Summary of New Hospital Harms Technical Expert Panel (TEP) Evaluation of Measures

Patient Safety Measure Development and Maintenance

7/9/2020

Version # 2

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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with IMPAQ International 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, IMPAQ and its partners convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

IMPAQ is obtaining expert and stakeholder input to inform the development of three new hospital harm measures. This report summarizes the feedback and recommendations made by the Technical Expert Panel (TEP) during the meetings to discuss the new hospital harm 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 IMPAQ, UC Davis, and Kennell & Associates. In preparation for the development of a falls with injury measure (the first of the three new hospital harm measures), Dr. Allison Russo, Christina Superina, and the Kennell team worked with Dr. Jacqueline Stocking, Dr. Patrick Romano, and the UC Davis team to summarize the findings from the information gathering report to guide the initial discussions with the TEP. Presenters and moderators for the first TEP meeting were Dr. Patrick Romano, Maggie Lohnes, and Christina Superina. Dr. Patrick Romano, MD, MPH, leads the measure development task, Dr. Jacqueline Stocking is the clinical director for the project, and Christina Superina manages the information gathering task for the project.

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

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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 three new hospital harm measures. The role of the TEP is to provide guidance on key methodological and clinical decisions. The New Hospital Harms TEP is comprised of 16 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. Two 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. Input was also sought from additional key stakeholders through the recommendation of TEP and TAG members.

TEP PURPOSE & OBJECTIVES

The TEP is comprised of individuals with knowledge of the new hospital harm measure topics under consideration (falls, peri-operative venous thromboembolism, and diagnostic errors). The overarching goals of the TEP are to provide information, support, feedback, and perspective to the IMPAQ team on the development, specification, testing, maintenance, re-evaluation, and implementation of three new 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 three new 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

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TAG PURPOSE & OBJECTIVES

The TAG is comprised of individuals with working knowledge of the new hospital harm measure topics under consideration, including falls, peri-operative venous thromboembolism, and diagnostic errors, 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.

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Technical Expert Panel Meeting #1

March 16, 2020 2:00 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the first TEP meeting to introduce the TEP and TAG members to the project, introduce the concept of eCQMs, and present the first topic for a new eCQM under CMS consideration. At the direction of CMS leadership, the IMPAQ team is exploring the development of a falls with injury eCQM and held this TEP meeting to discuss the background and significance of a falls with injury measure, and discuss how falls with injury are documented and reported at the hospital and health system level. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck and background materials for review and preparation for discussion. During the meeting, the TEP members introduced themselves, announced any personal disclosures, and ratified the TEP charter. The TEP then engaged in discussion around the topics as presented by the IMPAQ team, noting the methods by which their organizations track falls with injury. The TEP discussed the level of integration of the adverse events reporting system and electronic health record at their organizations and the differences in reporting based on unit type.

Attendance:

TEP Members: Brian Callister, Lillee Gelinas, Helen Haskell, Kevin Kavanagh, Joseph Kunisch, Anna Legreid-Dopp, Grant Lynde, Lisa Riggs, Hardeep Singh, Bruce Spurlock, Ashley Tait-Dinger
> *Not Present: Cynthia Barnard, David Classen, Hazel Crews, Shabina Khan, Amy Wilson*

TAG Members: Brigitte Chiu-Ngu, Stephen Davidow, Tricia Elliot on behalf of Brigette DeMarzo, Sharon Hibay, Timothy Lowe, Amita Rastogi, Patricia Zrelak
> *Not Present: David Levine, Barbara Pelletreau, Sheila Roman*

CMS: Joseph Clift, Yuling Li

IMPAQ: Kendall Hall, Jensen Chiu, Anna Michie, Stacie Schilling, Bo Feng, Maggie Lohnes, Hannah Klein, Molly Mantus, Priya Chatterjee, Chana West, Michelle Lefebvre

Kennell: Allison Russo, Christina Superina, Courtney Colahan

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UC Davis: Patrick Romano, Meghan Weyrich

SUMMARY OF TEP DISCUSSION

1. **TEP Introductions and Ratification of TEP Charter:** Hannah Klein, the TEP lead, reviewed the purpose and expectations for the TEP and the Technical Advisory Group (TAG), and reviewed the TEP charter. The TEP charter was ratified by consensus with no comment. The TEP and TAG members introduced themselves and their background, noting any disclosures (see Appendix A for a list of the TEP members and any relevant disclosures).

2. **Introduction to Electronic Clinical Quality Measures (eCQMs):** Maggie Lohnes, the eCQM lead for the MIDS Patient Safety team, introduced the eCQM project team and explained the eCQM team's roles and responsibilities. These responsibilities include supporting the development of an eCQM that uses the electronic health record (EHR) as a data source, advising the MIDS Patient Safety team on the suitability of the EHR as a data source, authoring clinical quality language (CQL) code and specifications, developing value sets using a list of numeric codes to describe clinical concepts, and recruiting test sites and evaluating testing results.

