHSM-500-2013-13001I; Task Order HHSM-500-T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders, experts, and patient representatives who contribute direction and thoughtful input to the measure contractors during measure development and maintenance. The purpose of the 2014-2015 Ventilator Quality Development technical expert panel (TEP) meetings was to gain input on the development of LTCH ventilator weaning quality measures and the items for inclusion on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set. Through ongoing deliberations during in-person TEP and webinar meetings held in 2014-2016, RTI and CMS identified several measure development priorities, and recommended consideration of one ventilator-related outcome measure and one process measure as candidates for ongoing measure and instrument development and implementation.

Toward the goal of strengthening patients and caregivers as partners in their own care, CMS strives to involve persons and/or family representatives in measure development in a meaningful way throughout the development process. This is known as “person and family engagement,” and may occur during any step(s) of measure development, including during TEP meetings. The inclusion of former patients and caregivers (those without professional healthcare training) helps to identify 1) issues that are important and meaningful to public consumers, and 2) the information that they need to make informed decisions regarding their care. Involving

patients and their families in the measure development process is critical for gaining a full understanding of the measures' impact on all stakeholders.

TEP members provided input to guide the development of the quality measures, including feedback on the individual LTCH CARE Data Set ventilator weaning items, the target population, inclusion and exclusion criteria, and patient demographic and clinical factors that could affect ventilator weaning outcomes (risk adjustors). Patient advocates offered insight into the importance and relevance of the draft ventilator weaning quality measures from their experiences on mechanical ventilation in the LTCH setting.

1.3 The Measure Development Team

The RTI ventilator measure development team is multidisciplinary and includes individuals with knowledge and experience in the areas of quality measure development, pulmonology, long-term acute care hospitals, medical and nursing care, epidemiology, gerontology, statistics, public health, health services research, and health care policy. A complete list of those involved in ventilator quality measure development is provided in **Table 1**.

Table 1
RTI Ventilator Quality Measure Development Team

Name	Project Role
Shannon Carson, MD	Consultant to RTI Project Team Professor of Medicine and Division Chief, Pulmonary Diseases and Critical Care Medicine, University of North Carolina at Chapel Hill School of Medicine
Terry Eng, PhD, RN	LTCH Setting Lead, Quality Measurement and Health Policy Program
Nicole M. Jarrett, MSPH	Analyst, Healthcare Quality and Outcomes Program
Rebecca Lewis, MPH	Analyst, Healthcare Quality and Outcomes Program
Lauren A. Martin Palmer, PhD	Analyst, Quality Measurement and Health Policy Program
Tri Le, PhD, MPH	Analyst, Quality Measurement and Health Policy Program
Lindsey Free, BS	Analyst, Quality Measurement and Health Policy Program
Amarilys Bernacet, MPH	Analyst, Quality Measurement and Health Policy Program
Sarra Sabouri, MPH	Analyst, Quality Measurement and Health Policy Program
Laura Morgan, MA*	Analyst, Healthcare Quality and Outcomes Program
Maryann Nguyen, MS*	Analyst, Quality Measurement and Health Policy Program
Margot Schwartz, MPH	Analyst, Healthcare Quality and Outcomes Program
Olivia Berzin, BA	Analyst, Healthcare Quality and Outcomes Program
Katherine Leibel, BA*	Analyst, Healthcare Quality and Outcomes Program
Karen Reilly	Project Director, Quality Measurement and Health Policy Program
Samruddhi Thaker, MBBS, MHA, PhD*	Former LTCH Setting Lead, Quality Measurement and Health Policy Program

*No longer at RTI International.

1.4 Organization of the Report

The following sections of the report discuss the development of the ventilator weaning quality measures, and summarize the feedback obtained from TEP members during the TEP meetings. ***Section 2*** summarizes the TEP process and names the TEP members, and ***Section 3*** summarizes the TEP discussions and conclusions. ***Section 4*** provides an overview of the draft admission and planned and unplanned discharge assessments item sets, while ***Section 5*** summarizes feedback from three patient advocates.

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SECTION 2 TEP PROCESS

2.1 Nomination Process

In March 2014, RTI submitted a Call and Nomination Form for TEP members to CMS for posting on the CMS website; the TEP nomination period closed on March 21, 2014. Information about the opportunity to participate as a TEP member was also disseminated to national provider and professional associations, measure development experts, patient advocacy groups, potential consumer/patient representatives, and other stakeholder organizations. At the close of the nomination period, RTI finalized the TEP composition by selecting 12 of the 15 total nominees with a diverse range of clinical, research, and administrative expertise, including experienced LTCH clinicians, researchers, administrators, and a respiratory therapist. TEP members included experts in LTCH patient care (e.g. LTCH medical directors) as well as prominent methodological experts and clinical researchers with relevant expertise to inform measure development. Panel experts represented approximately 80% of LTCH beds in the United States. A list of all TEP members and their affiliations is provided in **Table 2**.

**Table 2
TEP Membership List**

Name	Affiliation and Location	Year
T. Brian Callister, MD, FACP, FHM	National Medical Director, The LifeCare Family of Hospitals, Reno, NV	2014-2015
Christopher Cox, MD, MPH, MHA	Co-Director, Duke University Medical Intensive Care Unit Director, Duke Program for Supporting People and Enhancing Recovery (ProSPER), Duke University Medical Center, Durham, NC	2014-2015
Margaret Crane, RN	President and CEO, Barlow Respiratory Hospital	2014
Karen Finerty, RN, BSN, MBA	Director of Organizational Performance Improvement, RML Specialty Hospital, Hinsdale, IL	2014-2016
Jeremy M. Kahn, MD, MS	Professor of Critical Care, Medicine and Health Policy, University of Pittsburgh School of Medicine and Graduate School of Public Health, Pittsburgh, PA	2014-2016
Samuel I. Hammerman, MD, MMM, CPE, FCCP	Chief Medical Officer for LTACH Division of Select Medical, Mechanicsburg, PA	2014-2016
Meg Stearn Hassenpflug, MS, RD, FCCM	Research Administrator and Quality Officer, Barlow Respiratory Hospital, Los Angeles, CA	2015-2016
Neil Ross MacIntyre, Jr., MD	Medical Director of Respiratory Care Services, Pulmonary Function, Laboratory, and Pulmonary Rehabilitation Program, Duke University Medical Center, Durham, NC	2014-2016
Sean R. Muldoon, MD, MPH, MS	Chief Medical Officer, Kindred Healthcare, Louisville, KY	2014-2016

(continued)

Table 2 (continued)
TEP Membership List

Name	Affiliation and Location	Year
Michael S Niederman, MD, MACP, FCCP, FCCM	Clinical Director, Pulmonary and Critical Care Medicine New York Presbyterian/Weill Cornell Medical Center New York, NY	2014-2016
Louise Rose, RN, PhD	TD Nursing Professor in Critical Care Research at Sunnybrook Health Sciences Centre Associate Professor, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Ontario, Canada Adjunct Scientist Institute for Clinical Evaluative Sciences CIHR New Investigator Director of Research, Provincial Centre of Weaning Excellence, Toronto East General Hospital	2014-2016
Michael Smith, RRT	Manager, Spartanburg Hospital for Restorative Care, Spartanburg, SC	2014-2015
John Votto, DO, FCCP	President and CEO of Hospital for Special Care, Hospital for Special Care, New Britain, CT	2014-2016

Prior to the final TEP meeting, RTI attempted to recruit one or more former -patients or patient caregivers to serve as patient advocates on the TEP. RTI conducted a national search for patient advocates to participate in the TEP by reaching out to multiple stakeholders in the East, Midwest, and West geographic regions. In order to be able to speak to issues and information relevant to mechanically ventilated patients, patient advocates were eligible if they had been weaned from mechanical ventilation in an LTCH, or were the caregiver of such a patient. Due to this restricted criteria, RTI was unable to recruit patient advocates until after the final TEP meeting. As a result, feedback on the quality measures by the former patients and caregiver was gathered after the final TEP webinar.

Two former patients previously weaned in separate LTCHs and the primary caregiver of one of the patients were successfully recruited to participate in one-on-one interviews. Both patients had been placed on mechanical ventilation in an acute care setting due to complications related to life threatening emergencies; both patients were subsequently transferred to LTCHs for weaning from mechanical ventilation, following unsuccessful weaning attempts in the acute care setting.

2.2 Meetings

TEP meetings began in April 2014, continued through August 2016, and included 2 all-day, in-person meetings and 7 webinars or teleconferences. A complete list of all TEP meeting dates, meeting types, and discussion topics for development of the ventilator-related quality measures is provided in **Table 3**. At the end of each meeting, TEP members were invited to send written feedback, in addition to verbal feedback provided during the meetings. Both in-person

TEP meetings were audio recorded and transcribed by a professional transcriptionist for the purpose of summarizing TEP proceedings in this report.

The first TEP meeting was a webinar meeting held on April 28, 2014. At this meeting, RTI oriented TEP members to the LTCH QRP and LTCH CARE Data Set, presented TEP goals and procedures, and charged TEP members with brainstorming potential ventilator-related LTCH quality measure concepts for discussion during the first in-person meeting.

Table 3
Ventilator Quality Measure Development TEP Meetings

Date	Type	Purpose
April 28, 2014	Webinar	Kickoff and orientation
June 17, 2014	In-person	Identification and selection of potential measure concepts for further development
August 15, 2014	Webinar	Refinement of ventilator outcome measure
September 12, 2014	Webinar	Refinement of ventilator outcome measure
September 19, 2014	Webinar	Refinement of ventilator process measures
April 27, 2015 and May 4, 2015	Webinars	Review of all draft measure specifications
June 2015	Teleconferences	Feedback on Post-Acute Care Payment Reform Demonstration (PAC-PRD) CARE Tool based risk factors
August 26, 2015	In-person	Input on the measures concept and specifications; feedback on PAC-PRD CARE Tool data analyses of risk factors
August 9, 2016	Webinar	Obtain final TEP input on quality measures; review public comment results and preliminary pilot testing results

The first all-day, in-person meeting convened in Baltimore, MD, on June 17th, 2014. Eleven TEP members plus one RTI physician consultant attended the meeting. Discussion was facilitated by the measure lead, Samruddhi Thaker, and the physician consultant, Dr. Shannon Carson, with support from the RTI quality measure development team and representatives from CMS. At this meeting, the TEP focused on identifying measure development priorities and compiling a list of ventilator-related quality measure concepts, selecting measure concepts for further development, and drafting initial specifications for both process and outcome measures.

Follow-up webinars and teleconferences held in August and September 2014 focused on narrowing the list of potential quality measures, defining key terms, identifying the appropriate target populations, and providing feedback on draft measure specifications. The TEP considered potential unintended negative consequences of key decisions regarding both the process and outcome measures throughout the development process.

