Summary of Hospital Harm Technical Expert Panel (TEP) Evaluation of Measures

Patient Safety Measure Development and Maintenance

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Contents

Submitted To

Centers for Medicare & Medicaid Services (CMS)
Center for Clinical Standards and Quality (CCSQ)

Attention

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Project

Patient Safety Measure Development and Maintenance
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Task & Deliverable

Chapter 4: Quality Measure Development and Reevaluation
Deliverable 4.3 Summary of Hospital Harm TEP Evaluation of Measures

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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with American Institutes for Research (AIR) to develop and maintain patient safety measures of hospital harm for implementation in CMS programs. The contract name is Measure & Instrument Development and Support (MIDS) Patient Safety Measure Development and Maintenance. The contract number is 75FCMC18D0027. As part of its measure development process, AIR convenes groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

AIR is obtaining expert and stakeholder input to inform the development of nine hospital harm electronic clinical quality measures (eCQMs). This report summarizes the feedback and recommendations made by the Technical Expert Panel (TEP) during the meetings to discuss these measures. The report will be updated to include feedback and recommendations from future meetings as they occur.

Measure Development Project Team

The Patient Safety Measure Development and Maintenance project team is comprised of staff from AIR, UC Davis, Clinician-Driven Quality Solutions, and Kennell & Associates. Presenters and moderators for this TEP meeting were Mia Nievera (AIR), Dr. Patrick Romano (UC Davis), Irina Tokareva (UC Davis), and Dr. Rich White (UC Davis).

Mia Nievera, MSN, RN, is the Project Director for this work and leads the eCQM development. Dr. Rich White, MD, is a practicing physician at UC Davis Health and a clinical subject matter expert (SME) for the project team. Irina Tokareva, RN, BSN, MAS, CPHQ is a clinical SME for the project team. Dr. Patrick Romano, MD, MPH, leads the measure development task for the project.

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

Overview of the Technical Expert Panel

In alignment with the CMS Measures Management System Blueprint, the project team convened a Technical Expert Panel (TEP) to provide guidance on the development of nine hospital harm electronic clinical quality measures (eCQMs). The role of the TEP is to provide guidance on key methodological and clinical decisions. The TEP is comprised of 21 individuals representing a variety of viewpoints and backgrounds, including experience in critical care, acute care, and emergency care as well as expertise in patient safety and hospital harms, electronic health record (EHR) systems, quality improvement, and risk adjustment. Three TEP members represent patient/caregiver perspectives. The full TEP membership is listed in **Appendix A**. In addition to the TEP, the project team convened an additional group of experts for a Technical Advisory Group (TAG) to further inform the TEP and the measure developer on specific relevant topics for the measure development process.

TEP Purpose & Objectives

The TEP is comprised of individuals with knowledge of the hospital harm measure topics including opioid-related adverse events, severe hypoglycemia, severe hyperglycemia, falls with major injury, anticoagulant-related major bleeding, post-operative venous thromboembolism, postoperative respiratory failure, acute kidney injury, and pressure injury. The overarching goals of the TEP are to provide information, support, feedback, and perspective to the AIR team on the development, specification, testing, maintenance, re-evaluation, and implementation of these hospital harm measures for possible future use in CMS programs. The TEP's role is to provide input and advice to the measure developer on the information gathering, measure development, testing, maintenance, and re-evaluation of nine hospital harm measures.

The TEP will:

- Review pre-meeting materials and provide written feedback
- Discuss feedback and revisions during virtual meetings along with other relevant topics
- Review and comment on meeting minutes and associated post-meeting documents along with any follow-up action items

TAG Purpose & Objectives

The TAG is comprised of individuals with working knowledge of the hospital harm measure topics as well as issues specific to measure development, including risk adjustment methodologies, and clinical workflows. The TAG's role is to provide input to the measure

developer and the TEP for consideration in the discussions throughout the measure development process.

Technical Expert Panel Meeting #6

June 28, 2022, 12:30 pm ET

Summary of Presentation

The AIR team convened the sixth TEP meeting with members from both the TEP and TAG to provide updates on the testing of Pressure Injury and Acute Kidney Injury as well as the development of the Falls with Major Injury, Postoperative Venous Thromboembolism and Anticoagulant-Related Major Bleeding eCQMs. Prior to the meeting, the AIR team provided the TEP and TAG members with the presentation slide deck and a reference slide deck in preparation for the discussion. During the meeting, the TEP and TAG members introduced themselves and announced any personal disclosures. The meeting began with Mia Nievera providing a brief overview of the suite of project measures, objectives and TEP scope. Next, Dr. Patrick Romano provided an update on the Acute Kidney Injury measure activities, risk adjustment methodology and pilot testing results. Irina Tokareva then provided a review of the Pressure Injury measure activities and pilot testing results. Next, Dr. Romano shared updates on the Falls with Major Injury measure, providing an overview of measure activities and risk adjustment variables under consideration for the measure. Finally, Dr. Richard White provided a review of the Postoperative Venous Thromboembolism and Anticoagulant-Related Major Bleeding measures. Dr. White discussed updates to the measures' denominator exclusions and risk adjustment variables under consideration. Dr. White also reviewed the 30-day postoperative evaluation period under consideration for the Postoperative Venous Thromboembolism measure and outlined the Anticoagulant-Related Major Bleeding measure stratification approach.