3. **Background & Significance: Falls with Injury:** Dr. Patrick Romano introduced the topic of hospital falls with injury, the hospital harm concept for the first TEP discussion. Future TEP meetings will cover other hospital harm concepts. Dr. Romano explained that falls with injury are serious and potentially preventable events, and can result in fractures, dislocations, closed-head injuries, immersion injury, etc. Additionally, CMS has emphasized to the measure developer the importance of focusing on falls with death or serious injury. During this meeting, the team presented existing measures for falls, but focused the discussion on falls *with injury*.

   a. **Considerations:** There is a substantial amount of empirical evidence that falls with injury are inconsistently reported across hospitals. Injuries associated with falls in hospitals need to be reported in the medical record, but if a patient falls without an injury, there may not be any way of knowing the fall actually occurred because it was not likely documented. There is also a concern that facilities with a more transparent culture could be disproportionally penalized by this measure if they are more willing to document falls with injury.

   b. **Impact:** 700,000 to 1,000,000 inpatient falls occur each year and more than one-third of inpatient falls result in injury, although the denominator remains unclear

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because many falls are undocumented.[1] Up to 11,000 falls result in death. On average, falls with injury add 6.3 to 11 days to the hospital stay and are associated with an additional cost of $2,680 to $15,491 per inpatient stay.[2,3] The additional cost associated with imaging is substantial as well. Inpatient falls are a significant problem and patient safety improvements need to be made.

4. **Existing Falls with Injury Measures:** Christina Superina introduced several existing falls with injury measures that the team identified through the information gathering process.

   a. **American Nurses Association (ANA) National Database of Nursing Quality Indicators (NDNQI) Falls with Injury Measure (NQF#0202):** The ANA NDNQI measure is widely used in NDNQI participating hospitals. It is NQF-endorsed and is currently seeking re-endorsement. The measure is nurse-centric and includes risk assessment indicators that not all hospitals are required to report. The measure has complicated logic for several variables, including the injury definition. The numerator is the total number of patient falls with injury level minor or greater, so it includes a large group of patients with a fall. This measure is included in the NDNQI Database, which is populated by data from EHRs, other paper records, and incident reports (largely manual abstraction).

   b. **Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) 08: In-Hospital Fall with Hip Fracture Rate (NQF #0531):** The AHRQ PSI 08 is currently NQF-endorsed as part of the PSI 90 composite. This measure only uses claims data, so it is unable to identify the fall itself and instead identifies whether the patient has a hip fracture that is not the primary diagnosis.

   c. **CMS Hospital Acquired Conditions (HAC) 05: Falls and Trauma:** The CMS HAC 05 measure looks at discharges identified through the use of ICD-10 codes for patients that have a fracture, dislocation, intracranial injury, crushing injury, burn, or electric shock. Like PSI 08, HAC 05 is a claims-based measure and does not identify whether the injury was due to the fall. Instead, it identifies the injury itself and that the injury wasn't present on admission.

   d. **Previous CMS Contract Hospital Harm Performance Measure - Falls:** The previous MIDS Patient Safety contractor identified a falls measure, which was

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[1] AHRQ. Patient Safety Primer: Falls. AHRQ PSNet. https://psnet.ahrq.gov/primers/primer/40/Falls. Published 2019. Accessed July 24, 2019.

[2] Currie L. Fall and Injury Prevention. In: Hughes RG E, ed. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville: Agency for Healthcare Research and Quality; 2008:195-250.

[3] Bysshe T, Yue Gao M, Krysta Heaney-Huls M, et al. *Draft Final Report Estimating the Additional Hospital Inpatient Cost and Mortality Associated with Selected Hospital Acquired Conditions*.; 2017. www.ahrq.gov.

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specified as an eCQM. The falls measure looked at all falls rather than only falls with injury. This measure was halted after Phase 1 testing for several reasons, including that the testing found that the fall rate did not increase with age. This measure had a fairly simple numerator and denominator to identify patients that experienced an inpatient fall.

5. **Information Gathering Discussion: Falls with Injury Reporting within the Electronic Health Record:** Dr. Romano opened the discussion by walking through the different data workflows of existing eCQMs, since the intent of this work is to develop an eCQM rather than a claims-based measure. Dr. Romano shared an example of one hospital's fall measure workflow:
    1- A patient falls
    2- The immediate care is rendered
    3- Care documented in the EHR narrative
        a. RN and MD progress notes in a free text format
    4- An incidence/ adverse event report may be completed
        a. This could be in a system that is completely separate from the EHR
    5- Then aggregate falls data are reported internally and benchmarked externally via manual data entry (e.g. NDNQI database for Magnet hospitals) by unit, type of unit and facility.