The purpose of the webinars held in April and May 2015 was to review and update the measure specifications and data collection elements for all three ventilator quality measures, as outlined in the NQF Measure Submission Forms (MSFs). The outcome from the webinar was to

evaluate the feasibility of the identified measure specifications and data collection elements through a pilot test. The key discussion goals and topics from the webinars were:

1. Summarize the advantages and disadvantages of recommending at least 72 consecutive hours as the cut-off for determining fully-weaned patients for the outcome measure.
2. Summarize rationales for and against inclusion of patients who die during the LTCH stay in the outcome measure.
3. To discuss whether the outcome measure exclusion criteria might incentivize facilities not to attempt to wean certain patients categorized as non-weaning at admission.
4. To discuss whether the proposed exclusion criteria help mitigate the likelihood of this measure's potential adverse impact on limiting access to LTCH services for patients seen as less likely to wean.
5. To discuss whether either measure would incentivize facilities to attempt weaning before it is safe or appropriate for patients to do so.
6. To discuss the draft measure data elements, and draft NQF Measure Submission Forms (MSFs) and Measure Evidence Forms (MEFs).

The second all-day, in-person TEP meeting took place in Baltimore, Maryland, on August 26, 2015. Eleven TEP members plus one RTI physician consultant attended the meeting. The purpose of the August 2015 in-person meeting was to resolve questions related to selection of exclusion factors and risk adjusters, and further refine draft data collection elements. The following key discussion topics were covered during this meeting:

1. Draft LTCH CARE data set ventilator admission assessment items and measure specifications for the process measure: compliance with Tracheostomy Collar Trial (TCT) or Spontaneous Breathing Trial (SBT) by Day 2 of LTCH stay.
2. Results of PAC-PRD data analyses of potential risk factors for ventilator weaning (liberation) rate.
3. Selection of measure risk factors and exclusion criteria.
4. Draft LTCH CARE data set ventilator admission assessment items and measure specifications for the outcome measure: ventilator weaning (Liberation) rate specifications and data collection items.
5. Address challenges related to the feasibility of data collection for the second process measure, Daily compliance with TCT or SBT during LTCH Stay: Day 3 of LTCH stay through the date when patient is fully weaned/through the discharge date.

The final TEP webinar, held August 9, 2016, had four main objectives: (1) to discuss selected unresolved or unclear issues from the August 2015 in-person TEP; (2) to discuss stakeholder feedback from the public comment period (May 19 – June 9, 2016), (3) to provide an overview of preliminary results from Ventilator Weaning (Liberation) Quality Measures Pilot Testing and (4) to obtain final TEP input on the two invasive mechanical ventilation quality measures that may be used in the LTCH QRP. Nine out of the 12 TEP members attended the meeting. Discussion was facilitated by Dr. Shannon Carson, with support from various members of the RTI team, as well as representatives from CMS. Key topics covered during this discussion were:

1. Feasibility of determination of weaning status by Day 2
2. Assessment of liberation outcome for patients who die
3. Changing “Irreversible” to “Severe” for draft Item I4403, Irreversible neurological injury, disease, or dysfunction
4. Addition of “Weaning status cannot be determined” to draft Item O0200A responses.
5. Potential unintended consequences
6. Disposition in the outcome measure of patients with planned withdrawal of ventilator support (i.e. “terminal weans”)
7. Risk Factors for the outcome measure, Ventilator Liberation Rate
8. Inclusion of partial liberation as a separate outcome numerator category for Ventilator Liberation Rate.

With respect to the patient advocates, the two former patients and one caregiver were provided with background materials to review prior to a telephone orientation meeting on October 7, 2016. Each person also participated in one of two semi-structured audio recorded telephone interviews on October 14 and October 19, 2016. Discussion during both interviews was facilitated by the measure lead, Nicole Jarrett, with support from the RTI quality measure development team, and the RTI physician consultant, Dr. Shannon Carson, who attended one of the interviews. These interviews focused on the patients’ and caregiver’s ventilator weaning experience as well as their perspective on the importance and utility of the two ventilator weaning quality measures. Questions asked during both semi-structured interviews are provided in **Appendix D**.

Sections 3 and 4 provide an overview of the key themes discussed by the TEP members during the meeting, and present final recommendations and rationale for the TEP’s decisions. *Section 5* provides a summary of the feedback received from the two former patients and one caregiver.

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SECTION 3

OVERVIEW OF KEY THEMES AND RECOMMENDATIONS

This section presents a summary of TEP discussions and recommendations regarding the development of the LTCH ventilator weaning quality measures and is organized into four subsections. Subsection 3.1 presents a summary of the original measure concepts discussed by TEP members, and the final concepts selected for further quality measure development. The next three subsections present the key themes and recommendations for the selected concepts: Subsection 3.2 outlines the TEP discussions for topics relevant to both measures, Subsection 3.3 presents topics relevant to the process measure, and Subsection 3.4 examines topics relevant to the outcome measure.

3.1 Conceptualization of the LTCH Ventilator Quality Measures

3.1.1 Evolution of measure concepts

Early in the development of these QMs, TEP members discussed several concepts for ventilator-care associated quality measures. The original measure concepts proposed by TEP members during the in-person meeting on June 17, 2014 were:

1. Ventilator Weaning Rate
2. Assessment for tracheostomy collar trial (TCT) readiness on admission.
3. Percent of days “on ventilator weaning protocol,” meaning that if a patient meets all five of the criteria below, they should have a trach collar trial, unless a medical opt-out button is checked (example opt-out reasons: temperature of 40°C, septic shock, transfer to ER)
 - a. If PEEP ≤ 5 ,
 - b. $F_{iO_2} \leq 0.4$,
 - c. Absence of vasoactive medications
 - d. Regular spontaneous efforts present, and
 - e. Heart rate ≤ 110
4. Medication review upon admission for unnecessary or duplicate medications (e.g. antibiotics).
5. Percent of ventilated days that the patient was screened for delirium using a validated delirium assessment tool.

In addition to the five measure concepts above, several sedation-related measures were discussed at length. However, TEP members were not able to reach agreement on an operational

sedation-related measure. They noted that despite the importance of the construct, “sedation” is a vague term, and that in practice, sedation use is complicated by patient anxiety.

Based on the importance to clinicians and patients, feasibility and burden of implementation, and strength of evidence, the TEP narrowed the list of concepts during the 2014 follow-up webinars to three measure concepts: 1) an outcome measure to assess ventilator weaning (liberation) rate, 2) a process measure to assess initial implementation of SBTs for mechanically ventilated patients, and 3) a process measure to assess adherence to weaning protocols for patients undergoing weaning attempts.

In August 2015, after additional consideration of the third measure concept, *Assessment of Daily Adherence to Weaning Protocols*, the TEP reached consensus that the anticipated limitations and burden of measuring adherence to weaning protocols outweighed the benefit of further developing this concept at that time. The TEP acknowledged that some measure of daily compliance with clinical guidelines and weaning protocols is important for encouraging quality care of ventilated patients. One TEP member stated that this topic would apply to both LTCH and ICU settings; thus, the TEP suggested to CMS that a separate, cross-setting panel be convened to develop a quality measure for assessing daily adherence to weaning protocols in multiple settings. At the conclusion of the meeting, TEP members recommended the following LTCH ventilator weaning (liberation) quality measures for continued development:

1. Compliance with SBT, including TCT or CPAP Breathing Trial, by Day 2 of LTCH Stay (Process Measure)
2. Ventilator Weaning (Liberation) Rate (Outcome Measure)

TEP discussions related to these two measures are described in Subsections 3.2 through 3.4 of this document.

3.2 Measure Characteristics and Topics Relevant to Both Measures

3.2.1 Target population

Because the process measure and outcome measure are intended to be complementary, the TEP agreed that both measures should address the same population of mechanically ventilated patients. The TEP identified two potential measure target populations:

1. All patients who are on invasive mechanical ventilation support upon admission to the LTCH and all patients who undergo invasive mechanical ventilation following admission.
2. Only those patients who are on invasive mechanical ventilation support upon admission to the LTCH.

TEP members in support of Option 1 felt that including all patients on invasive mechanical ventilation, both upon admission and following admission to the LTCH, provided a more accurate representation of the weaning population. Other TEP members supported Option 2 for two reasons. First, patients who are on mechanical ventilation support upon admission to the

LTCH represent the majority of invasive mechanically ventilated LTCH patients. TEP members stated that the proportion of patients who undergo invasive mechanical ventilation in the LTCH, following admission, is small. Second, TEP members on the staff of LTCHs thought that identifying patients who undergo invasive mechanical ventilation in the LTCH following admission would place substantial burden (time and personnel) on providers.

The TEP reached consensus that the target population for both the process and outcome measures would include all patients on invasive mechanical ventilator support at the time of admission to the LTCH (Option 2). For the purpose of this measure, the TEP defined invasive mechanical ventilation support as the use of a device to assist or control pulmonary ventilation, inclusive of the weaning period, either intermittently or continuously through a tracheostomy or by endotracheal intubation. Lung expansion devices such as intermittent positive-pressure breathing (IPPB); nasal positive end-expiratory pressure (nasal PEEP); and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).

Additionally, the TEP recommended that the definition of “on invasive mechanical ventilation at the time of admission” should not depend on the length of time patients are ventilated *prior* to admission (e.g. “on invasive mechanical ventilation within 24 hours prior to admission”) due to increased potential for confusion among healthcare providers. Furthermore, such a restriction would limit the included population in a manner that conflicts with the intent of the measures, which are to assess weaning processes and outcomes for any patient on mechanical ventilation at the time of admission to the LTCH. They suggested that no minimum amount of time on invasive mechanical ventilation prior to the LTCH admission should be specified in the target population definition (e.g., “on mechanical ventilation for a duration of at least 24 hours prior to admission”).

Finally, the TEP agreed that the definition of the target population should not specify a minimum amount of time on invasive mechanical ventilation *following* admission to the LTCH. This decision emerged from a discussion regarding whether to include patients who are immediately weaned upon admission in the target population. TEP members agreed that if an LTCH succeeded in weaning the patient very shortly after admission, the LTCH should receive credit for successfully weaning the patient.

3.2.2 Exclusion criteria

Given that the proposed quality measures focus on weaning processes and outcomes, the TEP agreed to exclude patients who are not expected to undergo weaning attempts. They identified two options for quality measure denominator exclusion criteria; both options are related to the definition of patients who were not expected to undergo weaning attempts during the LTCH stay:

1. Identification of a list of comorbidities to exclude patients with specific conditions who are considered unlikely to undergo weaning attempts

2. The use of a more general “non-weaning” data element, in order to exclude patients for whom no weaning attempts are anticipated by providers, regardless of comorbidities.

TEP members in favor of Option 1 argued that the use of exclusion criteria based on specific comorbidities was potentially more reliable than the use of a “non-weaning” category; given the Option 1 requirement for specific diagnoses, it would be more difficult for providers to “over declare” or incorrectly categorize patients as excluded from the measure, compared to Option 2. In addition, some TEP members felt that using specific comorbidities provides more granular (i.e. more detailed) data for analysis of comorbidities in the future.

