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

Patient Safety Measure Development and Maintenance

September 5, 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 (HACRP). 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 comprised 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

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 a 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 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.

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

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 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

[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.

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.

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 in order 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.

[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.

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.

Table 4. Results of Severe Hyperglycemia and Severe Hypoglycemia polling

	The measure is meaningful and produces information that is valuable in making care decisions	There are no unintended consequences or concerns regarding the measure
Measure	**Average score**	**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).

Appendix A

Table A.1. Patient Safety Team

Role	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 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 chairman	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

Name, title	Organization, Location	Attendance/Conflicts
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.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

Name, title	Organization, Location	Attendance/Conflicts
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
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.

Appendix C

Hospital Harm TEP Meeting #1 Materials

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:

    - 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? (*continued*)	• 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.

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