Public Comment Summary Report: Hospital Harm – Postoperative Respiratory Failure eCQM

Project Title: Patient Safety Measure Development and Maintenance

Dates: The Call for Public Comment ran from **August 23, 2022** and closed on **September 30, 2022**.

Project Overview: The Centers for Medicare & Medicaid Services (CMS) has contracted with American Institutes for Research (AIR) and subcontractor University of California, Davis to develop and maintain patient safety measures of hospital harm. The contract name is Measure and Instrument Development and Support (MIDS) Patient Safety Measure Development and Maintenance. The contract number is 75FCMC18D0027. As part of its measure development process, the AIR-UCD Team requests interested parties to submit comments on the candidate or concept measures that may be suitable for this project. The AIR-UCD Team seeks feedback on the draft measure specifications and workflow for an outcome electronic clinical quality measure (eCQM) titled, Hospital Harm—Postoperative Respiratory Failure (PRF) as part of the measure development process.

Information About the Comments Received: The measure developer solicited public comments by posting to the CMS Measure Management System (MMS) website, sending electronic communications to the MMS list-serv, eCQM Governance, MAT/Bonnie User Groups, and the HL7 CQI workgroup, electronic outreach to patient safety and other professional organizations, and through announcements to the Technical Expert Panel (TEP) and Technical Advisory Group (TAG). Respondents completed an online survey collecting both quantitative (5-point Likert scale questions ranging from agree to strongly disagree) and qualitative feedback (free-text boxes) on measure definitions, importance, implementation, unintended consequences, feasibility, risk-adjustment variables, required data elements, and clinical and eCQM workflows.

We received 4 responses on this topic.

Stakeholder Comments

General Stakeholder Comments:
This public comment period solicited feedback on the Hospital Harm—Postoperative Respiratory Failure measure. No general comments were received. A summary of all the measure-specific comments received is included below.

Measure-Specific Stakeholder Comments:
This section summarizes the public comments received for the Hospital Harm—Postoperative Respiratory Failure measure and is categorized into the six major themes that emerged during the developer's review.

1. **Importance.**

a. **Measure focus.** Three of four respondents agreed or strongly agreed that the measure focuses attention on an outcome that holds the potential for substantial impact on the health status and health outcomes of individual patients as well as improving the health status of communities and populations. The fourth respondent noted that this is an important measure that can contribute to organizational learning around the management of patients on mechanical ventilation.

b. **Measure completeness:** One commenter noted necessary revisions to the measure justification form and additional consideration around some of the factors contributing to post-operative respiratory failure.

2. **Denominator**

a. **Population definition**. Two of four respondents agreed that the denominator statement clearly describes the population of interest. One respondent strongly disagreed and noted that patients undergoing inpatient operative procedures are a diverse population and cannot be grouped as a single entity for measurement purposes. One respondent felt that the current definition of "elective" was unclear, and another respondent wondered how the measure would address patients whose admission type changed (i.e., from elective to urgent) after discharge.

b. **Denominator exclusions**. Two of four respondents agreed that the denominator exclusion criteria are clear and appropriate. One respondent strongly disagreed and noted a need to more clearly define patients already at increased risk for complications. One respondent suggested excluding severely respiratory compromised patients, perhaps through the use of home oxygen or the presence of a pulmonary function test. One respondent also noted that more clear definitions of the exclusion criteria are needed. One respondent suggested clarifying the exclusions for PaO2 as well as non-elective surgeries, clarifying the timeframe for mechanical ventilation and suggested adding exclusions for patients requiring extended ventilation. One commenter inquired as to why denominator exclusions for PSI 11 are not also exclusions for this measure.

c. **Non-invasive positive pressure ventilation.** Two of four respondents agreed that non-invasive positive pressure ventilation (e.g., continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP)) is commonly used in lieu of endotracheal intubation and mechanical ventilation to treat respiratory failure in post-operative patients. One respondent noted the need to consider other adjuncts as well as home use of CPAP which would be continued in the hospital setting.

3. **Numerator**

a. **Outcome definition.** Two of four respondents agreed that the numerator statement clearly describes the outcome being measured and that the numerator criteria are appropriate. One respondent strongly disagreed and raised concerns around that the 30-day time window is too long.

