National Consensus Development and Strategic Planning for Health Care Quality Measurement

Fall 2023 Management of Acute and Chronic Events Meeting Summary

Overview

Battelle, the consensus-based entity (CBE) for the Centers for Medicare & Medicaid Services (CMS), convened the Management of Acute Events and Chronic Conditions committee on January 29, 2024, for discussion and voting on measures submitted to the committee for endorsement consideration for the Fall 2023 cycle.

Meeting participants, including the Recommendations and Advisory Group committee members, joined virtually through the Zoom platform. The Recommendations Group was responsible for discussing the measures, and both groups voted during the meeting using a virtual voting platform. Measure stewards and developers and members of the public were also in attendance.

The objectives of the meeting were to:

- Review and discuss measures submitted to the committee for the Fall 2023 cycle;
- Review public comments received for the submitted candidate measures; and
- Render endorsement decisions for the submitted candidate measures.

This summary provides an overview of the meeting, the committee's deliberations, and the endorsement decision outcomes. Full measure information, including all public comments received, staff preliminary assessments, and committee independent reviews, can be found on each respective measure page on the PQM website.

After the committee's endorsement meeting, measures and the committee's endorsement decisions enter an appeals period for three weeks, from February 26 to March 18, 2024. Any interested party may submit an appeal, which Battelle staff will review for eligibility according to the criteria within the endorsement and maintenance (E&M) Guidebook. If the appeal is eligible, the Appeals Committee, consisting of all co-chairs from the five E&M project committees, will convene to evaluate the appeal and determine whether to maintain or overturn the subject endorsement decision.

Welcome, Roll Call, and Disclosures of Interest

Nicole Brennan, Executive Director of the Partnership for Quality Measurement (PQM), welcomed the attendees to the meeting and introduced her co-facilitator Matt Pickering, Endorsement & Maintenance Technical Lead. Dr. Brennan also introduced the committee co-chairs, Marybeth Farquhar and Whitney Bowman-Zatzkin, who each provided welcoming remarks.

Dr. Pickering then conducted roll call, and members disclosed any perceived conflicts of interest regarding the measures under review. Four committee members were recused from voting

based on Battelle's conflict of interest policy. For CBE #4120e, Lisa Suter was recused due to her participation on a contract that developed early concepts for the measure and due to her employment with Yale School of Medicine Center for Outcomes Research & Evaluation (Yale CORE), which is the developer of the measure. For CBE #0694, Jason Wasfy was recused due to his serving as chair of the American Cardiology Metrics Measures Subcommittee, which evaluated and provided feedback on the measure's workgroup. For CBE #4120e and CBE #4130e, Ashley Tait-Dinger was recused due to her participation on a technical expert panel (TEP) that reviewed both measures. For CBE #4125, Eleni Theodoropoulos was recused due to her participation as a TEP member on the measure.

After roll call, Battelle facilitators established whether quorum was met and outlined the procedures for discussing and voting on measures. The discussion quorum required the attendance of at least 60% of the active Recommendations Group members (at least 11 out of 18) during roll call. Voting quorum required at least 80% of active Recommendations Group plus Advisory Group members (at least 40 out of 50) who had not been recused from voting. Discussion quorum was established; however, voting quorum was not. Therefore, the committee discussed each measure and votes were collected after the meeting using an online voting tool.

Evaluation of Candidate Measures

Dr. Pickering provided an overview of the five measures under review. For Fall 2023, the committee received four new measures and one measure undergoing maintenance endorsement review (Figure 1). The measures focused on hospital harm, surgical complications, and patient understanding.

