Summary of Hospital Harm Technical Expert Panel (TEP) Evaluation of Measures (Deliverable 4-3)

Patient Safety Measure Development and Maintenance

December 20, 2024

Submitted to:

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Background

The Centers for Medicare & Medicaid Services (CMS) contracted the Patient Safety Measure Development and Maintenance (Patient Safety) project team to support the development and maintenance of quality measures for the Hospital Inpatient Quality Reporting (IQR) program and the Hospital-Acquired Conditions Reduction Program. The contract number is 75FCMC18D0032, and task order number is 75FCMC24F0023. The Patient Safety team convenes groups of interested parties and experts who contribute direction and thoughtful input during measure development and maintenance. This report summarizes the feedback and recommendations made by the Technical Expert Panel (TEP) during meetings to discuss Hospital Harm electronic clinical quality measures (eCQMs). The report will be updated to include feedback and recommendations from future meetings as they occur.

Measure Development and Maintenance Team

The Patient Safety team is comprised of staff from Mathematica, and its partners, ICF and Dr. Sean Townsend.

A full list of the staff supporting this work is listed in Appendix A.

TEP Purpose and Objectives

The TEP is composed of individuals to advise the Patient Safety team on development and maintenance activities for hospital harm measures. The TEP includes clinicians with expertise in acute care hospital settings, performance measurement, coding and informatics, electronic health records (EHRs), and patient and family caregivers. The TEP will advise on:

- Measure gaps
- Refining measure concepts
- Maintenance activities
- Testing activities and results
- Meaningfulness to patients

Technical Expert Panel Meeting #1

June 5, 2024

Patient Safety team staff: Ethan Jacobs, Joelencia Leflore, and Ryan Anderson

The Patient Safety team convened the first TEP meeting under the Patient Safety contract on June 5, 2024, and 21 TEP members were present. Appendix B.1 lists the TEP members at the meeting and their organizational affiliations. This memo summarizes their feedback and recommendations (see Appendix C for detailed feedback).

Meeting Summary

Measure overview

The Patient Safety team introduced the two measures (Table 1) and acknowledged that the TEP has reviewed and supported the development of these measures through its work with CMS's predecessor contractor. Appendix C lists the draft specifications for the measures.

- The Patient Safety team said that, before the meeting, one TEP member contacted the team to note that the VTE measure's numerator has incorrect units for dalteparin sodium (Fragmin), a medication used in the numerator criteria to indicate whether a provider ordered a nonheparin anticoagulation medication within 24 hours after the end of an imaging study. The Patient Safety team will review this discrepancy with clinical project team members and make the appropriate corrections.

Table 1. Descriptions of Hospital Harm measures

Measure name	Description
Hospital Harm—VTE	The proportion of inpatient hospitalizations for patients ages 18 and older, who have at least one surgical procedure performed inside the operating room during the encounter and who suffer the harm of a VTE during the encounter or within 30 days after the first surgical procedure.
Hospital Harm—ARMB	The proportion of inpatient hospitalizations for patients ages 18 and older who were administered at least one anticoagulant medication within the first 24 hours of admission and had a subsequent bleeding event. Bleeding events must occur during the encounter.

Testing overview

The Patient Safety team said the goal of the testing is to assess the measures' importance, reliability, validity, and need for risk adjustment or stratification to support (1) the measures' potential inclusion in CMS quality programs and (2) Consensus-Based Entity endorsement. These activities require patient-level data from hospitals.

- **TEP members recommended ensuring the measures focus on preventable events.** One TEP member said the Agency for Healthcare Research and Quality conducted a national validation survey of measures to determine whether the events specified in the measure actually took place and if the hospital or clinicians could have prevented the events. Another TEP member agreed that examining whether events are preventable is important and said some clinical events are not preventable. The member also said that balancing measures are valuable for assessing whether a clinical event took place and if hospital staff took the proper actions to prevent the event.
- **One TEP member asked if the testing entails examining whether patients included in the measure numerator truly experienced the outcomes of interest or had incorrect data in their patient records.** The Patient Safety team said data-element validity, which the team plans to assess, involves comparing key data elements from (1) the electronic data submitted to score the measure and (2) a manual chart review. The team added that the measures' specifications were drafted with the goal of accurately measuring quality, noting that one of the ARMB measure's numerator conditions requires multiple confirmations of a drop in hemoglobin levels, not just a single instance of a drop.

- **TEP members said artificial intelligence (AI) might have future uses in quality measurement.** TEP members agreed that, in the future, AI might be useful for pulling information from unstructured fields to feed into measure scoring, noting that research has shown AI methods to be valid and feasible when assessing quality measures.

Accounting for patient risk

The Patient Safety team asked TEP members for input on patient risk factors for the ARMB and VTE measures to support the team's development and testing of risk-adjustment and risk-stratification approaches.

Patient demographic characteristics

The Patient Safety team asked TEP members if they would expect postoperative VTE and ARMB rates to differ by payer, race, ethnicity, and sex assigned at birth.

- **TEP members discussed the association between race and risk of VTE and bleeding.** A TEP member emphasized the strong association between people identifying as Black and increased rates of perioperative deep-vein thrombosis (DVT). Another TEP member said the Agency for Healthcare Research and Quality's National Health Disparities report discussed patient safety indicators and revealed a modest disparity in outcomes by race. Another TEP member said Black people with sickle-cell anemia have a higher risk of bleeding. A TEP member asked if the association between race and events such as bleeding or DVT is due to a genetic factor or due to treatment in hospitals. In reply, another member said they conducted a study and found that race was associated with VTE risk independent of social status.
- **TEP members discussed other patient demographic characteristics associated with VTE and bleeding risk.** One TEP member described a multifactor analysis they performed examining multiple patient safety outcome measures, based on the Healthy Places Index and Social Vulnerability Index. In this analysis, patient characteristics (including rural or urban status) had a weak correlation with outcomes. Another TEP member said female sex is associated with hypercoagulability in the peripartum phases or any stage of pregnancy. One member said whether a patient was transferred to the hospital after receiving care from another hospital could be a risk factor. A member said the payer is a possible risk factor and correlates with social determinants of health. Another TEP member said a patient's insurance can affect the type of medication they are prescribed (for example, a novel anticoagulant versus standard Warfarin). Another TEP member said Warfarin poses an increased risk for bleeding and requires a higher therapeutic range for certain conditions, such as conotruncal anomaly face syndrome and antiphospholipid antibody syndrome. Finally, one member cited age as a possible risk factor for both measures.

Possible clinical risk factors for the VTE measure

The Patient Safety team asked TEP members whether there are procedures or clinical risk factors associated with a higher risk of VTE that are outside the hospital's control.

- **TEP members agreed that trauma and length of stay are associated with an increased risk of postoperative VTE.** One TEP member said trauma and the nature of injuries are linked to an increased

risk of postoperative VTE. A second member added that trauma patients have complex care needs and longer stays in the hospital than nontrauma patients, increasing their risk for postoperative VTE. A third TEP member agreed that length of stay could be a risk factor for VTE. This third member said use of the intensive care unit (ICU) could be a risk factor and might mean a patient has had an adverse event that could precede and increase the risk of VTE. A fourth TEP member said factors leading to a longer stay differ from factors leading to an ICU level of care, and a patient's admission to the ICU for a complication could be an avoidable event.

- **The TEP identified comorbidities associated with an increased risk of postoperative VTE.** One TEP member said obesity raises the risk for VTE. This member also said obesity and smoking rates are higher in rural areas, noting that smoking can make a person more hypercoagulable and thus increase the risk of VTE. A second TEP member said diabetes is another comorbidity associated with an increased risk of VTE. A third TEP member recommended considering malignancy, thrombophilia, or prior VTE as possible risk factors for the VTE measure.
- **The TEP discussed but did not reach consensus on whether sedentary behavior is a risk associated with postoperative VTE.** One TEP member said sedentary behavior is a potential risk factor associated with poor recovery from procedures such as hip or knee replacements, and it raises the risk of VTE. Another member said some patients are discharged to home the same day as surgery, and a patient's use of preventative measures such as compression socks is outside the hospital's control. Two TEP members disagreed that sedentary behavior is outside the hospital's control, arguing that hospitals can reduce sedentary behavior through patient engagement.
- **Some TEP members said hospitals should be held accountable for identified risk factors as part of delivering high-quality care.** One TEP member provided the example that cancer is associated with a higher frequency of DVT and thromboembolism, but hospitals can implement measures for patients with cancer that reduce the chance of these events. Another TEP member suggested expanding the VTE measure numerator condition to require a 30-day follow-up from the surgeon to confirm that surgeons are tracking the care of their patients and patients are receiving feedback from surgeons. The member also said the VTE measure denominator exclusion should apply only to acute COVID-19 present during admission or within 48 hours but should not exclude patients who contract COVID-19 in the hospital because hospitals can prevent COVID-19 transmission. One TEP member suggested clinician variability, with respect to how they prescribe medications for hip and knee replacements, as a risk factor for the VTE measure. This member said hospitals should increase quality of care by ensuring clinicians use best practices.
- **The TEP identified indices and scoring algorithms to predict VTE risk.** One TEP member said a scoring system such as the Padua Prediction Score for Risk of VTE, Caprini Score for Venous Thromboembolism, or COBRA model should be evaluated for risk adjustment or stratification. The National Surgical Quality Improvement Program model has predictive capability, but it does not have betas for the individual risk factors it considers. The TEP member proposed that hospitals choose their scoring system and said one scoring system does not have greater sensitivity or specificity than another.
- **TEP members expressed concern that patients might use different hospitals in 30-day period.** The TEP said data might be missing for the VTE measure if a patient is admitted to a different hospital

during the 30-day period from the original admitting hospital, or a surgeon might "game" the measure by recommending that a patient seek treatment at a different hospital for a postoperative VTE.

Appropriateness of risk-adjusting the VTE measure

The Patient Safety team asked the TEP if risk-adjustment is appropriate for the VTE measure. All members of the TEP who response verbally or in the chat agreed that risk adjustment is appropriate.

Appropriateness of the risk-stratifying the VTE measure

The Patient Safety team asked the TEP if risk-stratification is appropriate for the VTE measure. All members of the TEP who response verbally or in the chat agreed that risk stratification is appropriate.

Possible clinical risk factors for the ARMB measure

The Patient Safety team asked the TEP if any procedures or risk factors are associated with a higher risk of bleeding events that are outside the clinician's or hospital's control.