TEP members in support of Option 2 argued that Option 2 allows providers more flexibility to determine a patient’s weaning status, and that a complete list of all potential reasons that a patient may be considered non-weaning is impracticable and open to questioning by stakeholders. In addition, these TEP members argued that some LTCHs specialize in weaning patients with specific conditions that other hospitals may consider non-weaning (e.g. amyotrophic lateral sclerosis). Obligatory exclusion of patients with these conditions could deter attempts to wean them from invasive mechanical ventilation. Furthermore, the addition to the LTCH CARE Data Set of a long checklist of potential contraindications to weaning would increase the burden of data collection on providers.

The TEP concluded that a more general “non-weaning” data element (Option 2) should be used to exclude patients who are unlikely to undergo weaning attempts. The TEP members recommended that “non-weaning” should be defined as objectively as possible, using specific diagnoses as examples.

For the purpose of these measures, the TEP defined “non-weaning” patients as patients on invasive mechanical ventilation upon admission to the LTCH, for whom at admission weaning attempts are NOT expected or anticipated (*e.g.*, patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). These patients will be excluded from both measures. Consideration of a patient as non-weaning *must* be based on documentation found in the patient’s medical record at admission.

The TEP also addressed situations in which patients were declared non-weaning on admission, but were subsequently able to be weaned. These patients would not be counted in either measure due to the exclusion criterion. TEP members agreed that this group of patients comprises a relatively small percentage of patients admitted on mechanical ventilation.

Finally, TEP members discussed the time frame for determining weaning status on admission in great detail (See 3.3.4 below) in order to clearly define the length of time following admission that LTCHs should assess and categorize patients as weaning or non-weaning. Some TEP members, especially those on staff of LTCHs, expressed concern that classification of a patient as weaning or non-weaning is difficult within the agreed upon 2-day time frame. They recommended exploring this issue during the pilot test and public comment period.

3.2.3 Burden

Several TEP members were LTCH clinicians or administrators with experience completing the existing LTCH CARE Data Set. These TEP members expressed concern that the expansion of the LTCH CARE Data Set to include additional measures will lead to increased burden on LTCH staff.

3.2.4 Unintended consequences

Based on their deliberations, issues identified by stakeholders through public comments, and feedback from pilot test participants, TEP members developed a list of potential unintended consequences that may result from implementation of the candidate ventilator liberation quality measures. In no particular order, the list of potential unintended consequences includes:

1. *Selection bias/negative influence on LTCH processes and policies:* LTCHs may modify admission practices to favor patients who are more likely to be weaned, in order to increase their weaning rate, at the expense of patients with poorer weaning prognoses. LTCHs might also rush admission and patient assessment practices in order to meet the Day 2 time window.
2. *Fewer weaning attempts for patients less likely to wean:* TEP members were concerned that patients with certain high-risk conditions, such as ALS, might be more likely to be categorized as non-weaning in order to exclude them from the outcome measure. This could result in fewer weaning attempts for these patients.
3. *Patient safety:* There may be increased risk to patient safety if staff who are less skilled in readiness assessment are too rushed to complete a thorough patient evaluation.
4. *Potential to affect health care disparities:* One TEP member acknowledged that some providers may subconsciously overlook or view racial and ethnic minority patients as high risk, which in turn may disproportionately affect health care access for under-represented minority patients; the risk of selection bias exists for all measures related to patient outcomes. TEP members noted that LTCHs specialize in treatment of high-risk patients and suggested that future measure maintenance include analysis of the potential impact of the ventilator weaning measures on healthcare disparities.
5. *Imperfect risk adjustment* has the potential to penalize high performing but lower outcome facilities. Adjusting for medical conditions lessens the effects of different patient mixes among facilities; risk adjustment must be sufficiently adequate so as not to penalize highly proficient providers who accept high-risk patients.
6. *Terminal weans:* Implementation of a measure related to weaning status at discharge may impact when and how often the discussion about end-of-life care is broached with ventilated patients and/or patient family members or caregivers.

The August 2016 TEP members discussed the likelihood that LTCHs might over-declare patients as non-weaning in order to exclude the most difficult patients from the outcome

measure. The TEP also noted that although providers will continue to take high-risk patients, subconsciously there may be selection bias with coding weaning and non-weaning, and advised that this be monitored if the measure is implemented. However, if there is a shift toward admitting more likely to wean patients, this may result in a more efficient use of facilities that are optimized for weaning. TEP members expressed concern that imperfect risk adjustment could affect high-performing LTCHs.

3.3 Topics Pertaining to 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

3.3.1 Definition of spontaneous breathing trial (SBT)

During the June 2014 in-person meeting, the TEP reviewed definitions for SBT, TCT and CPAP breathing trials and briefly discussed which were appropriate for inclusion in the measure. For the purpose of these quality measures, the TEP defined SBT as including TCT or CPAP breathing trial, in order to capture all methods commonly used to determine whether a patient is ready to begin the weaning process.

3.3.2 Numerator components

The TEP members discussed the process quality measure numerator components at length. Numerator categories proposed by the TEP for consideration included:

1. the number of patients eligible for SBT
2. the number of eligible patients assessed for SBT by Day 2
3. the number of patients found ready for SBT who receive SBT by Day 2
4. the number of patients who pass an SBT by Day 2

The TEP reached consensus over inclusion of numerator components 2 and 3 above as the most parsimonious set of sub-measures, while still accurately capturing the measure concept and reflecting quality of care. Thus, the process measure numerator reports two categories of patients:

1. The percentage of patients assessed for readiness for SBT by Day 2 of LTCH stay.
2. The percentage of patients found ready for SBT, for whom an SBT was performed by Day 2 of LTCH stay.

3.3.3 Numerator inclusion criteria considerations

TEP members discussed the use of specific parameters to define patients as ready for SBT, and for SBT success or failure (e.g. PEEP, FiO₂) but decided against it for several reasons. First, the use of SBT alone satisfies consensus-based weaning guidelines (MacIntyre 2005; Boles 2007). Second, the TEP felt that reaching consensus on weaning parameters/criteria would likely

be difficult. Third, TEP members noted that the use of weaning parameters by CMS for the LTCH QRP might be seen as operationalization of a particular weaning protocol. Finally, several TEP members noted that excluding weaning parameters/criteria from the wording of the definition promotes individualized patient care based on physician and/or respiratory therapist discretion while still encouraging adherence to some aspect of evidence-based weaning guidelines. The TEP also defined SBTs, TCTs, and CPAP breathing trials.

1. For the purpose of this measure, SBT is a trial of unassisted breathing for a certain period of time during the day and full ventilator support at night, administered to patients with endotracheal tubes. This includes TCT or CPAP breathing trial.
2. For the purpose of this measure, TCT is a trial of unassisted breathing via a tracheostomy collar (mask) with aerosol (mist), administered to patients with tracheostomy tubes. TCT would apply only to patients with tracheostomy tubes.
3. For the purpose of this measure, CPAP breathing trial is a trial of unassisted breathing for a certain period of time administered while the patient is wearing any type of continuous positive airway pressure respiratory support device that prevents the airways from closing by delivering slightly pressurized air through a mask continuously or via electronic cycling throughout the breathing cycle.

3.3.4 Numerator time window

TEP members considered four time options for the measure numerator for SBT from the time of admission:

1. SBT by Day 5. This was the day observed in a study of SBT methods for invasive mechanically ventilated patients (Jubran 2013) as the day by which one third of patients admitted to the LTCH on invasive mechanical ventilation (184 of 500) were weaned.
2. SBT by Day 3. This aligns with the period of time allowed by CMS for completion of the LTCH CARE Data Set Admission Assessment.
3. SBT by Day 2, which some TEP members argued represented reasonable expectation of the time to assess for readiness for SBT.
4. SBT by Day 1, which was discussed as the day of admission.

Though SBT by Day 5 was discussed by the TEP, all TEP members felt that Day 5 was overly long compared to best practices for patient weaning. The TEP unanimously agreed that LTCH patients admitted on invasive mechanical ventilation should be assessed for weaning prior to Day 5. Discussion concerning options 2 and 3 was more divided. Some TEP members argued for SBT by Day 3 because they felt it better aligned with CMS rules for completing the LTCH CARE Data Set Admission Assessment. It also accounts for any delays in completing an admission assessment due to weekends, and allows providers and additional day to determine a patient's weaning status on admission (weaning vs. non-weaning). Other TEP members argued for use of by Day 2 because evidence-based guidelines state that weaning processes should begin

as early as possible. The TEP members gave the example of patients admitted on Friday, and stated that these patients can and should be assessed for weaning readiness no later than Saturday evening. TEP members noted that option 4, Day 1, or the day of admission, did not allow sufficient time for comprehensive patient assessment and administration of SBT if appropriate. The panel unanimously agreed to edit the wording of this process measure to reflect receipt of SBT by the second calendar day of the stay (e.g. Day 2 of LTCH stay, where Day 1 is the day of admission) in consideration of circumstances where, because of administrative or other non-clinical reasons, the patient was not assessed for SBT until Day 2.

The TEP recommended that this issue (i.e., by Day 3 or Day 2) be tested during the public comment period and pilot test. Based on mixed feedback from public comments and feedback in support of Day 2 from pilot sites, the TEP discussed the implications of choosing either the Day 2 or Day 3 timeframe. The members of the TEP reiterated that determination of weaning status is a process measure. As such, they concluded that for the measure to encourage high quality care, the standard should be high. As an alternative to the “by Day 2” determination timeframe, the TEP considered the option to shift the determination timeframe to “within 48 hours” to address late LTCH admissions while still maintaining a high standard of care. Most TEP members did not acknowledge a significant difference between “by Day 2” and “within 48 hours” in implicating quality of care in determining weaning status. However, the TEP felt that this change to “within 48 hours” would require providers to count hours and would be more burdensome. Therefore, the TEP unanimously voted to keep the “by Day 2” timeframe in place.

3.4 Topics Pertaining to the Outcome Measure, Ventilator Weaning (Liberation) Rate

3.4.1 Definition of “fully weaned”

During several meetings, TEP members debated the length of time off invasive mechanical ventilation prior to discharge required for a patient to be considered fully weaned. The TEP considered definitions used in the literature (e.g., 48 hours, 72 hours, 96 hours, and 1 week) as well as variations in discharge practices observed among LTCHs. A few TEP members noted that some variation in the length of time between weaning and patient discharge is due to the type and quality of post-acute care facilities available to patients following LTCH discharge. For example, LTCHs associated with SNFs equipped to treat more acute patients may discharge patients sooner after weaning compared to LTCHs with more limited discharge options. They further noted that this varies geographically.

TEP members also considered potential unintended consequences related to longer vs. shorter time frames in the definition of fully weaned. Some TEP members were concerned that using 48-hours as the definition of fully weaned could permit premature discharge of recently weaned patients. The TEP agreed that a time period of approximately 72 hours, or two full days between the last date of ventilation and the discharge date (assuming a half-day of ventilator-free time on last date of ventilation and date of discharge) best reflects the literature, promotes patient safety, and minimizes any tendency toward prematurely discharging weaned patients.

The TEP thus recommended that “fully weaned” be defined as approximately 72 hours free from mechanical ventilation. For the purpose of this measure, a patient is considered fully

weaned if s/he does not require any invasive mechanical ventilation support for at least 2 consecutive full calendar days immediately prior to the day of discharge from the LTCH.