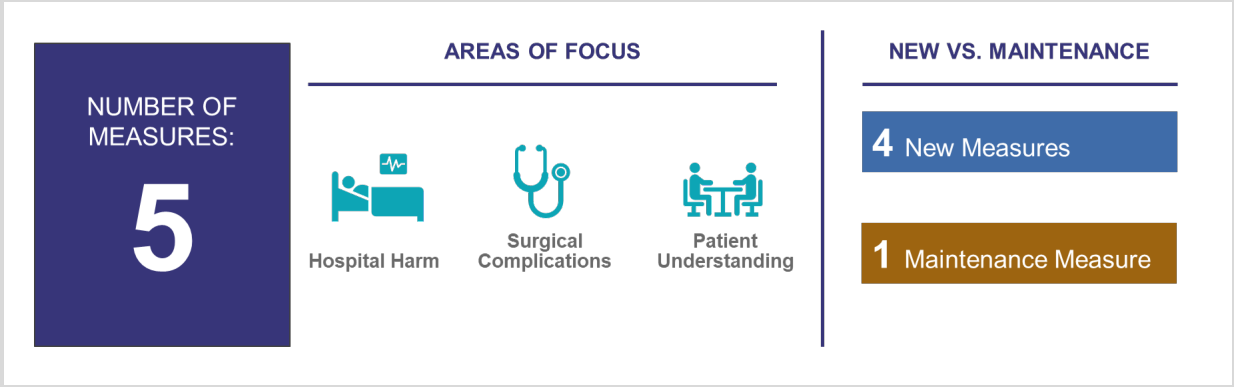

Figure 1. Fall 2023 Measures for Committee Review

At least three weeks prior to an E&M committee endorsement meeting, the Recommendations and Advisory Groups received the full measure submission details for each measure up for review, including all attachments, the PQM Measure Evaluation Rubric, the public comments received for the measures under review, and the E&M staff preliminary assessments.

Members of both groups had the opportunity to review each measure, independently, using the PQM Measure Evaluation Rubric. Committee members assigned a rating of "Met," "Not Met but Addressable," or "Not Met" for each domain of the PQM Measure Evaluation Rubric. In addition, committee members provided associated rationales for each domain rating, which were based on the rating criteria listed for each domain. Battelle staff aggregated and summarized the results and distributed them back to the committee, and to the respective measure developers and/or stewards, for review at least one week prior to the endorsement meeting. Battelle

facilitators compiled these independent committee member ratings and the facilitators and committee co-chairs used them to guide committee discussions.

After collection of all quorum votes, the committee voted to endorse three measures, voted to endorse one measure with conditions, and did not reach consensus on one maintenance measure, which resulted in removal of endorsement (Table 1). Summaries of the committee's deliberations for each measure along with any conditions for endorsement are noted below.

Table 1. Fall 2023 Management of Acute Events and Chronic Conditions Measure Endorsement Decisions

CBE ID	Measure Title	New / Maintenance	Endorsement Decision	Endorse | N (%)	Endorse with Conditions | N (%)	Not Endorse/Remove Endorsement | N (%)	Recusals
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measurement	**New**	Endorse	36 (81.82)	5 (11.36)	3 (6.82)	1
4130e	Hospital Harm – Postoperative Respiratory Failure	**New**	Endorse	33 (75.0)	9 (20.45)	2 (4.54)	1
4120e	Hospital Harms – Falls With Injury	**New**	Endorse	44 (100.0)	0 (0.0)	0 (0.0)	1
4125	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue)	**New**	Endorse with Conditions	10 (23.26)	31 (72.09)	2 (4.65)	1
0694	Hospital Risk-Standardized Complication Rate Following Implantation of Implantable Cardioverter-Defibrillator (ICD)	**Maintenance**	Endorsement Removed due to No Consensus	4 (9.3)	24 (55.81)	15 (34.88)	1

CBE #4210 – Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measurement [Yale Center for Outcomes Research and Evaluation (Yale CORE)/CMS]

Specifications | Committee Independent Review Summary

Description: This measure assesses how well facilities provide clear, personalized discharge instructions to patients aged 18 years or older who had a surgery or procedure at an outpatient facility. It uses a nine-item survey to obtain patient's feedback on three domains: applicability; medications; and daily activities. Facility scores are calculated by averaging the individual patient scores for each facility. Individual patient scores are calculated using a top-box approach measuring the percentage of the total number of items given the most favorable responses ("Yes" or "Very Clear") out of the total number of relevant items.

Committee Final Vote: Endorse

Conditions:

- None

Vote Count: Endorse (36 votes; 81.82%), Endorse with Conditions (5 votes; 11.36%), Not Endorse (3 votes; 6.82%); recusals (1).