- **The TEP identified comorbidities associated with an increased risk of bleeding.** A TEP member said renal disease, liver disease, and alcohol use disorder are risk factors for the ARMB measure. Another member agreed that kidney and liver disease should be considered risk factors due to some anticoagulant medications affecting a person's kidney or liver disease. A third TEP member agreed that comorbidities raise the risk of bleeding and recommended that the project team consider risk prediction tools for bleeding, such as HAS-BLED, to identify risk factors.
- **The TEP said surges of COVID-19 cases are linked to an increased risk of bleeding complications.** One TEP member mentioned a strong correlation between supratherapeutic ranges of anticoagulant medications used to treat COVID patients early in the COVID-19 pandemic and bleeding complications. The member said a study of a 300-hospital collaborative showed that early surges of COVID-19 were accompanied by a higher incidence of bleeding events, mainly because people had hypercoagulable conditions that were in supratherapeutic ranges. However, the member said the general approach to treating COVID-19 has changed, and clinicians are now more selective about which cases are treated this way.
- **The TEP identified a link between medications and bleeding risk.** One TEP member said the project team should consider certain medications that might make people more hypercoagulable. Another member said bleeding risk increases with certain over-the-counter medications.

Appropriateness of risk adjusting the ARMB measure

The Patient Safety team asked the TEP if risk adjustment is appropriate for the ARMB measure. All TEP members who responded to the prompt agreed that risk adjustment of the measure is appropriate.

Appropriateness of risk stratifying the ARMB measure

The team then asked the TEP if risk stratification is appropriate for the ARMB measure. All TEP members who responded to the prompt said risk stratification might be appropriate, with the following caveats:

- One TEP member asked fellow members for clarification on the potential risk factor of an anticoagulant given for VTE prophylaxis. The member said clinicians must document either therapeutic or prophylactic administration of an anticoagulant. Another TEP member said the project team should consider testing the type of anticoagulant (direct oral anticoagulants [DOACs] versus intravenous anticoagulants) for risk stratification. The member said there are inconsistencies with DOAC dosing, whereas intravenous anticoagulants are consistently dosed and titratable. Thus, the dosing of intravenous anticoagulants is linked to a clinical action and might produce a different risk of bleeding versus the administration of DOACs.
- One TEP member said drug interactions should not be risk adjusted or stratified because bleeding risk is preventable.

Face validity of Hospital Harm measures

The Patient Safety team polled the TEP members on the face validity of the VTE and ARMB measures as currently specified. Table 2 shows the responses to the questions that used response scales, and Appendix C shows TEP members' answers to open-ended questions.

For the VTE measure, 89 percent of TEP members (17 of 19 voting) agreed or strongly agreed that the measure score accurately reflects quality, and 79 percent (15 of 19 voting) agreed or strongly agreed that the measure score can be used to distinguish between good and poor quality of care.

For the ARMB measure, 90 percent of TEP members (16 of 20 voting) agreed or strongly agreed that the measure score accurately reflects quality, and 84 percent (16 of 19 voting) agreed or strongly agreed that the measure score can be used to distinguish between good and poor quality of care.

Table 2. Face-validity polling results

Measure	Category	The measure score accurately reflects quality of care Number of experts (percentage)	The measure score can be used to distinguish between good and poor quality of care Number of experts (percentage)
Hospital Harm—Postoperative VTE	Strongly agree	5 (26%)	4 (21%)
	Agree	12 (63%)	11 (58%)
	Disagree	2 (19%)	4 (21%)
	Strongly disagree	0 (0%)	0 (0%)
Hospital Harm—ARMB	Strongly agree	2 (10%)	1 (5%)
	Agree	16 (80%)	15 (79%)
	Disagree	2 (10%)	3 (16%)
	Strongly disagree	0 (0%)	0 (0%)

Implications

The TEP members agreed that the Hospital Harm measures accurately reflect quality and can distinguish between good and poor quality of care. They supported considering risk adjustment or risk stratification to account for differences outside the control of hospitals or to show how performance on the measures differs for different patient populations. During measure testing, the Patient Safety team will include the potential risk factors identified by the TEP in its risk-adjustment and risk-stratification testing.

Next Steps

In the coming months, the Patient Safety team will obtain data from test sites, conduct beta-testing analyses, and share a testing report with CMS. The team will convene the TEP in July to discuss maintenance for the Hospital Harm measures implemented in CMS programs.

Technical Expert Panel Meeting #2

July 30, 2024

Patient Safety team staff: Kingsley Weaver, Moriah Bauman, Michael Kerachsky, Erin Buchanan, Arnold Chen, Anita Somplasky, and Anouk Lloren

The Patient Safety team convened the second Hospital Harm (HH) Technical Expert Panel (TEP) meeting to discuss the seven HH eCQMs included or proposed for inclusion in the IQR program. The meeting's goals were to provide a status update on the HH eCQMs and to solicit the TEP's recommendations for potential changes under consideration for the measure specifications. Prior to the meeting, the Patient Safety team provided TEP members with the presentation slide deck for review.

Meeting Summary

The Patient Safety team convened the second HH TEP meeting under the Patient Safety contract on July 30, 2024, with 19 TEP members present. Appendix B.2 lists the TEP members at the meeting and their organizational affiliations. During the meeting, the TEP members introduced themselves and announced any potential conflicts of interest, also included in Appendix B.2. The Patient Safety team gave a status update on the HH eCQMs and posed several questions for discussion:

- Whether it was appropriate to introduce risk adjustment in the Severe Hypoglycemia and Severe Hyperglycemia measures.
- Whether to include metformin 500 milligram (mg) when used alone or low-dose insulin as qualifying hypoglycemic medications for the Severe Hypoglycemia measure.
- Whether to retain or remove the denominator exclusion of all patients with a COVID-19 diagnosis from the Pressure Injury measure.
- Whether the denominator criteria of the seven HH eCQMs should be expanded to include adolescents ages 12 through 17 years.

In preparation for the upcoming applications for consensus-based entity (CBE) re-endorsement of the Severe Hypoglycemia and Severe Hyperglycemia measures, the Patient Safety team also polled the TEP's patient and caregiver representatives to assess the value and potential unintended consequences of the two measures. This memo summarizes the TEP's feedback and recommendations.

Measure overview

The Patient Safety team introduced the seven HH eCQMs (Table 3) and acknowledged that the TEP has reviewed and supported the development and maintenance of these measures through its work with CMS's predecessor contractor.

Table 3. Descriptions of Hospital Harm eCQMs

Measure name	Description
Hospital Harm – Severe Hyperglycemia (CMS871v4)	This ratio measure assesses the number of inpatient hospital days for patients age 18 and older with a hyperglycemic event (harm) per the total qualifying inpatient hospital days for that encounter.
Hospital Harm – Severe Hypoglycemia (CMS816v4)	This proportion measure assesses the number of inpatient hospitalizations for patients age 18 and older who were administered at least one hypoglycemic medication during the encounter and who suffer the harm of a severe hypoglycemic event during the encounter.
Hospital Harm – Opioid-Related Adverse Events (CMS819v3)	This proportion measure assesses the number of inpatient hospitalizations for patients age 18 and older who have been administered an opioid medication outside of the operating room and are subsequently administered a non-enteral opioid antagonist outside of the operating room within 12 hours, an indication of an opioid-related adverse event.
Hospital Harm – Acute Kidney Injury (CMS832v2)	This proportion measure assesses the number of inpatient hospitalizations for patients age 18 and older who have an acute kidney injury (stage 2 or greater) that occurred during the encounter. Acute kidney injury stage 2 or greater is defined as a substantial increase in serum creatinine value, or by the initiation of kidney dialysis (continuous renal replacement therapy, hemodialysis or peritoneal dialysis).
Hospital Harm – Pressure Injury (CMS826v2)	This proportion measure assesses the number of inpatient hospitalizations for patients aged 18 and older who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury.
Hospital Harm – Postoperative Respiratory Failure* (CMS1218v1)	This proportion measure assesses the number of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure.
Hospital Harm – Falls with Injury* (CMS1017v1)	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 age 18 years and older.

* At the time of the TEP meeting, these were program candidate measures that had been proposed through the fiscal year (FY) 2025 Inpatient Prospective Payment System (IPPS) proposed rule. Since the meeting, the two measures were finalized for 2026 reporting in the IQR program through the FY 2025 IPPS final rule, published in early August 2024.

eCQM maintenance activities

The Patient Safety team provided an overview of the HH eCQM maintenance activities. Each year, measure developers participate in an annual update process to apply changes to the measures that were identified in the previous year.

The 2025 annual update cycle will begin in September 2024 and conclude in May 2025 with the publication of eCQMs for the 2026 reporting period. In preparation for the start of the 2025 annual update process, the Patient Safety team has been collecting feedback and conducting research to identify potential changes that may be appropriate or necessary for the seven HH eCQMs. The team's information-gathering efforts have included literature reviews, clinical guideline reviews, and this TEP meeting.

When assessing potential changes to the HH eCQMs for the next annual update cycle, the Patient Safety team considered public comments received on the fiscal year (FY) 2025 Inpatient Prospective Payment

System (IPPS) proposed rule for the two program candidate HH eCQMs, the Postoperative Respiratory Failure measure and the Falls with Injury measure. The team also reviewed comments and questions submitted year-round by implementers via the Office of the National Coordinator for Health Information Technology (ONC) Jira eCQM Issue Tracker.[1]

Two of the HH eCQMs, Severe Hypoglycemia and Severe Hyperglycemia, are due for CBE re-endorsement in spring 2025. The Patient Safety team has begun preparations to submit applications to maintain endorsement for the measures.

Risk adjustment overview

As part of the discussion on measure-specific questions, the Patient Safety team solicited the TEP's input on whether the Severe Hypoglycemia and Severe Hyperglycemia measures should remain without risk adjustment. To frame this discussion, the Patient Safety team provided a high-level overview of the purpose of risk adjustment. The team described how risk adjustment can promote fair and accurate comparison of outcomes across measured entities (for example, hospitals) by controlling for patient-level characteristics outside of hospitals' control. Some of these patient-level characteristics may include clinical characteristics (for example, types, number, or severity of conditions), demographic characteristics (for example, age, gender), functional characteristics (for example, ability to walk), and social characteristics (for example, income, education, geography).

Measure-specific questions

The Patient Safety team posed several measure-specific questions, outlined below, to TEP members for discussion and input.

Hospital Harm – Severe Hypoglycemia, Question #1

The Patient Safety team asked TEP members if they agreed that the Severe Hypoglycemia measure should remain unadjusted. In other words, the team asked the TEP whether hospitals should be able to effectively manage comorbidities related to the outcome of interest.