4. **Risk-Adjustment**

a. **Defining patients at risk for post-operative respiratory failure.** One of four respondents expressed concerns that the measure does not clearly define patient factors that increase risk of the complication (e.g., morbid obesity, frailty, congestive heart failure).

b. **Operative complexity.** One respondent suggested that the measure adjust for operative complexity based on patient risk factors.

5. **Feasibility**

a. Data elements

i. **Routine capture.** Two of four respondents agreed that the required data elements are routinely captured in structured data.

ii. **Cumulative mechanical ventilation time.** Three of four respondents agreed that EHR data is able to capture the cumulative time a patient is on mechanical ventilation during their hospitalization. One respondent noted that post-procedure ventilation is captured differently than ventilation in the operating room.

6. **Implementation and Public Reporting**

a. **Unintended consequences.** Two of four respondents agreed that this measure may result in unintended consequences.

Preliminary Recommendations

This section provides a summary of our analysis of the six major themes and final recommendations.

1. **Importance**

a. **Measure completeness:** We thank the commenter for the feedback on the measure form completeness. At this time, the measure is still in active development, so several details have not yet been determined. Nonetheless, we appreciate the commenter's attention to detail and will carefully review measure information material and update it to ensure that it is accurate and complete before seeking additional public input.

2. **Denominator**

a. **Population definition:** We thank the commenters for their feedback regarding the denominator definition. The denominator is indeed diverse, so risk adjustment will be an important aspect of the measure. We plan to evaluate all available information about pre-operative characteristics of patients in selecting parameters for risk adjustment, including age, sex, comorbidities, height and weight, indication for the operation, the index operation, laboratory values, and possibly pre-operative studies.

b. **"Elective" definition:** We thank the commenters for their feedback regarding the denominator definition. Elective status has traditionally been defined at the level of the entire hospitalization (not procedure) based on the "admission status" field as reported by hospitals (e.g., UB-04 form). We plan to evaluate this definition relative to other available information, potentially including the type of first procedure performed and its timing during the hospitalization.

c. **Use of non-invasive positive pressure ventilation/BiPAP:** We thank the commenters on their feedback related to use of non-invasive positive pressure ventilation. We will take it into consideration as we continue to further refine this measure, and during data testing and evaluation.

d. Denominator Exclusions

i. **Mechanical ventilation timeframe:** We thank the commenters for their feedback related to denominator exclusions. The measure would exclude patients who had already undergone mechanical ventilation during the index hospitalization for more than one hour in duration, prior to the first OR procedure.

ii. **PO2:** We thank the commenters for their feedback related to denominator exclusions. We would like to clarify that the preoperative PaO2 is an exclusion

criterion and to limit the exclusion to patients on room air before surgery would contradict stated intent pointing to different level of additional support and risk for ventilation. We agree that patients on continuous home oxygen therapy and patients on high-flow oxygen before surgery should be excluded, even if their PaO2 was normal. We also agree that patients whose only operation was for treatment of respiratory failure (i.e., tracheostomy, ECMO) should be excluded.

iii. **Staged planned procedures:** We thank the commenter for the feedback related to the denominator exclusions. Planned staged procedures do not always represent an appropriate indication for an extended period of intubation with mechanical ventilation, in the absence of respiratory failure. It is sometimes preferable to extubate such patients between operations. Although it is unlikely that there will be information available on the elective status for each operation (or whether an operation was planned as a staged procedure), we plan to exclude hospitalizations with non-elective admission status, patients whose first operation is a tracheostomy, those who have a condition or operation that suggests prolonged intubation is necessary for airway protection (rather than respiratory failure per se), and those who undergo mechanical ventilation for more than one hour before the first operation. Acute infection with COVID or influenza is unlikely among elective hospitalizations, but we will explore the need for and appropriateness of risk adjustment if these characteristics appear common.

iv. **PSI 11 exclusions:** We thank the commenter for this observation. We note that most of the PSI 11 exclusions that are referenced were not included due to concerns that PRF would frequently be non-preventable in those contexts. However, we plan to evaluate the impact of these exclusion criteria during empirical testing of this eCQM.

v. **Home O2:** We thank the commenter on the feedback related to the denominator exclusion. We agree that patients on continuous home oxygen therapy and patients on high-flow oxygen before surgery might warrant exclusion on the grounds that postoperative respiratory failure is not preventable, even if the preoperative PaO2 was nominally in the “normal” range. We plan to evaluate this during measure testing.