Dr. Romano emphasized that this is one facilities' workflow and that other institutions may have different workflows. For example, at UC Davis Health, providers document incidents in a system called RL Solutions. In designing an eCQM, the team is interested in understanding the workflows that will support abstraction of relevant information from EHRs.

a. **Discussion Point #1:** How are inpatient hospital falls with injury typically reported within the medical record at your institution?

i. **TEP Input:** Dr. Kunisch explained that at Memorial Hermann, they use RL Solutions as well, which is a separate system from the EHR. Providers enter demographic information into the EHR, which has specific fields and checkboxes, for internal lookup purposes. There are specific policies and procedures that require a full assessment of a patient in the event of a fall, regardless whether the fall resulted in injury. The nurses enter the assessment findings into a template form using both free text and checkboxes, which is then sent to the physician. The current form Memorial Hermann uses wouldn't support a "falls with injury" eCQM, but the workflow they use could support the measure. It would be possible for them to make changes to the form to add

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discrete fields. The template is part of the EHR. Memorial Hermann also participates in the NDNQI.

ii. Lisa Riggs shared that she is not aware of any hospitals within the American Association of Critical Care Nurses' membership that use a discrete field for capturing falls in their EHR. Lisa Riggs' organization uses narrative notes in a template for significant events, including falls with injury. Other physicians in her health system use free text and don't have a template within the medical record.

iii. Dr. Callister said that a few of the hospitals staffed by members of the American College of Physicians noticed false positives based on RN narratives. He provided the example of a patient who falls out of bed and slightly touches their head or reports altered mental status. The common response is to order a non-contrast head CT, which may require the doctor to document some alteration of mental status before the scan can be performed urgently. This workflow often results in a discrepancy in what is documented between the order entry and the physician or nurse's note. Once a "fall with injury" is included in the nurse narrative, it will be reported as an incident.

1. Dr. Kavanagh felt the measure should not penalize hospitals for falls that are only noted in the CT scan order.

2. Dr. Callister clarified that falls may be documented in the CT scan order due to the radiology templates that are used to facilitate ordering of urgent head scans. From a liability standpoint, if someone wants to rule out a subdural hematoma, a CT is required.

3. Dr. Kavanagh commented that an injury such as a subdural hematoma should be assumed to be a fall, so the measure logic should not require separate documentation of a fall.

4. Dr. Callister responded that a closed head injury after a fall may lead a physician to document "altered medical status," which would be classified as an injury even if the CT scan is normal.

iv. In summary, Dr. Romano reflected that there are a variety of places in the EHR where the diagnosis may appear, but the imaging order is not an accurate data source.

v. **Additional Expert Input:** One TAG member said that at her organization, Kaiser Permanente, the nurses use a dot-phrase in the medical record to capture information about falls with injury in free text.

b. **Discussion Point #2:** Are your adverse events reporting system and electronic health record integrated or totally separate?

i. **TEP Input:** Dr. Lynde said Emory University Hospital's adverse events reporting system is completely separate from their EHR. In Georgia, these systems must be kept completely separate for medical legal reasons, because anything in the EHR is discoverable by lawyers.

ii. Dr. Singh said the VA has a separate reporting system that is not integrated into the EHR, but there are several ways that falls could be reported in the EHR. There are templates that use structured fields and narrative data for data collection pre- and post-falls. Dr. Singh provided the database of falls measurement and prevention run by the VA National Center for Patient Safety as a resource for the measure developer team. The database doesn't include anything specific to eCQMs, but it has resources and lessons learned.

iii. **Additional Expert Input:** One TAG member added that Kaiser's adverse events reporting system and EHR are separate.

iv. Another TAG member shared that Pennsylvania uses a system called the PA-PSRS – Pennsylvania Patient Safety Risk System. The system is enforced by a state mandate to record documentation of falls. In the data elements, they are trying to incorporate level of severity. There is an effort to integrate the PSRS reporting with the EHR, but this may require a third party to facilitate the data integration, and the TAG member added there are also Logical Observation Identifiers Names and Codes (LOINC) codes available to report falls. The TAG member offered to share resources on this reporting system with the measure developer.

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c. **Discussion Point #3:** Are there differences in reporting based on unit type (i.e. acute care, critical care, step-down, rehab) – are different reporting systems or fields used?

    i. **TEP Input:** Dr. Kunisch shared that all the inpatient units are standardized across the entire Memorial Hermann system. No TEP members expressed disagreement.

    ii. Lisa Riggs confirmed that the question focus is acute care hospitals rather than long-term care or inpatient rehabilitation facilities. She noted that there are significant differences in how her system reports across these levels of care (but not within acute care hospitals).

d. **Discussion Point #4:** Does your institution only report all "Falls" that result in injury, or only those that result in moderate to severe injuries?

    i. Dr. Romano opened the discussion, offering that many institutions may be using the ANA NDNQI measure's definition of falls, which includes falls with any type of nursing or medical intervention, including bruises, bandages or splints, which is a rather low threshold.

    ii. **TEP Input:** Dr. Kunisch explained that Memorial Hermann's policy and procedures support documentation of falls whether there is an injury or not. A head-to-toe assessment is done on high risk patients, which is then documented and the physician is notified. Falls with injury are documented in the adverse event reporting system and the reports are reviewed by a committee that meets to discuss serious safety events to grade the event and assess the severity. The level of severity may depend on whether there was a patient harm, whether the harm was permanent, whether it resulted in death, etc. There is some variance in how falls are handled across the system.

    iii. **Additional Expert Input:** One TAG member said that Kaiser Permanente does not use a discrete field, but instead uses a dot-phrase text, which can be pulled from the EHR but is not included in any reports. Kaiser uses several process measures, including but not limited to falls, in daily mobility reports shared with physicians to manage progressive mobility in each unit.