Measure Discussion:

Battelle received two public comments prior to the meeting, both supporting the measure. The comments stated that personalized, clear discharge instructions are important for patient follow-through and compliance with medical recommendations. As outpatient procedures are becoming increasingly common, this measure allows for comparison between provider locations, resulting in patients being more informed.

One committee member asked for clarification regarding exclusions and the total number of patient-reported outcome performance measures (PRO-PMs) a patient may be eligible to complete. The developer responded by saying that the measure has no exclusions; however, the time frame is set to be different from other surveys, and items were harmonized to avoid duplication. The same committee member asked if patients who walked out against medical advice were included. The developer said providers likely would still want information from them. Another committee member said they agreed with including individuals who left against medical advice, as long they received the procedure, because discharge instruction should start before the procedure. The developer said they intended the survey to reflect all information the patient received from the time the patient decided to have the procedure.

Another committee member asked if the survey may be extended to languages beyond English and Spanish. The developer said the survey has only been tested and validated in English and Spanish but that the survey could be given through a translator or through a proxy or caregiver. The developer said they are open to translations.

The developer further clarified where the applicability items fell within the survey, stating that they are the first couple of questions. The first two questions are specific to applicability in that they are asking whether a patient's health needs and preferences were considered, and that

information should be personalized to be effective. This is why the developer did not provide a "Did not apply" option for the first two questions.

In terms of importance, the committee expressed that getting feedback from patients is important and felt that the literature review is sufficient.

In terms of feasibility, the developer provided feedback to some of the limitations identified in the committee's preliminary assessments. The developer stated that the survey link can be texted. The developer anticipates that implementation will be less burdensome than it was during testing. The developer also said that they administered the survey after discharge, because that is when the discharge instructions are given and when instructions may be less clear. The developer recognized that it may be a challenge for non-CMS organizations to obtain PRO data. One committee member reiterated that multi-modal survey administration is important, particularly as to not skew the data. The developer said they have found access to completing surveys on the web is widespread. One committee member asked when the results are being evaluated. The developer said the intended period of performance is annually, but that final implementation is within CMS's purview.

In terms of scientific acceptability, the developer responded to feedback from the staff preliminary assessments. The developer said they ran into a challenge with competing for resources against Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) and the hip/knee PRO-PM, which impacted the ability to implement in a broader testing sample. The developer also provided more information about the development of the survey itself, saying that it is a novel survey that was not based on existing surveys. The survey was shortened to its original form based on patient feedback and trying to avoid duplication with OAS CAHPS. The developer looked at whether all items were valid and reliable within the survey itself using a Cronbach's alpha test.

The developer also clarified that its TEP had 15 panel members, including two patient representatives. The developer specifically sought members in clinical practice, care coordination, quality measurement and survey design and analysis, performance improvement, health care disparities, and payers and purchasers. In addition to the TEP, the developers had a patient and family workgroup.

One committee member asked for the survey response rate. The overall response rate was around 11%; the developer clarified that for facilities that were implementing more ideally, it was closer to 30%. The developer said COVID and the implementation of OAS CAHPS affected their return rates.

In terms of equity, the developer said equity was important to Yale CORE and CMS and was part of the decision to not risk-adjust the measure in order for facilities to meet patients where they are and tailor instructions to them.

In terms of use and usability, the developer responded to limitations identified by the committee's preliminary assessments by saying providers receive raw results, potentially in real time, allowing them to make improvements. One committee member asked about the follow-up process. The developer confirmed they recommend following up by seven days.

Additional Recommendations: Potential additional recommendations for the developer to consider are translating the survey into languages other than English and Spanish.

CBE #4130e – Hospital Harm – Postoperative Respiratory Failure [American Institute for Research (AIR)/CMS]

Specifications | Committee Independent Review Summary

Description: This electronic clinical quality measure (eCQM) assesses the proportion of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure (PRF).

Committee Final Vote: Endorse

Conditions:

- None

Vote Count: Endorse (33 votes; 75%), Endorse with Conditions (9 votes; 20.45%), Not Endorse (2 votes; 4.54%); recusals (1).