Attendance:

TEP Members: David Baker, David Classen, Lillee Gelinas, Helen Haskell, Steven Jarrett, Kevin Kavanagh, Joseph Kunisch, Anna Legreid-Dopp, Timothy Lowe, Christine Norton, Amita Rastogi, Bruce Spurlock, Ashley Tait-Dinger, David Hopkins

> *Not Present: Cynthia Barnard, Brian Callister, Grant Lynde, Shabina Khan, Grant Lynde, Lisa Riggs, Hardeep Singh*

TAG Members: Brigitte Chiu-Ngu, Stephen Davidow, Sharon Hibay, David Levine, Amita Rastogi, Sheila Roman, Patricia Zrelak

CMS: Ngozi Uzokwe

AIR: Mia Nievera, Hannah Klein, Anna Michie, Bo Feng, Katie Magoulick, Michelle Lefebvre, Tracy Haidar

Kennell: Christina Superina, Courtney Colahan

UC Davis: Patrick Romano, Garth Utter, Rich White, Irina Tokareva

Summary of TEP Discussion

Hospital Harm- Acute Kidney Injury (AKI):

1. **Measure Overview:** Patrick Romano provided an overview of the Acute Kidney Injury (AKI) eCQM specifications and the activities to date.
    - **AKI Key Measure Changes:** Patrick Romano provided an overview of the key AKI specification changes made to the measure since its transition to AIR from Yale CORE. Revisions were made to improve measure alignment with the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines and in response to testing results. The team made several updates to the measure denominator exclusions to remove patients who present to the hospital already in AKI based on creatinine values obtained during the first 48 hours of the hospitalization. Patients are also excluded if they present with chronic kidney disease at stage 3 or greater based on the index eGFR (estimated glomerular filtration rate) value. Moreover, encounters with at least one specified diagnosis present on admission considered extremely high risk for developing AKI or at least one procedure during the encounter considered extremely high risk for developing AKI are now excluded. Finally, numerator revisions include adopting a two-stage approach to identify patients in AKI based on a 1.5-fold increase in serum creatinine and then staging the AKI to identify patients in AKI stage 2 or greater.
    - **AKI Risk Adjustment:** Patrick Romano provided an overview of the AKI risk adjustment methodology. The measure now incorporates risk adjustment to account for patient risk of developing AKI by adjusting for patient sex and age, vitals at the encounter start, index eGFR based on the index serum creatinine (patient sex and age; race neutral), comorbidities and hospital length of stay.
2. **AKI Pilot Testing Results:** Patrick Romano presented the pilot site testing results. Thirty-four hospitals participated in the feasibility survey assessment conducting workflow discussions, EHR reviews and data queries. Twenty hospitals out of the thirty-four that completed the feasibility survey participated in data collection and extraction. The

hospitals were diverse including 15 non-academic and 5 academic medical centers. Sites were mostly located in the western United States in urban and suburban settings, though several rural hospitals were included, with both Cerner and Epic electronic health record systems represented. In summary, key testing results include the weighted average across these 20 hospitals at a rate of 1.52%, but it varied from 0.76% to 4.43% across 20 hospitals during calendar year 2020 which indicated both clinically and statistically significant variation. Testing also identified several hospitals that had performance rates significantly better than or worse than the system weighted average. The team was able to demonstrate high reliability at the hospital level for the measure using a standard signal to noise approach. Dr. Romano then reviewed the key testing findings that motivated changes to the measure specification. Data analysis showed that sites did not use the same eGFR formula; there was not always a 1:1 match in the number of serum creatinine to eGFR values. This issue was alleviated by applying the race neutral eGFR formula in the measure specification. Next, testing identified that roughly 24% of the sites offering dialysis services still captured this documentation in unstructured fields. Lastly, testing demonstrated that the initial serum creatinine value on admission may be artifactually high due to medication non-adherence, dehydration, and other patient factors. The team therefore instituted a two-stage approach using the lowest serum creatinine value in the first 48 hours of admission to identify the patient's baseline.

3. **AKI Face Validity:** Patrick Romano reviewed the results of the face validity survey the team distributed to subject matter experts. Ten individuals and two test sites provided feedback. Out of the 12 respondents, 83% (n=10) agreed that the measure meets criteria for face validity. Next, Dr. Romano discussed concerns and additional feedback as provided by the commenters. First, experts expressed concern that pre-admission use of diuretics would lead to hypovolemia at the start of the encounter. The team addressed this concern by including denominator exclusions for CKD (Stage 3a or greater) or AKI within the first 48 hours. Next, respondents expressed concern regarding the method for estimation of eGFR. This was addressed through the introduction of the new, non-race-based, equation used for all patients, regardless of what hospitals reported which eliminated variability due to differences in facility policies. Finally, experts provided feedback accounting for other potential reasons for dialysis. The team addressed this through the denominator exclusion for any dialysis modality within 48 hours after start of encounter.

4. **AKI Expert Input:** The TEP and TAG members discussed the AKI measure updates and testing results.

- David Baker inquired about the frequency of missing risk factors.
    - Patrick Romano responded that vital signs were not missing at all and since the comorbid conditions used in the model rely on the ICD-10 CM coded diagnoses, there were no issues with missing data. The team obtained a data dump of all coded diagnoses from the test sites; however, if any diagnosis is determined by the hospital not to meet coding criteria, then it would not be available for risk adjustment.