One member noted that the TEP did not consider, during brainstorming of measure concepts, whether the outcome measure definition should incorporate a time frame for weaning (e.g., 2-month liberation rate) in order to encourage timely weaning attempts. The TEP acknowledged that LTCHs are already under pressure not to keep patients beyond a certain time frame and that facilities are highly incentivized to wean patients off the ventilator. Therefore, setting a threshold for liberation time is unnecessary.

3.4.2 Disposition of ventilated patients who die in the outcome measure denominator

Early in measure development discussions, TEP members discussed whether the assessment of a weaning (liberation) rate should be based on all ventilated patients, including those who pass away in the LTCH, or only those who are ventilated and discharged alive (i.e. patients who die would be excluded from the measure denominator).

Several TEP members supported the retention of patients who die in the measure denominator, and provided the following rationale. First, TEP members were concerned that exclusion of patients who die may have unintended and undesirable consequences on patient quality of care. Examples of unintended negative impact provided by the TEP included failure to identify deaths related to weaning, and failure to capture patients who were successfully (fully or partially) weaned in the LTCH and subsequently die due to reasons unrelated to weaning. Second, TEP members noted that excluding patients who die from the measure denominator impacts interpretation of the measure score, shifting it to the liberation rate of ventilated patients who survive, rather than the liberation rate of all patients admitted on mechanical ventilation. Furthermore, this may be viewed as falsely inflating weaning rates because inclusion of patients who died in the measure would likely increase the denominator more than the numerator. Finally, some TEP members argued that the ventilator weaning rate is an outcome measure that is focused on patient status at the end of the stay. Patients who die from a comorbidity acquired during the stay should not be excluded.

TEP members who supported exclusion of patients who die from the measure denominator provided several arguments in support of their opinion. First, some TEP members argued that retention in the denominator of patients who die would automatically mark the patient stay as a failure in the Ventilator Weaning (Liberation) Rate if they are always counted as not fully weaned (i.e. not counted in the measure numerator). Consequently, LTCHs may be less likely to admit ventilated patients with a high risk of mortality. Second, TEP members noted that exclusion of patients who died during the stay (which would also subsume terminal weans) from the measure denominator may help to address the issue of terminal weans (see Section 3.4.4) without further complicating the measure, and without making a prescriptive statement about a very complex issue. Finally, a few TEP members suggested that exclusion of patients who die might facilitate analysis of risk adjustment factors by separating mortality outcomes from weaning (liberation) outcomes.

The TEP reached consensus that patients who die should not be excluded from the outcome measure denominator.

3.4.3 Disposition of fully weaned patients who die in the outcome measure numerator

Following the decision to include patients who die in the outcome measure denominator, the TEP addressed whether to report the weaning status of these patients in the outcome measure numerator. As discussed above in 3.4.1, the TEP agreed that fully weaned patients are those patients who do not require any invasive mechanical ventilation support for at least 2 consecutive full calendar days immediately prior to the day of discharge. The original measure numerator components of weaning status at discharge as proposed by the TEP in 2014 comprised four categories:

1. The number of patients reported as fully weaned on Planned or Unplanned Discharge Assessment (alive)
2. The number of patients reported as not fully weaned on Planned or Unplanned Discharge Assessment (alive)
3. The number of patients reported as fully weaned on Expired Discharge Assessment (deceased)
4. The number of patients reported as not fully weaned on the Expired Discharge Assessment (deceased)

The TEP asked the measure developer to analyze these patient populations during pilot testing and provide the TEP with more information at future meetings. Most pilot participants agreed that the inclusion of separate numerator categories for the weaning outcome of patients who die (Categories 3 and 4) is neither clinically important nor useful for quality assurance programs. TEP members reviewed this feedback and discussed the meaning and implications of reporting liberation status for patients who die in the LTCH.

TEP members who supported reporting fully weaned patients who die as a numerator component believed that the weaning outcome should be calculated across all patients admitted on mechanical ventilation, regardless of mortality. Some members mentioned that this may provide a more complete understanding of the impact of weaning protocols in a facility. A few TEP members also noted that it would allow LTCHs to receive credit for every patient weaned.

TEP members who advocated against reporting fully weaned patients who die in the measure numerator agreed with pilot testing and stakeholder opinion that measurement of this population would add complexity to the measure with little advantage in terms of utility. TEP members also noted that the population of weaned patients who pass away three calendar days or more after the last date of ventilation would be small.

At the final webinar, TEP members voted unanimously to report only the percentage of patients who were fully weaned alive at discharge. As of August 2016, the numerator

component for this measure was defined as the number of patients reported as fully weaned (alive), as recorded on the Planned or Unplanned Discharge Assessment.

3.4.4 Disposition of terminal weaning in calculating the outcome quality measure

The disposition of patients for whom withdrawal of ventilator support with the intent to end life is requested by the patient or patient's family, also referred to as "terminal weans," was viewed as a confounding issue. The practice of "terminal weaning," as defined above, is considered by the TEP and CMS as a positive patient care outcome. However, including terminally weaned patients in the denominator of the outcome measure -- pursuant to the TEP decision not to exclude patients who die (Section 3.4.2) -- but not in the numerator (Section 3.4.3) may negatively impact the measure score by decreasing the numerator with respect to the denominator, despite consideration of terminal weaning as a positive process.

TEP members who supported the inclusion of terminally weaned patients in the weaning (liberation) rate numerator did so because, if used appropriately, the process of terminal weaning represents good quality of care. In addition, some TEP members were concerned that excluding terminally weaned patients from the measure numerator may negatively impact the practice of terminal weaning, because providers seeking to increase their liberation rate might postpone discussions of terminal weaning with family members in favor of conducting additional weaning attempts.

TEP members who did not support including terminally weaned patients in the measure numerator noted that providers seeking to increase their quality measure score might falsely classify patients who failed to wean as terminally weaned patients, in order to reduce the impact of unsuccessful weaning attempts on their measure score. Alternatively, family members of patients who are failing to wean may request that the patient be removed from the ventilator, which would likewise convert the patient from being categorized as unsuccessfully weaned to terminally weaned. Under both scenarios, the liberation rate could be interpreted as artificially increased. Inclusion of terminally weaned patients in the measure numerator may therefore significantly reduce the effectiveness of the quality measure. Additionally, the majority of patients who are terminally weaned do not survive for three or more calendar days following withdrawal of ventilator support, and therefore should not be represented in the measure numerator as defined.

TEP members briefly considered the inclusion of terminally weaned patients as a separate category in the numerator. While this would allow these patients to be counted as a success, and might facilitate quality measure interpretation, multiple TEP members did not support this option for the reasons listed above. In addition, one TEP member noted that some providers may resist separate reporting of terminally weaned patients due to negative public opinion, even though TEP members agreed that removing these patients from mechanical ventilation reflects good quality of care.

In summary, TEP members agreed that the issue of terminally weaning patients is very complex. After discussion, the TEP voted unanimously against including terminally weaned patients in the measure numerator.

3.4.5 Reporting partially-weaned patients as an outcome numerator category

During early meetings, several TEP members raised the concept of including partially-weaned patients as a separate numerator category for the outcome measure. This concept was discussed repeatedly at subsequent TEP meetings.

Some TEP members advocated for the inclusion of partially-weaned patients in the numerator, for two reasons. First, they felt that a separate numerator component should be used to capture patients who are partially weaned. Capturing this population rewards LTCHs who successfully partially wean ventilated patients who were admitted on 24-hour invasive mechanical ventilation support. Second, the TEP stated that partial weaning may represent an improvement in a patient's quality of life.

Other TEP members advocated against reporting of partially weaned patients as a numerator category, citing several reasons. First, while all TEP members agreed that the outcome measure should be risk adjusted, they believed that appropriate risk adjustment for a multinomial outcome (fully weaned, partially weaned, and not weaned) may be difficult. Second, the TEP found it difficult to reach consensus on the amount of time providers are allowed in order to determine a successful partial wean, and to set non-arbitrary cut-offs for the definition of partially weaned. Third, TEP members suggested that partial weaning may or may not represent an improvement in patients' quality of life. Fourth, it was articulated that the inclusion of partial weaning increases the quality measure complexity and also the burden on providers in terms of identification, categorization, and recording of the weaning time intervals.

Finally, some TEP members felt that reporting partially weaned patients in the measure numerator may have unintended negative consequences. For example, several TEP members were concerned that facilities might extend the length of SBTs beyond appropriate duration for some patients, in order to meet the threshold for partial weaning and thus count these patients in the partially-weaned numerator component (e.g., a 10-hour SBT could be extended to 12 hours if the threshold for partial weaning was 12 hours). Similarly, providers may seek to avoid or prolong terminal weaning of invasive mechanical ventilator support, in order to count the patient in the partially-weaned measure numerator component.

To help resolve the debate, the TEP reviewed feedback from the public comments and pilot testing sites with respect to partial weaning. Public comments supported the feasibility and utility of determining partial weaning status as an outcome. Mixed feedback was received from pilot sites; some providers indicated that partial weaning status contributes positively to patient quality of life and outcomes, while other providers stated that partial weaning is neither useful nor of significant clinical importance. TEP members noted that several pilot sites were concerned about the detailed data collection on admission that would be required to establish baseline weaning status at admission for comparison to weaning status at discharge. At the final TEP meeting, 7 of the 9 TEP members in attendance agreed that partial weaning should not represent a numerator category for the ventilator weaning (liberation) rate.

3.4.6 Importance and Timing of Implementation of Risk Adjustment

TEP members were asked their opinion about including, identifying, and implementing risk factors at this stage of the measure development. Several TEP members who advocated for including risk adjustment in the measure specifications noted that risk adjustment for high-risk patients might help mitigate unintended negative consequences related to patient selection, such as penalizing high performing LTCHs who specialize in weaning patients with specific comorbidities. One TEP member stated that including risk factors at this stage of measure development would also contribute to the measures' face validity, given that risk adjustment is usually recommended for outcome measures. The TEP acknowledged that public comments and pilot sites generally supported the importance of risk adjustment for the outcome measure.

TEP members who were against implementing risk adjustment at this stage of measure development emphasized the absence in the literature of consistent evidence supporting any conditions as risk factors for ventilator liberation; although factors have been identified that predict mortality as a ventilator outcome, no factors have been identified in the literature that reliably predict liberation at discharge (see *Section 3.4.7*). These TEP members noted that some studies have shown that no risk adjustment may be preferred to poor (i.e. unscientific) risk adjustment.

The TEP concluded that risk adjustment should be included in the outcome measure specifications, but that the risk adjustment model should be refined when more evidence becomes available. TEP members recommended that measure developers conduct additional potential risk factor analyses and collect data on multiple potential risk factors for future assessment.

3.4.7 Identification of Risk Factors

TEP members were asked to provide input on factors that affect patients' weaning outcomes, for use as risk adjustors. TEP members were instructed to make suggestions based on their clinical experience as well as any findings from research they had conducted or reviewed. There was considerable discussion of the merits and limitations of a number of potential risk factors, including those related to age, chronic mechanical ventilation, sepsis, dialysis, irreversible neurological injury or neuromuscular disease, spinal cord injury or disorder, multi-organ failure, renal failure or other kidney disease, vasoactive medications, heart failure, and metastatic cancer, among others.

