

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



Summary of Patient Safety Indicators Technical Expert Panel (TEP) Evaluation of Measures

Patient Safety Measure Development and Maintenance

8/21/2020
Version # 3



SUBMITTED TO

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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 TEP Evaluation of Measures
Patient Safety Indicators

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The materials presented in this document do not represent final measure specifications for the PSI measures

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Background

Under the Measure & Instrument Development and Support (MIDS) Patient Safety Measure Development and Maintenance project (contract no. 75FCMC18D0027), the Centers for Medicare & Medicaid Services (CMS) has contracted with IMPAQ International to maintain the Patient Safety Indicator (PSI) 90 composite measure, its PSI components, and PSI 04, which are harmonized with the Agency for Healthcare Research and Quality (AHRQ) PSIs where feasible, but specified explicitly for implementation in CMS programs. As part of its measure development process, the IMPAQ team convenes groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

The IMPAQ team has obtained expert and stakeholder input to inform improvements and changes for the measures. This report summarizes the feedback and recommendations made by the TEP during the November 2019, May 2020 and July 2020 meetings discussing the PSI 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. Presenters and moderators for these TEP meetings were Dr. Patrick Romano, Dr. Jacqueline Stocking, and Dr. Kendall Hall. A full list of the staff supporting this work is listed in the exhibit below.

Exhibit 1: 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
Hannah Klein	TEP Lead
Leah Dillard	TEP Meeting Coordination & Support
UC Davis Team	
Name	Role
Patrick Romano, MD, MPH	PSI Measure Development Lead
Jacqueline Stocking, PhD, MSN, RN	Clinical SME
Garth Utter, MD, MSc	Clinical SME
Daniel Tancredi, PhD	Statistical SME
Guibo Xing, PhD	PSI Measure Testing Lead
Monika Ray, PhD	Computer Science SME
Meghan Weyrich, MPH	Project Manager

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Overview of the Technical Expert Panel

In alignment with the CMS Measures Management System Blueprint, the project team convened a TEP to provide guidance on the maintenance of the PSI 90 composite, its component measures, and PSI 04. The role of the TEP is to provide guidance on key methodological and clinical decisions. The PSI TEP is comprised of 16 individuals representing a variety of viewpoints and backgrounds, including experience with PSIs and expertise in healthcare delivery, performance measurement, quality improvement, and risk adjustment. Two TEP members represent patient/caregiver perspectives. The full TEP membership is listed in Appendix A.

TEP PURPOSE & OBJECTIVES

The TEP is comprised of individuals with knowledge of the PSIs, their technical specifications, and associated methodological challenges (Appendix A). The overarching goals of the TEP are to provide feedback to the IMPAQ team regarding maintenance of and refinements to the PSI 90 composite, its component measures, and PSI 04. The primary areas of focus are clinical and methodological issues as well as broader issues related to the measurement cycle.

The TEP will:

- Provide input to inform the approach to narrative and technical specification refinement and maintenance
- Review analytic and testing results
- Assist with the adjudication of public comments

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Technical Expert Panel Meeting #1

November 18, 2019 10:00 AM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the first TEP meeting to introduce the PSI 90 composite, its component measures and PSI 04, and discuss proposed changes to the measures in preparation for the upcoming measure maintenance activities. During the meeting, the TEP members introduced themselves, announced any personal disclosures and ratified the TEP charter. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck for review and preparation for discussion.

Attendance:

TEP Members: John Bott, Chad Craig, Irene Fraser, Kathy Hallock, Sharon Hibay, D'Anna Holmes, Stephanie Ledbetter, Michelle Martin, Amy Rosen, Ilan Rubinfeld, Bruce Spurlock, Patricia Zrelak, Patient Representative

Not Present: Ann Borzecki, Eleni Theodoropoulos, Julie Wall

CMS: Katrina Hoadley

IMPAQ: Kendall Hall, Mike Sacca, Anna Michie, Stacie Schilling, Hannah Klein, Molly Mantus

UC Davis: Patrick Romano, Jacqueline Stocking, Meghan Weyrich, Daniel Tancredi, Oluseun Atolagbe

AHRQ: Maushami Desoto, Rhona Limcangco

SUMMARY OF TEP DISCUSSION

PSI 90: Dr. Patrick Romano introduced the composite measure and provided background on the measure design and intent. The team provided the TEP with the changes to the component measures that have been implemented since the last NQF review in 2015 and presented the proposed measure changes for discussion.

1. **PSI 03: Pressure Ulcer:** In general, NQF is concerned about broad denominator exclusions and requests strong justification. Heterogeneity in the population is better handled through more narrow exclusions and risk adjustment whenever possible.