Exclusions and Stratification Considerations

- Brigitte Chiu asked whether there is any concern about medication that would warrant an exclusion criterion. For example, some medications have a warning that they can cause an AKI, such as Hespan (brand name) for treating hypovolemia. Some groups, especially Jehovah's Witnesses, cannot use albumin, so Hespan is probably the only option for their treatment for hypovolemia.
    - Patrick Romano responded that this is an interesting scenario that did not come up during testing. He said there may be some situations in which it is the best alternative for volume replacement, so the AIR/UCD team will investigate that. He added that, in general, we do not want to exclude patients based on medication that the hospital administers, as this is the process of care. Hospitals often have alternatives: either to monitor patients more carefully to prevent AKI or to use safer alternatives. For example, the team specifically does not include contrast media that might be used in association with imaging procedures because it is well established that the risk of AKI can be minimized.
- Sharon Hibay asked whether the measure will be stratified by race, ethnicity, and age as the team noted it is currently 'race neutral'. She also asked for more information about the testing population beyond the urban/rural and academic/nonacademic breakdown as well as the total patient volume for the testing samples.
    - Patrick Romano clarified that the term 'race neutral' refers to the eGFR calculation. The concern was that by including race, the previous formulas could underestimate the incidence and prevalence of kidney disease in African American patients, which has been a point of controversy. He also confirmed the measure would not be stratified and noted that the team did look at social determinants of health during the testing process, which

the team will hold for future consideration. The team did not find any available social determinants that would really influence the performance classification of facilities. Dr. Romano also noted that the denominator volume ranged across test sites from 151 up to about 8,000. The overall volume was quite large and quite diverse, with some variation across sites. For example, the Black or African American percentage was 10%, 12% and 15% at several sites and was representative of the communities in which the hospitals were situated.

COVID-19 Exclusion

- Sharon Hibay asked whether COVID is an exclusion for this measure and added that if the testing data are from 2020, then there is likely some impact from COVID on the testing results. She stated that many COVID patients received dialysis and the measure should not penalize hospitals for something that is outside of their control.
- Patrick Romano confirmed that COVID diagnosis information was evaluated during testing and that the impact of excluding COVID patients from the measure was minimal. He stated there was a little bit higher risk in COVID patients compared with the non-COVID patients, but the impact compared with other measures was actually quite minimal. Specifically, There was a substantial COVID impact in the second quarter of 2020, but in the third and fourth quarters there was essentially no impact from excluding COVID. Dr. Romano stated that this indicates that by the fourth quarter of 2020, hospitals figured out how to treat COVID in a way to prevent AKI.
    - Ashley Tait-Dinger asked if there is a way to indicate the exclusion of COVID patients until it is no longer a pandemic or an epidemic. She noted that flu and pneumonia are not currently excluded, so eventually we would want to include COVID.
    - Patrick Romano suggested continuing the COVID exclusion topic with the group during the Pressure Injury review.

Potential Competing Measures

- Joe Kunisch asked if the team did a comparison of this measure to the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) measure for the postoperative AKI. He acknowledged that the NSQIP measure is a chart abstracted, so it differs from this eCQM, but he wondered if the team did a comparison of the subpopulation. The concern was about using two measures

that may theoretically measure the same concept, but performance may differ between the two (e.g., high performance on NSQIP and poor on HH-AKI).

- Patrick Romano responded that the team has not had the opportunity to compare with NSQIP because it is used with a registry program and access to the data is limited.
- Garth Utter responded that he is a general surgeon on the project. He noted one of the problems that is encountered with NSQIP is the sampling scheme produces little overlap when comparing NSQIP data to other metrics.

Face Validity Discussion:

- Patrick Romano stated that the team is interested in TEP input on whether the measure will provide meaningful information to hospitals to be able to act on to prevent development of AKI in their patient population. KDIGO guidelines go into great length about the specific methods for minimizing the risk of acute kidney injury, which are currently being updated. By next year, the team anticipates that there will be a new set of guidelines that reflect the best literature on this topic, which will be very useful for hospitals and physicians.
- See AKI Face Validity section below for poll results. Comments on polling below:
  - Bruce Spurlock responded he submitted, "Maybe". His experience with simply reporting measures is that it leads to a modest reduction over time. The team has not been able to demonstrate causality with reporting on several measures.
  - Ashley Tait-Dinger responded she would hope the release of the measure is not limited to CMS quality reporting programs, and that employers would have access to the measure to allow for performance-related contracting incentives.
  - Joe Kunisch responded, "Maybe". He stated it depends on the initial baseline and how it compares to other quality metrics. With more than 100 metrics to track, hospitals must limit which ones they direct their limited resources to improve.
  - Christine Norton responded that the facility emphasizes the importance of improving this measure and provides training and support. She believes the measure will drive improvement.

Hospital Harm- Pressure Injury (PI)

5. **Measure Overview:** Irina Tokareva led an overview of the measure, highlighting the recent activities.

    - **PI Key Measure Changes:** Irina Tokareva reviewed the refinements to the measure since it was originally transitioned to AIR from the Yale CORE. She notified the TEP that the measure is currently undergoing preparations for the Fall 2022 NQF submission. Irina then provided an overview of the measure numerator and denominator changes made in response to public comments received. She noted that deep tissue injury (DTI) found on exam within 72 hours after the start of the encounter, encounters with stage 2, 3, 4 or unstageable pressure injury found on exam within 24 hours after the start of the encounter and patients with a diagnosis of COVID 19 infection during the encounter are excluded from the denominator. Next, Irina reviewed that the measure now utilizes the 'present on admission' indicator to a diagnosis of DTI, stage 2, 3, 4 or unstageable pressure injury would result in the patient meeting the denominator exclusion versus numerator population. Also, the measure numerator includes DTI found an exam greater than 72 hours after the start of the encounter and stage 2, 3, 4 or unstageable pressure injury found on exam greater than 24 hours after the start of the encounter.