The TEP agreed that none of the current evidence-based models for predicting weaning success Acute Physiologic and Chronic Health Evaluation system (APACHE), Acute Respiratory Distress Syndrome (ARDS), and Arterial Blood Gas (ABG) have proven reliable in either LTCHs or intensive care units (ICUs). The Prolonged Mechanical Ventilation Prognostic Model (ProVENT) model is more reliable, but uses mortality as the outcome. Evidence provided by the RTI analysis of PAC-PRD data was inconclusive.

The TEP recommended that a finite list of risk factors be proposed for the Ventilator Weaning (Liberation) Rate measure risk adjustment. In August 2015, the panel identified the following categories of factors for outcome measure risk adjustment: age, dialysis, metastatic

cancer, left ventricular assistive device/dysfunction, progressive or irreversible neuromuscular disease or injury, or prior functional dependence. They stated that these decisions should be reconsidered when stronger evidence becomes available. TEP members also commented that these risk factors must be present at the time of admission in order to represent true risk factors; therefore, they are included only on the draft Admission Assessment Item Set.

After reviewing feedback from public comments and pilot testing sites, the TEP found that providers sought additional clarification on the vasoactive medications and transplant measures and “severe left ventricular/systolic dysfunction” terminology. The TEP recommended additional clarification and examples for providers on what conditions/medications to include for each item. For example, the TEP discussed the potential difficulty in categorizing “severe” left ventricular/systolic dysfunction, and suggested the alternative use of Ejection Fraction (EF) numbers. It was recommended that an EF <30% be used as a cutoff for patients though the TEP acknowledged that these item instructions would likely be burdensome on providers. While discussing vasoactive medications, the TEP noted the role that they can play in readmissions, and the consequent effect on the weaning outcome measure. The TEP discussed concerns over capturing vasoactive medications and agreed that providing examples for providers was critical. The TEP also discussed transplant status, noting that a pre-transplant patient would not be weaned. They also discussed if the amount of time that has passed following transplant plays a role in weaning, and stated that the intent of this risk adjustor is to capture post-transplant patients within a certain timeframe.

Pilot site feedback also suggested the current language of the risk adjustor for neurological conditions was confusing. One participant suggested the changing the wording of “*irreversible* neurological injury, disease, or dysfunction” to “*severe* neurological injury, disease, or dysfunction” in order to account for comorbidities that may be reversible. The TEP discussed and voted unanimously to change the language to “severe.” Although the panel acknowledged that interpretation of this item may be difficult and vary according to personal interpretation, they nonetheless recommended using this broader terminology. They encouraged the measure developer to list several examples of severe neurological conditions for providers.

SECTION 4

DATA COLLECTION ELEMENTS AND DRAFT ITEM SETS

This section provides an overview of the LTCH CARE Data Set data elements for the two measures under development. Some data elements were already included in LTCH CARE Data Set Version 3.00, which was implemented in April 2016; these items were tested alongside new draft data items to refine the measures under development.

4.1 Draft Data Elements and Coding for Admission Item Set

The TEP reviewed and provided feedback on multiple versions of the draft LTCH CARE Data Set Admission Item Set. Data elements include items related to screening and inclusion/exclusion for both measures, risk adjustment factors for Ventilator Weaning (Liberation) Rate, and data elements related to 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.

Feedback from public comments indicated some concern regarding data validity and unintended consequences of determining weaning status by Day 2, prompting the inclusion of an additional “weaning status cannot be determined by Day 2” category during pilot testing. During the pilot test, most pilot sites were able to determine weaning status by Day 2; the “weaning status cannot be determined by Day 2” category was coded for less than 5% of patients (6/150). The TEP deliberated over the inclusion of this additional “cannot be determined” coding option, ultimately deciding that this option would provide marginal usefulness over a binary measure (weaning vs. non-weaning) while increasing the data collection burden. The TEP also discussed the impact of an additional category on the calculation of the measure. The TEP felt that the ultimate purpose of Item O0200A is to exclude patients who will not undergo weaning attempts from the measures. Because the addition of the “cannot be determined” response category does not contribute to this purpose, the TEP voted that it should not be included in future drafts of the Admission Assessment Item Set.

4.2 Draft Data Elements and Coding for Planned/Unplanned Discharge and Expired Item Sets

The TEP reviewed and provided feedback on multiple versions of the draft LTCH CARE Data Set Discharge and Expired Assessments Item Sets. Data elements include items for identifying patients in the Ventilator Weaning (Liberation) Rate measure numerator. In addition to including the planned discharge and unplanned discharge assessments, this item is also listed on the Expired assessment, in order to capture information on the number of patients who die (i.e., the third component of Ventilator Weaning (Liberation) Rate).

The TEP voted not to capture liberation status on discharge for patients who die in the LTCH, because they felt that it is neither important nor useful to capture the weaning (liberation) status of patients who die (see *Section 3.4.3*). Therefore, the draft data element for Ventilator Weaning (Liberation) Status on discharge will not be included on the Expired Assessment Item Set. Additionally, options related to partial weaning status on discharge will not be included as responses for the Ventilator Weaning (Liberation) Status discharge data element, because the

majority of TEP members voted not to capture partial liberation status on discharge for any patient (*Section 3.4.5*).

SECTION 5

PATIENT ADVOCATE FEEDBACK

In order to assess the relevance and usefulness of these ventilator weaning (liberation) quality measures to patients and caregivers, RTI recruited and interviewed two former patients with a history of mechanical ventilation weaning in LTCHs, as well as the caregiver of one of the patients, to discuss their interest in and response to the measures. (For more information on patient recruitment, please refer to *Section 2*.) This section of the report summarizes findings from the -patient and caregiver interviews with respect to their experiences being on an invasive mechanical ventilator at an LTCH and undergoing the weaning process, as well as their understanding and interpretation of the quality measures.

5.1 Patient Experience on Invasive Mechanical Ventilation

Both patients were taken to their local hospital's emergency department, one with a diagnosis of congestive heart failure and the other for an aortic aneurysm. The patient with congestive heart failure reported being placed on a ventilator within minutes of arriving at the emergency department. The other patient underwent emergency surgery for the aneurism. During his acute care hospital stay, this patient contracted pneumonia requiring the initiation of mechanical ventilation. Both patients spent several weeks in the intensive care unit, where ventilator weaning attempts were unsuccessful. They were subsequently transferred to LTCH facilities for weaning from the ventilator.

Both patients had very different experiences on invasive mechanical ventilation. One patient felt the machine was "necessary" and when describing the machine simply stated, "if you need something to breathe, then you need something to breathe." He felt his experience with the feeding tube was more challenging and uncomfortable than his experience with the ventilator. This patient did not recall the process of being removed from the ventilator, but did remember removal of the feeding tube.

In contrast, the other patient's mechanical ventilation experience was more traumatic, including multiple ruptures of the tracheostomy balloon in the acute care setting, which rendered him unable to breathe for short periods of time. These experiences left him extremely anxious about subsequent efforts to wean from the ventilator in the acute care setting.

Both patients described a professional and encouraging environment once they were transferred to the LTCHs. The patient who experienced trauma while on the ventilator in the prior setting said that the difference between the ICU staff and the LTCH staff was "night and day." Upon arrival to the LTCH, the patient and his caregiver recalled a doctor and nurses at his bedside within 30 minutes. The team was there to describe the process of weaning and to give them a timeline for getting off the ventilator. He describes this as somewhat overwhelming, but the timeline and expectation of successful weaning helped counteract his anxiety over weaning attempts in the LTCH. This patient reports beginning SBTs within the first two days of admission to the LTCH.

When asked what facility characteristics were important for helping patients on a ventilator, both patients articulated the importance of "good people to care for you" and having

staff to “help us understand what was going on.” One of the patients had a family member who conducted extensive research on LTCHs before he was transferred for weaning, including site visits to potential LTCHs to assess the demeanor of the LTCH staff and quality of care as reported by other LTCH patients and their family members.

5.2 Patient Understanding and Perspective on Ventilator Weaning Quality Measures

The second half of the semi-structured interviews focused on a discussion of the quality measures. When asked if they could describe the quality measures to a friend, only one patient was able to describe both, though both patients and the caregiver felt that having the process and outcome information could be helpful to patients and families doing research about LTCHs. The patient who was able to describe the two measures felt that it was important to track this information, and both the patient and his caregiver thought that numbers like these reflected the kind of information that their daughter might have used when she was choosing an LTCH for her father’s care. However, this patient noted that these statistics do not address the demeanor of LTCH healthcare providers who interact with patients, which they felt to be extremely important. Both the patient and his caregiver felt that they would be better able to understand the measure specifications if brief, plain-language descriptions were supplied, but the caregiver stated that the mental state of a patient or caregiver during the time they are deciding to transfer to an LTCH may still make it challenging to understand the quality measures. They also both agreed that they would be encouraged by receiving information regarding a facility’s discharge ventilator liberation rates, even if a 60% liberation rate at a facility meant that 40% of patients were not liberated at discharge. The caregiver mentioned, however, that this lack of negative impact (e.g. discouragement from knowing that 40% of patients were not weaned) might be due more to her personal faith: “As an individual, I knew my husband would survive this. Like I say, those numbers to me, probably wouldn’t affect me [negatively]. Myself, personally.”

The other patient had a better understanding of the process measure than the outcome measure, and stated that it was important to have a standard protocol and procedures in place so that ventilator weaning efforts are provided equally, regardless of the facility. He did not feel he could speak to the advantages and disadvantages of having aggressive weaning efforts, but did state that it made sense to have a safe protocol that everyone is following to ensure comparable care.

We learned from our conversations with these individuals that quality measurement is important to patients and their families, but that they had difficulty comprehending the measure concepts and the outcomes as they were described in the background materials provided them.

SECTION 6

SUMMARY OF TEP AND PATIENT ADVOCATE DISCUSSIONS

Through ongoing deliberations during in-person and webinar TEP meetings, the TEP recommended that RTI focus measure development efforts on two ventilator weaning (liberation) quality measures for the LTCH QRP. These measures are:

- Compliance with Spontaneous Breathing Trial (SBT)(including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay (Process Measure)
- Ventilator Weaning (Liberation) Rate (Outcome Measure)

Draft measure specifications were developed for both measures. The TEP voted that the target population for these measures should include all patients admitted to the LTCH who were receiving invasive mechanical ventilation, regardless of the duration of ventilation prior to the LTCH admission, and that patients who were categorized as “non-weaning” should be excluded from the measures. TEP members agreed that patients who undergo mechanical ventilation in an LTCH after LTCH admission would not be included in the measures. The TEP voted that the processes of care assessed by the measure “Compliance with SBT” should be completed by Day 2 of the LTCH stay, and that the outcome measure for ventilator liberation status should assess the number of patients who were fully weaned (alive) at discharge, where full liberation is defined by the absence of mechanical ventilation for two calendar days prior to the date of discharge. Finally, the TEP provided a list of risk factors that should be considered for adjustment of the ventilator liberation rate outcome measure, and discussed at length the potential unintended consequences of implementing these two measures.