- **The Patient Safety team's clinical subject matter experts (SMEs) believe that there are no risk factors, within the inpatient setting, beyond the hospital's control that would impact the measure outcome and warrant risk adjustment. However, the Patient Safety team solicited and considered input from the TEP on this matter.** The Patient Safety team noted the most common causes of severe hypoglycemia are lack of caloric intake, overuse of anti-diabetic agents, or both, and that prior TEP members and clinical experts (including endocrinologists) have recommended *not* risk adjusting the measure based on clinical practice guidelines from the American Diabetes Association. While the CMS CBE last endorsed the measure without risk adjustment in 2019, the measure is due for CBE re-endorsement in spring 2025, and the Patient Safety team would like to confirm that risk adjustment is still not appropriate for the measure prior to submitting the measure for re-endorsement.
- **The Patient Safety team answered several clarifying questions about the measure from TEP members.** The Patient Safety team confirmed that the measure allows point-of-care testing as well as

[1] ONC Jira eCQM Issue Tracker. https://oncprojectracking.healthit.gov/support/projects/CQM/summary.

laboratory test values for the hypoglycemic reading. One TEP member also asked several questions about whether the measure would include patients who experience hypoglycemia in the emergency department or upon their admission to the hospital. The Patient Safety team clarified that for the purposes of this measure calculation, inpatient hospitalizations include time in the emergency department and observation when the transition between these encounters (if they exist) and the inpatient encounter are within an hour or less of each other; however, the measure does not count hypoglycemia that is present on admission. Similarly, the measure does not count a hypoglycemic event that occurs as a result of the patient taking a hypoglycemic medication *before* the start of their hospitalization. The measure looks only for hypoglycemic events that occur within 24 hours of the hospital's administration of a hypoglycemic medication. Several TEP members suggested that the language describing the measure's numerator and denominator criteria could be made clearer.

- **One TEP member noted that the longer a patient is in the hospital, the more risk that the patient has of suffering one or more hospital harms.** The member asked if there was any way to account for long hospitalizations (for example, by incorporating length of stay into a risk adjustment model), so that hospitals with patients who have extended hospitalizations and those that treat more complex patients are not penalized. The Patient Safety team said that another Hospital Harm eCQM in the IQR program (Acute Kidney Injury) does use length of stay as a risk-adjustment variable, so this is something that the Patient Safety team could consider.
- **Most TEP members agreed with the Patient Safety team's assessment that risk adjustment is not required for this measure, as severe hypoglycemia as defined in the measure (glucose test results below 40 mg/deciliter [dL]) is one of the so-called "never events" (patient safety events that should never occur and are preventable).**[2] The members, including one member who is an endocrinologist, noted that a glucose level below 40 mg/dL is extreme and should never happen during a hospitalization. Additionally, one TEP member suggested that measures with a never event as an outcome should never be risk adjusted. A more intensive level of nursing and monitoring could prevent this outcome even for the sickest patients in a hospital, and TEP members agreed that hospitals should be able to provide appropriate care to prevent severe hypoglycemia for all patients, regardless of the severity of their illness. One TEP member disagreed that severe hypoglycemia is a never event, as the member believes that this outcome happens often. However, this member agreed that risk adjustment is still not needed.
- **One TEP member noted the measure includes patients with severe liver disease and pancreatic tumors, who might experience severe hypoglycemia that is out of physicians' control.** The member explained that this situation is rare and does not necessitate the use of risk adjustment in the measure. However, the TEP member suggested that this situation may warrant the exclusion of patients with pancreatic tumors from the measure.
- **Hospital Harm – Severe Hypoglycemia, question #1 takeaways:** Keep the Severe Hypoglycemia measure unadjusted.

[2] Bowman, C.L., R. de Gorter, J. Zaslow, J.H. Fortier, and G. Garber. "Identifying a List of Healthcare 'Never Events' to Effect System Change: A Systematic Review and Narrative Synthesis." BMJ Open Quality, vol. 12, no. 2, 2023, e002264. https://doi.org/10.1136/bmjoq-2023-002264.

Hospital Harm – Severe Hypoglycemia, Question #2

The Severe Hypoglycemia measure identifies patients who experience severe hypoglycemia during inpatient hospitalization, when a hypoglycemic medication was administered within 24 hours prior to the start of the hypoglycemic event. The Patient Safety team asked TEP members if they think that it is appropriate to add (1) metformin 500 mg when used alone or (2) low-dose insulin to the list of qualifying hypoglycemic medications for this measure.

- **The Patient Safety project SMEs believed it would be atypical for metformin 500 mg when used alone or low-dose insulin to result in a hypoglycemic event.** An implementer requested via the eCQM Issue Tracker that these medications be considered as qualifying hypoglycemic medications, and the Patient Safety team solicited the TEP's thoughts on this request. Though metformin is included in the hypoglycemic medication value set, it only qualifies as a hypoglycemic medication in the measure when it is used in conjunction with other medications.
- **The TEP agreed that metformin when used alone should not be included in the measure as a qualifying hypoglycemic medication**. One TEP member, a pharmacist, confirmed that metformin is appropriate to include when it is used in conjunction with glipizide. The combination of metformin and glipizide is used to treat high glucose levels caused by type 2 diabetes but can cause low blood sugar.
- **Several TEP members questioned the definition of low-dose insulin and noted that the administration of several units of short-acting insulin has the potential to cause hypoglycemia in a hospital setting.** The Patient Safety team clarified that insulin in various forms are included in the measure and asked if TEP members had suggestions on guidelines on insulin dosage to include in the measure. Several TEP members, including one endocrinologist, recommended that any dose or form of short-acting low-dose insulin in a hospital setting should be considered as a qualifying hypoglycemic medication in the measure; they noted that long-acting low-dose insulin is less likely to cause hypoglycemia and would not be appropriate to add as a qualifying hypoglycemic medication to the measure.
- **Hospital Harm – Severe Hypoglycemia, question #2 takeaways:** Leave metformin 500 mg as a qualifying hypoglycemic medication when used in conjunction with other medications. After the TEP meeting, the Patient Safety team verified that short-acting insulin is already included as a hypoglycemic medication in the measure value set.

Hospital Harm – Severe Hyperglycemia, Question #1

The Patient Safety team asked TEP members if the Severe Hyperglycemia measure should remain unadjusted. The team asked the TEP whether hospitals should be able to effectively manage comorbidities related to the outcome of interest.

- **The Patient Safety team clinical SMEs identified potential risk-adjustment variables that could be added to the measure (for example, type 1 diabetes and steroid-induced hyperglycemia), as patients respond to treatments differently depending on the underlying cause of the hyperglycemia. Despite the presence of potential risk-adjustors, project SMEs did not believe that risk adjustment for the measure is warranted.** The Patient Safety team noted that prior TEP members and clinical experts (including endocrinologists) have recommended *not* risk adjusting the measure

based on clinical practice guidelines from the American Diabetes Association. While the CMS CBE last endorsed the measure without risk adjustment in 2020, the measure is due for CBE re-endorsement in spring 2025, and the Patient Safety team would like to confirm that risk adjustment is still not appropriate for the measure prior to submitting the measure for re-endorsement.

- **TEP members asked several clarifying questions about the measure, including whether hospitals are penalized for patients who are admitted to the hospital with hyperglycemia.** The Patient Safety team clarified that the numerator does *not* evaluate the first 24 hours of the encounter, and the measure also excludes patients with a glucose result of greater than or equal to 1,000 mg/dL any time one hour prior to the start of the encounter or up to six hours after the start of the encounter. The intention of these components of the measure is to avoid penalizing hospitals who have patients that are admitted with (severe) hyperglycemia (for example, those with uncontrolled type 2 diabetes or those with an initial presentation of type 1 diabetes).
- **The TEP agreed that risk adjustment is not necessary for this measure.** However, some TEP members expressed continued concern that this measure may penalize hospitals with patients who are admitted with extreme hyperglycemia below the 1,000 mg/dL exclusion threshold and who may have other clinical presentations (for example, hyperosmolarity) that would make it difficult for a physician to manage a patient's glucose results, even after the initial 24 hours of the encounter.
- **Hospital Harm – Severe Hyperglycemia, question #1 takeaways:** Keep the Severe Hyperglycemia measure unadjusted.

Hospital Harm – Pressure Injury, Question #1

The Pressure Injury measure currently excludes any patient with a diagnosis of COVID-19 during their inpatient hospitalization. The Patient Safety team asked the TEP whether it is still appropriate to exclude all patients with a COVID-19 diagnosis or whether the exclusion can be removed from the measure.

- **Given the many developments in the presentation and treatment of COVID-19 since 2020, the Patient Safety team aimed to seek input from the TEP on whether it is still appropriate to exclude patients with a diagnosis of COVID-19 from the measure.** The COVID-19 exclusion was originally put in place after (1) measure testing in 2020 identified inconsistencies in coding COVID-19-related skin changes incorrectly as pressure injuries, and (2) public comments on the measure noted that while prolonged prone positioning is a risk factor for pressure injuries, prone positioning was recommended and frequently used during the early stages of the pandemic to improve oxygenation among COVID-19 patients.
- **The Patient Safety team mentioned several additional factors for TEP members to consider in relation to this question.** First, the team noted that the National Institutes of Health still recommend prone positioning as a treatment for COVID-19, but only for patients with a COVID-19 diagnosis with adult respiratory distress syndrome who are on mechanical ventilation. Second, this measure was only tested with the COVID-19 exclusion in place. This measure has not yet been used for reporting in the IQR program; hospitals can first report this measure in the 2025 reporting period.
- **TEP members agreed that it is no longer necessary to exclude all patients with a COVID-19 diagnosis from the measure and recommended the removal of this exclusion.** One TEP member

suggested that the Patient Safety team could revisit testing data and use the historical testing data to assess the impact of removing the COVID-19 exclusion from the measure.

- **Hospital Harm – Pressure Injury, question #1 takeaways:** Modify the Pressure Injury measure's exclusions so that it does not exclude all patients with a COVID-19 diagnosis. The Patient Safety team will consider whether it is appropriate to exclude only a subset of patients with a COVID-19 diagnosis.

Patient safety in the pediatric population

The denominator criteria of the seven HH eCQMs include patients ages 18 years and older. CMS requested the Patient Safety team solicit feedback from TEP members on the possibility of expanding the denominator criteria for the HH eCQMs to include the pediatric population—specifically, those patients ages 12 through 17 years. One of the Patient Safety team's clinical SMEs discussed how pediatric patients can also experience hospital harm and are at even greater risk of medication error when compared to adults. The team requested the TEP's preliminary input on this potential change, acknowledging that if CMS and the Patient Safety team seriously consider this change, there would be many other factors and details to consider.