3. **Numerator**

a. **30-day time period:** We thank the commenters on their feedback related to the numerator. We agree that it may be appropriate to shorten the maximal time window of 30 days post the index procedure, as later episodes of respiratory failure are likely to represent new illnesses unrelated to perioperative management. We plan to evaluate this question empirically during measure testing

4. **Risk-Adjustment**

a. **Pre-existing comorbidities:** We thank the commenters for their feedback related to risk adjustment. We agree with the importance of risk-adjustment and careful selection of candidate features, including baseline laboratory values, morbid obesity, malnutrition, and other known risk factors for PRF. We anticipate that the measure will adjust for a variety of baseline characteristics and other preoperative information.

b. **Operative complexity:** We thank the commenters for their feedback related to risk adjustment. We agree with the importance of risk-adjustment and careful selection of candidate features, including baseline laboratory values, morbid obesity,

malnutrition, and other known risk factors for PRF. We anticipate that the measure will adjust for a variety of baseline characteristics and other preoperative information.

5. **Feasibility**
    - **a. Data elements**
        - i. **Availability:** We thank the commenters for feedback on the availability of discrete data elements for capture. We know there is variability in how information is captured within the EHR and other documentation software across healthcare organizations. We will consider the availability of these fields in the measure refinement process to minimize provider burden.
        - **ii. Cumulative ventilation time:** We thank you for your comments on the ability to capture the cumulative time a patient is on mechanical ventilation. We know there is variability in how mechanical ventilation times are documented intraoperatively and postoperatively within the EHR and other documentation software across healthcare organizations. During testing we will consider these workflow variations in the data collection and analysis for measure specification refinement.
        - **iii. Admission type changes:** We thank the commenter for this feedback. We recognize there will be instances where the admission type will change based on whether the surgical procedure was upgraded from 'elective' to 'urgent'. However, hospitals are not consistently converting the admission encounter type after the patient has been admitted for pre-op. We are aware of these workflow variances for consideration into the final measure specifications.
6. **Implementation and Public Reporting**
    - a. **Reintubation rate:** We thank the commenter on the feedback related to measure interpretation. We agree with the point that reintubation and/or prolonged mechanical ventilation may not be completely preventable. Accordingly, a reintubation rate of 0% may suggest that a hospital is not being sufficiently aggressive in extubating patients at the conclusion of the operation. Despite this, the measure may still provide useful information about the occurrence of postoperative respiratory failure, and risk adjustment should help address variation across hospitals in the proportion of cases of postoperative respiratory failure that are truly non-preventable.

Overall Analysis of the Comments and Recommendations

The AIR-UC Davis Team highlights that PRF, defined as unplanned endotracheal reintubation, prolonged inability to wean from mechanical ventilation, or inadequate oxygenation and/or ventilation, is the most common serious postoperative pulmonary complication, with an incidence of up to 7.5% (the incidence of any postoperative pulmonary complication ranges from 10-40%)[2-12] and an in-hospital mortality rate of 25 to 40%.[2,13] The incidence of PRF varies by hospital, with higher reported rates of PRF in nonteaching hospitals than teaching hospitals.[1] Disparities in the incidence of PRF across hospitals suggest that there is an opportunity to reduce the occurrence of these events. An electronic measure of Hospital Harm – Postoperative Respiratory Failure would ensure that PRF events are tracked, identify hospitals that have persistently high rates of PRF, and enable hospitals to more reliability assess harm reduction efforts.

We acknowledge and thank commenters for their carefully considered feedback on key items such as the denominator definition and exclusions, numerator 30-day time period, importance of risk-adjustment and careful selection of candidate features, and availability of discrete data elements. During pilot testing and data analysis, we will consider commenter feedback and recommendations and determine where refinements may be appropriate.