The TEP also provided feedback on the wording of the new and existing data elements for both measures. Data will be collected for these measures using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set Admission Assessment and Planned and Unplanned Discharge Assessments.

Feedback from two former patients and one caregiver indicated that the information provided by these quality measures would be relevant to patients undergoing weaning from mechanical ventilation in LTCHs. Descriptions of the measures should be brief and provided in plain language.

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MacIntyre NR, Epstein SK, Carson S, et al. Management of patients requiring prolonged mechanical ventilation: report of a NAMDRRC consensus conference. *Chest*. 2005;128(6):3937-3954.

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**APPENDIX A:
TEP MEETING AGENDAS**

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Outcomes and Process Elements Quality Measures Development
Technical Expert Panel Meeting**

8:30 AM – 4:30 PM, Tuesday, June 17, 2014

CMS Media Center, Baltimore, MD

Web Conference URL: <https://www.connectmeeting.att.com>

Dial-in Number: 888-706-0584 Access Code: 8233211

- | | |
|--------------------------|---|
| 8:00-8:30 AM | CMS Security Clearance and Check-in |
| 8:30-9:00 AM | Opening Remarks, Goals, and Background <ul style="list-style-type: none">• Welcome and Introductions• Review Agenda• TEP Goals and Responsibilities• Meeting Deliverables<ul style="list-style-type: none">– Ventilator Weaning Rate: DRAFT Measure Specifications– Ventilator Weaning Process Elements: DRAFT Measure Specifications– Non-Vent Process Elements: DRAFT Measure Specifications• Background and Context: LTCH Quality Reporting Program |
| 9:00-10:00 AM | Ventilator Weaning Rate Workgroup Deliberations <ul style="list-style-type: none">• Develop DRAFT Measure Specifications |
| 10:00-10:45 AM | Ventilator Weaning Rate Workgroup Summary
TEP Discussion <ul style="list-style-type: none">• DRAFT Measure Specifications<ul style="list-style-type: none">– Points of Consensus– Points for Further/Future Consideration– Unintended Consequences– Data Collection and Reporting Burden |
| 10:45-11:00 AM | 15-minute Break |
| 11:00 AM-12:00 PM | Process Elements – Prioritize Measure Characteristics <ul style="list-style-type: none">• Relevance• Evidence base• Feasibility• Other |

Ventilator Weaning Process Elements

Non-Vent Process Elements

12:00 – 1:00 PM

1-hour Lunch Break - CMS Cafeteria

1:00 – 2:30 PM

Process Elements Workgroup Deliberations

- **Ventilator Weaning Process Elements Workgroup**
 - Spontaneous Breathing Trials, Unassisted Breathing
 - Daily assessment of readiness to extubate
- **Non-Vent Process Elements Workgroup (Prioritize/Add)**
 - Daily documentation of compliance with institutionally established sedation minimization protocol
 - Daily documentation of sedation interruption/awakening trials
 - Daily documentation of deep-venous thrombosis prophylaxis
 - Daily head of bed elevation (30 degrees or other)
 - Mobility (plan for early mobility and exercise or documentation of milestones)
 - Use of care checklist during daily rounds or at patient bedside
 - Documentation of daily therapy goals
 - Daily oral care: e.g., Chlorhexidine mouth wash; tooth brushing regimen every 8 hours, etc.
 - Daily peptic ulcer disease prophylaxis (not a priority)
 - Delirium monitoring and management
 - Other process elements (TEP Recommendations)

2:30-2:45 PM

15-minute Break

2:45–3:45 PM

Process Elements Workgroup Summary and TEP Discussion

- Ventilator Weaning Process Elements DRAFT Measure Specifications
- Non-Vent Process Elements DRAFT Measure Specifications
 - Consensus on Priorities and Measure Specifications
 - Points for Further/Future Consideration
 - Unintended Consequences
 - Data Collection and Reporting Burden

3:45–4:15 PM

Summary and Next Steps

4:15-4:30 PM

Feedback, Next Steps, and Closing Remarks

4:30 PM

Meeting Adjourned

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Outcomes and Process Elements Quality Measures Development**

Technical Expert Panel Follow-up Meeting #1

Friday, August 15, 2014, 2:00-4:00 PM ET

Web Conference URL: <https://www.connectmeeting.att.com>
Dial-in Number: 888-706-0584 Access Code: 8233211#

2:00-2:10 PM	Welcome and Introductions
2:10-2:25 PM	Background, Context, and Goals for Today's Meeting <ul style="list-style-type: none">• Review Agenda• Update on the CMS LTCH Quality Reporting Program• Summary of TEP Activities to-date TEP• Deliverable: Ventilator Weaning Rate: DRAFT Measure Specifications
2:25-3:45 PM	Ventilator Weaning Rate <ul style="list-style-type: none">• Review and Finalize DRAFT Measure Specifications• Summary of TEP Discussion<ul style="list-style-type: none">– Points of Consensus– Points for Further/Future Consideration (if any)
3:45-3:55 PM	Next Steps, Feedback, and Closing Remarks
4:00 PM	Meeting Adjourns

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Outcomes and Process Elements Quality Measures Development**

Technical Expert Panel Follow-up Meeting #2

Friday, September 12, 2014, 1:00-2:45 PM ET

Web Conference URL: <https://www.connectmeeting.att.com>

Dial-in Number: 888-706-0584 Access Code: 8233211#

- | | |
|---------------------|--|
| 1:00-1:10 PM | Welcome and Introductions |
| 1:10-2:35 PM | Summary of TEP Activities to-date <ul style="list-style-type: none">• Deliverable: Ventilator Weaning Rate: DRAFT Measure Specifications Revised with TEP Input<ul style="list-style-type: none">– Points of Consensus– Points for Further Discussion / Consideration<ul style="list-style-type: none">▪ Definitions▪ Patients who die – include or exclude from the measure▪ Unintended negative consequences▪ Risk Adjustment▪ Stratification▪ Measure’s applicability to ICU patients in short-stay acute care hospitals |
| 2:35-2:45 PM | Next Steps, Feedback, and Closing Remarks |
| 2:45 PM | Meeting Adjourns |

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Outcomes and Process Elements Quality Measures Development**

Technical Expert Panel Follow-up Meeting #3

Friday, September 19, 2014, 1:30-4:00 PM ET

Web Conference URL: <https://www.connectmeeting.att.com>

Dial-in Number: 888-706-0584 Access Code: 8233211#

- | | |
|---------------------|---|
| 1:30-1:40 PM | Welcome and Introductions |
| 1:40-3:40 PM | Ventilator Process Elements: DRAFT Measure Specifications <ul style="list-style-type: none">• Points for Discussion / Consideration<ul style="list-style-type: none">– Quality Measures<ol style="list-style-type: none">1. Compliance with Tracheostomy Collar Trial (TCT) or 2-hour Spontaneous Breathing Trial (SBT) during 24 hours of admission2. Compliance with TCT or SBT each day during LTCH stay3. Compliance with Ventilator Weaning Protocol during LTCH stay<ul style="list-style-type: none">▪ ?Patient Passed or Failed TCT or 2-hour SBT▪ ? Patient Passed or Failed TCT or SBT each day– Definitions, Denominator and Numerator Population– Data Elements– Patients who die – include or exclude from the measures– Stratification and Risk Adjustment– Unintended negative consequences |
| 3:40-3:55 PM | Summary, Next Steps, Feedback, and Closing Remarks |
| 4:00 PM | Meeting Adjourns |

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Weaning (Liberation) Rate and Process Quality Measures Development**

**Technical Expert Panel Meeting #1
Monday, April 27, 2015, 1:00-4:00 PM ET**

Web Conference URL: <https://www.connectmeeting.att.com>
Dial-in Number: 888-706-0584 Access Code: 4057254#

1:00-1:10 PM	Welcome and Introductions <ul style="list-style-type: none">• Conflicts of Interest
1:10-1:20 PM	Purpose, Goals and Approach for Today's Meeting <ul style="list-style-type: none">• Review of Agenda• Update on Measure and Instrument Development Activities• TEP review and feedback on Measure Specifications• Summary of TEP Discussion<ul style="list-style-type: none">– Points of Consensus– Points for Further/Future Consideration (if any)• TEP Deliverables: DRAFT Measure Specifications<ul style="list-style-type: none">– Ventilator Weaning (Liberation) Rate– Process Measures
1:20-2:10 PM	Outcome Measure: Ventilator Weaning (Liberation) Rate
2:10-3:00 PM	Process Measure 1: Compliance with Tracheostomy Collar Trial (TCT) or Spontaneous Breathing Trial (SBT) by the end of Day 1 following the Date of Admission to the LTCH
3:00-3:45 PM	Process Measure 2: Daily Compliance with TCT or SBT during LTCH Stay: On Day 2 following the Date of Admission to the LTCH through the Date when the Patient is Fully Weaned / through the Discharge Date
3:45-3:55 PM	Next Steps and Closing Remarks
4:00 PM	Meeting Adjourns

AGENDA

**Centers for Medicare & Medicaid Services
Long-Term Care Hospital Quality Reporting Program
Ventilator Weaning (Liberation) Rate and Process Quality Measures Development**

**Technical Expert Panel Meeting #2
Monday, May 4, 2015, 1:00-4:00 PM ET**

Web Conference URL: <https://www.connectmeeting.att.com>
Dial-in Number: 888-706-0584 Access Code: 2026365#

1:00-1:10 PM	Welcome and Introductions <ul style="list-style-type: none">• Conflicts of Interest
1:10-1:20 PM	Purpose, Goals and Approach for Today's Meeting <ul style="list-style-type: none">• Review of Agenda• Update on Measure and Instrument Development Activities• TEP review and feedback on Measure Specifications• Summary of TEP Discussion<ul style="list-style-type: none">– Points of Consensus– Points for Further/Future Consideration (if any)• TEP Deliverables: DRAFT Measure Specifications<ul style="list-style-type: none">– Ventilator Weaning (Liberation) Rate– Process Measures
1:20-2:10 PM	Outcome Measure: Ventilator Weaning (Liberation) Rate
2:10-3:00 PM	Process Measure 1: Compliance with Tracheostomy Collar Trial (TCT) or Spontaneous Breathing Trial (SBT) by the end of Day 1 following the Date of Admission to the LTCH
3:00-3:45 PM	Process Measure 2: Daily Compliance with TCT or SBT during LTCH Stay: On Day 2 following the Date of Admission to the LTCH through the Date when the Patient is Fully Weaned / through the Discharge Date
3:45-3:55 PM	Next Steps and Closing Remarks
4:00 PM	Meeting Adjourns

TECHNICAL EXPERT PANEL MEETING AGENDA

Centers for Medicare & Medicaid Services Long-Term Care Hospital Quality Reporting Program