- **The majority of TEP members agreed that it is appropriate to expand the denominator criteria for all seven HH eCQMs to include patients ages 12 through 17 years.** Several TEP members noted that hospitalized children are uniquely vulnerable, and these measures could help prevent the occurrence of hospital harms among pediatric patients. One TEP member noted that it is important to consider the risk that the pediatric population faces in experiencing hospital harm events relative to the additional burden to providers that would be introduced if the denominator criteria were expanded.
- **While TEP members agreed with the recommendation to expand the HH eCQMs' denominator criteria, several TEP members noted that it may be appropriate to add stratification to the measures if their denominator criteria are expanded.** One TEP member stated that the inclusion of a younger population in a measure could artificially bring down the performance rate if the measure is reported as a single rate. The Patient Safety team will discuss the possibility of stratifying these measures with CMS.

Polling questions

The Patient Safety team will submit the Severe Hypoglycemia and Severe Hyperglycemia measures for CBE re-endorsement in spring 2025. CBE re-endorsement requires evidence that patients find measures meaningful to assess measure importance.[3] In preparation for the re-endorsement application process, the Patient Safety team polled the TEP patient and caregiver representatives on the meaningfulness and potential unintended consequences of the two measures.

A total of six patient and caregiver representatives responded to the polling questions; two were unable to attend the TEP meeting and provided responses via email. Results were converted to numeric values to calculate an average 4-point scale (strongly agree = 4, agree = 3, disagree = 2, strongly disagree = 1). Scores above 2.5 were considered passing or a consensus that the patient and caregiver representatives agreed.

[3] Partnership for Quality Measurement. "Endorsement and Maintenance (E&M) Guidebook." October 2023. https://p4qm.org/sites/default/files/2023-12/Del-3-6-Endorsement-and-Maintenance-Guidebook-Final_0_0.pdf.

Table 4. Results of Severe Hyperglycemia and Severe Hypoglycemia polling

Measure	The measure is meaningful and produces information that is valuable in making care decisions Average score	There are no unintended consequences or concerns regarding the measure Average score
Hospital Harm – Severe Hyperglycemia	3.5	2.8
Hospital Harm – Severe Hypoglycemia	3.7	3.3

The poll results (Table 4) will be included in the Patient Safety team's CBE re-endorsement applications for the Severe Hypoglycemia and Severe Hyperglycemia measures. Patient and caregiver representatives agreed that both measures are meaningful and produce information that is valuable in making care decisions. They also agreed that there were no unintended consequences or concerns regarding the measure. Feedback included that the need for repeat testing to check blood glucose levels would take staff time away from other duties and increase the cost of the hospitalization. Patient and caregiver representatives also gave several recommendations to improve these measures, such as to include adolescent patients (lower age range to start at age 12 years), to limit blood glucose re-testing to at-risk populations, and to modify the blood glucose result threshold in the Severe Hyperglycemia numerator and denominator exclusions from 1,000 mg/dL to 500 mg/dL.

Next Steps

The Patient Safety team thanked the TEP members for their time and input. Over the next month, the team will compile the key takeaways from the TEP meeting into a summary report, which the Patient Safety team will share with the TEP. TEP members can reach out to the Patient Safety team with any questions or additional comments by emailing Kingsley Weaver (kweaver@mathematica-mpr.com).

Technical Expert Panel Meeting #3

December 4, 2024

Patient Safety team staff: Dmitriy Poznyak, Sam Simon, Joelencia Leflore, Honoka Suzuki, Suzie Rastgoufard, Anouk Lloren, Anita Somplasky

The Patient Safety team convened the third Hospital Harm (HH) Technical Expert Panel (TEP) meeting to discuss the methodological framework for the new HH electronic clinical quality measure (eCQM) composite, herein referred to as the HH eCQM composite. The goal of the meeting was to gather expert input on the HH eCQM composite methodology, with the goal of maximizing its validity, reliability, and usability. Specifically, the team sought TEP guidance on two key methodological considerations:

1. **Composite structure**: inclusion of risk-adjusted and non-risk-adjusted eCQM component measures in the composite
2. **Composite methodology**: approach for combining eCQM component measures into the composite

The methodological considerations the Patient Safety team raised to the TEP were informed by findings from the environmental scan, which the team presented to the Centers for Medicare & Medicaid Services (CMS) as part of the HH eCQM Composite Alpha Testing Report (Deliverable 6.2).

For this TEP meeting, the Patient Safety team also invited eight nationally recognized experts in patient safety and compositing methodology as guest members, seeking to facilitate an exchange of diverse perspectives and promote knowledge sharing among clinicians, patients, and methodology experts.

Appendix B.3 and B.4 list the TEP and guest members at the meeting and their organizational affiliations.

Meeting Summary

Background

To give TEP members context on the rationale for developing the HH eCQM composite, the Patient Safety team started with an overview of the Patient Safety and Adverse Events Composite (CMS PSI 90) composite and its content and computation. PSI 90, an existing claims-based composite measure of hospital harm, is computed as a weighted average of 10 PSI component measures. Each PSI component is risk-adjusted to account for differences in patient case mix across hospitals and reliability-adjusted to account for uncertainty in hospitals' performance due to low volume. The PSI components are weighted based on the frequency of the adverse event (volume weights) and severity of harm (harm weights).

The Patient Safety team reiterated that although PSI 90 is an important benchmark of hospital patient safety, it has received criticism over the years. The rationale for the HH eCQM composite is rooted in the limitations of PSI 90's reliance on administrative claims data. In particular, Medicare claims data lack clinical detail, as the data's intent is to support billing, and they capture only Medicare fee-for-service beneficiaries, a subset of a hospital's patient population. Furthermore, these data require a six-month postsubmission period to confirm the accuracy of the claims, which increases the time between event incidence and measure performance reporting and delays the actionability of PSI 90.

The Patient Safety team then offered a rationale for using electronic health record (EHR) data to develop a composite measure of hospital harm. EHR data can offer significant advantages over claims data owing to (1) greater clinical detail, which better captures patient safety events and patient-specific risk factors; (2) a significantly larger patient population, expanding the measure population to all payers; and (3) improved harm measurement and management through more timely data. The team also said that interested parties, including the Consensus-Based Entity (CBE) Patient Safety Committee, have expressed a strong interest in transitioning to electronic measures of patient safety.

Next, the Patient Safety team introduced the nine candidate HH eCQMs being considered for inclusion in the HH eCQM composite (Table 5). Seven eCQMs have been developed and endorsed by the CBE, and two are under development. The nine eCQMs contain risk-adjusted and non-risk-adjusted measures as well as ratio and proportion measures.

Table 5. Candidate HH eCQMs for the HH eCQM composite

CMS ID	eCQM title	Measure scoring	Risk-adjusted?	Reporting start year	CBE endorsed
826	HH—Pressure Injury (CMS826v2)	Proportion	No	2025	2023
816	HH—Severe Hypoglycemia (CMS816v4)	Proportion	No	2023	2019
871	HH—Severe Hyperglycemia (CMS871v4)	Ratio	No	2023	2020
819	HH—Opioid-Related Adverse Events (CMS819v3)	Proportion	No	2024	2021
1017	HH—Falls with Injury (CMS1017v1)	Ratio	Yes	2026	2024
832	HH—Acute Kidney Injury (CMS832v2)	Proportion	Yes	2025	2023
1218	HH—Postoperative Respiratory Failure (CMS1218v1)	Proportion	Yes	2026	2024
877	HH—Anticoagulant-Related Major Bleeding	Proportion	TBD	TBD	TBD
1061	HH—Postoperative Venous Thromboembolism	Proportion	TBD	TBD	TBD

Note: The specifications for the HH—Anticoagulant-Related Major Bleeding eCQM and HH—Postoperative Venous Thromboembolism eCQM are in development.

The Patient Safety team provided an overview of the alignment between the PSI components and HH eCQMs (Table 6). The team informed the TEP that although some clinical topics overlap across the PSI and HH eCQM candidate component measures, exact specifications might differ. For example, the Pressure Ulcer Rate (PSI 03) captures Stage 3 and 4 and unstageable pressure ulcers, whereas the Pressure Injury eCQM (CMS ID 826) captures ulcers at Stage 2 through 4.

Table 6. Comparison of the PSI 90 component measures with candidate component measures for the HH eCQM composite

PSI	PSI Component title	CMS ID	HH eCQM title
03	Pressure Ulcer Rate	826	Pressure Injury
06	Iatrogenic Pneumothorax Rate	--	--
08	In-Hospital Fall-Associated Fracture Rate	1017	Falls with Injury
09	Postoperative Hemorrhage or Hematoma Rate	871	Anticoagulant-Related Major Bleeding
10	Postoperative Acute Kidney Injury Requiring Dialysis Rate	832	Acute Kidney Injury
11	Postoperative Respiratory Failure Rate	1218	Postoperative Respiratory Failure
12	Perioperative Pulmonary Embolism or Deep-Vein Thrombosis Rate	1061	Postoperative Venous Thromboembolism
13	Postoperative Sepsis Rate	--	--
14	Postoperative Wound Dehiscence Rate	--	--
15	Abdominopelvic Accidental Puncture or Laceration Rate	--	--
--	--	816	Severe Hypoglycemia
--	--	871	Severe Hyperglycemia
--	--	819	Opioid-Related Adverse Events

The Patient Safety team did not request input from the TEP during the background discussion. However, TEP members brought up several considerations and questions:

- **One TEP member asked whether the HH eCQM composite will replace PSI 90.** The Patient Safety team said these two composites will likely coexist for some time. It takes time for measures to be added to the Hospital-Acquired Conditions Reduction Program, as they must first be reported in the Inpatient Quality Reporting (IQR) program for two years.
- **TEP members inquired about the rationale behind the nine HH eCQMs.** One TEP member asked why the HH eCQM composite does not include a sepsis measure. The Patient Safety team said there is currently no eCQM sepsis measure developed or maintained under the Patient Safety contract. Another TEP member asked why these nine eCQMs were selected, given that other eCQMs could be considered HH measures. The Patient Safety team said the nine selected eCQMs are the HH eCQMs developed and maintained under the Patient Safety contract. The team added that most other eCQMs in the IQR program are process measures, whereas the nine eCQMs in Table 5 are outcome measures. One TEP member said they are on a team that is developing a sepsis eCQM that might be available for inclusion consideration in several years. The Patient Safety team thanked the member for this information.
- **TEP members reiterated the shortcomings of PSI 90 and stressed the importance of addressing these limitations in the HH eCQM composite.** Specifically, TEP members mentioned limited actionability, lack of sensitivity and specificity, and the ability for hospitals to "game" the measure. One TEP member said that as a practicing physician, it is difficult to know how to improve performance on PSI 90 given that it is an aggregate measure. The Patient Safety team acknowledged the importance of learning from the shortcomings of PSI 90. The team also reiterated the scope of its task, which is to work with these nine eCQMs and to assemble them into a composite measure in the best way possible. One TEP member said the PSI 90 methodology is flawed and cautioned against using it to guide the

development of the HH eCQM composite. However, another member disagreed and cited PSI 90's ability to aid in targeting preventable adverse events.