References

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Public Comment Verbatim Report

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
9/14/2022	Stephanie Ledbetter; East Alabama Health	Hospital	Data Elements: Routine capture	In general, yes but not all are captured discretely.	We thank the commenters for feedback on the availability of discrete data elements for capture. We know there is variability in how information is captured within the EHR and other documentation software across healthcare organizations. We will consider the availability of these fields in the measure refinement process to minimize provider burden.
9/14/2022	Stephanie Ledbetter; East Alabama Health	Hospital	Data Elements: Cumulative vent time in structured fields	If you are referring to mechanical ventilation post procedure, then yes but that is captured differently than the events in the operating room.	We thank you for your comments on the ability to capture the cumulative time a patient is on mechanical ventilation. We know there is variability in how mechanical ventilation times are documented intraoperatively and postoperatively within the EHR and other documentation software across healthcare organizations. During testing we will consider these workflow variations in the data collection and analysis for measure specification refinement.
9/14/2022	Stephanie Ledbetter; East Alabama Health	Hospital	Use of non-invasive positive pressure/BiPAP	no; An option for most of the time would be appropriate. It depends on the timing of the respiratory event. If it is immediately post-op, then no but if after that, then yes.	We thank the commenters on their feedback related to use of non-invasive positive pressure ventilation. We will take it into consideration as we continue to further refine this measure, and during data testing and evaluation.
9/14/2022	Stephanie Ledbetter; East Alabama Health	Hospital	Denominator Exclusions: Home O2 exclusion	There are some patients that are at significant risk for events related to their current health status. I am not sure how to limit an exclusion to the severely respiratory compromised patients but there should be something that sets them apart - maybe home O2 use or a pulmonary function test - just something that captures that small population.	We thank the commenter on the feedback related to the denominator exclusion. We agree that patients on continuous home oxygen therapy and patients on high-flow oxygen before surgery might warrant exclusion on the grounds that postoperative respiratory failure is not preventable, even if the preoperative PaO2 was nominally in the “normal” range. We plan to evaluate this during measure testing.
9/21/2022	J Tilly; Leapfrog Group	Research Group	Data Elements: Routine capture	Yes; With a caveat that I don't have the domain expertise to answer this completely.	We thank the commenters for feedback on the availability of discrete data elements for capture. We know there is variability in how information is captured within the EHR and other documentation software across healthcare organizations. We will consider the availability of these fields in the measure refinement process to minimize provider burden.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
9/21/2022	J Tilly; Leapfrog Group	Research Group	Data Elements: Cumulative vent time in structured fields	Yes; With a caveat that I don't have the domain expertise to answer this completely.	We thank you for your comments on the ability to capture the cumulative time a patient is on mechanical ventilation. We know there is variability in how mechanical ventilation times are documented intraoperatively and postoperatively within the EHR and other documentation software across healthcare organizations. During testing we will consider these workflow variations in the data collection and analysis for measure specification refinement.
9/21/2022	J Tilly; Leapfrog Group	Research Group	Use of non-invasive positive pressure/BiPAP	Yes; This is my understanding based on the literature.	We thank the commenters on their feedback related to use of non-invasive positive pressure ventilation. We will take it into consideration as we continue to further refine this measure, and during data testing and evaluation.
9/21/2022	J Tilly; Leapfrog Group	Research Group	Measure Focus: Importance	Thank you for your work to develop this new eCQM version of PSI 11. PSI 11 is a current valuable measure in the Leapfrog Hospital Safety Grade program, and we commend ongoing efforts to develop new eCQMs to improve the ease of use and data collection of these measures for hospital. We look forward to additional opportunities to review and comment on detailed specifications as these arise.	We thank the commenter for their support and agree the measure concept is important.
9/13/2022	Brendan Daley; Northwestern Medicine	Hospital	Results and Interpretability: Reintubation rate	Data regarding ventilator liberation views that a small percentage of reintubations is considered to be an indicator that there is a healthy and aggressive weaning protocol in place. If you have a 0% reintubation rate it is likely you are not being aggressive enough. Last I looked 2.5-4% is a “healthy” reintubation rate.	We thank the commenter on the feedback related to measure interpretation. We agree with the point that reintubation and/or prolonged mechanical ventilation may not be completely preventable. Accordingly, a reintubation rate of 0% may suggest that a hospital is not being sufficiently aggressive in extubating patients at the conclusion of the operation. Despite this, the measure may still provide useful information about the occurrence of postoperative respiratory failure, and risk adjustment should help address variation across hospitals in the proportion of cases of postoperative respiratory failure that are truly non-preventable.