Measure Discussion:

Six public comments were received prior to the meeting. Two comments were supportive of the measure. One comment supported the measure, while encouraging the developer to consider non-elective hospitalizations to improve monitoring. One comment was supportive of the measure, emphasizing that post-op respiratory failure is the most prevalent and serious post-op pulmonary complication. Two comments supported the measure with the condition that it should receive CBE endorsement before implementation and encouraged assessing the feasibility of collecting data from electronic health records (EHRs) and using more vendor systems and hospitals in that assessment.

One comment indicated concern about the feasibility of the measure without more information on the specification of electronic components of the measure. One comment noted several areas of concern that may make the measure unsuitable for use, including non-standardized data capture and sensitivity of screening technologies overshadowing performance. The commenter indicated that there is serious potential for unintended consequences.

During their opening remarks, the developer clarified how they define “postoperative respiratory failure.” The developer said that while the criteria may appear complicated, they were selected to be functional. They said that while they set out to track information on intubations, extubations, and ventilator settings, they also had to account for discrepancies.

One committee member asked about arterial blood gas (ABG) exclusions, stating that patients with severe chronic obstructive pulmonary disease (COPD) are often not able to get ABG analysis in 48 hours. The committee member was concerned about creating an undue burden if a patient then has to get an ABG the day of the procedure. The committee member added that the measure was important and suggested the developer should add to their evidence the practice guidelines on qualitative monitoring of neuromuscular blockers. In response, the developer said their intent is not to burden providers who are taking care of patients with bad COPD, and that those patients should be included in the denominator and accounted for in the risk adjustment. The criteria are intended to weed out patients who are clearly very sick from a respiratory standpoint and will likely not apply to patients who have just COPD.

In terms of importance, the developer responded to limitations identified in the preliminary assessment by saying that PRF is significant when it occurs. They said that because a PRF can

occur in so many ways and is more in the realm of common knowledge, the literature about risk factors is lacking. One committee member stated that they believed the many available interventions represent a potential strength of the measure. Another committee member said they supported the measure overall. They believed it may result in patient-selection issues but that the selection may be appropriate.

In terms of feasibility, the developer provided more information about unstructured fields. They said while they expected to collect intubation information, extubation information, and mechanical ventilation settings, the records sometimes also contained errant information. The developer felt they had successfully addressed the issue of unstructured fields during measure development. In terms of the potential burden, the developer said hospitals should already be capturing this information and that the measure may help standardize how that information is captured. The developer clarified that it was clinical workflow variation and how the systems utilized the fields that was not standardized.

In terms of scientific acceptability, the developer provided information about the makeup of the hospitals the measure was tested in. They said the measure was tested in smaller hospitals (of smaller than 100 beds), community teaching hospitals, and larger academic settings.

In terms of equity, use, and usability, the committee recognized that the developer used an extensive evidence base to evaluate disparities and design the risk adjustment model and that the measure is planned for use in the CMS Hospital Inpatient Quality Reporting Program.

Additional Recommendations: Not discussed.

CBE #4120e Hospital Harms – Falls with Injury [AIR/CMS]

Specifications | Committee Independent Review Summary

Description: This ratio measure assesses the number of inpatient hospitalizations where at least one fall with a major or moderate injury occurs among the total qualifying inpatient hospital days for patients aged 18 years and older.

Committee Final Vote: Endorse

Conditions:

- None

Vote Count: Endorse (44 votes; 100%), Endorse with Conditions (0 votes; 0%), Not Endorse (0 votes; 0%); recusals (1).

Measure Discussion:

Eleven comments were received prior to the meeting. Three comments supported the measure and encouraged the developer to clarify the denominator exclusions language. Another comment supported the measure with the condition that it receive endorsement consideration before implementation.

Four comments raised concern that this measure may lead to the reduction of mobilization for patients in order to reduce fall numbers. Four comments raised concern with the classification

categories for injury used in the measure. Lastly, two comments emphasized the challenges associated with electronic clinical quality measures (eCQMs) and implementation and burden.