Composite structure

Overview of HH eCQMs

The Patient Safety team reviewed the nine HH eCQMs, noting that they include both risk- and non-risk-adjusted measures. The team then discussed risk adjustment as a statistical method that modifies hospitals' measure scores based on patients' characteristics and health conditions, which helps account for differences between hospitals' patient case mix and other factors unrelated to hospital quality of care.

The Patient Safety team said outcome quality measures are often, but not always, risk-adjusted. The four non-risk-adjusted HH eCQMs successfully earned CBE endorsement, and the CBE Patient Safety Standing Committee agreed with the developer's rationale for not risk-adjusting these measures.

Implications for the HH eCQM composite

The Patient Safety team said as risk-adjusted and non-risk-adjusted measures have different scales and interpretations, combining them into a single composite might complicate interpretations of the composite score. The team presented four options for combining components into a HH eCQM composite, with the advantages and disadvantages of each option (Table 7).

Table 7. Suggested approaches for combining risk- and non-risk-adjusted HH eCQMs into the composite

Option	Combining approach	Advantages	Disadvantages
1	Combine both risk-adjusted and non-risk-adjusted HH eCQMs into a single composite	Most comprehensive as it includes all component measures	Complicates compositing methodology as it will require rescaling; more difficult for interested parties to understand
2	Create a composite using the risk-adjusted HH eCQMs only	Accounts for variation in patient case mix across hospitals; more familiar to interested parties as the approach is the same one used for PSI 90	Excludes up to four HH eCQMs
3	Create a composite using the non-risk-adjusted HH eCQMs only	Simpler methodology; easier for interested parties to understand	Excludes up to five HH eCQMs
4	Create two separate composites: one using the risk-adjusted HH eCQMs and one using the non-risk-adjusted HH eCQMs	Most comprehensive as it includes all component measures	Complicates development process; undermines intent of composite to holistically assess hospital harm using a single measure, which could complicate quality improvement efforts

Discussion on composite structure: Risk adjustment

The Patient Safety team solicited feedback from TEP members on which of the four composite structure options (Table 7) will (1) be most meaningful to interested parties, (2) provide the most accurate assessment of patient safety events, and (3) best support hospital quality improvement. In addition, the

team asked for input on potential implications these options might have for public reporting and pay-for-performance programs.

- **Some TEP members advised against risk adjustment, with a patient representative noting it's not always meaningful to patients.** TEP members stressed that factors should only be risk-adjusted if the associated risks cannot be mitigated with increased resources or by taking the appropriate steps. For example, hospitals serving a larger share of older patients need to expend more resources and follow best practices to minimize risks of falls, rather than risk-adjusting for age. Furthermore, even if a risk is not related to a hospital's quality of care, it is nevertheless a risk to the patient and should be reflected in a measure score. One TEP member expressed concern that risk-adjusting for many factors could make it difficult for interested parties to understand and interpret the measure.
- **Several TEP members expressed support for risk adjustment, citing its importance in creating fair comparisons across hospitals.** TEP members agreed that measures should not be risk-adjusted for factors that are preventable, but they upheld the importance of risk adjustment in general. Without risk adjustment, hospitals would be unduly penalized for serving high-acuity patients, which could dissuade hospitals from taking such patients. Similarly, hospitals could appear to perform well only because of their less-complex patient case mix, which could mislead patients in their care decisions. Another TEP member said they are more comfortable with risk adjustment using EHR data than claims data.
- **Some TEP members expressed specific support for Option #1, citing the empirical advantages of combining multiple components into a single composite.** A TEP member said infrequent events, on their own, can generate noisy estimates and provide poor discrimination between hospitals. By combining multiple component measures, a composite offers enhanced signal strength, higher discrimination, and larger variation across hospitals. TEP members did not express concerns, statistical or conceptual, about combining risk- and non-risk-adjusted measures (once measures are made consistent in scaling and directionality), noting that several CBE-endorsed measures use this approach.
- **One TEP member said these options should be weighed alongside empirical testing results.** A TEP member noted the importance of empirical testing and that it would be difficult to make a recommendation without having seen how results differ across these methods.
- **TEP members said their recommendations depend on the context in which the composite is used.** TEP members had mixed reactions to using non-risk-adjusted measures in pay-for-performance programs. One member expressed support for combining risk- and non-risk-adjusted measures when the goal is quality improvement. However, the member opposed this approach for pay-for-performance programs in which hospitals might face penalties. Another member said they would recommend using risk-adjusted measures only for pay-for-performance purposes.
- **TEP members stressed the importance of reporting individual components measures in addition to the composite to maximize meaningfulness and usability for patients.** The TEP said patients are often interested in specific measures that are applicable to their care and hospital stay, whereas a composite measure can contain unrelated information.

Discussion on composite structure: Other considerations

The Patient Safety team also asked the TEP whether any of the candidate HH eCQMs should be excluded from the composite, aside from risk adjustment considerations.

- **Some TEP members expressed concerns with specific HH eCQMs due to potential for surveillance bias and low sensitivity.** One TEP member said past validation studies on hypoglycemia and hyperglycemia measures have revealed issues of low sensitivity. Two TEP members expressed concern about the potential surveillance bias of the postoperative venous thromboembolism (VTE) eCQM, in which hospitals with more rigorous testing and screening procedures tend to report more events. The Patient Safety team confirmed that the VTE eCQM was updated to align with PSI 12 (Perioperative Pulmonary Embolism or Deep-Vein Thrombosis Rate) to mitigate the risks of surveillance bias by (1) capturing only proximal (groin/thigh) vein thromboses, excluding distal (calf) thromboses, and (2) excluding solitary subsegmental pulmonary emboli.
- **One TEP member expressed concern about the inclusion of the two postoperative eCQMs (Postoperative Respiratory Failure and Postoperative Venous Thromboembolism), given that they are clinically and conceptually distinct from the other nonsurgical measures.** The TEP member said including them in the composite might make interpretation difficult, as the components would be measuring different constructs: quality of postoperative care and overall care quality for all medical patients. However, other TEP members disagreed and supported the inclusion of the postoperative measures to create a comprehensive composite and to maximize signal strength.
- **Several TEP members suggested including perinatal measures in the HH eCQM composite to capture maternal health**. A TEP member recommended the inclusion of the Severe Obstetric Complications eCQM (PC-07) in the composite. Other members agreed, noting that the composite is currently missing a significant population and that maternity care is a major service offered by many hospitals. The Patient Safety team said that although PC-07 is not maintained under the Patient Safety contract, the team agreed that it is applicable to the composite and will submit this recommendation for CMS's consideration.

Polling questions and results

The Patient Safety team polled the TEP members on the suggested options for combining risk- and non-risk-adjusted HH eCQMs into the composite. One TEP member said rank ordering of the polling options could produce useful information. Table 8 shows the results of the polling, and Appendix D contains TEP members' answers to open-ended questions.

At least half of all TEP members indicated that a single composite including both risk-adjusted and non-risk adjusted measures would be the most meaningful to interested parties (65 percent), would most accurately measure patient safety (50 percent), and would best support hospital quality improvement (54 percent), compared with creating a single composite of only non-risk-adjusted measures, a single composite of only risk-adjusted measures, or two separate composite measures.

Table 8. Results of composite structure polling

Question	Option 1: A single composite with risk-adjusted and non-risk-adjusted measures Number of experts (percentage)	Option 2: A single composite with only non-risk-adjusted measures Number of experts (percentage)	Option 3: A single composite with only risk-adjusted measures Number of experts (percentage)	Option 4: Two composites, one with risk-adjusted measures and one with non-risk-adjusted measures Number of experts (percentage)
Which of these four options will produce a composite that is most meaningful to interested parties?	17 (65%)	1 (4%)	2 (8%)	6 (23%)
Which of these four options will most accurately measure patient safety (that is, will be most valid at face value)?	13 (50%)	2 (8%)	3 (12%)	7 (30%)
Which of these four options will best support hospital quality improvement?	13 (54%)	1 (4%)	3 (13%)	7 (29%)

Composite methodology

The Patient Safety team introduced weighting as a key consideration for the composite measure. Broadly, component weighting can serve two purposes. First, conceptual or theoretical weights reflect key characteristics of each component measure, such as frequency of patient safety events or a degree of associated harm. Second, empirical weights (reliability weights) can reduce uncertainty associated with estimates from low-volume hospitals. As such, weighting can improve the reliability and validity of composites as well as enhance hospitals' ability to drive quality improvement by directing attention to certain types of events.

The Patient Safety team suggested a composite methodology for the HH eCQM composite that accounts for uncertainty in hospital estimates, the volume of adverse events, and the severity of harm associated with the events. Table 9 summarizes the three aspects of the suggested composite methodology.

Table 9. Aspects of the suggested composite methodology

#	Methodology aspect	Explanation	Purpose
1	**Reliability adjustment** (also referred to as smoothing or shrinkage)	Hospital estimates are adjusted based on their reliability. The amount of shrinkage depends on the signal-to-noise reliability ratio for each hospital.	Reduce the uncertainty of the estimates in low-volume hospitals by pulling their estimates closer to the population (or peer-group) mean
2	**Volume weights** (numerator based)	Component weights depend on the number of adverse events in the reference population.	Increase the weight of adverse events that affect more patients
3	**Harm weights** (based on empirical evidence and expert or consumer judgment)	Component weights depend on the amount of harm associated with an event.	Increase the weight of adverse events likely to cause more harm

Discussion on composite methodology

The Patient Safety team solicited recommendations from the TEP on a composite methodology that will be most meaningful to interested parties, provide the most accurate assessment of patient safety, and best support hospital quality improvement.