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- a. The previous measure developer, AHRQ, has already removed some denominator exclusions.
 - b. **Proposed change:** Limit the numerator to pressure ulcers that are stage 3, stage 4, or unstageable to allow for the exclusion of deep tissue injuries (DTI).
 - c. **TEP Input:** Dr. Rubinfeld, Dr. Spurlock, Ms. Hallock, Dr. Craig, Dr. Rosen, Mr. Bott, and Dr. Hibay supported the proposed change. Panelists highlighted the fact that increased surveillance has led to apparent increases in PSI 03 rates at many hospitals, and the importance of training hospital staff in distinguishing pressure injury stages and DTI.
- 2. PSI 08: In Hospital Fall with Hip Fracture:** The measure uses in-hospital fractures to capture in-hospital falls as there is no way to consistently measure falls with coded data.
- a. AHRQ has already expanded the denominator to include both medical and surgical patients.
 - b. **Proposed change:** Exclude patients with prosthesis-associated fractures because these fractures often occur without a fall.
 - c. **TEP Input:** No opposition from the TEP.
- 3. PSI 11: Postoperative Respiratory Failure Rate:** Stakeholders have suggested additional exclusions for patients likely to require prolonged endotracheal intubation and/or mechanical ventilation for airway protection and not respiratory failure per se.
- a. AHRQ has already removed some exclusions for diagnostic codes for craniofacial abnormalities and narrowed the codes for patients having craniofacial procedures that may lead to swelling requiring prolonged endotracheal intubation and mechanical ventilation.
 - b. **Proposed change:** Add a denominator exclusion for malignant hyperthermia.
 - c. **TEP Input:** Dr. Hibay and Dr. Zrelak supported the proposed change.
- 4. PSI 12: Perioperative Pulmonary Embolism and Deep Vein Thrombosis:** With the increased specificity possible in ICD 10, stakeholders have suggested additional exclusions.
- a. AHRQ previously added a denominator exclusion for certain thromboembolism-related procedures that take place in the procedure room rather than the operating room and a denominator exclusion for acute brain or spinal injuries present on admission.

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- b. **Proposed change:** Narrow the numerator to exclude isolated distal DVT and solitary subsegmental PE.

- c. **TEP Input:**

- i. Dr. Craig thought it reasonable to exclude distal DVTs and noted there are data that isolated peripheral PE events are associated with recurrent VT events and pulmonary hypertension. Dr. Craig would include solitary subsegmental PE events, acknowledging that clinicians don't always know if they are present.
- ii. Dr. Rubinfeld and Dr. Hibay agreed.
- iii. Dr. Rubinfeld shared that his hospital sees a discrepancy between their registry and PSI 12 data. They are working on finding possible reasons for the discrepancy.
- iv. Dr. Spurlock agreed with excluding distal DVTs and questioned the preventability of subsegmental PEs.
- v. Dr. Rubinfeld shared his understanding that subsegmental PEs are less likely to be treated and are much harder to prevent. He also noted that this makes subsegmental PEs less actionable in terms of measuring harm and that the rates of these events are likely to reflect utilization (or overutilization) of CT pulmonary angiography, especially in academic medical centers.

5. **PSI 13: Postoperative Sepsis:** The proposed updates to this measure involve an update to the infection list used in the denominator exclusion to eliminate that don't cause sepsis.

- a. AHRQ previously removed exclusions for immunocompromised states because they are handled through risk adjustment. AHRQ also previously removed a length of stay exclusion (<4 days).
- b. **Proposed change:** Limit the list of preexisting infection exclusions to active bacterial infections.
- c. **TEP Input:** Dr. Hibay wanted to make sure the methodology looks at potentially avoidable conditions and that readmissions (for PSIs) and previous index stays are considered.

6. Risk Adjustment and Potential Measures to Add/Drop:

- a. **TEP Input:** Dr. Rubinfeld suggested using a machine learning approach to support feature selection, given the challenges of traditional risk-adjustment with tens of thousands of procedure codes. He expressed particular concern about rare problems, such as liver transplant, and extracorporeal membrane oxygenation (ECMO), that are associated with extremely high risk but may not get into traditional risk models. He added that his hospital found that PSI 12 is sensitive to social determinants and behavioral health diagnoses.

7. PSI 90 Measure Testing Plan: The team shared plans to test the PSI 90 component measures in the next 6-8 months and update the composite weights for version 10.

a. TEP Input:

- i. Dr. Hibay suggested the measure testing plan include looking at hospitals that have relatively higher surgical proportion as well as hospital size.
- ii. Mr. Bott suggested the testing plan include a risk decile plot analysis and a second analysis of denominator volume with observed to expected ratios to see if there are any substantial outliers.
- iii. Dr. Spurlock suggested the testing plan consider the variation in harm factors, not just the mean effects. He suggested that high variation in these harm estimates could suggest discrimination in care.

PSI 04: Dr. Romano presented a brief overview of PSI 04 and the measure strata, and presented four potential refinements to the measure under CMS consideration.

- 1. Limit the denominator to patients in general surgical, vascular, and orthopedic DRGs for consistency with Silber et al., and to create more homogeneous population.
- 2. Broaden the definition of complications to include other complications that may predispose a patient to death.
- 3. Exclude patients transferred in from other hospitals or find another way to handle this issue.
- 4. Capture post-discharge death within 30 days of admission.

a. TEP Input:

- i. Dr. Spurlock commented that the priorities are to expand rather than limit the denominator and to use risk adjustment. He suggested there might be

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ways to limit or refine the eligible diagnoses, but to just use elective cases would limit the usefulness of the measure. He supported seeking a consensus compromise on how to handle the transfer issue, perhaps stratified reporting.

- ii. Dr. Hibay agreed that the denominator should be expanded and suggested risk stratifying transfer-in patients.
- iii. Dr. Craig agreed with Dr. Spurlock and Dr. Hibay. He supported capturing post-discharge admissions with associated deaths. He found there is reasonable data that most events that happen within a month of discharge are related to the index hospital stay.
- iv. Ms. Ledbetter gave examples to show that transfers can look different in rural communities and noted there are limiting factors for more rural areas that would need to be considered for this measure. She expressed particular concern about critically ill patients who expire within hours after transfer.
- v. Dr. Rubinfeld shared that his hospital found that rapid response teams increase rates of PSI 04, apparently because patients who survive a “code” situation are assigned complication diagnoses that put them into the PSI 04 denominator.
- vi. Ms. Ledbetter agreed with Dr. Rubinfeld’s comments about the rapid response teams, focusing on the increasing number of patients who survive a cardiac arrest but do not survive the hospitalization.
- vii. Mr. Bott recommended keeping transfers in and procedures performed on a non-elective basis in the denominator.
- viii. Dr. Rosen would keep transfers in and was unclear why PSI 04 needs to be consistent with Silber’s definition.
- ix. Dr. Fraser believed it would be useful to explore the potential for further clinical details (i.e., triggering complications) in ICD-10.