6. **PI Pilot Testing Results:** Irina Tokareva presented the results of the pilot site testing. Twenty hospitals participated in feasibility survey assessment. Eighteen out of the twenty hospitals that completed the feasibility survey participated in data collection and abstraction of the measure. Participating hospitals were primarily academic medical centers in the western region of the country and Hawaii. Hospitals were almost evenly spread in both rural and urban settings and the majority utilized the Cerner EHR platform and one hospital utilized Epic. Irina then reviewed the measure performance testing results. The weighted-average hospital-level measure performance score (rate) was 1.06% with a range from 0% to 2.02% across 18 hospitals in calendar year 2020, indicating substantial room for quality improvement. Several hospitals' performance scores were consistently below the system-level weighted average, while others were above that mean demonstrating a wide performance gap by several hospitals. Next, signal-to-noise ratio demonstrated a robust score level reliability. Lastly, to evaluate score level validity, the team compared the pressure injury measure to similar quality and patient safety NQF endorsed measures and found expected correlation. Also, a strong correlation for nursing care measures was observed.

    - **PI Key Findings Supporting Specification Changes:** Irina Tokareva provided a review of key testing findings which prompted changes to the measure

specification. First, workflow inconsistencies were revealed during testing which identified inconsistencies in staging documentation. This prompted the team to use a union of coded diagnoses and structured clinical documentation to allow for greater capture of harm rates. Also, inconsistencies in coding COVID-19 related skin changes were identified during testing, which moved the team to remove these patients from the measure population. Lastly, Irina reviewed that across all pilot sites, data element validity scores were near perfect at 97-100%. Overall, she discussed these results offer clear evidence that the measure, as currently specified, can detect true hospital acquired pressure injuries with high precision and that the measure will have very low false positives in implementation.

- **PI Face Validity and Risk Adjustment:** Irina Tokareva reviewed the results of the face validity survey completed by subject matter experts, including the TEP. Nine individuals and two test sites provided feedback. Out of the 11 respondents, 91% (n=10) agreed that the measure meets criteria for face validity. Next, Irina addressed measure concerns and feedback as received by the survey respondents and provided clarification on the measure intent: the measure numerator is not limited to pressure injuries that occurred greater than 72 hours after the start of encounter. In review, any encounter without a pressure injury documented as present on admission, that then has a documented pressure injury qualifies for the numerator conditioned on denominator exclusions. The numerator includes stage 2 for consistency with other NDNQI measures, and as stage 2 pressure injuries are considered to be potentially preventable; stage 2 pressure injuries will be captured through nursing documentation structured fields. Because not all stage 3 or 4 ulcers were previously stage 2, sometimes they start as DTI, the denominator exclusion for DTI within 72 hours of the encounter start was added. Also, to clarify materials provided during public comment, nursing workload may be associated with reduced risk of pressure injury if staffing is adequate. The measure development team addressed the concern about documentation issues by counting both physician documentation via ICD-10-CM coding and nursing documentation in structured fields. Risk adjustment was addressed by pointing out to that at this time NQF endorsed measures for pressure injury are not risk-adjusted in order to ensure equal evaluation and capturing of each event. To address feedback in public comments related to risk adjustment or exclusion for patients who cannot be turned, patients with COVID – 19 infection were excluded from the denominator. The measure development team is considering exclusion of patients under comfort care/end-of-life care and will continue to

evaluate pilot testing data for risk adjustment in the future. The team recommends harmonizing this measure with NDNQI and other CMS measures. Lastly, Ngozi Uzokew from CMS provided feedback on public comments received addressing the similarities between the Pressure Injury and PSI measures.

7. **PI Expert Input:**

Stage II pressure injuries inclusion

- Kevin Kavanagh asked for clarification on the measure denominator exclusions and sought to understand why stage 2 pressure injuries were excluded. He stated that stage 2 should be included because it is hard to differentiate from Stage 3 as there is skin breakdown.
    - Patrick Romano responded that there may have been a misunderstanding. The team was responding to the concern by some individuals that stage 2 pressure injuries were included in the measure, and we were trying to provide justification of its inclusion.

COVID-19 Exclusion

- Kevin Kavanagh expressed that regardless of whether a pressure injury is in patients with COVID, it is no different if a pressure injury is in patients with a gallbladder disease. It should not affect getting the pressure ulcer even on a vent and cannot be turned because of 400 pounds weight. A small percentage of hospitalized patients are on vents, maybe less than 5%. He did not understand excluding COVID. He thought of it as just another admission diagnosis—such as someone admitted for flu, or gallbladder—that if there is a patient who is on a vent that cannot be turned, this could be an exclusion criterion versus excluding COVID patients. He noted about 95% of COVID patients are not on vents. These are still preventable and that should not be an exclusion criterion.
    - Joe Kunisch provided insight from the healthcare front lines treating COVID, especially in the first surge. The issue was pronation, not the ability to turn. This was a new approach to treatment for some of the staff. There was a notable increase of pressure injuries at that point.
    - Irina Tokareva responded that one of the things identified in the literature in terms of COVID patients is that sometimes their skin manifestations are difficult to decipher between skin pressure injury versus COVID symptoms. After consulting with subject matter experts on pressure injuries, the conclusion that we arrived to is to make that an exclusion because of these findings.