- **TEP members supported reliability adjustment to address concerns for low-volume hospitals.** A TEP member said that small, rural hospitals are often excluded from measures, or their scores fluctuate from year to year, due to low case volume. Reliability adjustment can address these issues, and although low-volume hospitals will often score near the average after reliability adjustment, this is better than not receiving a score at all. Another TEP member suggested the use of confidence intervals in addition to a point estimate for a measure score to alleviate concerns about low-volume hospitals.
- **TEP members supported the use of volume and harm weights.** A TEP member said volume weights are important, as the frequency of adverse events varies significantly across events. Another member said concerns about infrequent events could also be alleviated by measuring hospitals over multiple years. In addition, TEP members emphasized the importance of harm weights, which matter most from a patient perspective, as the safety events in this potential composite measure have long-term consequences.
- **One TEP member recommended using an ordinal scale for the harm weights.** A TEP member said the literature on harms is mixed and that a lot of value judgment goes into quantifying the severity of harm. An ordinal scale might make these weights more concrete compared with a continuous scale. Another member agreed with the idea of ordinal harm weights and asked about the source of input for assigning weights for the HH eCQM composite. The Patient Safety team said it would seek input to inform the harm weights in a future TEP meeting and suggested an empirical approach to evaluating the association between events and harm outcomes as another option.
- **One TEP member asked whether volume and harm weights will be combined in an additive or multiplicative manner.** The Patient Safety team said it envisions the weights to be multiplicative, such that for larger-volume events with low harm, one set of weights could balance out the other.

Polling questions and results

The Patient Safety team polled the TEP members on the suggested compositing methodology for the HH eCQM composite (Table 9). Table 10 shows the results of the poll, and Appendix D contains TEP members' answers to open-ended questions. One TEP member recommended that they be able to vote separately on each aspect of the proposed composite methodology, and the Patient Safety team clarified that members could share feedback on individual aspects of the methodology through the open-ended section of the poll.

TEP members agreed that the proposed composite methodology will enhance the meaningfulness of the composite for interested parties (92 percent), improve the accuracy of estimating harm events (85 percent), and support hospital quality-improvement efforts (85 percent).

Table 10. Results of composite methodology polling

Suggested composite methodology	Question	Yes Number of experts (percentage)	No Number of experts (percentage)
Reliability adjustment, volume weights, and harm weights	Will the proposed methodology enhance the meaningfulness of the composite for interested parties?	24 (92%)	2 (8%)
	Will the proposed methodology improve the accuracy of estimating harm events?	22 (85%)	4 (15%)
	Will the proposed methodology support hospital quality improvement efforts?	22 (85%)	4 (15%)

Implications

Most TEP members supported combining both risk-adjusted and non-risk-adjusted eCQMs in the HH eCQM composite. However, some members said they would only recommend risk-adjusted measures for pay-for-performance purposes. The TEP also largely supported the suggested composite methodology that includes reliability adjustment, volume weights, and harm weights for the HH eCQM component measures.

Next Steps

The Patient Safety team thanked the meeting participants for their time and input and said they will receive a meeting summary in early 2025. The team informed them that the next meeting on the composite will likely occur in February or March 2025.

Appendix A

Table A.1. Patient Safety Team

Key Staff	
Project leadership	Suzie Rastgoufard, MPA Anouk Lloren, Ph.D.
Senior advisor	Sam Simon, Ph.D.
Clinical advisors	Sean Townsend, MD Arnold Chen, MD, MSc Anita Somplasky, RN, CHTS-CP, CHTSPW
Testing advisor	Dmitriy Poznyak, Ph.D.
Technical advisor	David Clayman, DPM, MBA
Measure development and testing lead	Ethan Jacobs, MPP
Measure maintenance lead	Kingsley Weaver, MPH
Measure maintenance team	Erin Buchanan, MPH Michael Kerachsky, BA Moriah Bauman, MBA, MPH Shardae Sims, MPH Abdullah Rafiqi, BS
Measure testing team	Ryan Anderson, MS, MPH Joelencia Leflore, MPH Honoka Suzuki, MS Abigail Green

Appendix B

Table B.1. Hospital Harm TEP Attendance for Meeting #1

Name, Title	Organization, Location	Attendance/Conflicts
David Baker, MD, MPH; executive vice president for health care quality evaluation	The Joint Commission, Oakbrook Terrace, IL	Absent
Brian Callister, MD, FACP, SFHM; physician; governor of Nevada-ACP; professor of medicine	American College of Physicians, University of Nevada, Reno School of Medicine, Reno, NV	Present
Brigitte Chiu-Ngu, MS, RPh; retired pharmacist[a]	El Dorado Hills, CA	Present
David Classen, MD, MS; professor of medicine and infectious diseases	University of Utah School of Medicine, Pascal Metrics, Salt Lake City, UT	Present
Stephen Davidow, MBA-HCM, CPHQ, APR, LSSBB; clinical patient safety officer	Saint Anthony Hospital, Chicago, IL	Present
Helen Haskell, MA; caregiver representative[a]	Mothers Against Medical Error, Columbia, SC	Absent
Sharon Hibay, DNP, RN; measurement methodologist, coding, and quality and health equity subject matter expert[a]	Advanced Health Outcomes, Center Valley, PA	Present
David Hopkins, MS, PhD; Director of Health Information Improvement Division, Pacific Business Group in Health, Adjunct Affiliate at the Center for Health Policy and the Department of Health Policy	Stanford University, Stanford, CA	Present
Steven Jarrett, PharmD; medication safety officer	Atrium Health	Present
Kevin Kavanagh, MD, MS; volunteer board chair	Health Watch USA, Lexington, KY	Present
Shabina Khan; patient representative[a]	Chicago, IL	Present
Joseph Kunisch, PhD, RN-BC, CPHQ; vice president	Harris County Health System, Houston, TX	Present
David Levine, MD, FACEP; chief medical officer	Vizient, Chicago, IL	Present
Timothy Lowe, PhD; director, health care research	Premier, Inc., Charlotte, NC	Present
Grant Lynde, MD, MBA; staff physician and vice chair of quality	HCA Healthcare, Atlanta, GA	Present
Christine Norton, MA; patient caregiver[a]	Minnesota	Present
Kevin O'Leary, MD, MS, associate vice chair for quality	Northwestern University, Feinberg School of Medicine, Chicago, IL	Present
Amita Rastogi, MD, MHA, MS, FACHE, chief medical officer	OxBridge Health	Present
Sheila Roman, MD, MPH; independent health care consultant, part-time associate professor of medicine	Johns Hopkins Medical Institutions, Baltimore, MD	Present
Hardeep Singh, MD, MPH; chief of health policy, quality, and informatics program	Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX	Absent
Bruce Spurlock, MD; president and CEO	Cynosure Health, Cal Hospital Compare, Roseville, CA	Present

Name, Title	Organization, Location	Attendance/Conflicts
Ashley Tait-Dinger, MBA; director of analytics, alternative payment models, and finance[a]	Florida Alliance for Healthcare Value, Winter Springs, FL	Present
Kayla Waldron, PharmD; director, medication Use and Quality Improvement	American Society of Health-System Pharmacists, Pharmacy Quality Alliance, Bethesda, MD	Present
Patricia Zrelak, PhD, FAHA, NEA-BC, CNRN, SCRN, RN; quality & safety improvement consultant	Kaiser Foundation Hospitals, Sacramento, CA	Present

[a] Indicates a patient representative.

Table B.2. Hospital Harm TEP Attendance for Meeting #2

Name, Title	Organization, Location	Attendance/Conflicts
David Baker, MD, MPH; executive vice president for health care quality evaluation	The Joint Commission, Oakbrook Terrace, IL	Absent
Brian Callister, MD, FACP, SFHM; physician; governor of Nevada-ACP; professor of medicine	American College of Physicians, University of Nevada, Reno School of Medicine, Reno, NV	Absent
Brigitte Chiu-Ngu, MS, RPh; retired pharmacist[a]	El Dorado Hills, CA	Present
David Classen, MD, MS; professor of medicine and infectious diseases	University of Utah School of Medicine, Pascal Metrics, Salt Lake City, UT	Present/Patient safety grants and part-time employment for patient safety organization
Missy Danforth	The Leapfrog Group	Present
Stephen Davidow, MBA-HCM, CPHQ, APR, LSSBB; clinical patient safety officer	Saint Anthony Hospital, Chicago, IL	Present
Helen Haskell, MA; caregiver representative[a]	Mothers Against Medical Error, Columbia, SC	Present
Sharon Hibay, DNP, RN; measurement methodologist, coding, and quality and health equity subject matter expert[a]	Advanced Health Outcomes, Center Valley, PA	Present
David Hopkins, MS, PhD; Director of Health Information Improvement Division, Pacific Business Group in Health, Adjunct Affiliate at the Center for Health Policy and the Department of Health Policy	Stanford University, Stanford, CA	Present
Steven Jarrett, PharmD; medication safety officer	Atrium Health	Absent
Kevin Kavanagh, MD, MS; volunteer board chairman	Health Watch USA, Lexington, KY	Present
Shabina Khan; patient representative[a]	Chicago, IL	Absent
Joseph Kunisch, PhD, RN-BC, CPHQ; vice president	Harris County Health System, Houston, TX	Absent
David Levine, MD, FACEP; chief medical officer	Vizient, Chicago, IL	Present
Timothy Lowe, PhD; director, health care research	Premier, Inc., Charlotte, NC	Present
Grant Lynde, MD, MBA; staff physician and vice chair of quality	HCA Healthcare, Atlanta, GA	Present
Christine Norton, MA; patient caregiver[a]	Minnesota	Present

Name, Title	Organization, Location	Attendance/Conflicts
Kevin O'Leary, MD, MS, associate vice chair for quality	Northwestern University, Feinberg School of Medicine, Chicago, IL	Present
Amita Rastogi, MD, MHA, MS, FACHE, chief medical officer	OxBridge Health	Present
Sheila Roman, MD, MPH; independent health care consultant, part-time associate professor of medicine	Johns Hopkins Medical Institutions, Baltimore, MD	Present
Hardeep Singh, MD, MPH; chief of health policy, quality, and informatics program	Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX	Present / Federal grants, co-chair Leapfrog Diagnostic Project
Bruce Spurlock, MD; president and CEO	Cynosure Health, Cal Hospital Compare, Roseville, CA	Present
Ashley Tait-Dinger, MBA; director of analytics, alternative payment models, and finance[a]	Florida Alliance for Healthcare Value, Winter Springs, FL	Absent
Kayla Waldron, PharmD; director, medication Use and Quality Improvement	American Society of Health-System Pharmacists, Pharmacy Quality Alliance, Bethesda, MD	Present
Patricia Zrelak, PhD, FAHA, NEA-BC, CNRN, SCRN, RN; quality & safety improvement consultant	Kaiser Foundation Hospitals, Sacramento, CA	Present

[a] Indicates a patient representative.