SUMMARY OF TEP DECISIONS

No official votes were held during the first TEP meeting, however the TEP did provide input on the proposed changes to the measures. Per the TEPs feedback, the IMPAQ team gathered the following for next steps:

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- PSI 03: Support for the proposed change to limit the numerator to pressure ulcers that are stage 3, stage 4, or unstageable to allow for the exclusion of deep tissue injuries.
- PSI 08: No opposition to exclude patients with prosthesis-associated fractures because these fractures often occur without fall.
- PSI 12: Strong support for narrowing the numerator to exclude isolated distal DVT, but mixed views on excluding solitary subsegmental PE.
- PSI 13: There was no opposition to limiting the list of pre-existing infection denominator exclusions to active bacterial infections.
- PSI 04: Support for expanding, rather than limiting, the denominator and retaining both elective and non-elective procedures. Support for retaining patients transferred in from other hospitals and exploring risk-stratification. Mixed views on for capturing deaths within 30-days post discharge.

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes and continued to move forward with the measure testing in alignment with the results of the TEP input. As noted for PSI 12, the MIDS Patient Safety team will test both retaining and excluding the solitary subsegmental emboli (note: these codes were introduced in October 2019).

Technical Expert Panel Meeting #2

May 1, 2020 1:30 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the second TEP meeting to review the TEP's recommended changes that were approved by CMS, review the PSI 90 testing approach and discuss preliminary validity and reliability testing results, and review exploratory analyses informing potential changes to PSI 04. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck for review and preparation for discussion.

Attendance:

TEP Members: Ann Borzecki, John Bott, Chad Craig, Irene Fraser, Sharon Hibay, Stephanie Ledbetter, Michelle Martin, Amy Rosen, Ilan Rubinfeld, Bruce Spurlock, Eleni Theodoropoulos, Julie Wall, Patricia Zrelak, Patient Representative

Not Present: Kathy Hallock, D'Anna Holmes

CMS: Annese Abdullah-Mclaughlin, Yuling Li, Katrina Hoadley

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

UC Davis: Patrick Romano, Jacqueline Stocking, Garth Utter, Meghan Weyrich, Daniel Tancredi, Monika Ray

AHRQ: Maushami Desoto, Rhona Limcangco

SUMMARY OF TEP DISCUSSION

At the beginning of the meeting, the TEP members introduced themselves and noted any new conflicts of interest since the prior meeting.

Review of November 2019 TEP Meeting: Dr. Romano presented a summary of the discussion from the November 2019 TEP meeting. He reviewed the proposed changes for PSI 03, PSI 08 and PSI 12 (PSI 90 component measures). The TEP generally supported excluding deep tissue injuries (DTI) from PSI 03, excluding patients with prosthesis-associated fractures from PSI 08, and excluding distal (calf) deep vein thromboses from PSI 12. Dr. Romano reviewed the PSI 04

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options under consideration. The TEP expressed support for expanding and retaining patients and support for retaining patients transferred in from other hospitals using risk-adjustment instead of exclusions. The TEP expressed mixed views on capturing deaths within 30-days post-discharge.

1. TEP Input:

- a. Yuling Li (CMS) asked whether the support for expanding – rather than limiting – the denominator would include expanding the list of complications used to trigger the denominator.
 - i. Dr. Romano said that expanding the list of complications was not discussed in detail previously and asked for input from the TEP.
 - ii. Dr. Spurlock said that we are learning more about early warning systems and the idea of identifying patients who are getting into trouble at the earliest possible time. We are getting more recommendations about how to proceed in a variety of different environments, such as acute kidney injury (which may or may not be preventable). The notion of broadening our ability to intervene and interrupt a death or serious harm with patients after surgery is increasing. The literature is going in the direction of finding more actionability because of the electronic health record (EHR) and early warning trigger systems for detecting patients at risk.
 - iii. Dr. Zrelak agreed with Dr. Spurlock, stating that Kaiser Permanente in her region has folks who are using the EHR to alert action teams to patients who may be getting sicker.
 - iv. Dr. Rubinfeld shared the observation that his hospital has a good code team so many patients survive but then go on to have complications, such as sepsis or DVT, and are flagged by PSI 04. This is problematic when they compare their data to neighboring community hospitals without as active code teams or rapid response teams – those hospitals have fewer PSI 04 events but they get hurt on their 30-day risk-adjusted mortality measures. Academic medical centers have often invested in early warning systems, rapid response teams or code teams to get better results. He again expressed concern about including transfers in PSI 04 due to lack of control over the pre-hospital care received elsewhere. We know from the National Surgical Quality Improvement Program (NSQIP) and the Michigan Surgical Quality Collaborative (MSQC) that it takes very good severity adjustment with a lot of specific covariates to make emergent or urgent cases at teaching hospitals balance out healthier elective cases.

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PSI 90 Testing Approach: Dr. Romano reviewed the PSI 90 reliability testing approach including signal-to-noise and split-half reliability approaches, as well as the use of intraclass correlation coefficients (ICCs). He also reviewed validity testing and risk-adjustment approaches.

PSI 90 Preliminary Results: Dr. Romano presented the preliminary reliability and validity testing results for PSI 90.