- Kevin Kavanagh responded to than we should consider excluding diabetics as they have small vessel disease too. He stated that COVID should not have skin breakdown unless there is a pressure injury. There is no difference between that and someone who has diabetes, as far as small vascular disease, they are both at higher risk for pressure injury. This just means that hospitals need to be more careful and implement strategies to prevent it.
- Patrick Romano responded that he wanted to emphasize and return to one the of the excellent comments that was raised earlier that we would view this as a temporary exclusion. There is robust literature in the last couple of years that highlights a wide variety of skin manifestations of COVID which hospitals have been confusing with pressure injury and sometimes reporting as pressure injury in the absence of clear coding guidance and clear evidence regarding the pathophysiology of COVID related lesions. He stated this is a transitional exclusion until such time the field develops a better consensus about what is COVID related tissue breakdown and what is pressure injury and how to treat these patients more effectively. Unlike in the previous case of AKI where it seems like the marginal risk has gone down, we are not seeing that yet for COVID, and so it may be another year or two before we get the literature and get the evidence to really understand how to prevent skin injury in COVID patients.
- Kevin Kavanagh disagreed. He stated many patients hospitalized with COVID do not have skin ulcers or skin breakdown. They may have changes of skin, though this is a small category. The other patients that are going to have COVID diagnoses, even if hospital acquired and admitted for something else, are now going to be excluded. This is not characteristic of COVID, though it can happen, but exceedingly rare. He restated that he did not support the COVID exclusion.
- Helen Haskell, a patient representative, expressed concerns to exclude COVID patients from these measures. She would like to be sure that we are considering patient care and patient outcomes, rather than what is making the hospitals look bad. She reemphasized this is really about patient care. Acknowledging that she is not a frontline clinical worker, she thinks there are steps that can be taken to prevent pressure ulcers besides turning, and that there is a need to incentivize people to take those steps for all of their patients.

- Sharon Hibay acknowledged the discussion about using COVID as a transitional type of exclusion and she wondered what CMS might be thinking about the timeline on this. She agreed with Helen Haskell's point. She stated that even if hospitals have difficulty, we should not be giving hospitals an excuse not to provide the care. If the team decides to keep COVID in as an exclusion, she would strongly recommend revisiting this prior to publication and launch. She also strongly recommended having some sort of note in the specification providing insight into the timing consideration of the COVID exclusion. She stated that patients that come into the hospital because they were in a motor vehicle accident and incidentally tests positive for COVID are very different than patients on a vent who need pronation. She stated we would not want a patient who had other problems to just be excluded, an incidental diagnosis is very different than having COVID as a primary diagnosis and she would not make COVID a sweeping diagnostic exclusion.
- Bruce Spurlock stated that exclusion for COVID 19 is important because some patients require pronation. Data of pressure injuries showed non-system bias based on hospitals' ability to prone or not to prone patients. The prone process created a huge number of pressure injuries and not every hospital that had an ICU and was able to prone. Pronation requires technical equipment and skilled staff, which is not uniformly distributed across the country. Even though the current strain has not had a dramatic impact from the pulmonary standpoint and the need to do prone positioning, it is still a non-system bias, that will go on for an indefinite length of time. He suggested the measure could have an exclusion for prone positioning. .
- Patrick Romano thanked the members for their feedback. He responded that the team has been in close contact with the National Pressure Injury Advisory Panel and wound care specialists to focus in on this area of expertise as it is their life's work to prevent pressure injuries. He stated that it was clear, at least initially, for the first year or two that experts had no idea what they could do to prevent pressure injuries. He stated however, that the literature is evolving and so it does highlight our need to revisit this exclusion.
- David Classen indicated that it is important to know when this measure will officially be rolled out. If the measure is not going to be officially rolled out until 2025 or 2026, then he does not believe we need a COVID 19 exclusion. He asked if there was a timeline of when CMS plans to roll out this mission.

- Ngozi Uzokwe responded that unfortunately there is not a timeline at this time, but it is something CMS will continue to look at and as soon as that information is available, it will be shared.
- Mia Nievera responded that the measure is going through the processes now. She stated assuming it goes through public comment in the next update it will go through the 2023 MAP approval discussion meeting and for public comment next year.
- Patrick Romano responded that the team hears the concerns and will be looking for ways to sunset the COVID exclusion, just as soon as we can get the stakeholders on board and get the evidence base to support.

End of Life Care

- David Baker requested clarification on if the team is considering end of life care as a risk adjustment variable or exclusion. He stated studies that came out of Cleveland Health Quality Choice state there is a lot of variation in the use of end-of-life care orders.
    - Helen Haskell expressed a concern about exclusion of comfort care patients. She stated that we would not want to add pressure ulcer to other medical issues experienced by patients who are receiving palliative care.
    - The AIR/UCD Team responded that there are skin changes at the end of life that make it more difficult to diagnose and stage pressure injuries correctly in those patients, which is why this has been discussed. End of life care is not a current exclusion, although it is an area that the team is sensitive to because stakeholders have raised it as a major concern. It will be an area of ongoing evaluation.

Prevalence studies and Comparison to PSI-03

- Bruce Spurlock asked a question regarding comparing testing results to prevalence studies. He asked if the team compared results from testing to hospitals that are using quarterly prevalence studies to assess the level of concordance. There seems to be, especially when evaluating claims-based measures, a very strong disagreement between those two measuring strategies. He stated the prevalence study in many ways is considered the gold standard because it is purposely looking for an event and not just waiting for it to be recorded. He noted that the documentation challenges are well known in the literature and affect surveillance bias dramatically, it depends on how many people are touching the patient and the accuracy of

their documentation, and that a future way to strengthen this measure is to compare it to prevalence studies.

- Patrick Romano responded that the team did not complete a comparison with quarterly prevalence studies. However, a comparison was completed with PSI-03 which is claims-based, using coded/billing data alone, and has suboptimal sensitivity. This eCQM, which uses both nursing assessments and physician (coded) documentation captures 97% to 98% of the events that can be found within the medical record. It, therefore, is not surprising the correlation with PSI-03 is not very strong.
- David Classen asked what percentage of injuries were picked up by PSI-03 and if this would be less than 10%.
- Patrick Romano responded it was an interesting question. He noted he would need to get that answer, but for stage 3 and 4 it picks up the majority of injuries and less for stage 2 , probably not less than 10%, but he will get back to the members with this information.