Table B.3. Hospital Harm TEP Attendance for Meeting #3

Name, Title	Organization, Location	Attendance/Conflicts
David Baker, MD, MPH; executive vice president for health care quality evaluation	The Joint Commission, Oakbrook Terrace, IL	Absent
Brian Callister, MD, FACP, SFHM; physician; governor of Nevada-ACP; professor of medicine	American College of Physicians, University of Nevada, Reno School of Medicine, Reno, NV	Absent
Brigitte Chiu-Ngu, MS, RPh; retired pharmacist[a]	El Dorado Hills, CA	Present
David Classen, MD, MS; professor of medicine and infectious diseases	University of Utah School of Medicine, Pascal Metrics, Salt Lake City, UT	Present
Missy Danforth	The Leapfrog Group	Present
Stephen Davidow, MBA-HCM, CPHQ, APR, LSSBB; clinical patient safety officer	Saint Anthony Hospital, Chicago, IL	Present
Helen Haskell, MA; caregiver representative[a]	Mothers Against Medical Error, Columbia, SC	Present
Sharon Hibay, DNP, RN; measurement methodologist, coding, and quality and health equity subject matter expert[a]	Advanced Health Outcomes, Center Valley, PA	Present
David Hopkins, MS, PhD; Director of Health Information Improvement Division, Pacific Business Group in Health, Adjunct Affiliate at the Center for Health Policy and the Department of Health Policy	Stanford University, Stanford, CA	Present
Steven Jarrett, PharmD; medication safety officer	Atrium Health	Absent
Kevin Kavanagh, MD, MS; volunteer board chairman	Health Watch USA, Lexington, KY	Present

Name, Title	Organization, Location	Attendance/Conflicts
Shabina Khan; patient representative[a]	Chicago, IL	Present
Joseph Kunisch, PhD, RN-BC, CPHQ; vice president	Harris County Health System, Houston, TX	Present
David Levine, MD, FACEP; chief medical officer	Vizient, Chicago, IL	Present
Timothy Lowe, PhD; director, health care research	Premier, Inc., Charlotte, NC	Present
Grant Lynde, MD, MBA; staff physician and vice chair of quality	Lynde Consulting, Atlanta, GA	Present
Christine Norton, MA; patient caregiver[a]	Minnesota	Present
Kevin O'Leary, MD, MS, associate vice chair for quality	Northwestern University, Feinberg School of Medicine, Chicago, IL	Present
Amita Rastogi, MD, MHA, MS, FACHE, chief medical officer	OxBridge Health	Present
Sheila Roman, MD, MPH; independent health care consultant, part-time associate professor of medicine	Johns Hopkins Medical Institutions, Baltimore, MD	Present
Hardeep Singh, MD, MPH; chief of health policy, quality, and informatics program	Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX	Absent
Bruce Spurlock, MD; president and CEO	Cynosure Health, Cal Hospital Compare, Roseville, CA	Present
Ashley Tait-Dinger, MBA; director of analytics, alternative payment models, and finance[a]	Florida Alliance for Healthcare Value, Winter Springs, FL	Present
Kayla Waldron, PharmD; director, Medication Use and Quality Improvement	American Society of Health-System Pharmacists, Pharmacy Quality Alliance, Bethesda, MD	Present
Patricia Zrelak, PhD, FAHA, NEA-BC, CNRN, SCRN, RN; quality & safety improvement consultant	Kaiser Foundation Hospitals, Sacramento, CA	Present

[a] Indicates a patient representative.

Table B.4. Hospital Harm Guest Expert Attendance for Meeting #3

Name, Title	Organization, Location	Attendance/Conflicts
J. Matt Austin, PhD	Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine	Absent
Ann Borzecki, MD[a]	Center for Healthcare Organization and Implementation Research, Veterans Health Administration, Chobanian & Avedisian School of Medicine, Boston University	Absent
David Nerenz, PhD	Center for Health Policy and Health Services Research, Henry Ford Health System	Present
Sean O'Brien, PhD	Duke University Medical Center	Present
Amy Rosen, PhD[a]	VA Boston Healthcare System, Chobanian & Avedisian School of Medicine, Department of Surgery, Boston University	Present
Alex Sox-Harris, PhD	Surgery Policy Improvement Research and Education Center, Stanford University	Present

[a] Indicates a Patient Safety Indicator TEP member.

Appendix C

Hospital Harm Measure Specifications

Hospital Harm—Anticoagulant-Related Major Bleeding

The following measure specifications are in draft form.

- **Description:** The proportion of inpatient hospitalizations for patients ages 18 and older who were administered at least one anticoagulant medication within the first 24 hours of admission and had a subsequent bleeding event. Bleeding events must occur during the encounter.
- **Denominator:** Inpatient hospitalizations for patients ages 18 and older with a length of stay of 48 hours or longer, without a diagnosis of obstetrics, and at least one anticoagulant medication was administered within the first 24 hours of the hospitalization.
- **Denominator exclusions:** Inpatient hospitalizations for:
  - Patients who had a critical or noncritical site bleeding diagnosis present on admission
  - Patients who received dialysis during the hospitalization
  - Patients who had a diagnosis of a coagulation disorder during the encounter
  - Patients who had extracorporeal membrane oxygenation during the hospitalization
- Denominator exceptions: None.
- Numerator: Inpatient hospitalizations that include bleeding events during the encounter following an anticoagulation medication administration during the same encounter.

  A bleeding event is defined as the presence of one of the following:

  - *Criterion A:* A diagnosis of acute bleeding at or into a critical anatomic site, with the bleeding diagnosis not present on admission—that is, a bleeding diagnosis Present on Admission indicator = N (diagnosis was not present at time of inpatient admission) or U (documentation insufficient to determine if the condition was present at the time of inpatient admission)

    OR

  - *Criterion B:* One evidence factor of a bleeding event and a diagnosis of acute bleeding at or into a noncritical anatomic site, with the bleeding diagnosis not present on admission—that is, a bleeding diagnosis Present on Admission indicator = N (diagnosis was not present at time of inpatient admission) or U (documentation insufficient to determine if the condition was present at the time of inpatient admission)

    - Evidence of Criterion B bleeding event is determined by either:
      - An absolute decrease in hemoglobin results of 2 g/dL within a 48-hour period, excluding the first 24 hours of arrival, and within five days of the anticoagulation administration. An absolute decrease is determined when a confirmatory decrease is identified using the highest hemoglobin level within 24 hours of the initial hemoglobin drop.

        OR

- Transfusion of whole or red blood cells, excluding the first 48 hours of arrival in the hospital (including the emergency department and observation) and within five days of the anticoagulation administration

Hospital Harm—Postoperative Venous Thromboembolism

The following measure specifications are in draft form.

- **Description:** The proportion of inpatient hospitalizations for patients ages 18 and older who have at least one surgical procedure performed inside the operating room during the encounter and who experience a postoperative venous thromboembolism (VTE) during the encounter or within 30 days after the first surgical procedure.
- **Denominator:** Inpatient hospitalizations for patients ages 18 and older, without a diagnosis of obstetrics, in which a surgical procedure was performed inside the operating room during the encounter.
- **Denominator exclusions:**

  Inpatient hospitalizations for:

  – Patients with a VTE diagnosis present on admission
  – Patients who had extracorporeal membrane oxygenation during the hospitalization
  – Patients with acute brain or spinal injury or hemorrhage present on admission
  – Patients who had a thrombectomy procedure before or on the same day as the first surgical procedure during the hospitalization
  – Patients with a diagnosis of a COVID-19 infection during the encounter
  – Patients who had intracranial or spinal surgery during the encounter and who were discharged less than five days after the end of the surgery
  – Patients who had a duration of stay less than two calendar days
- Denominator exceptions: None.
- Numerator: Inpatient hospitalizations for patients with a postoperative VTE within 30 days of the first surgical procedure.

  Evidence of a postoperative VTE is determined by Criterion A, B, or C:

  – *Criterion A:* A surgical encounter with a diagnostic imaging study performed during the encounter and within 30 days or less after the end of the first surgical procedure performed during the encounter (cannot be an intracranial or spinal surgery procedure) and at least one of the following:

    o A nonheparin anticoagulation medication order within 24 hours after the end of the imaging study during the same encounter in which an anticoagulant medication was not active before or on the day of the first surgical procedure. A nonheparin anticoagulation medication order is evidenced by:

      - Enoxaparin (Lovenox) > 80 mg per day
      - Apixaban (Eliquis) >= 10 mg per day

- Rivaroxaban (Xarelto) >= 20 mg per day
- Fondaparinux (Arixtra) >= 5 mg per day
- Dalteparin sodium (Fragmin)>= 10,000 kg per day; or

○ A heparin intravenous administration within 24 hours after the imaging study, with at least two aPTT heparin therapy monitoring tests or at least two anti-factor Xa assays within 35 hours of the start of heparin intravenous therapy administration, where an anticoagulant medication was not active before or on the day of the first surgical procedure; or

○ Placement of an inferior vena cava filter within 24 hours after the end of the imaging study; or

○ A diagnosis of VTE that was not present on admission

– *Criterion B:* An intracranial or spinal surgery encounter with a diagnostic imaging study performed during the encounter and between five days and up to 30 days after the end of the first surgical procedure performed during the encounter, and at least one of the following:

○ A nonheparin anticoagulation medication order within 24 hours after the end of the imaging study during the same encounter, where an anticoagulant medication was not active before or on the day of the first surgical procedure. A nonheparin anticoagulation medication order is evidenced by:

- Enoxaparin (Lovenox) > 80 mg per day
- Apixaban (Eliquis) >= 10 mg per day
- Rivaroxaban (Xarelto) >= 20 mg per day
- Fondaparinux (Arixtra) >= 5 mg per day
- Dalteparin sodium (Fragmin)>= 10,000 kg per day; or

○ A heparin intravenous administration within 24 hours after the imaging study, with at least two aPTT heparin therapy monitoring tests or at least two anti-factor Xa assays within 35 hours of the start of heparin intravenous therapy administration, where an anticoagulant medication was not active before or on the day of the first surgical procedure, or

○ Placement of an inferior vena cava filter within 24 hours after the end of the imaging study, or