9/13/2022	Brendan Daley; Northwestern Medicine	Hospital	Denominator Exclusions: PSI 11	There are many PSI11 exclusions (including MDC 4, 5, 14, lung cancer among others) which are not included which would probably require manual review.	We thank the commenter for this observation. We note that most of the PSI 11 exclusions that are referenced were not included due to concerns that PRF would frequently be non-preventable in those contexts. However, we plan to evaluate the impact of these exclusion criteria during empirical testing of this eCQM.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
9/13/2022	Brendan Daley; Northwestern Medicine	Hospital	Data Elements: Admission type changes	Sometimes admission type changes (i.e. from elective to urgent) after discharge – will the measure be accommodating of this?	We thank the commenter for this feedback. We recognize there will be instances where the admission type will change based on whether the surgical procedure was upgraded from 'elective' to 'urgent'. However, hospitals are not consistently converting the admission encounter type after the patient has been admitted for pre-op. We are aware of these workflow variances for consideration into the final measure specifications.
9/14/2022	Krista Kaups; UCSF	Academic/ University	Measure Focus: Measure completeness	The measure justification form appears to be in a relatively preliminary form. For example 5.6, "identification of meaningful differences in performance" has NO content. 1. The justification does NOT appropriately analyze or reference the cited references. As one of many examples, in 4.1.4,(Association with process of care), the authors cite a systematic review by Lawrence et al (NOT included in the references) and state that the article [suggests] "that nasogastric tube decompression after abdominal surgery reduces risk" which misstates the conclusion of the article entirely. Another example: an article by Rahman (NOT included in the reference list) is cited several times as evidence that patients in teaching hospitals have higher rates of post-operative respiratory failure, but on review of the article, (which is further misquoted in the eCQM) actually relates to patients with brain tumors, the majority of which (84%) had non-operative management. Furthermore, the article actually states "The likelihood of being diagnosed with a PSI or HAC was higher for patients admitted to nonteaching hospitals for postoperative hip fractures (OR = 1.38, P < .0001), postoperative physiologic derangement (OR = 1.17, P = .03), sepsis (OR = 1.19, P < .0001), falls and trauma (OR = 1.10, P < .001), and manifestations of poor glycemic control (OR = 1.17, P = .04)" so it's unclear how this was extrapolated.	We thank the commenter for the feedback on the measure form completeness. At this time, the measure is still in active development, so several details have not yet been determined. Nonetheless, we appreciate the commenter's attention to detail and will carefully review measure information material and update it to ensure that it is accurate and complete before seeking additional public input.
9/14/2022	Krista Kaups; UCSF	Academic/ University	Measure Focus: Measure completeness	In the current form, the measure is incomplete, incorrect in many (if not most) of the assumptions made and demonstrates a limited understanding of factors contributing to post-operative respiratory failure. This is an important topic and far better construction and comprehension. Consider involving medical professionals with expertise in the field	We thank the commenter for the feedback on the measure form completeness. At this time, the measure is still in active development, so several details have not yet been determined. Nonetheless, we appreciate the commenter's attention to detail and will carefully review measure information material and update it to ensure that it is accurate and complete before seeking additional public input.

Date Posted/ Received	Name, Credentials, and Organization of Respondent	Type of Organization	Measure Set or Measure	Text of Comments	Response
9/14/2022	Krista Kaups; UCSF	Academic/ University	Use of non-invasive positive pressure/BiPAP	yes; But also need to consider other adjuncts - and consider that patients may use CPAP routinely (eg for obstructive sleep apnea) and this would be continued in the hospital setting	We thank the commenters on their feedback related to use of non-invasive positive pressure ventilation. We will take it into consideration as we continue to further refine this measure, and during data testing and evaluation.
9/14/2022	Krista Kaups; UCSF	Academic/ University	Measure Focus: Measure completeness	Please see my previous comments. In present form, this measure requires substantial revision - and needs to be completed	We thank the commenter for the feedback on the measure form completeness. At this time, the measure is still in active development, so several details have not yet been determined. Nonetheless, we appreciate the commenter's attention to detail and will carefully review measure information material and update it to ensure that it is accurate and complete before seeking additional public input.