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e. **Discussion Point #5:** Are you able to share your policies/procedures for inpatient falls? & **Discussion Point #6:** Do you have a "falls" expert who might be willing to provide more detailed input on documentation and workflow as a subject matter expert?

    i. Dr. Romano asked the TEP members to share their policies and procedures and contact information for their organization's expert on falls so the MIDS Patient Safety team can coordinate information gathering interviews.

    ii. **TEP Input:** Several TEP and TAG members expressed willingness to share materials related to their policies and procedures and agreed to follow up separately after the meeting.

    iii. Dr. Spurlock said Cal Hospital Compare[4] doesn't work on the measurement side, but on the improvement side. He commented on the lack of insight into fall prevention at the national level. He remarked that the initiative to achieve a falls rate of zero has negative consequences (because it may lead to keeping high-risk patients in bed) and suggested that the emphasis be on safe mobility. He referenced the Up Campaign, which looks to focus on falls in the context of mobility and decreasing delirium, pressure injuries, and other complications in the hospital. They are currently developing a plan for progress on mobility.

        1. Dr. Romano asked Dr. Spurlock to share materials from the Up Campaign initiative.

    iv. **Additional Expert Input:** One TAG member shared that Kaiser Permanente's local and regional initiatives incorporate injuries into a portion of nursing leaders' performance appraisals. Everyone is held to certain targets and receives information on benchmarks, including mobility and delirium measures. Kaiser Permanente reports on AHRQ's PSI 08, but doesn't use the AHRQ measures internally.

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[4] https://calhospitalcompare.org/ Cal Hospital Compare features quality and performance information on California hospitals to help healthcare consumers make smarter and more informed choices when making medical decisions.

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SUMMARY OF TEP POLLING RESULTS

The TEP members were asked to provide information on the method(s) their organization uses to track falls with injury by responding to a polling question. As the poll was intended to gather information broadly on the methods used in practice, all members on the call were invited to respond. Members were given the option to either respond during the meeting or send their response via email after the meeting. Individuals could select multiple options in their response and the results of the polling are as follows:

Exhibit 1: Polling Results

Question	Responses
Please select the method(s) your organization uses to track falls with injury.	Internal Incident/Adverse Event Reporting (8 votes)
	AHRQ PSI 08 (6 votes)
	NDNQI (3 votes)
	CMS HAC 05 (3 votes)
	Other (2 votes)

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes. As noted during the discussion, several TEP & TAG members offered to provide the MIDS Patient Safety team with their organizations' policies and procedures for inpatient falls and contact information for a "falls" expert at their organization, as possible. IMPAQ plans to collect availability for the second TEP meeting in the coming weeks, aiming to hold the second TEP meeting in May 2020. IMPAQ plans to focus on possible fields for data collection in the EHR; measure specifications, including numerator, denominator, and exclusions; the definition of injury; and whether risk adjustment is needed during the next TEP meeting. In addition, there will be discussion of at least one other potential hospital harm measure.

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Technical Expert Panel Meeting #2

June 22, 2020 2:30 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the second TEP meeting to further the discussion of the development of a falls with injury electronic clinical quality measure (eCQM) and introduce the concept for the next harm, venous thromboembolism (VTE). Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck in preparation for discussion. During the meeting, the TEP members introduced themselves and announced any personal disclosures, the IMPAQ team provided a summary of the first TEP meeting on this topic and relevant information gathering updates, then the IMPAQ team provided an overview of their meetings with subject matter experts (SMEs) that informed the feasibility and development considerations of a Falls eCQM. Finally, the TEP members engaged in discussion around the topics as presented by the IMPAQ team, including recommendations for the definition of a fall with injury, numerator and denominator, inclusion and exclusion criteria, and risk factors to be adjusted.