Racial Disparities and Social Determinants Stratification

- Bruce Spurlock noted that in the data that he has reviewed, that there is a dramatic racial difference, especially in patients with dark skin. He reported this was true with multiple hospitals and multiple settings that dark skin caused a dramatic increase in the number of pressure injuries predominantly from its difficulty in detection. Because there is literature and experience on this finding, we should intervene and be more proactive to improve outcomes by either including a racial difference factor to strengthen the analysis or to as a risk adjustment. He stated that it could be done post measure implementation and parse measures based on racial characteristics and skin characteristics. He noted that the data should be oversampled because there are not as many older African Americans or other racial ethnicities with dark skin; but it is a clinical consideration and something to consider from an improvement standpoint.
- AIR/UCD Team responded that a majority of the patients involved in data analysis were non-Hispanic or white patients, although the data does include some African American patients; however, complexion is not a factor available for electronic measurement. The team also wants to avoid risk adjustment for the reasons that Kevin Kavanaugh and others have described.
- See PI Face Validity for poll results, comments are below:

- Patrick Romano requested further clarification and the reason for any *maybe* responses . He stated the team appreciates the concern about inconsistencies in documentation even though we are using both nursing documentation, as well as physician documentation to identify injuries. He also stated, as Dr Spurlock and others have pointed out, if you do not look for something you do not find it, so there may still be some pressure injuries that are not identified because hospitals have not been monitoring the skin. This is an ongoing concern. He pointed out for the next poll the team would like to again presume that the COVID exclusion is a transitional exclusion and that, ultimately, the denominator would include COVID patients, as well as non-COVID patients.
- Patrick Romano pointed out the comments made by Joe Kunisch related to already existing significant efforts on NDNQI measures and PSI 03 by wound care specialists responded that his prior organization, Memorial Hermann, which is the largest healthcare system in Houston, scrutinized every pressure injury. He stated the clinical documentation improvement specialists reviewed literally every case looking for documentation as is the same at Harris Health. He reported they initiated a lean six sigma project around it and found out they were following best practices. It was a lack of sharing across the organization on some of those best practices. He noted his system does great on PSI-03 and almost has zero events. He stated NDNQI is tougher to achieve, but there are probably some organizations that might not be looking at it as intensely or have the resources.
- Patrick Romano asked Sharon Hibay to summarize her comments related to post performance stratification. Sharon stated that without risk adjustment there should be some other information that measure provides to allow for better understanding of the difference in performance; so providing stratification by social, practice and by community factors as well, allows the hospitals to be actionable in their work. She indicated that reports and proposed rules are requesting feedback on ability to capture these data, and this will allow for normalization and apples-to-apples comparison, especially when risk adjustment is not used. Sharon pointed out concerns with nurse staffing related to pressure injury performance, specifically: the shift in nurses leaving patient care and during COVID height. She expressed concerns about the measure lacking sufficient details and lacking actionable information for understanding performance. She indicated that the burden of implementation is heavy, and we should make efforts to ensure that useful information is obtained in the process.

- Patrick Romano reported that one of the interesting things that was found in the validation work was a very strong correlation at the facility level between patients' ratings of nurse staff responsiveness and pressure injury rates , roughly 0.68 correlation. He commented that this is very high for this kind of hospital level correlation and that it indicates that patients can perceive when they are not getting high-level nursing care at the bedside.

Hospital Harm: Falls with Major Injury

8. **Falls with Major Injury Updates:** Patrick Romano provided a review and update of the measure specification and activities for the Falls with Major Injury measure. He reported the team will begin measure testing in the summer of 2022 and is preparing to submit to NQF in the Spring of 2023. Next, he reviewed the measure will be risk adjusted as some patients are inherently more likely to fall than others. Also, he noted the NDNQI measure did not pass NQF endorsement due to lack of risk adjustment. He then provided an overview of the risk variables under consideration and noted the adjustment approach incorporates pre-existing characteristics of patients. Finally, he explained that the team will collect social factors for analysis but cautioned the group that these factors may serve as proxies for poor quality of care and would most likely not be included in the final model.
9. **Falls with Major Injury Expert Input:**
    - Kevin Kavanagh expressed concern regarding risk adjusting when falls are largely preventable. His perspective was that more interventions should be instituted to prevent falls in these higher risk populations rather than adjusting for fall risk.
    - Helen Haskell questioned why somebody would fall at all if they did not have one of these conditions or risk factors. She strongly felt that there is a need to take greater measures to prevent falls. She strongly disagreed with the social factors under consideration and could not conceive of how those factors would contribute to a fall.
    - Patrick Romano indicated that while NQF requires us to consider these social risk factors, they are unlikely to be included in the final model.
    - Bruce Spurlock pointed out that this is a difficult measure for which to do risk adjustment simply because the frequency is low. Therefore, making distinctions on multiple different conditions will present a real challenge. Trying to risk-adjust every sort of condition causes problems. He stated that if providers know that a prescribed treatment is causing people to fall, they should be reducing use

of those treatments. He felt the team should go back to the purpose of this measure and risk adjust based on that purpose.