In terms of importance, several committee members, including patient members, said this was an important measure.

In terms of feasibility, the developer responded to limitations identified in the preliminary assessments, saying the measure was constructed to support electronic health records (EHRs) that do not or are not able to capture fall documentation in structured fields; those hospitals that do not have structured fields can utilize International Classification of Diseases (ICD)-10 codes.

One committee member asked about how to close gaps in small or rural hospitals where a patient falls and the fall is not on the claim. The developer responded by saying that patients who had a fall that was present on admission were removed from the denominator population to eliminate whether the injury was related to a fall or not. The developer also said the data are not reliant on the claim but instead on the final coding for ICD-10 and emphasized that the measure focuses on moderate and major injuries.

In terms of scientific acceptability, the developer responded to limitations identified in the preliminary assessments by providing information on how the hospitals in the sample size were selected. They said the hospitals were widespread in terms of urbanicity and geographic location, including large academic settings, community hospitals, and small hospitals with less than 100 beds. They reiterated that this measure is feasible in any location that uses ICD-10 codes. They said that testing is sometimes more difficult for rural hospitals because of the burdens of time commitment and resources.

One committee member asked how rural hospitals are being supported in the implementation of eCQMs. The developer said they offer resources to help offset those difficulties to allow sites to participate.

One committee member asked for more information around validity. The developer said that across all sites, for the denominator, they found 519 events according to the clinical abstraction and 521 according to the measure, which led to a positive predictive value (PPV) of greater than 98% and sensitivity of 100%. For the numerator, the numbers were 87 on abstraction and 94 based on the EHR, which led to a PPV of 98.8% and a sensitivity estimate of 88%. One committee member asked about the false negatives. The developer said issues were related to admission-discharge-transfer issues; discrepancies with coding issues where injuries were documented as being hospital-acquired when the injury was actually one the patient came in with; and times when the injury was not documented at the time of the fall.

In terms of equity, the developer discussed how bone mineral density varies across race and ethnic groups, which affects the rates of injury resulting from falls. Because of that, the measure slightly favors hospitals with higher African-American populations. However, the developer did not want to adjust for race as a proxy, so this slight favoring is acceptable for use.

In terms of use and usability, one committee member asked if complications from a fall that worsen over time were reflected in the measure. The developer said that often the consequences of a fall are not understood immediately; however, the measure captures the injury at any point during a hospitalization. The measure may miss the injury if it is not captured at all. The developer said they did not find that occurrence in their validation effort.

One committee member asked about the burden to hospitals. The developer said that in any eCQM, implementation comes with some burden. However, one of the overall purposes of an eCQM is also to decrease clinician burden.

One committee member asked if it was fair to assume that hospitals would not reduce mobility in order to reduce falls as a result of the measure. The developer emphasized that the evidence does not support restricting mobility to reduce falls. Rather, the literature says to adjust risk factors, medications, and nursing care; provide physical therapy and incorporate early mobility; and to encourage family members and staff to spend more time at bedside. The developer also added that CMS has other balancing measures to help address concerns about mobility. Battelle staff reminded the committee that developers are asked to identify any unintended consequences during maintenance review.

One committee member asked about what the developer thought the uptake of electronic measures would be. The developer answered by saying they believe a small number of rural and small hospitals may not have EHRs, but the greater challenge would be bringing electronic measures into other settings, such as ambulatory settings and skilled nursing facilities. One committee member said that rural hospitals often do have EHRs, but that the cost of adding something new to the workflow can be a burden.

One committee member asked about how the range for the denominator was chosen. The developer responded by saying the denominator is a constant, and that the measure is a ratio measure, so they are looking at the number of falls per inpatient days. The developer clarified that the measure will only take emergency department (ED) falls into account if the patient is then admitted to inpatient hospitalization.

Additional Recommendations: The committee recommended monitoring how this measure performs in rural hospitals as well as monitoring for the potential unintended consequence of decreased patient mobilization.

CBE #4125 Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) [AIR/CMS]

Specifications | Committee Independent Review Summary

Description: Percentage of surgical inpatients who experienced a complication and then died within 30 days from the date of their first “operating room” procedure. Failure-to-rescue is defined as the probability of death given a postoperative complication.