Attendance:

TEP Members: Cynthia Barnard, Brian Callister, Hazel Crews, Lillee Gelinas, Helen Haskell, Kevin Kavanagh, Shabina Khan, Joseph Kunisch, Anna Legreid-Dopp, Grant Lynde, Lisa Riggs, Hardeep Singh, Bruce Spurlock, Ashley Tait-Dinger
  Not Present: David Classen, Amy Wilson

CMS: Annese Abdullah-McLaughlin

IMPAQ: Kendall Hall, Jensen Chiu, Anna Michie, Stacie Schilling, Bo Feng, Maggie Lohnes, Hannah Klein, Leah Dillard, Katie Magoulick, Chana West, Michelle Lefebvre

Kennell: Allison Russo, Christina Superina, Courtney Colahan

UC Davis: Jackie Stocking, Patrick Romano, Meghan Weyrich

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SUMMARY OF TEP DISCUSSION

1. **Summary of TEP Meeting #1 and Updated Information Gathering:** Once the TEP members introduced themselves and noted any updates to their disclosures (see Appendix A), Dr. Allison Russo, the information gathering lead, briefly recapped the discussion and results from the first meeting of the TEP. She highlighted that there are no existing eCQMs for acute care inpatient falls with injury, and that while falls risk assessments and risk management interventions are common, there is variation in EHR documentation standards across health systems.

2. **Summary of Additional SME Calls:** Dr. Russo provided an overview of conversations with ANA and Press Ganey, the Pennsylvania Patient Safety Authority, the Nursing Knowledge Big Data Science Information Modeling Workgroup, and a group of nurse leaders. These discussions touched on injury type categories, risk adjustment, data management, state reporting mandates, and the NQF process, among other topics relevant to measure development and the current state of falls measures. A key takeaway was the lack of consistency in how and when different facilities document falls in their EHR and Incident Reporting systems.

3. **Nursing Knowledge Big Data Science Information Modeling Workgroup:** Maggie Lohnes presented a falls prevention information model created by the Nursing Knowledge Big Data Science Information Modeling Workgroup, which outlines the details of a fall for recording and integrating into Falls Risk Assessment tools. This model could serve as the vehicle for translating the concepts in the Falls with Injury Cycle into the discrete coded fields that would be necessary to develop and utilize a Falls eCQM. The workgroup presented level of injury definitions and associated guidelines, which the measure development team used as the foundation to build out a list of emerging EHR terminology codes (LOINC, SNOMEDCT, and ICD-10), which they will select from and use to build the logic and value sets for the measure, given that they are used consistently enough that they can be used for an eCQM.

4. **Falls with Injury Measure Options and Recommendations:** Dr. Jackie Stocking opened the discussion on the specific recommendations for the eCQM by presenting the known factors: the measure will be a de novo eCQM for measuring hospital harm due to falls with injury using existing coded values for the adult, acute care inpatient population. She opened the floor for discussion on inclusion and exclusion criteria for the measure.

   a. Dr. Kevin Kavanagh spoke first, cautioning the measure developer against overthinking the concept of falls because a fall is a fall. He noted that comorbidities should not be an exclusion because all falls are preventable. The measure should be outcome-based. Dr. Kavanagh stated that any type of fall, regardless of if it results in injury, is a harm. He additionally stated that almost all

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falls are preventable – risk adjusting could lead hospitals to pull resources away from patients who are at most risk of falling. He is not concerned with the severity of the fall and recommended a simpler, outcomes-based measure, and stated it is up tot hospitals to prevent the fall. He likened this issue of falls to hospital infections.

b. Several TEP members voiced disagreement with the option of excluding Obstetrics (OB) patients from the measure.

   i. Dr. Grant Lynde gave the example of an OB patient with analgesia who falls, this is a fall that should be monitored and therefore should be included in the measure. He also noted that in order for a measure to work for payment, metrics must be verifiable.

c. Dr. Brian Callister noted that all falls are not the same. From a clinical perspective, as one example, physical therapists are trained to count a 'sit down' as a fall, though it would not be the kind of fall this measure aims to track. This emphasizes that there should be some nuances and mechanism should be considered.

d. Dr. Grant Lynde recommended including OB patients and provided rationale. He also stated that the data need to be verifiable and agreed with Dr. Callister's point.

   i. Dr. Stocking reaffirmed that the example exclusions/ inclusions were listed merely as options for consideration, the OB exclusion was based on the National Database of Nursing Quality Indicators (NDNQI) measure which excludes obstetrics patients. There is also a separate assessment completed for falls for those patients. She confirmed that the feedback from this group supports not excluding OB patients.

e. Helen Haskell cautioned against excluding psychiatric patients and gave the example of orthostatic hypotension, a side effect of many psychiatric medications, which can increase risk for falls. She added that though not currently captured in the electronic health record (EHR), it would also be interesting to see how the patient/ family/ caregiver could record the fall and injury information as they would be aware of whether a fall took place. For example, the fall and injury information could be collected during discharge or in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.