1. **Reliability Testing:** Dr. Romano explained that signal-to-noise reliability estimates are bound between 0 and 1 and that more frequent events tend to have higher signal-to-noise reliability (>0.5) than rare events (<0.3); the testing results show that some PSI 90 component measures are more reliable than others. Dr. Romano noted that score level reliability testing focused on within-hospital consistency resulted in ICCs in the 0.4 to 0.6 range, except for small hospitals with <100 beds. Dr. Romano also noted higher consistency with ICC when the analysis is conducted using all-payer claims data from several states.
2. **Validity Testing:** Dr. Romano explained that the first step of validity testing is assessing the risk-adjustment models using C-statistics, which represent the probability that a randomly sampled patient with the adverse outcome was ranked higher (based on predicted risk) than a randomly sampled patient without that outcome. C-statistics are bounded between 0 and 1, and C-statistics greater than 0.75 are generally considered strong for this type of model. Dr. Romano next presented the predictive validity of the PSI 90 component measures for various patient outcomes, such as length of stay at the hospital or skilled nursing facility. Dr. Romano discussed the construct validity of the PSI 90 composite, noting that the hospital-level correlations vary from low (PSI 08, 14) to high (PSI 03, 11, 12, 13) but that all are consistently positive. He presented results for convergent validity testing between PSI 90 and other measures, which found positive but weak correlations for all measures except for catheter-assisted urinary tract infection. Dr. Romano also presented the results of known groups construct validity testing. Finally, Dr. Romano asked the TEP for feedback, concerns or suggestions regarding reliability and validity testing results.

3. TEP Input

- a. Dr. Rubinfeld wondered why CMS would keep component measures that don't perform very well on signal-to-noise reliability testing since each measure should have some degree of strength.
 - i. Dr. Romano clarified that each measure should contribute some information but that each measure doesn't have to be intrinsically reliable.

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The concept of composite design is that the individual components don't have to have high reliability so long as they contribute unique information.

- b. Dr. Hibay asked whether there was any investigation or review of the individual components that are less reliable to understand their impact, using in-hospital fall with hip fracture (PSI 08) and postoperative wound dehiscence (PSI 14) as examples.
 - i. Dr. Romano explained that the TEP is looking at reliability at the hospital level and not the data element level, so the reason some of these events are unreliable is because they are quite rare. When you analyze the overall pattern across hospitals, it appears as if these rare events are randomly distributed across hospitals. One cannot estimate a reliable hospital-level rate of these rare events. For example, one year a hospital may be high and the next year it may be low, but this change is attributed to random variation than to a true change in quality.
- c. Dr. Spurlock asked how the measure developer determines whether each component measure is contributing additional information to the composite and its reliability. He further asked whether the measure developer examines correlations among the component PSIs.
 - i. Dr. Romano explained that part of this assessment is based on face validity and part is based on empirically estimating the overlap or covariation among the components. He confirmed that the measure developer does look at correlations among PSI 90 components.
- d. Dr. Hibay asked for clarification regarding the predictive validity of PSI 06 related to admission to a SNF or number of SNF days.
 - i. Dr. Romano clarified that all of the component measures have independent associations with all of the outcomes with the exception of pneumothorax (PSI 06), which resolves fully before hospital discharge and does not affect the need for long-term care.
- e. Dr. Hibay asked whether the measure developer looks at combinations of these PSI 90 components to better understand the weight of each the components.
 - i. Dr. Romano confirmed that the measure developer did look at this, but did not find any significant interaction effects among PSI components.

- f. Dr. Spurlock said that when Cal HospitalCompare¹ looked at the item-total correlations for the PSI 90 composite, some hospitals didn't have enough data to capture an individual measure, yet they had a PSI 90 score. He asked how the team took into consideration the frequencies of individual measures, especially for small hospitals or hospitals that do not report many of these events.
 - i. Dr. Romano said that this is handled through the shrinkage or smoothing process but consequently small hospitals look like they have ratios of 1. To the extent that small hospitals might be systematically worse on average compared to large hospitals that could lead to bias in the estimates that are reported. In general, when information about a hospital's actual performance is lacking due to its size, the default assumption is that they are the same as the national average. The measure developer realizes that there are some problems with that assumption.
- g. Dr. Hibay asked for clarification about what HospitalCompare would report in situations like the one that Dr. Spurlock described.
 - i. Dr. Romano explained that CMS policy in general is to report on all hospitals that have at least 3 cases that qualify for the denominator of a component PSI. As 3 cases would not lead to a reliable estimate, this is handled through shrinkage – if you look at hospitals with 3-10 cases, their rates all look like the national average. CMS has tried to keep the reporting as broad and inclusive as possible.
- h. Dr. Rosen noted that many of these are surgical indicators and wondered how well that reliability might correlate with surgical volume at a particular hospital. She has noted that PSI 14 (postoperative wound dehiscence) has a low reliability and correlation with everything and asked how we would explain that issue.
 - i. Dr. Romano agreed with her comment and said that surgical volume has not been evaluated except to the extent that it is reflected in the denominator of the component indicators. Since CMS tries to report on as many hospitals as possible, if data are missing on some of the measures because the hospital's surgical volume is low, then other component measures (e.g., PSI 03) get weighted more heavily in that hospital's overall score. Dr. Romano noted that the TEP has the opportunity to

¹ <https://calhospitalcompare.org/> , accessed 9/10/2020.

make recommendations to CMS if the TEP feels that changes, such as a larger minimum denominator, are needed.