- Patrick Romano noted that all the measures that we develop and test for CMS are intended for public reporting and accountability, so that has to be kept in mind. He emphasized that the majority of the medications referenced for the risk model are home medications that may have lagged effects depending on when the patient presents to the hospital. The only medication considered during the hospitalization is an anticoagulant. He reminded the TEP that these are all just ideas at this point for testing and will aid in analysis.
- Sharon Hibay expressed concerns with limiting risk adjustment medications to only home medications, highlighting that any new medications in the hospital could also increase the likelihood of falling, particularly with those who are admitted from long term care facilities (example provided for hip replacement patients on a morphine pump).
- Patrick Romano indicated that the hospital controls the morphine pump and presumably can make decisions together with a patient about how to manage pain in a way that is safe and effective for the patient. In the example, risk adjustment would theoretically adjust for the fact that they had a hip replacement. He stated a surgical patient who had a lower extremity procedure may be at a higher risk, but we generally do not want to adjust for the specific details of how the patient was treated because those process details represent the opportunity to improve care.
- Sharon Hibay suggested that morphine in the hospital in conjunction with prescribed home medications could potentially make them a higher fall risk. There should be some mechanism for understanding falls and polypharmacy.
- Patrick Romano indicated that it was a valid point, however for a hospital accountability measure, the hospital needs to take into account what medications the patient was receiving at home. They will then need to determine what needs to be done to make the patient's journey as safe as possible in the hospital. That is really part of the hospital's scope to decide how to manage pain in a way that minimizes the risk of falling. He reported that is why we need to make this distinction between what the patient is admitted on and if it was still in their system when they presented, versus what the hospital administers.

- Amita Rastogi requested clarification on whether we were looking at all falls or only falls with major injury, and whether the reason for the injury was documented.
- Patrick Romano clarified that the measure is limited to those with major injury base on diagnosis codes suggestive of major injury.

Hospital Harm: Postoperative (Postop) Venous Thromboembolism (VTE)

10. **Postop VTE Updates:** Richard White provided a review and update of the measure specification and activities for the Postoperative Venous Thromboembolism measure. He reported the team will begin measure testing in the summer of 2022 and is preparing to submit to NQF in the Spring of 2023. Specifically, Richard discussed the addition of COVID and intracranial/spinal surgery denominator exclusions and a 30-day postoperative evaluation period in the numerator. Lastly, he reported the team is considering risk adjusting the measure.
11. **Postop VTE Expert Input**
    - Helen Haskell reported she did not realize that 30-day evaluation measures do not have a true way to track the patients after discharge as there is no universal patient identifier.
    - Patrick Romano responded that the 30-day mortality and readmission measures that are used by CMS are limited to Medicare Fee for Service patients and utilize the Medicare Beneficiary Identifier. He noted that eCQMs are intended to be all-payer measures and are limited by the lack of a unique identifier to track patients across hospitals.
    - Helen Haskell reported that she is concerned with risk adjusting the measure and considering types of surgeries and their risk of VTE.
    - Patrick Romano responded that it is useful to distinguish procedures where prophylaxis is underused and therefore it may appear the rate of VTE is high because people are not providing optimal care versus procedures that inherently have higher risk. We know that certain procedures inherently have higher risk, and we also know that even in the best randomized controlled trials, only about half or sometimes less than half of these events can be prevented, so this is not like pressure injuries, where we anticipate a very high level of prevention.

Hospital Harm: Anticoagulant-Related Major Bleeding (ARMB)

12. **ARMB Updates:** Richard White provided a review and update of the measure specification and activities for the Anticoagulant-Related Major Bleeding measure. He

reported the team will begin measure testing in the summer of 2022 and is preparing to submit to NQF in the Spring of 2023. Specifically, Richard explained that the team will stratify the measure reporting by indication, and denominator exclusions have been added for coagulation disorders and length of stay less than 48 hours.

13. ARMB Expert Input

- Bruce Spurlock reported there has been recent research to suggest that patients who were given hypertherapeutic (elevated) doses of anticoagulants to prevent, or at least mitigate, the hypercoagulable state in COVID-19 sustained more bleeding episodes. He stated a recent article in Annals of Internal Medicine reported that high-intensity anticoagulation was life saving for many patients, based on stratifying the risk for certain categories of patients. He supported paying attention to COVID patients as even in the current setting (based on data from a 300-hospital network) there may be high-intensity anticoagulant use that would cause more bleeding episodes in a lifesaving treatment approach.
- Richard White stated that he is aware of that data but the extent to which all hospitals are going to implement high dose intensive treatment for COVID-19 patients remains to be seen. This may be a temporary issue given the development of better treatments for COVID-19 patients, leading to shorter hospital stays.
- David Classen inquired about whether this measure needs to be risk adjusted. He suggested that it is an open question where it should be stratified by indication or reported as a single measure with risk adjustment. He suggested that stratification would be the easiest for hospital implementation but stated that he did not have any strong feelings for either approach.
- Patrick Romano indicated that it is an open question, and the team is open to the TEP's input. The team is currently approaching this question starting from the indication for anticoagulation and the associated dosing.
- Patrick Romano thanked Amita Rastogi for her comment about valve replacement and confirmed that the team will consider the duration of hospital time that is spent on anticoagulation.

Summary of TEP Voting Results

AKI Face Validity

Poll #1: Do you agree that performance on this risk-adjusted measure of acute kidney injury, as evidenced by a substantial (stage 2) increase in the serum creatinine value, provides a representation of relevant quality in a facility?

Poll Response	Count (%)
Yes	10 (71%)
Maybe (explain)	4 (29%)
No (explain)	0 (0%)
Total	**14 (100%)**

Poll #2: Do you agree that implementation of this measure, as specified by the development team, in hospital inpatient quality reporting programs, is likely to lead to a reduction in acute kidney injuries while maintaining other quality-related outcomes?

Poll Response	Count (%)
Yes	12 (86%)
Maybe (explain)	2 (14%)
No (explain)	0 (0%)
Total	**14 (100%)**

PI Face Validity

Poll #1: Do you agree that performance on this measure of pressure injury, as evidenced by onset of a NEW stage 2, 3, 4, or unstageable/deep tissue injury, provides a representation of relevant quality in a facility?

Poll Response	Count (%)
Yes	13 (100%)
Maybe (explain)	0 (0%)

Poll Response	Count (%)
No (explain)	0 (0%)
Total	**13 (100%)**

Poll #2: Do you agree that implementation of this measure, as specified by the development team, in hospital inpatient quality reporting programs, is likely to lead to a reduction in new-onset pressure injuries while maintaining other quality-related outcomes?