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f. Lisa Riggs expressed concern about lack of recognition for the preventable falls and stated some falls are preventable and some are not; for example, the NDNQI measure definition counts a patient who falls out of a chair during a cardiac event as a fall, which would not be preventable. This is significant because due to the infrequency of falls, this kind of nuance could make or break a system's falls rate.

    i. Hazel Crews agreed with Lisa Riggs and Dr. Kavanagh about the need to focus on preventability. Hazel Crews stated that we need to recognize the difference between the few non-preventable falls that occur. Also pointed to the significance of falls with minor injury, as they signify the potential for greater harm

    ii. Lillee Gelinas and Dr. Lynde expressed agreement with Lisa Riggs' comments

g. Dr. Bruce Spurlock recommended expanding the patient population within the inpatient setting to also include other inpatient areas besides acute care (i.e. radiology) because cases.

    i. Dr. Stocking mentioned that the importance of specifying at the inpatient level is that we can control more where we get the data from and access to the data. The example was provided of NDNQI – only falls that occur on the unit are counted.

h. Dr. Stocking noted that we may look to create a simpler measure first, considering what is clinically meaningful and technically feasible, then perhaps look to re-specify it as more complex as the EHR becomes more robust. She reiterated data for an eCQM must come from discrete fields.

i. Lillee Gelinas stated that when it comes to the field of patient safety, there should be no exclusions so that a complete picture of the hospital's overall performance is clear

5. **Discussion Item #1 - Definition of Injury:** Using the initial suggestions for focusing on major injury and death, Dr. Stocking asked the TEP to weigh in on options for the definition of injury and what to include as a major injury.

a. Dr. Joe Kunisch raised the issue of relating the outcome to the fall. He gave the example of a patient with coding to indicate that they received blood products or had coagulopathy, but it would not be linked to a fall event in a discrete field. There would have to be some documentation in a text field, and you might have a lot of disconnect on the outcome of the fall

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b. Dr. Cindy Barnard added in the chat that she agreed with desirability of evaluating (a) preventable falls (b) irrespective of harm. However, it is almost impossible to think how to do either with current electronic medical record (EMR). She also added that it is interesting to note that there is a decent body of nursing focus on the importance of preventing injury rather than just preventing falls. Dr. Barnard recommended consideration of a standardized approach to post-fall assessment, which does not exist today, but could be a good way to evaluate once a standard is agreed such as NDNQI. Her organization does have a standard post-fall assessment in the EMR and it is likely that many others do too, but they are not currently standardized across hospitals. Dr. Barnard agreed that these injuries may occur without a fall.

c. Dr. Barnard also added that achieving the aim of this measure will be difficult as some of the injuries associated with falls could also occur without a fall. It would be great to have a standard for post-falls assessment using something like what is in the NDNQI measure, but there is no standard. The presented list of identified injuries is problematic because not all of these things are related to a fall. For example, oncology patients could have spontaneous fracture, so identifying the injury as the evidence of a fall is not as simple as it looks.

    i. Dr. Stocking validated the concerns and reaffirmed that the measure would look for the injury in the presence of a fall, not just the injury alone. She added that the team will be looking at the feasibility of using existing codes to identify the fall.

d. Dr. Spurlock emphasized the importance of the severity of injury for improvement and acknowledged the importance of precision for payment purposes. He supported the use of a less precise definition to start to help drive improvement.

e. Dr. Barnard asked how the identification of the fall would be associated with the treatment

    i. Dr. Stocking confirmed that the logic would link the code to the documentation for the injury

    ii. Maggie Lohnes added that while this approach is not ideal, it is similar to the methodology used for another eCQM, which links the code for naloxone administration to infer an opioid overdose.

f. Dr. Kunisch commented that coding happens at discharge rather than the time of event. So there is not anything coded during the stay, it happens after the stay. Don't have date of when the even occurred. Then you don't have a timeline for

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the coding and relating it (fall then three hours later liver laceration) you would just see primary and secondary diagnosis, which would be complex for this.

g. Dr. Stocking acknowledged that this is true of Dx codes, especially if hospitals do not have a concurrent program in place through a Clinical Documentation Improvement System. Although, real time coding can take place regarding SNOMED CT and LOINC codes. Maggie Lohnes confirmed this and provided and example.

6. **Discussion Item #2 - Risk Adjustment/ Risk Stratification:** Dr. Stocking introduced the next topic of whether the TEP believed risk adjustment is needed and noted that if the answer is yes, this would be the first ever risk-adjusted, NQF-endorsed eCQM. She asked the TEP to name variables that would be important for risk adjustment. Age, gender, and length of stay were listed.

a. In terms of other variables to include, the TEP offered altered mental status, stroke, low mobility score (i.e. -6 clicks mobility < 18 or 20).

b. Dr. Kavanagh suggested adjusting for patient characteristics that could not be mitigated for fall risk. He also cautioned that risk adjusting away high-risk patients could allow facilities to allocate resources away from these patients.

   i. Dr. Lynde disagreed with the allocation of resources statement. Hospitals will continue to allocate; however, one unintended consequence of no risk adjustment would be greater use of restraints, both chemical and physical.

c. Helen Haskell raised concern about risk-adjusting for falls because falls are always preventable, and risk adjustment would allow hospitals an excuse to not monitor high risk patients. Additionally, she raised the question of whether risk adjustment would be an issue for getting NQF endorsement as an eCQM.