- i. Dr. Hibay asked about the reliability of the individual component measures and whether present on admission (POA) is assessed only based on the claims and whether there is any validation mechanism for POA.
 - i. Dr. Romano confirmed that the present on admission methodology only uses what is available in the claims but with the exception that in the risk adjustment models, comorbid conditions (e.g., diabetes) are treated as chronic regardless of POA reporting.
- j. Dr. Hibay asked how much of PSI 90 is based on electronic data, since this is not an eCQM, and whether any of the component measures are also specifiable as electronic measures, allowing the data to be validated using that methodology.
 - i. Dr. Romano confirmed that PSI 90 is a claims-based measure but the team is working on eCQMs related to pressure injury and falls with injury, so there is opportunity to compare claims diagnoses to EHR data. He also noted that the team is working with AHRQ on accessing the Patient Safety Monitoring System, which is a national mechanism for tracking patient safety events using a random sampling of medical records that are reviewed by their Clinical Data Abstraction Center, which would allow further analysis of some of the events.
- k. Dr. Hibay recommends risk stratification based on race, ethnicity, and payer with cross-stratification. She asked for additional clarification around the smoothing of the individual components of the composite measure and the preferred threshold.
 - i. Dr. Romano noted that risk stratification is tricky and a topic of ongoing debate. He explained that NQF has traditionally used a minimum reliability threshold of 0.4 but may be moving toward 0.6.
- l. Dr. Hibay asked about the reliability of the component measures and the numerator requirements for reliability.
 - i. Dr. Romano said that this is a possibility to explore further. The team is currently using CMS' minimum denominator of 3 cases for each PSI component and relying on statistical smoothing to deal with the small hospitals.
 - ii. Dr. Hibay responded that this is not always explicitly noted on Hospital Compare, and that it's difficult for the general public to understand this

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information because it is so complicated. She suggested that additional clarification around why hospitals are not meeting the numerator thresholds would be helpful in explaining this to the general public

- m. Dr. Fraser noted the use of all-payer datasets and asked whether the reliability differs, as there are many more cases in smaller hospitals in the all-payer datasets.
 - i. Dr. Romano said that in general, the results are robust to missing data for individual indicators but this problem primarily affects small hospitals and warrants further investigation.
- n. Mr. Bott asked about interpretation of the ICC analysis and whether the measure developer is asserting that the ICC score is a quality indicator for a measure. Do measure scores closer to zero indicate that measure is doing a poor job or just that quality scores change over time?
 - i. Dr. Romano said that the answer lies somewhere in between – if the score were zero, then what's the point in reporting the measure because the measure is not telling us anything about current performance? But if the score is 1, then hospitals are never changing and that is undesirable as well. We are looking for scores somewhere around 0.5 – 0.8.
- o. Dr. Rosen noted that the type of risk adjustment system used may affect the results and asked whether we considered using the CMS DXCG or the Hierarchical Condition Category (HCC) systems (as opposed to the AHRQ comorbidity system) to see whether the results change.
 - i. Dr. Romano said that the team could use the HCC system, which captures data from other claims such as outpatient claims and prior episodes of care. This would be a substantial change in the methodology but is worth discussing.
 - ii. Dr. Rosen responded that she has not used the HCC system at her organization but would be interested in seeing the results of using this system in the PSI 90 risk adjustment.
- p. Dr. Spurlock asked what is seen when you compare one year of PSI 90 to multiple years of deaths or readmissions. He commented that his organization is looking at the hospital versus departmental effect, since no hospital does well on all measures and even if they do well on most measures, there will be a few that they perform poorly on. His hypothesis is that sometimes different hospital

departments perform differently but PSI 90 assumes a hospital-level effect, which may not always exist.

- i. Dr. Romano confirmed that we have examined different time periods. He noted that we could stratify hospitals to look at correlations within strata and the department-level effect also merits exploration.

PSI 04 Preliminary Results: Dr. Romano presented the preliminary reliability and validity testing results for PSI 04, as well as results of the exploratory analyses related to excluding transfers and capturing 30-day post-discharge deaths. Romano presented the results of the 30-day mortality analysis, which found that a substantial number of deaths occur after discharge to home or post-acute settings. Switching to a 30-day mortality outcome would require an entirely different risk adjustment model incorporating information from prior episodes of care, but it would modestly improve the convergent validity of the measure.

1. TEP Input

- a. Dr. Fraser thought it was interesting that subtracting transfers did not make a difference in the overall rates or the rates for teaching hospitals, as her understanding is large teaching hospitals often raise validity concerns when these data are publicly reported and attribute their scores to these transfers. She noted that it is more accurate to include transfers, but if it reduces face validity to include the transfers without any benefits, then maybe it's not worthwhile to do so.
 - i. Dr. Romano says that excluding transfers reduces reliability, which is a downside.
- b. Ms. Ledbetter noted that excluding the transfers would eliminate a portion of the PSI 04 logic that states that this applies to elective patients or have those that have a procedure within 2 days of admission. She shared that at her hospital they get lots of patients transferred in specifically for procedures and that these patients may have significant comorbid conditions, so now we are comparing patients getting elective procedures with patients who may be very ill and then they have an adverse outcome. She is concerned that these populations are not equitable for comparison.
 - i. Dr. Romano clarifies that the data shows that risk adjustment handles this issue.
- c. Dr. Craig noted that while the data you presented support that transfers can reasonably be included, this observation will fly in the face of popular beliefs, and many folks (including some on the call) may have trouble believing this, despite the data. Communicating to all stakeholders the supporting data in a transparent and