○ A diagnosis of VTE that was not present on admission

– *Criterion C:* A VTE that occurs during a subsequent encounter and within 30 days or less after the end of the first surgical procedure that occurred during the surgical encounter, as evidenced by:

○ A diagnosis of VTE during the subsequent encounter, and

○ Anticoagulation therapy ordered or prescribed during the subsequent encounter

Table C.1. Open-Ended Responses to Questions on Face Validity and Mathematica's Feedback on Selected Responses

Questions	Comments
Hospital Harm—Postoperative Venous Thromboembolism (VTE)	
The measure score is an accurate reflection of quality. If you disagree or strongly disagree, please explain.	• The quality of care is not determined by just ONE failed measure. One has to consider the whole picture. • I agreed but want to flag that the 30 day inclusion while I believe a reflection of quality may not be under hospital's control. • I agreed but I would say that it depends a bit in part on other factors. • There are too many variables and questions discussed related to the measure that leave many loose ends. I strongly recommend providing draft specifications for TEP members to review. • Agree. • Depends on approach for risk adjustment.
The measure can be used to distinguish between good and poor quality of care. If you disagree or strongly disagree, please explain.	• Did not disagree on previous question - but there are limitations to the quality of care implications - did the care givers do all they could and a VTE still occurred - this is certainly possible. • I do not feel this is specific enough given what can happen outside the provider initial. • Again, the quality of care should not be determined by ONE failed measure. The sum of measures should be factored in the consideration. • If possible, would be helpful to see if there are a significant number of VTEs diagnosed at other hospitals during the beta testing. • There are too many variables and questions discussed related to the measure that leave many loose ends. I strongly recommend providing draft specifications for TEP members to review. The information provided in the slides is the description and data source. • Too many risk factors/variables to control for. • Agree.
Do you have any recommendations that would help strengthen the face validity of the VTE measure?	• Need appropriate risk adjustment and risk stratification. need apples to apples comparisons as hospital populations of acuity and case type vary. An institution that does not do surgeries does not have VTE. Need to look at tertiary care differently. • My only concern is that at the end of the time period (27-30 days), the causal relationship for the complication may well shift from the provider to the patient due to factors outside the control of the hospital; not a criticism, but a caution. • I look further performance and population findings. Please include a broader reflection antecedents (e.g., community & practice characteristics) that drive outcomes.

Questions	Comments
Do you have any recommendations that would help strengthen the face validity of the VTE measure? (cont.)	• Provision of best practices to both physicians and patients. Perhaps a companion measure that can assess whether the patient has appropriate education and follow up for the post op period. • Risk stratification. Exclude patients with massive blood loss, exclude patients with preexisting hyper/hypocoagulable states. • Would like more info about risk adjustment in next meeting and would be helpful to see if there are VTEs diagnosed at other hospitals during beta testing and get a sense of whether this affects measure performance. • Yes, only disallow a COVID diagnosis, when it is acute COVID-19 and present on admission or within 48 of admission. • None at this time. • Doing a study to look at missed opportunities. Maybe looking for missed events (events that coded). • Would beta test in non-teaching hospitals in addition to any teaching hospitals. • Exclusions will have to be many.
Hospital Harm—Anticoagulant-Related Major Bleeding (ARMB)	
The measure score is an accurate reflection of quality. If you disagree or strongly disagree, please explain.	• You will need to consider both risk factors for bleeding AND anticoagulant dosing for both prophylactic and therapeutic anticoagulation. Also, DOACs DO have variable dosing (contrary to what Sommer said). • Maybe the hospital does not have good procedures in preventing bleeding events. • There are too many variables and questions discussed related to the measure that leave many loose ends. I see the full specifications at the end of the slides.
The measure can be used to distinguish between good and poor quality of care. If you disagree or strongly disagree, please explain.	• Bleeding event could be initiated by the patient's action. • It depends on risk stratification, etc. There should be exclusions for this, too. For example, patient received heparin or lovenox and then just spontaneously bled. This happens, and I'm not sure this is a quality issue. • Need to factor risk AND agent/dosing of anticoagulants. • I don't think it is specific enough to make that determination. It is one consideration but not complete. • Agree. • There are too many variables and questions discussed related to the measure that leave many loose ends.

Questions	Comments
Do you have any recommendations that would help strengthen the face validity of the ARMB measure?	• Not ready to make a recommendation yet. • Share results by agent category (DOACs vs. Non-DOACS. • Need to see entire list of Risk Factors being proposed. • Clarification of why the first 24 hours is distinguished for this measure versus throughout the entire admission. Bleeding risk remains anytime these medications are used. • I look forward to reviewing the findings from MPR's beta testing with a review of stratified performance based on clinical, demographic, social, community, and practice characteristics to guide feedback. Thank you for the opportunity to comment. • We have had problems with measures like this in the past in the inability to assess medications taken prior to admission. • Appropriate risk adjustment and cohorting when reporting out. Being able to drill down to types of case vs. a blunt rate will help for improvement and patient information. • Exclude or risk adjust for trauma patients. • Make sure it's risk stratified. Vs DVT, I think zero harm is less likely this route. • Risk adjustment and/or risk stratification. • Would like to learn more about risk adjustment at next meeting. Also, would be very helpful to account for duration of exposure. For example, would be good to identify and just adjust for number of days the patient received therapeutic anticoagulation during the hospitalization. • None at this time.

Appendix D

Table D.1. Open-Ended Responses to questions on structure and methodology

Questions	Comments
Structure	
Are there any unintended consequences for any of these options?	• There is always the chance of gaming risk adjustment and for patient selection if not risk adjusted. • Complex risk adjustment and combining both unadjusted and adjusted measures into a single composite can complicate quality improvement efforts and usefulness to patients and healthcare consumers. • The biggest unintended consequence is that non-included topics/measures will be ignored. In other words, unexpected newborn complications will not receive as much attention as hypoglycemia (which will be infrequent with such a low threshold) and therefore, less QI done on that topic. • ANY composite is potentially misleading to individual patients if the component measures are uncorrelated and they are only likely or able to experience one or two of the component harms. All options share this "consequence. • will really need to test all methods to understand the impact on the scores. For process improvement, we will need to look at each individual metric performance. • Lack of understanding of the details and how the information can and should be used. Without appropriate testing, could impact hospitals. • Lack of risk adjustment encourages hospitals to be inappropriately selective in which patients they aim to serve (and accept for transfer. • Working backwards, who is the primary audience. If it is a nonclinical audience, I am sure there would be a slight towards those who want to use it in a clinical setting and vice versa. I think acknowledging this limitations would be helpful. • Gaming of results. Lack of actionability of a composite measure, false messages to public of where safe care is for a specific condition. No social determinant of health considerations- may lead to cherry picking patients. • None. • I don't think this is an unintended consequence but as I said in the chat, I don't think that patients are primarily interested in composite measures. I do think patients are interested in the individual measures. Most patients aren't impacted by most of the measures in the composite or even a few of the measures. But they will care about the individual measures that relate to them or the person they are caring for. • I have no conceptual or methodological issues combining adjusted and non adjusted measure. But I think there are some important questions about whether some of the currently non adjusted measures should be (e.g., pressure ulcers). My second choice option would be using just the risk adjusted measures. • While useful for the public and well-resourced hospitals, safety-net hospitals do not have the resources to make improvements, therefore they will increasingly have difficulty meeting the needs of their populations further exacerbating health disparities. But this is about measures, not improvement.

Questions	Comments
	• I'm in favor of option 5, which should be we need an environmental scan, data, and testing results, including pre-admission circumstance and SDOH to understand the model for developing the composite, the populations of use, and a host of other testing considerations and results before any empirical and evidence-based guidance may be provided to understand and create a composite risk adjustment method. • I think there should be additional options. Also, how the measures are used, requires several different reporting methods. One for comparison - but then hospitals need to see their absolute numbers, component rates, etc. so that they can do performance improvement and unravel the complexities of the composite. • Yes, the risk adjustment has the potential to inject additional bias (which is normally what we are trying to avoid) based on some of the things discussed during the meeting (i.e., SDOH); however, some of these things, such as access to food and adequate level of public safety, are difficult to measure and are potentially highly subjective in terms of their clinical impact. • Yes, we just need to have a clear vision of the purpose of these measurements, for the hospitals or for the patients.
Methodology	
If you think an alternative methodology is preferred, please list the components of that methodology.	• None. • Would consider increasing the data collection period for low frequency events (1 to 5 yrs). • Weighting by level of harm helps the end users to determine which ones to focus on for performance improvement. We currently do this with the PSIs. • Per my comment earlier, I think the issue of how the weights are combined is very important. We don't want to end up giving even moderate overall weights to measures of events that are common but have very minor harm consequences. The accidental laceration measure in PSI-90 might be an example. • N/A. • We should have been able to vote on each aspect of the proposed methodology. I am fine with shrinkage and harm weights. I have questions about volume weights. • I like the proposed methodology. If we are accounting for uncertainty, frequency, and severity of events, I don't know why we wouldn't also account for patient characteristics (risk adjustment). • As I added to the chat, I would consider a spline function vs Bayesian shrinkage methods. • In addition to these three proposed weighting components, Leapfrog has found it valuable to include a variability score that applies a higher weighting factor to measures where there is more hospital variability and a lower weighting factor to measures where there is less variability. This helps improve the overall usefulness of the composite. • Too much emphasis on a composite measure which is flawed vs. focus on individual measures that are actionable and meaningful to payers, providers, and patients. Need to see some preliminary data runs to assess better. • It would be nice to see the data first and some validation prior to answering these questions. Most of my answers were maybe. • It is worthwhile to study the properties of the final chosen weights empirically to ensure they are behaving as expected. You may want to ensure that no single item is dominating the composite as a result of the weight assigned to it...especially if it is an item with relatively less statistical reliability or importance.

Questions	Comments
	• Hospitals can breakdown composites into individual components to address there greatest OFIs without difficulty. What they need help with is understanding the relative impact of a single measure OFI to the total composite score. While the weighting methods improve accuracy they can also confuse. What would be helpful is a single value for each measure that indicates to hospitals their total relative weight. Also, for severity I recommend a few categories in a simple weight versus a continuous or highly s • Again, I wish there were a 3rd option that says "maybe" to show me the data, testing, etc. first before I make a recommendation. This is highly complex content with significant facility and populations diversity. We are breaking new ground here and need empirical quantitative and qualitative content to make sound guidance. • I am not a statistician, but I think that data is more reliable the closer it is to raw data. If you want to have a measure that is solely for comparing hospitals for purposes of pay or penalties, then that could be alongside the stratified data. Even small samples can be meaningful.

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