   i. Dr. Lynde also disagreed that falls are always preventable- they are frequently preventable, but not always.

   ii. Dr. Patrick Romano responded that it is well established that not all falls are preventable, and that if hospitals are having no falls, it is an indication that they are not getting patients mobile enough. The idea is that falls would not be excused but that there would be a recognition that some patient types are at higher risks.

  iii. Dr. Stocking added that patients spend too much time in bed and with getting out of bed earlier and more mobility, there are better outcomes, and fewer falls.

  iv. Dr. Barnard noted agreement with Dr. Romano and pointed to the similar situation of infection coding for National Healthcare Safety Network (NHSN) which uses a careful definition of an algorithm to identify healthcare-associated infection (HAI) - but that is not yet possible to infer from discrete data elements, hence the need for abstraction.

d. Dr. Callister asked if "Acute Care" includes long-term acute care hospitals (LTACH) facilities and Dr. Stocking confirmed that this measure does not apply to LTACHs.

e. Dr. Barnard suggested using a precise definition of falls to avoid the need for risk adjustment altogether and instead employ specific exclusions to capture problems such as a fall subsequent to cardiac arrest.

f. Lisa Riggs asked if the risk adjustment is related to likelihood of injury if fall or increase risk of fall or both. She would like to think we can separate the risk adjustment for risk for fall rather than risk for injury.

g. Dr. Spurlock agreed with Dr. Romano that the goal of reaching zero falls has its own issues. He mentioned the evidence that getting up and moving reduces chances of delirium and improves outcomes. Since cognitive challenges are an indicator, it could be possible to use a cognitive diagnostic as an indicator for risk adjustment.

  i. Dr. Callister agreed that falls are not always preventable; and that without risk adjustment, we will definitely encourage the increased use of restraints etc. He added that in his experience LTACHs are technically "acute care hospitals" so the measure will need to use clear nomenclature.

  ii. Dr. Lynde also agreed with Dr. Spurlock.

h. Dr. Kavanagh suggested that improving hospital staffing could reduce falls, but hospitals are not hiring and instead use patient sedation or restraints to reduce falls. He advocated for standards to ensure adequate staffing and added that risk adjusting for patient acuity allows for hospitals to continue with poor staffing practices.

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> i. Lisa Riggs and Dr. Barnard did not agree that more staffing will eliminate all falls.

> ii. Dr. Barnard added that there is also an issue of falls in the bathroom when staff refrain from accompanying the patient in the bathroom to allow for patient privacy. In this case staffing is not necessarily the issue, instead staff perhaps mistakenly respecting the patient's privacy and accommodating the patient's request for privacy by standing outside the bathroom rather than coming in with the patient. Another example of this is when staff allow the patient to use the bathroom rather than the bedside commode, while this may seem better for the patient to feel that they are recovering, it creates a risk of fall with injury since bathrooms are particularly terrible places to fall.

> i. Dr. Kunisch agreed with Dr. Romano's comments and added that to not risk adjust is to say that all populations are the same, which is not true. A possible risk adjustment would be looking at how patients came in (e.g., transfer from another facility, transfer from nursing home/ SNF).

> j. Overall, the TEP agreed that there should be some level of risk adjustment for this measure.

7. **Discussion Item #3- Denominator:** Dr. Stocking asked the TEP to consider whether the measure developer should pursue a denominator based on the total number of eligible encounters, as is standard with other eCQMs, or if it should be based on the total number of patient days, as is standard with NDNQI and CDC measures.

   a. Dr. Barnard voiced support for using total number of patient days as it better reflects the total "exposure" to the risk of fall.

   b. Helen Haskell asked why one would use the non-standard approach for eCQM methodology and stated the encounter approach would be simpler.

   > i. Maggie Lohnes confirmed that the eCQM standard to use encounter methodology is to simplify cases where a stay extends into more than one reporting period.

   c. Dr. Callister added that encounters can vary a lot so comparing encounters with 3 days and others with 25 days would be like comparing apples and oranges.

   > i. Four other TEP members (Lillee Gelinas, Ashley Tait-Dinger, and Dr. Lynde) agreed that patient days is the better option.

8. **Discussion Item#4- Numerator:** Dr. Stocking presented options for the numerator for the TEP's consideration. One option would be to report on only major injuries, another option would be to stratify by major or non- major severity of injury, or finally, to stratify by level of injury severity and unit type. However, unit type is not standardized and there can be different names for the same unit across hospitals.

    a. Dr. Kavanagh asked for the reason why it is necessary to indicate the severity of the injury and unit type, when that could be an issue of chance.

        i. Dr. Stocking acknowledged that in a perfect world we would capture all injuries, but for now maybe we stick to the more severe injuries and as the EHR evolves, we can revise the measure to add specifications for less severe injuries.

        ii. Dr. Barnard added that reporting a non-severe harm will be much more variable and by focusing on more severe injuries, the reporting is more consistent.