- simple/ easy to comprehend manner may help in gaining acceptance of the reasoning for including transfer data.
- d. Dr. Hibay asked for confirmation that the measure specifically risk-adjusts for elective transfers rather than just acute patients who come into the hospital.
 - i. Dr. Romano clarified that risk adjustment addresses whether the patient was transferred in, the condition of the patient upon transfer and the type of surgery they had at the index (receiving) hospital.
 - ii. Dr. Hibay asked for clarification whether the type of surgery the patient received at the index hospital denotes whether it is elective or does CMS assume “elective” based on the type of admission field on the claim.
 - iii. Dr. Romano responded that one cannot rely on the ‘type of admission’ data element so it is better to look at whether the patient was transferred and then the specific type of surgery they had.
 - e. Dr. Hibay asked whether pneumonia is treated as a subset (i.e., community-acquired versus hospital-acquired) and whether post-surgical pneumonias are excluded from the measure. She further asked whether the timing of the procedure is included in the risk-adjustment model.
 - i. Dr. Romano explained that post-surgical pneumonia is a trigger in PSI 04. The risk adjustment handles separately if the patient comes in to the hospital where the surgery was done with evidence of pneumonia. The team is exploring other changes to the definition of complications, such as broadening the list of complications.
 - f. Dr. Rubinfeld commented that there is not always transparency with 30-day mortality information. Most hospitals use data systems such as Vizient or Premier and will mock up how they’re doing on the PSIs, but if a 30-day time frame is used, then hospitals cannot model it.
 - g. Dr. Borzeki noted that this may an inconsistent approach if none of the other PSIs use 30-day mortality.
 - i. Dr. Romano brought up the question of whether PSI 04 should be more consistent with the other PSIs or with the other risk-adjusted mortality measures that are reported by CMS.

- h. Dr. Zrelak commented that hospitals that are more efficient about the discharge process could have lower PSI 04 rates than hospitals that are less efficient at discharging their patients, but she cannot say how much that would impact the rates.
 - i. Dr. Romano confirmed that this question could be empirically explored.
- i. Mr. Bott said that the current focus of PSI 04 is measuring the hospital's ability to quickly save people who are rapidly declining, so it makes sense for the measure to reflect inpatient deaths. Changing this to a 30-day mortality measure might be diluting the focus from not only saving people quickly who are rapidly deteriorating but also coordinating the care for people upon discharge. He suggests that PSI 04 could be broken into two measures – PSI 04 in its current form and a 'PSI 04.1' that would measure death after discharge.
- j. Dr. Spurlock commented that if someone goes into a coma and is transferred to a SNF and dies, the harm occurred in the hospital but is not measured in the hospital. In his opinion, this measure presents an opportunity to make big impacts on quality of care in organizations compared to rare-event measures such as falls with injury. He supports adopting a 30-day mortality measure because the long term mortality of the patient is what matters.
- k. Dr. Fraser agreed with the 30-day mortality approach and suggests that this provides an incentive for hospitals to do what they can during discharge planning to ensure a healthier outcome. She wondered whether hospitals that are already being penalized for 30-day mortality in general would feel that a 30-day mortality PSI 04 measure would count the same adverse outcome twice.
 - i. Dr. Romano noted that CABG would need to be excluded since CABG 30-day mortality is already reported separately.
- l. Dr. Hibay asked about the measure construct and whether the measure calculates the five subsets rolled up or whether it calculates each subset separately.
 - i. Dr. Romano clarified that each subset is risk-adjusted separately to calculate an expected probability and these are then added up.
- m. Dr. Hibay asked how the five subsets were selected, as there are other causes that contribute to mortality and expressed interest in seeing more information on the other causes of mortality.
 - i. Dr. Romano agreed that it would be worth exploring the addition of other complications beyond the five current categories. He explained that these 5 categories were derived from previous work looking at nurse staffing and

nursing skill mix, but that the selection is not well-supported because about half of the deaths are dropped using only these 5 categories.

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes and continued to move forward with measure testing in alignment with the TEP input.

Technical Expert Panel Meeting #3

July 20, 2020 12:00 PM ET

SUMMARY OF PRESENTATION

The IMPAQ team convened the third TEP meeting to review the updated PSI 90 testing results and anticipated NQF evaluation of the measure, and to discuss and vote on recommendations to CMS for future refinement and validation. Prior to the meeting, the IMPAQ team provided the TEP members with the presentation slide deck for review and preparation for discussion.

Attendance:

TEP Members: Ann Borzecki, John Bott, Irene Fraser, Sharon Hibay, Stephanie Ledbetter, Amy Rosen, Ilan Rubinfeld, Bruce Spurlock, Eleni Theodoropoulos, Patricia Zrelak, Patient Representative

Not Present: Chad Craig, Kathy Hallock, D'Anna Holmes, Michelle Martin, Julie Wall

CMS: Yuling Li, Katrina Hoadley

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

UC Davis: Patrick Romano, Meghan Weyrich, Monika Ray

AHRQ: Maushami Desoto, Rhona Limcangco

SUMMARY OF TEP DISCUSSION

At the beginning of the meeting, the TEP members introduced themselves and noted any new conflicts of interest since the prior meeting.

Updated PSI 90 Testing Results: Dr. Romano presented the updated reliability and validity testing results for PSI 90.

1. **Reliability Testing:** Dr. Romano presented the results of split sample and test-retest reliability testing at the hospital level. For PSI 90, the current 24-month reporting period easily meets the accepted reliability standard for hospital-level reporting with a median intraclass correlation coefficient (ICC) using split samples of 0.74. Only about 17% of hospitals would fall below the “minimum accepted” reliability threshold of 0.4 using split

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samples. Using a test-retest approach, the current 24-month reporting period still meets the accepted reliability standard for hospital-level reporting with a median ICC of 0.61. Only about 28% of hospitals would fall below the “minimum accepted” reliability threshold of 0.4 using test-retest samples.