Ventilator Weaning (Liberation) Rate and Process Quality Measures Development

<p>Wednesday, August 26, 2015, 9:00-4:30 PM ET Salons ABC, BWI Airport Marriott 1743 W Nursery Rd, Linthicum Heights, MD 21090</p>	<p>Dial-in Information AT&T Line: 1-888-706-0584 Access Code: 2026365# https://www.connectmeeting.att.com</p>
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9:00-9:10AM	Welcome and Introductions <ul style="list-style-type: none"> • Conflicts of Interest
9:10-9:20AM	Purpose, Goals, and Approach for Today's Meeting <ul style="list-style-type: none"> • Review of Agenda • Update on Measure and Instrument Development Activities • TEP Feedback and Discussion <ul style="list-style-type: none"> – Data Elements – Results of PAC-PRD Data Analysis – Measure Specifications • Wrap Up, Next Steps, and Closing Remarks
9:20-11:30AM	Data Elements – TEP Feedback and Discussion
11:30AM-12:30PM	Lunch Break
12:30-2:00PM	Review and Discuss Findings from the Analysis of CARE Tool Data from the Post-Acute Care Payment Reform Demonstration to Identify Risk Factors for Ventilator Weaning (Liberation) Rate Quality Measure
2:00-2:15PM	Break
2:15-2:45PM	Process Measure 1: Compliance with Tracheostomy Collar Trial (TCT) or Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay (Date of Admission to the LTCH = Day 1 of LTCH Stay)
2:45-3:30PM	Process Measure 2: Daily Compliance with TCT or SBT during LTCH Stay: Day 3 (Date of Admission to the LTCH = Day of LTCH Stay) through the Date when the Patient is Fully Weaned / through the Discharge Date
3:30-4:15PM	Outcome Measure: Ventilator Weaning (Liberation) Rate
4:15-4:30PM	Concluding Remarks and Next Steps
4:30PM	Adjourn

TECHNICAL EXPERT PANEL MEETING AGENDA

Centers for Medicare & Medicaid Services Long-Term Care Hospital Quality Reporting Program

Ventilator Weaning (Liberation) Rate and Process Quality Measures Development

<p>Tuesday, August 09, 2016, 11:00-1:30 PM ET</p> <p style="text-align: center;">Webinar Site: https://www.connectmeeting.att.com</p>	<p>Meeting number: 8887060584 Code: 9432967 <i>Select the Windows-based Participant Application</i></p>
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11:00-11:05 AM	Welcome (RTI International and Centers for Medicare and Medicaid Services)
11:05-11:25 AM	Purpose, Goals, and Approach for Today's Meeting <ul style="list-style-type: none"> • Review of Agenda & Ground Rules • Questions About Background Materials
11:25-11:40 AM	Discussion on Topic 1 – Determination of Weaning Status by Day 2
11:40-11:45 AM	Final Decisions and Voting on Topic 1
11:45-11:55 AM	Discussion on Topic 2 – Assessment of Liberation Outcome for Patients Who Die
11:55-12:00 PM	Final Decisions and Voting on Topic 2
12:00-12:15 PM	Discussion on Topic 3 – Changing “Irreversible” to “Severe neurologic disease, dysfunction, or injury”
12:15-12:20 PM	Final Decisions and Voting on Topic 3
12:20-12:35 PM	Discussion on Topic 4 – Addition of “Weaning status cannot be determined” to O0200A Responses
12:35-12:40 PM	Final Decisions and Voting on Topic 4
12:40-12:55 PM	Discussion on Topic 5 – Unintended Consequences
12:55-1:05 PM	Discussion on Topic 6 – Disposition in Outcome Measure of Patients with Planned Withdrawal of Ventilator Support
1:05-1:20 PM	Discussion on Topic 7 – Risk Factors for Ventilator Liberation Rate
1:20-1:25 PM	Discussion on Topic 8 – Ventilator Liberation Rate: Inclusion of Partial Liberation as Separate Outcome Numerator Category
1:25-1:30 PM	Next Steps
1:30PM	Adjourn

APPENDIX B:
SUPPLEMENTAL TEP WEBINAR MATERIALS, AUGUST 2016

August 9, 2016

Topics and Questions for Ventilator QM TEP Webinar Discussion

Contents

TOPIC 1: Determination of weaning status by day 2 (Voting)	47
TOPIC 2: Assessment of liberation outcome for patients who die (Voting)	48
TOPIC 3: Changing “Irreversible” to “Severe” for Item I4403. ... neurological injury, disease, or dysfunction (Voting)	49
TOPIC 4: Addition of “Weaning status cannot be determined” to O0200A responses (Voting)	50
TOPIC 5: Unintended consequences (Discussion)	51
TOPIC 6: Disposition in outcome measure of patients with planned withdrawal of ventilator support (i.e. “terminal weans”) (Discussion)	52
TOPIC 7: Risk Factors for Ventilator Liberation Rate (Discussion)	54
TOPIC 8: Ventilator Liberation Rate: Inclusion of partial liberation as separate outcome numerator category (Discussion)	55

TOPIC 1: Determination of weaning status by day 2 (Voting)

Note: O0100F3 and O0100F4 have been combined under O0200A in order to make these mutually exclusive and to serve as screening questions.

Question posed to Stakeholders/Pilot sites:

“Is it feasible to determine patient weaning status (Weaning vs. Non-weaning) by Day 2?”

Key feedback:

1. Public Comments

- a. 2 of 8 commenters said that this determination was feasible.
- b. Others less supportive:
 - i. Not feasible for facilities who admit patients late on Day 1.
 - ii. May increase administrative burden
 - iii. Rushing proper comprehensive assessment of incoming ventilated patients may have unintended negative impact on patient care
 - iv. Forces clinical judgement of weaning status (weaning vs. non-weaning) in cases where there is not yet a true answer.
 - v. Window for Jubran 2015 study was 5 days.
- c. 2 commenters suggested use of “within 48 hours following admission” vs. “by Day 2”

2. Pilot Testing

- a. Most facilities (n=8) reported that they were able to determine weaning status by Day 2. The other 2 sites said this was challenging with current processes and staffing.
- b. Many sites interpreted O0200A as “was patient admitted for weaning?”
- c. 3 of 10 sites chose “weaning” for 100% of patients
 - i. Many pilot sites (n=6) had standing orders as part of the normal admission process and 3 sites explicitly stated that they will try to wean all vent patients;
 - ii. At least one site directs non-weaning patients (those there to live on ventilation due to lack of other care facilities) to a long-term care unit (Title 19)
- d. Time of day that most admissions occurs varies by site, from mid-afternoon to late evening
 - i. All facilities had a high proportion of patients admitted late in the day, but only 2 stated that determination of weaning status may be difficult
 - ii. Weaning or non-weaning status by Day 2 was indicated for 95% of admissions.
- e. 48 hours or “By Day 3”:
 - i. 2 sites said this may allow more time to assess patients admitted late on Day 1
 - ii. 8 sites felt extending the time to Day 3 would make no difference in their facility.
 - iii. Burdensome for some sites to judge timing based on hours vs. calendar day.

Voting Question (Y/N):

Should we change Day 2 to “within 48 hours after admission” in the measure specifications and data elements?

Affects: time window for process measure and for determination of exclusion criteria for both measures

TOPIC 2: Assessment of liberation outcome for patients who die (Voting)**Questions posed to Stakeholders/Pilot sites:**

Is liberation status on discharge an important and useful concept for inclusion in the outcome measure numerator?

Key feedback:*1. Public comments*

- a. No commenters addressed this issue.

2. Pilot Testing

- a. Based on preliminary feedback regarding the discharge assessment items, all 9 pilot sites who responded viewed this outcome category as irrelevant or not important for reporting, though several sites said they do track this information.
- b. Several sites said that feedback relating to this outcome would not affect their processes of care
- c. Several sites stated that weaning status of patients who die is not useful because many possible causes of death are completely unrelated to the fact that they are on ventilation.
- d. 2 sites felt that patients who die subsequent to complete ventilator liberation could reflect poor quality care and/or medical errors. They strongly discouraged counting these patients in the outcome measure numerator.
- e. Based on preliminary feedback, pilot sites seemed more interested in tracking terminal weans (see Topic 6)
- f. Of the 7 expired discharge assessments submitted to date, 1 patient was fully weaned at the time of death, 2 were partially weaned, and 6 were not weaned.

Voting Question (Y/N):

Should liberated patients who die be included as a separate numerator category for the outcome measure?

Affects: Outcome measure numerator; LCDS Expired Discharge Assessment item set

TOPIC 3: Changing “Irreversible” to “Severe” for Item I4403. ... neurological injury, disease, or dysfunction (Voting)**Questions posed to Stakeholders and Pilot sites:**

Requested general feedback from stakeholders on wording of item set

Pilot sites: Does it make sense to change “irreversible” to “severe” in Item I4403, Irreversible neurological injury, disease, or dysfunction (including due to cerebral palsy)?

Key feedback:*1. Public comments:*

- a. No comments specific to this item.

2. Pilot Testing:

- a. Based on preliminary feedback, 6 out of 10 sites found the word “irreversible” confusing
- b. 1 site suggested changing to “severe”
- c. Challenges with “irreversible” included
 - i. Whether a condition is irreversible is not always known (Example: spinal cord injury)
 - ii. Some relevant diseases may be cyclical
 - Guillain-Barre
 - iii. Specific conditions, such as Severe Anoxic Brain Damage, are already on the LTCH CARE Data Set.
- d. Some sites did not support a change to “severe”
 - i. the word “severe” may be just as confusing as “irreversible” if the physician does not use that word specifically.
 - ii. “severe” is even more dependent on the person collecting the data; its use would result in inconsistencies in what people code on assessment forms.

Voting Question:

Should “Irreversible neurological injury, disease, or dysfunction” be edited to “Severe neurological injury, disease, or dysfunction?”

Affects: Outcome measure risk factor; LCDS Admission Assessment item set

TOPIC 4: Addition of “Weaning status cannot be determined” to O0200A responses (Voting)

Questions posed to Stakeholders and Pilot sites:

“Weaning status cannot be determined” was originally intended only for the pilot test as an alternative to a dash for O0200A, and was therefore not included in the item set submitted for public comment.

In pilot measure calculations, this category was included in the denominator of both measures; in other words, the denominator included patients admitted for weaning and those whose weaning status could not be determined by Day 2.

Item O0200A. Invasive Mechanical Ventilation Support upon admission to LTCH

Responses: 0 (No), 1 (Yes, weaning), 2 (Yes, Non-weaning), 3 (Yes, *Weaning status cannot be determined by Day 2 of LTCH Stay*)

Key feedback:

1. Public comments:

- a. Stakeholders expressed concern regarding data validity and unintended consequences if providers were forced to select a weaning status by Day 2, but did not suggest addition of another category.