        iii. Dr. Callister commented that a fall with injury recorded as "none" would be non-sensical for inclusion in a falls with injury measure.

    b. Three TEP members (Dr. Spurlock, Dr. Callister, and Dr. Barnard) noted support for major injury inclusion only.

    c. Dr. Stocking also posed the question of how to handle patients with multiple falls for TEP input.

        i. Helen Haskell clarified that if you go by patient days, wouldn't you count all of the falls? Why would you not count them all?

        ii. Six TEP members (Dr. Lynde, Dr. Callister, Dr. Barnard, Lillee Gelinas, Shabina Khan, and Ashley Tait-Dinger) supported counting all falls for a total number

        iii. Additional suggestions included noting the severity of the worst injury, ensure definition of fall is truly reliable.

    d. Dr. Kavanagh added that the weight of the second fall should be more significant as he feels we need to avoid creating a healthcare system where instead of providing increased resources which are need for patients, we risk adjust away the need for providing these resources.

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9. **Venous Thromboembolism (VTE) Introduction:** Allison Russo briefly introduced the intended concept for the next hospital harm eCQM for further discussion at the next TEP meeting. The measure concept will be a postoperative and perioperative VTE measure, and will likely pursue a re-specification of the existing PSI-12 claims-based measure. Noted that the literature search has shown that there are no eCQMs targeting postoperative VTE and risk adjustment will be challenging, but the team will present on this in more detail at the next meeting.

   a. TEP Input: A few TEP members noted initial reactions to the introduction in the chat box for the meeting.

   b. Dr. Lynde: National Surgical Quality Improvement Program (NSQIP) does a good job of retrospective risk adjustment. There is also developing literature on this for surgical patients.

   c. Helen Haskell suggested risk stratifying rather than risk adjustment.

   d. Dr. Barnard commented there is significant ascertainment bias for PSI-12. She suggested the measure developer considers a process metric such as "perfect VTE prophylaxis" e.g. right patient, right dose, right order timing, right frequency, throughout entire inpatient stay without any misses.

      i. Dr. Lynde agreed and followed up to confirm whether we are limited to outcomes only, or if we can work on a process metric.

      ii. Dr. Barnard: Agreed that NSQIP has much to offer but there still is ascertainment bias. She added that especially in the era of COVID-19, there is so much we don't know, so why not focus on perfect care?

      iii. Dr. Lynde agreed that process metrics may be better for this topic.

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the measure developer circulated the meeting notes in the form of this updated TEP Summary Report for the TEP's reference and continued with preliminary testing. The input from the TEP members will inform the development of preliminary measure specifications for initial testing. IMPAQ plans to present the results of the initial testing for the falls with injury measure as well as detailed information for further discussion on the development of a VTE eCQM at the next TEP meeting.

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Appendix A: TEP Composition List

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
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
Hazel Crews, MHS, MHA, CPHQ, HACP Senior Director of Quality Improvement	Managed Health Services Indianapolis, IN	None
Lillee Gelinas, BSN, MSN, RN, CPPS, FAAN Clinical Executive	SaferCare Texas Division, 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
Kevin Kavanagh, MD, MS Volunteer Board Chairman	Health Watch USA Lexington, KY	None
Shabina Khan Patient Representative	Chicago, IL	None
Joseph Kunisch, PhD, RN-BC Informatics, CPHQ Enterprise Director of Clinical Quality Informatics	Memorial Hermann 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
Grant Lynde, MD, MBA Staff Physician and Vice Chair of Quality	Emory University Hospital, American Society of Anesthesiologists Atlanta, GA	None

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Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Lisa Riggs, MSN, RN, ACNS-BC, CCRN-K Volunteer Leader & Member	American Association of Critical Care Nurses Aliso Viejo, CA	None
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
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
Amy Wilson, RN, MSN, CPHQ Senior Vice President, Clinical Operations	Ascension St. Louis, MO	None

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Appendix B: Project Staff

IMPAQ Team	
Name	**Role**
Kendall Hall, MD, MS	Project Director
Jensen Chiu, MHA	Senior Oversight
Anna Michie, MHS	Project Manager
Stacie Schilling, MPH	NQF Lead
Bo Feng, PhD	NQF SME
Maggie Lohnes, RN, MSN	eCQM Lead
Michelle Lefebvre, RN, BSN	eCQM Authoring and Maintenance Lead
Chana West, RN, MSN	eCQM Testing Lead
Priya Chatterjee, MSPH	eCQM Project Manager
Hannah Klein	TEP Lead
Molly Mantus	TEP Meeting Coordination & Support
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	PSI Measure Development Lead
Christian Sandrock, MD, MPH	Clinical SME
Jacqueline Stocking, PhD, MSN, RN	Clinical SME
Garth Utter, MD, MSc	Clinical SME
Daniel Tancredi, PhD	Statistical SME
Guibo Xing, PhD	Measure Testing Lead
Monika Ray, PhD	Computer Science SME
Meghan Weyrich, MPH	Project Manager

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