Poll Response	Count (%)
Yes	11 (79%)
Maybe (explain)	3 (21%)
No (explain)	0 (0%)
Total	**14 (100%)**

Conclusion and Next Steps

Following the conclusion of the TEP meeting, the MIDS Patient Safety team produced the meeting summary report. AIR plans to begin testing for the Postop VTE, ARMB, and Falls measures during the summer of 2022. AIR plans to collect availability for the next meeting in the coming months, aiming for a meeting in Fall 2022.

Appendix A: TEP & TAG Composition List

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
David Baker, MD, MPH; Executive Vice President for Health Care Quality Evaluation	The Joint Commission Oakbrook Terrace, IL	None
Cynthia Barnard, PhD, MBA, MSJS Vice President, Quality; Assistant Professor	Northwestern Memorial Healthcare, Northwestern University Chicago, IL	None
T. 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	None
David Classen, MD, MS Professor of Medicine and Infectious Diseases	University of Utah School of Medicine, Pascal Metrics Salt Lake City, UT	AHRQ funding, VA funding, Pascal Metrics funding, NQF Chair
Lillee Gelinas, DNP, RN, CPPS, FAAN Assistant Professor Patient Safety Section Director	Texas College of Osteopathic Medicine, University of North Texas Health Science Center Fort Worth, TX	None
Helen Haskell, MA Caregiver Representative	Mothers Against Medical Error Columbia, SC	None; Patient Advocate
David Hopkins, MS, PhD Performance Measurement	Stanford University Stanford, CA	None
Steven Jarrett, PharmD	Atrium Health	None
Kevin Kavanagh, MD, MS Volunteer Board Chairman	Health Watch USA Lexington, KY	NQF CSAC Member
Shabina Khan Patient Representative	Chicago, IL	None
Joseph Kunisch, PhD, RN-BC Informatics, CPHQ Vice President	Harris County Health System Houston, TX	None
Anna Legreid-Dopp, PharmD Director, Clinical Guidelines and Quality Improvement	American Society of Health-System Pharmacists, Pharmacy Quality Alliance Bethesda, MD	None
Timothy Lowe, PhD Director, Healthcare Research	Premier, Inc. Charlotte, NC	None
Grant Lynde, MD, MBA Staff Physician and Vice Chair of Quality	Emory University Hospital, American Society of Anesthesiologists Atlanta, GA	None
Christine Norton, MA Consumer/ Patient Caregiver	 Minnesota	None
Amita Rastogi, MD, MHA, MS, FACHE	Munster, IN	None
Lisa Riggs, MSN, RN, ACNS-BC, CCRN-K Volunteer Leader & Member	American Association of Critical Care Nurses Aliso Viejo, CA	None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
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	AHRQ grants, VA grants, Gordon and Betty Moore Foundation grants, Cancer Research UK grant, consultant to Leapfrog Group
Bruce Spurlock, MD President & CEO	Cynosure Health, Cal Hospital Compare Roseville, CA	None
Ashley Tait-Dinger, MBA Director of Analytics, Alternative Payment Models & Finance	Florida Alliance for Healthcare Value, The Leapfrog Group Winter Springs, FL	None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Brigette Chiu-Ngu, MS, RPh Retired Pharmacist	El Dorado Hills, CA	None
Stephen Davidow, MBA-HCM, CPHQ, APR, LSSBB Quality Improvement Consultant	Self- employed	None
Sharon Hibay, DNP, RN Chief Executive Officer	Advanced Health Outcomes Center Valley, PA	None
David Levine, MD, FACEP Group Senior Vice President, Advanced Analytics and Product Management	Vizient Chicago, IL	None
Sheila Roman, MD, MPH Independent Healthcare Consultant, Part-time Associate Professor of Medicine	Johns Hopkins Medical Institutions Baltimore, MD	None
Patricia Zrelak, PhD, FAHA, NEA-BC, CNRN, SCRN, RN Clinical Practice Consultant	Kaiser Foundation Hospitals Sacramento, CA	None

Appendix B: Project Staff

AIR Team	
Name	**Role**
Mia Nievera, MSN, RN	Project Director, eCQM Lead
Anna Michie, MHS, PMP	Project Manager
Stacie Schilling, MPH	NQF SME
Bo Feng, PhD	eCQM Statistical Lead
Michelle Lefebvre, RN, BSN	eCQM Measure Lead
Katie Magoulick, MPH, MSW, LGSW	eCQM Measure Lead
Sajad Vahedi, PhD	eCQM Statistical Support
Tracy Haidar, PharmD, MS	eCQM Statistical Support
Hannah Klein, PMP	TEP Lead
Kennell Team	
Name	**Role**
Allison Russo, DrPH, MPH	Information Gathering Lead
Christina Superina, MPP	Project Manager
Courtney Colahan	Team Member
UC Davis Team	
Name	**Role**
Patrick Romano, MD, MPH	Clinical Director
Christian Sandrock, MD, MPH	Clinical SME
Richard White, MD	Clinical SME
Irina Tokareva, RN, BSN, MAS, CPHQ	Clinical SME
Garth Utter, MD, MSc	Clinical SME
Daniel Tancredi, PhD	Statistical SME
Guibo Xing, PhD	Claims Measure Testing Lead
Monika Ray, PhD	Computer Science SME
Meghan Weyrich, MPH	Project Manager
Clinician-Driven Quality Solutions Team	
Name	**Role**
Chana West, RN, MSN	eCQM Testing Lead

Appendix C: Meeting Materials

About the American Institutes for Research

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