- 2. Missing Data:** Dr. Romano explained that in situations where the hospital has fewer than three denominator cases for a PSI, the software substitutes the observed-to-expected ratio in the reference population (1.0) to construct the PSI 90 composite. The majority (89 percent) of hospitals have all 10 PSI components contributing to PSI 90. However, about 0.5% of hospitals (16/3,313) have 8 or more missing component PSIs; all end up with PSI 90 composite values of 1.0. Another 3.6% of hospitals have 7 missing components – typically all 7 perioperative/postoperative component PSIs. Since PSI 90 is driven largely by surgical complications, reporting PSI 90 values on hospitals that do not perform surgery on Medicare FFS adults (e.g., children’s hospitals, rehabilitation hospitals, behavioral health hospitals) may not be appropriate. The 75 hospitals with 4-6 missing components do perform surgery but are generally very small, and the available PSIs provide less than 50% of the total PSI 90 weight.
- 3. Validity Testing:** Dr. Romano presented the predictive validity of the PSI 90 component measures for various patient outcomes, such as length of stay at the hospital or skilled nursing facility. Dr. Romano discussed the item-total correlations for the composite, which varied from very low from low (<0.1) for PSIs 08 and 14 to high (>0.49) for PSIs 03, 11, 12, and 13, but were all consistently positive (all correlations are higher than would be expected from the component weights alone). Dr. Romano presented the assessment of the risk-adjustment models using C-statistics. In general, c-statistics >0.7 are considered sufficient for these types of risk-adjustment models; the c-statistics for each of the component measures exceeded this threshold in our analyses. Dr. Romano explained the performance of the risk model at distinguishing low- from high-risk patients. Dr. Romano discussed the convergent validity between PSI 90 and infection-related measures, 30-day readmission measures, and Leapfrog Survey safe practice scores. Finally, Dr. Romano presented the results of known groups construct validity testing and outlier analyses assessing meaningful differences in performance across hospitals.
- 4. Analytic Limitations:** Dr. Romano summarized analytic limitations to reliability and validity testing for PSI 90.
- 5. Anticipated NQF Evaluation:** Dr. Romano presented anticipated NQF evaluation of PSI 90. The team anticipates a ‘high’ score for importance, feasibility, and use and usability, and a ‘moderate’ score for overall reliability and validity. Dr. Romano also summarized the potential concerns that may arise during NQF evaluation.

6. Recommendations to CMS and TEP Voting: Dr. Romano presented the recommendations to CMS for future refinement and validation of PSI 90 and asked for TEP input on three of these recommendations.

7. TEP Input:

- a. Dr. Hibay brought up the high weighting of the surgical measures, noting that only three measures in PSI 90 are not surgically related. She asked whether there is a methodology for reporting hospital characteristics or the number of surgeries a hospital performed, from an outcomes perspective. For example, if Hospital A is performing a very low number of surgeries and Hospital B is performing a very high number, is there a methodology to show that information to the consumer? Dr. Hibay would like to see more ways to help the consumer differentiate when the hospital's PSI 90 score is more heavily weighted toward surgical procedures or events.
 - i. Dr. Romano said that in the long run, we'd like to bring additional non-surgical measures into PSI 90. For example, we'd like to broaden PSI 08 to include a broader set of injuries (beyond hip fracture) associated with in-hospital falls. As we broaden the measures to include additional events, that will naturally shift the weights so that there is less weight on the surgical measures and more weight on the measures with more events. In the short term, we are proposing to explicitly acknowledge that this measure is intended for hospitals that do surgery and that hospitals with only 4 or 5 of the component measures (e.g., rehabilitation, children's, or psychiatric hospitals) should be identified and excluded from the measure.
- b. Dr. Spurlock asked for additional clarification regarding the missing data threshold of 7 versus 6 measures for public reporting.
 - i. Dr. Romano explained that this is a grey zone because the majority of the hospitals with 4 missing PSI components don't meet 50% of the total weight because they are missing the higher weighted measures.
- c. Dr. Hibay asked whether the missing component analysis holds out over time.
 - i. Dr. Romano explained that we are limited to three years of data at our disposal (and two years go into the public reporting platform) and we did find inconsistencies when analyzing overlapping time periods of 2016-2018 and 2017-2019. There are very few hospitals with 4 or more missing

components, but these hospitals are stable over time (after factoring out hospitals that open, close, or merge during the study period).

- d. Dr. Hibay asked about the component measures included or excluded based on the missing data threshold and whether there were any substantive changes in the specifications of these measures over time, which would change the results.
 - i. Dr. Romano said that we didn't want to include confounding factors into the analysis so all of the analyses are done with the current version of the software (v10). We are beginning to analyze the impact of coding updates in v11 but that is beyond the scope right now.
- e. Mr. Bott asked for additional explanation of the decrease in the correlation with "total ...HAC score" from 2016-2018 and 2017-2019.
 - i. Dr. Romano clarified that the drop in correlation is because we are moving outside of the period of readmission reporting. We get the best correlation when we have the maximum overlap between the period used for readmission analysis and the period used for PSI 90 analysis.
- f. Dr. Rosen asked in the chat whether we had considered creating a separate composite for the surgical PSIs and another composite for the non-surgical ones (i.e., those infection-related)
 - i. Dr. Romano said that we did look at the correlations across components – if the correlations were weaker across the surgical and non-surgical subsets, that would be an argument for splitting the measure – but the correlations were not substantively weaker. The main difference is that two of the medical measures (PSI 06 and 08) are less reliable than the surgical measures, but they still add to the composite overall.
- g. Dr. Hibay would like to see the results of the item-total correlations analysis with and without the medical measures.
- h. Dr. Rubinfeld noted in the chat that PSI 06 used to measure poorly executed central line insertions and thoracentesis, but now it has become more about invasive radiologists doing difficult image-guided biopsies and cardiac electrophysiologist using subclavian access. Similarly, PSI 14 used to be about poor surgical technique and is now more about how many "abdominal catastrophe" operations are done on elderly patients.
 - i. Dr. Romano agreed with Dr. Rubinfeld's observation about PSI 14 and said that is why we rely heavily on risk-adjustment and why the risk-