Committee Final Vote: Endorse with Conditions due to the combination of Endorse votes and Endorse with Conditions votes being 75% or greater.

Conditions:

- Perform additional reliability testing for endorsement review, namely conducting additional simulation analyses of minimum case volume adjustments, since about half of the facilities had reliability below 0.6.

Vote Count: Endorse (10 votes; 23.26%), Endorse with Conditions (31 votes; 72.09%), Not Endorse (2 votes; 4.65%); recusals (1).

Measure Discussion:

Eleven comments were received prior to the meeting. Comments suggested a more narrow and well-scoped list of adverse events that need close monitoring post-op and requested further refinement of the numerator to add exclusions related to site of death, stating that a hospital should not be held accountable for traumatic accidents or other uncontrollable incidents within the 30-day window after surgery. One comment brought attention to the potential for the unintended consequence of discouraging patients from shifting their goals away from life-prolonging efforts within 30 days of surgery, and suggested excluding cases where care was appropriately shifted and natural death occurred.

Several comments expressed concern that the measure disregards site of death and that this can introduce scenarios outside of a hospital's control and concern with the lack of risk adjustment in the outcome measure, and suggested using patient population stratification. One comment recommended that testing be conducted to evaluate the measure for volume bias among facilities. The comment also promoted the use of artificial intelligence to reduce provider burden.

Lastly, this measure was submitted to the Pre-Rulemaking Measure Review (PRMR) committees for its use wihtin federal programs. Those comments expressed that the measure is unsuitable for federal programs due to concerns with reliability, risk adjustment, and specifications. The comments recommended the measure should be submitted for endorsement consideration before implementation.

Moving to the committee discussion, one committee member asked for clarification if the measure only related to Medicare patients, which the developer confirmed. The developer provided further information on how the measure has been designed to be compatible with CMS's portfolio of other 30-day mortality measures, including feedback from stakeholders about wanting a measure specific to surgical failure-to-rescue. The developer also clarified that a substantial population of Medicare recipients are under the age of 65 due to disabilities and having end-stage renal disease; these individuals are included in the measure with appropriate risk adjustment.

In terms of importance, the developer stated that while literature on this topic stretches back 30 years, the evidence has also been consistent since then. One committee member emphasized that they found this to be a strength.

In terms of scientific acceptability, the developer responded to limitations identified in the preliminary assessments, saying that the currently used Patient Safety Indicator (PSI) 04, Death Rate among Surgical Inpatients with Serious Treatable Complications (CBE #0200), has a reliability level of 0.256 on average. Therefore, CBE #4125's reliability is a dramatic improvement. The developer said they achieved this improvement due to the addition of Medicare Advantage patients and Medicare fee-for-service patients as well as broadening the complications that go into the denominator. The developer added that, since submission to PQM, they've worked to address the reliability issues. They found that the pandemic affected their reliability and that a modest adjustment to the minimum value threshold could have a significant impact. With that change, only 30% of facilities would have a reliability threshold below 0.6. The developer added that all risk-adjusted mortality measures face issues with reliability, and they are interested in working with CMS and other measure developers to achieve systematic improvements.

One committee member asked whether the measure should be designed to capture all-cause mortality, or rather, be designed to attribute each death to the preceding operation or not? The developer responded that it would introduce bias to attribute which factors were the cause of a death, and that this has been the consensus over the past 20 years. Instead, the "all-cause death" is used, knowing that the measure may be picking up some deaths that were unrelated to the major operation, but that this is a small number.

Another committee member asked if there was a concern with comparing hospitals who would admit a mixture of Medicare Advantage vs Medicare fee-for-service patients. The developer said that an increasing number of patients have moved to Medicare Advantage, and to understand the full picture, both populations need to be looked at.

In terms of equity, use, and usability, the committee recognized that potential disparities associated with race, ethnicity, age, and sex were evaluated and reported that the measure is planned for use for public reporting.

Additional Recommendations: Not discussed.