2. Pilot Testing:

- a. Providers selected this response for 6 of 150 patients
 - i. Of the 4 patients discharged to date for whom weaning status on admission could not be determined,
 - 1 received an assessment for SBT but was found not medically ready
 - 3 were not assessed for SBT by Day 2
 - 0 of 4 were liberated at discharge.
- b. Most facilities (n=8) were able to determine weaning status by Day 2. The other 2 sites said this was challenging with current processes and staffing.
- c. Many sites interpreted O0200A as “was patient admitted for weaning?”
- d. 3 of 10 sites chose “weaning” for 100% of patients
 - i. Many pilot sites (n=6) had standing orders as part of the normal admission process and 3 sites explicitly stated that they will try to wean all vent patients;
 - ii. At least one site directs non-weaning patients (those there to live on ventilation due to lack of other care facilities) to a long-term care unit (Title 19)

Voting Questions:

Should “3. Weaning status cannot be determined...” be included as a response to Item O0200A, *Invasive Mechanical Ventilation Support upon admission to LTCH*?

If yes, should patients in this category be excluded or included in the denominator for both measures?

Affects: Exclusion criteria for both measures; LCDS Admission Assessment

TOPIC 5: Unintended consequences (Discussion)

Questions posed to Stakeholders/Pilot sites:

What are the potential unintended consequences that may result from implementation of the process and outcome ventilator liberation quality measures?

Key feedback:

1. *Public comments – please refer to page 5 of the public comment summary for details*
 - a. 1 commenter did not associate any negative consequences with implementation of these measures
 - b. 6 commenters expressed concern regarding
 - i. **patient safety** (n=2),
 - ii. **negative effects on LTCH processes and policies** (n=3), and
 - iii. the **validity of weaning/non-weaning status**, specifically whether patients are inappropriately deemed unready for SBT (n=3)
 - c. One commenter believed providers may be able to game the system, for example, to alter the admission policy to favor patients with the best weaning prognosis in order to improve liberation statistics.
2. *Pilot Testing – potential negative impact*
 - a. Patient safety with respect to Day 2 was not viewed as a threat by most sites with respect to their own facilities.
 - b. Only 1 site felt patient safety may be at risk at some LTCHs due to staffing ratios.

For Discussion:

1. Given positive feedback from pilot sites and that the process measure credits LTCHs who appropriately delay SBTs for medically unstable patients, how concerned are you about **patient safety** with respect to the window for determination of weaning status and administration of SBT?
2. Given the feedback from the pilot testing sites, how concerned are you about **burden on LTCH resources** to extend the time frame for determination of weaning status and assessment for SBT?
3. Given the feedback from the pilot testing sites, how concerned are you about **validity of responses to O0200A, weaning status as determined by Day 2**?
4. How concerned are you about **changes in patient admission practices** (i.e., turning away high-risk patients) that might result from implementation of the outcome measure?

TOPIC 6: Disposition in outcome measure of patients with planned withdrawal of ventilator support (i.e. “terminal weans”) (Discussion)

Questions posed to Stakeholders/Pilot sites:

Under the current specifications for the outcome measure Liberation Rate at Discharge, “terminal weans” would be included in the measure denominator but never in the measure numerator; in other words, they would count as “not fully weaned.”

1. Should terminal weans be reported separately?
2. If they are included in the measure denominator but not numerator, does this pose implications for quality of patient care?

Key feedback:

1. Public comments

- a. No commenters addressed this issue.

2. Pilot Testing

- a. All sites agreed that terminal weans constituted good quality of care
- b. 3 sites voiced that terminal weans should not count against facilities’ weaning rate.
- c. Preliminary analysis of sites’ feedback on the discharge assessments suggests that, for many sites, terminal weans are viewed as unsuccessful weaning in their quality programs
- d. Most facilities track of this information, and several already report internally the number of patients with planned withdrawal of ventilator support.
 - i. 1 site stated that terminal weans are reported alongside the % not fully weaned in order to aid interpretation
 - ii. Sites that include a specific field for the number of terminal weans on internal tracking sheets said that tracking terminal weans would not involve burdensome data collection
 - iii. Other sites that are not currently tracking terminal weans reported that counting terminal weans would require burdensome documentation
 - iv. Separate reporting of terminal weans:
 - 2 sites felt this was not important information, and that only by understanding a patient’s weaning history prior to entering the facility could outcomes for terminal and partial weaning patients be meaningful
 - At least two sites supported reporting % fully weaned (alive), % not fully weaned (alive), and % terminal weans as numerator components for outcome measure
 - % terminal weans could be included in expired item set as number of patients with documentation of physician/family discussion of goals of care, similar to documentation for SBT (and hospice measures)
 - 1 site mentioned that “terminal weans” would not be admitted to/confessed publicly by some facilities due to negative connotations
- e. Regarding inclusion of patients who die in the measure denominator but not numerator, pilot sites’ suggestions about potential negative impact on care practices surrounding planned withdrawal of ventilator support included:
 - i. At least one site agreed that implementation of the outcome measure, which currently counts terminal weans in the denominator but never in the numerator, may be seen as negatively affecting a facility’s score.

- ii. One site suggested staff may be less willing to have conversations with patients/family on withdrawal of ventilator support. This may occur in facilities with a higher proportion of patients who elect withdrawal.
- iii. Terminal weans may not be admitted to/confessed publicly by some facilities due to negative connotations.
- iv. 1 site said these consequences would not begin until outcome was tied to payment.

For Discussion. *Given comments from the public and feedback from pilot sites, CMS is leaning toward counting planned withdrawals from ventilator support in the measure denominator but not in the numerator.*

TOPIC 7: Risk Factors for Ventilator Liberation Rate (Discussion)

Questions posed to Stakeholders/Pilot sites:

Is risk adjustment important for the outcome measure? What general feedback do you have on the selected risk factors?

Key feedback:

1. Public Comments

- a. 6 commenters expressed support for risk adjustment of outcome measure
- b. 2 commenters requested clarification of **Item O0100H1. Vasoactive medications**
 - i. Suggested item definition: vasoactive pressors, intravenous vasopressors, inotropes, and vasodilators.
 - ii. Continuous medication for pulmonary edema could merely be the ongoing use of diuretics; this language should be removed
- c. 2 comments regarding **transplant-related Item I7100**:
 - i. Add a qualifier such as “recent” or “in the previous 12 months”
- d. 3 commenters
 - i. asked that additional testing be completed
 - ii. suggested the following variables: multiple organ failures, opioid dependence, severe wounds, and additional pulmonary conditions

2. Pilot Testing

- a. Preliminary analysis of sites’ feedback on risk adjustment suggests most agree that risk adjustment of outcome measure is important
- b. Suggested changes to item wording
 - i. Determination of **Item I7300. Severe Left Ventricular/Systolic Dysfunction** was seen as difficult for a few facilities
 - 1 facility said this was “the most challenging of the new items”
 - Similar to the issue of “irreversible” above, 2 sites stated the word “severe” would create inconsistencies in interpretation and coding
 - ii. Clarification of **Item O0100H1. Vasoactive medications**
 - The item was interpreted differently by the sites. Some included both IV and Oral medications, some did not. Some included any type of vasoactive medication, even blood pressure medications to treat low-level conditions.
 - Two sites suggested a clear parameter, such as dosage.
 - iii. Clarification of transplant-related **Item I7100** as pre-transplant, post-transplant, or both
 - 4 of 10 sites interpreted this to mean both pre- and post-transplant.
 - 6 of 10 sites interpreted this as post-transplant only.

For Discussion and/or email:

1. Clarification of **Item I7300. Severe left ventricular/systolic dysfunction**
2. Clarification of **Item O0100H1. Vasoactive medications**: *RTI/CMS is leaning toward specifying intravenous vasoactive medications. Other suggestions?*
3. Clarification of **Item I7100**: *RTI/CMS is leaning toward specifying post-transplant patients only.*

TOPIC 8: Ventilator Liberation Rate: Inclusion of partial liberation as separate outcome numerator category (Discussion)

Questions posed to Stakeholders/Pilot sites:

1. “What is the clinical importance and utility of including partial liberation status at discharge as an outcome?”
2. “Is it feasible to determine partial liberation status at discharge, and at admission in order to provide a baseline?”

Key feedback:

1. Public Comments

- a. 3 of 8 commenters supported the feasibility and utility of partial weaning status as an outcome
- b. No other stakeholder submissions discussed partial weaning as an outcome

2. Pilot Testing

- a. Based on preliminary feedback regarding the discharge assessment items, a few sites supported clinical importance of partial weaning status for the following reasons:
 - i. Patient-centered approach: goal for many chronically ventilated patients admitted for exacerbation of other conditions (e.g. pneumonia)
 - ii. Improved patient quality of life: patients free to move around facility during the day
 - iii. Positive impact on patient discharge disposition
- b. Most sites that supported the importance of partial weaning stated that this outcome would be difficult or impossible to implement (see iv. below)
- c. Five of 10 sites did not support clinical importance of partial weaning status
 - i. Facility practice is to measure true weaning success based on full weaning
 - ii. Partial weaning was not seen as a significant improvement to patient quality of life
 - iii. Partial weaning did not change patient discharge disposition or cost to CMS
- d. Facilities stated that assessment of baseline partial weaning status may be problematic or very problematic due to:
 - i. Lack of sufficient information or difficulty in accessing documentation from admitting facility
 - ii. Reliability of documentation from admitting facility
 - iii. Timing of baseline measurement: Exacerbation of the number of hours on vent due to transport -- On arrival? 24 hours prior to transport? 24 hours after transport/admission?

CMS is leaning toward collapsing the outcome numerator categories for partially liberated at discharge and not liberated at discharge, resulting in a binary outcome measure of *fully weaned* vs. *not fully weaned*.

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APPENDIX C:
PATIENT ADVOCATE SEMI-STRUCTURED INTERVIEW GUIDE

Patient Representative Discussion Questions:

Your story

- Why were you originally admitted to the acute care hospital? Do you recall why you were admitted or transferred to the LTCH?
- What was your experience of being on the breathing machine (ventilator) like, if you remember?
- Can you share your experience of the process involved in being taken off the machine? (weaned from the ventilator?)
- Is there anything you recall about the process or the care you received that you did not expect? If so, would you mind sharing that with us?
- If there were times that you were on the breathing machine part-time (e.g. only a night, or for half the day), can you share with us how that compared to when you were on the breathing machine full-time?
- Given what you've experienced, what are the important characteristics of a facility that cares for patients on ventilators and seeks to get them off ventilators? What was important to you?
- Do you think that your experience would have been different if your life circumstances were different? For example, do you think the care you received as a patient on a breathing machine would have been different if you had higher or lower income, or if you lived in a different area of your city or state?

Your impression of the two quality measures

- If a friend asked you to explain each of the quality measures to them in your own words, how would you explain them?
- Given your experience as a patient on a breathing machine, do these measures that CMS is developing seem important? Why/Why not? Are they any more or less important for certain groups of people or patients?
- Do you think that these measures might be helpful for comparing different hospitals? What do you find is helpful or not helpful about them?
- Can you imagine any drawbacks to measuring these ideas in the hospitals? If so, what might those be?
- Do you have any questions about the way the measure scores are calculated? What is clear? What remains unclear? Could you explain the calculations to a friend?
- There are scientific studies that suggest the care that patients receive in hospitals varies according to race/ethnicity or gender, and other studies that suggest this is not true. Do you think either of these scenarios might apply to patients on breathing machines? If so, can you give us an example of why this could be true?