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adjustment models for PSI 14 are separated by open versus laparoscopic operations. The overwhelming majority of the events are happening in the top risk deciles so we think we have that problem under control via risk-adjustment.

- ii. Dr. Romano noted that the same observation about PSI 06 has been raised by other hospitals and asked whether those types of complications are okay; he argued that an iatrogenic pneumothorax is undesirable even if you are doing a cardiac EP study or an interventional radiology study.
- iii. Dr. Rubinfeld agreed that this is a harm no matter how it happens but clarified that the issue is hospitals transferring those cases (and that risk) to other facilities. Whereas previously every hospital was doing central lines via the subclavian route and thoracentesis, now the risk associated with these common procedures has been minimized and the remaining events occur after procedures for which patients are transferred. He wants to make sure that the risk-adjustment can sort that out.
- iv. Dr. Romano agreed and said that issue is worth exploring further.
- i. Mr. Bott noted that a prior study failed to show a correlation between the Leapfrog survey and a number of outcome measures, and asked for clarification about what we are assessing in this convergent validity analysis and the takeaways from the analysis.
 - i. Dr. Romano said that the takeaway is that there are negative correlations between hospital performance on most components of the Leapfrog safe practices score and PSI 90. In other words, the hospitals that have more safe practices have lower PSI 90 scores (fewer events) but these effects are weak and not statistically significant. We'd be more concerned if the direction of the effect were opposite.

SUMMARY OF TEP VOTING RESULTS

The TEP members were asked to vote on three recommendations for CMS. The results of the votes are as follows:

Exhibit 2. TEP Voting Results

Voting Question	TEP Voting Results
Do you agree with our recommendation to continue PSI 90 as a hospital-level composite measure, incorporating updates discussed in previous meetings, and subject to reassessment as additional validation data and measures become available?	92% agree (11 votes) 8% do not agree (1 vote)
Do you agree with our recommendation to implement a minimum volume threshold (e.g., 25) for public reporting of PSI 90 to address unreliability for very low-volume hospitals?	100% agree (12 votes)
Do you agree with our recommendation to exclude hospitals that are missing four or more component measures from public reporting of PSI 90 to address unreliability for very low-volume hospitals?	92% agree (11 votes) 8% abstain (1 vote)

CONCLUSIONS AND NEXT STEPS

Following the TEP meeting, the MIDS Patient Safety team produced the meeting summary notes and continued to move forward with submitting PSI 90 for NQF review during the Fall 2020 cycle.

Appendix A: TEP Composition List

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
D'Anna Holmes, MSHA, CPXP Caregiver Representative	Oak City, IL	None
Patient Representative	Florida	None
Ann Borzecki, MD, MPH Physician – Investigator	Center for Healthcare Organization and Implementation Research, Veterans Health Administration, Bedford, MA	None
John Bott, MBA, MSW Consultant – Healthcare Performance Measurement	Watertown, WI	None
Chad Craig, MD, FACP Assistant Attending Physician, Assistant Professor of Clinical Medicine	Hospital for Special Surgery, Weill Medical College of Cornell University, New York, NY	None
Irene Fraser, PhD Senior Fellow	NORC at the University of Chicago, Bethesda, MD	None
Kathryn Hallock, RHIA, CDIP, AHIMA ICD-10 Approved Trainer Lead Clinical Documentation and Coding Educator	Vanderbilt University Medical Center, Nashville, TN	None
Sharon Hibay, RN, DNP CEO & Principal	Advanced Health Outcomes LLC, Center Valley, PA	None
Stefanie Ledbetter, RN, BSN, MHI Manager of Quality, Clinical Decision Support and Clinical Documentation Integrity	East Alabama Medical Center and EAMC Lanier, Opelika and Valley, AL	None
Michelle Martin, MBA Vice President, Human Resources	CBS Corporation, New York, NY	None
Amy Rosen, PhD, BA Senior Research Career Scientist and Professor of Surgery, BU School of Medicine	VA Boston Healthcare System, Boston MA	None
Ilan Rubinfeld, MD, MBA, FACS, FCCP, FCCM Chief Quality Officer, Associate Chief Medical officer, Senior Staff Surgeon	Henry Ford Hospital, Detroit, MI	National Science Foundation Grant

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Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Conflict of Interest Disclosure
Bruce Spurlock, MD President & CEO	Cal Hospital Compare; Cynosure Health, Roseville, CA	None
Eleni Theodoropoulos, BS, CPHIMS Vice President, Quality, Research, & Measurement	URAC, Washington, DC	None
Julie Wall, RN, MBA, FACMPE System Vice President, Quality & Patient Safety	Benefis Health System, Great Falls, MT	None
Patricia Zrelak, PhD, RN, NEA-bc, SCRN, CNRN	Kaiser Foundation Hospitals, Sacramento, CA	AHRQ PSI intellectual interest

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