CBE #0694 Hospital Risk-Standardized Complication Rate Following Implantation of Implantable Cardioverter-Defibrillator (ICD) [American College of Cardiology]

Specifications | Committee Independent Review Summary

Description: This measure provides hospital specific risk-standardized rates of procedural complications following the implantation of an Implantable Cardioverter-Defibrillator (ICD) in patients at least 65 years of age. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) Electrophysiology Device Implant Registry (EPDI; formerly the ICD Registry) for risk adjustment linked with administrative claims data using indirect patient identifiers to identify procedural complications.

Committee Final Vote: Endorsement Removed due to no consensus. This was due to the lack of recent data to establish whether a performance gap remains; to determine reliability and validity of the measure, namely at the accountable entity level; and to establish whether the measure has improved over time. In addition, the measure is not currently being used.

Conditions:

- None

Vote Count: Endorse (4 votes; 9.3%), Endorse with Conditions (24 votes; 55.81%), Remove Endorsement (15 votes; 34.88%); recusals (1).

Measure Discussion:

No public comments were received for this measure.

One committee member asked if the measure is currently not in use, and the developer confirmed that is correct, because it cannot be linked to administrative data currently. Another committee member expressed concern over the limited data, particularly because the measure's intent is so important. Battelle staff advised the committee to consider the gap in care the measure may be addressing and the literature the measure developer provided. For a

maintenance measure, Battelle also added that it is preferable to see how the measure is affecting the gap in care and to consider the rationale the developer gave as to why the measure may not be affecting the gap in care, as it might not be.

In terms of importance, one of the committee members asked about the age of the results. The developer said they were published between 2015 and 2018. One committee member asked if it would be more feasible to include risk factors in the system rather than waiting for the CMS data through legislative changes. The developer said they have an inpatient model already; rather, it is the 30- and 60-day follow-up data that is the challenge currently because of the burden it places on hospitals. To get to the true intent of the measure, the developer said they need longer-term data.

In response to questions about how long the developers believe it will take them to get access to the needed data, they said it would take an act of Congress. The developer said they have plans once access is granted but are dependent on approval for implementation. The developer also said that receiving continued endorsement may or may not influence a decision from Congress. One committee member asked what the status of the measure would be without the needed change from Congress. The developer stated they would bring forward the inpatient model, acknowledging its timeframe limitations and that it does not address all feedback received from their TEP. In response to a question about how many hospitals report through the EP Device Implant (EPDI) registry, the developer said they believed it was 600 to 800 hospitals.

In terms of scientific acceptability, the developer responded to limitations identified in the preliminary assessment by saying that they encountered issues with the data they were using having indirect linkages, which resulted in lower numbers. The developer said they did not know the reliability in its current form and would like the opportunity to do testing with the data that they are trying to gain access to. One committee member, who said they had reviewed the measure under the prior CBE, indicated that they supported the measure with a condition of following up on some of the scientific acceptability testing numbers. One committee member asked Battelle if empirical testing was a requirement; Battelle staff said that such testing is not a requirement but is preferred.

One committee member asked if the developer had explored additional data sources for the measure. The developer said they did not think they had, but that the primary issue is the direct linkages and being able to use direct linkages, which is why they prefer to receive the data from CMS. Battelle said an additional condition could be that the measure come back for review in potentially three years rather than the standard five. The developer said they would do everything they could to meet that deadline if they had access to the updated data.

Additional Recommendations: Not discussed.

Opportunity for Public Comment

Dr. Pickering opened the floor for additional public comments; none were received.

Next Steps

Dr. Pickering noted that Battelle will post the meeting summary to the E&M committee project page by February 26, 2024. The summary will include any conditions placed on any of the measures. He noted that the appeals period for this cycle will begin on February 26, 2024, and end on March 18, 2024. He explained that any endorsement decision rendered by the committee can be appealed by any interested party based on the eligibility criteria, which can be found in the E&M Guidebook. The standing Appeals Committee meeting date is March 27, 2024. The Appeals Committee consists of all co-chairs from all project committees. Dr. Pickering closed the meeting by thanking participants, including committee members, members of the public, and the measure developers and stewards.