Summary of Technical Expert Panel (TEP) Meetings
Patient Safety Structural Measure (PSSM)

March 2023

Prepared by:
Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

This material was prepared by CORE under contracts to the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.

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Background

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (CORE) to develop quality measures of hospital and clinician performance. Under this contract, CORE is developing a Patient Safety Structural Measure (PSSM). The contract name is Measure Instrument Development and Support Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospitals and Eligible Clinicians, Option Period 4. The contract number is HHSM-75FCMC18D0042, Task Order Number HHSM-75FCMC19F0001.

CORE is obtaining expert and stakeholder input on the proposed measure. The CORE measure development team is comprised of experts in quality outcomes measurement and measure development. As is standard with all measure development processes, CORE convened a Technical Expert Panel (TEP) of clinicians, patients, patient advocates, and other stakeholders. Collectively, the TEP members brought expertise in patient safety, patient and caregiver experience, performance measurement, quality improvement, and hospital administration.

This report summarizes the feedback and recommendations received from the TEP during Meeting #1 and Meeting #2, which focused on the measure concept, the measure development approach, and proposed patient safety measurement domains and associated attestation statements. In addition to the two TEP meetings, results from the TEP Survey seeking feedback on draft measure specifications that was conducted between TEP Meetings #1 and #2 are included in the report.

Measure Development Team

Katie Apton, MPH, leads the measure development team for the PSSM and Mariel Thottam, MS, BCBA, leads Stakeholder Engagement for the PSSM measure. The remainder of the measure development team provides a range of expertise in outcome measure development, health services research, clinical medicine, statistics, and measurement methodology. See Appendix A for the full list of members for the CORE Measure Development Team.

The TEP

In alignment with the CMS Measures Management System (MMS), CORE held a 30-day public call for nominations and convened a TEP for the PSSM. CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team and stakeholder groups, email blasts sent to CMS email listservs, and through a posting on CMS's website. The TEP is composed of 19 members, listed in Table 1.

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions. The appointment term for the TEP is from February 2023 to March 2024.

Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP Nomination Form, statement of interest, and curriculum vitae
- Review background materials provided by CORE prior to each TEP meeting
- Attend and actively participate in TEP conference calls
- Provide input on key clinical, methodological, and other decisions
- Provide feedback on key policy or other non-technical issues
- Review the TEP summary report prior to public release
- Be available to discuss recommendations and perspectives following TEP meetings and public release of the TEP Summary Report to CMS

Table 1. TEP Member Name, Affiliation, and Location

Name and Credentials	Organization (if applicable) and	Location
Susan Attel	Patient Partners Innovation Community, Caregiver Expert	Dallas, TX
Rosie Bartel	Person and Family Engagement Network, Patient Expert	Chilton, WI
Kristin Bryant	Patient Partners Innovation Community, Patient and Caregiver Expert	Station, TX
Beth Daley-Ullem, MBA	Institute for Healthcare Improvement and Patients for Patient Safety, Patient Expert	San Juan Capistrano, CA
Melissa Danforth	The Leapfrog Group, Vice President of Healthcare Ratings	Washington, DC
Steven Faust	Emory Healthcare System, Patient Expert	Atlanta, GA
Thomas Gallagher, MD, MACP	University of Washington, Clinician and Researcher	Seattle, WA
Tejal Gandhi, MD, MPH, CPPS	Press Ganey, Chief Safety and Transformation Officer	Boston, MA
Elham Ghonim, PhD, MLS(ASCP), CIC, CPPS, CPHQ, LSSGB	Grady Health System, Vice President of Patient Safety	Atlanta, GA
Kendra Gustafson, MPA, BSN, RN, CPXP, CPPS	UnityPoint Health, Vice President of Clinical Excellence & Process Improvement	West Des Moines, IA

Name and Credentials	Organization (if applicable) and	Location
Martin Hatlie, JD	Project Patient Care, President & Chief Executive Officer; Patient Expert	Chicago, IL
Carole Hemmelgarn, MS, MS	Medstar Institute for Quality and Safety; Patient Expert	Highlands Ranch, CO
John James, PhD	Patient Safety America, Founder & Chief Executive Officer; Caregiver Expert	Houston, TX
Soojin Jun	Patients for Patient Safety US, Caregiver Expert	Libertyville, IL
Stephanie Mercado, CAE, CPHQ	National Association for Healthcare Quality, Chief Executive Officer	Chicago, IL
MaryBeth Nance, AdvCD (DONA), CLD(CAPPA), SBD, PFA	Changing Birth, Doula, Caregiver Expert	Delta, PA
Brett Powell, MPH, MBA, BSN, RN, CPHQ	HCA Healthcare, Associate Vice President of Patient Safety & HCA Healthcare Patient Safety Organization	Nashville, TN
Edward Seferian, MD, MS, FCCM, FACHE	Cedars-Sinai Medical Center, Chief Patient Safety Officer	Los Angeles, CA
Hardeep Singh, MD, MPH	Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Researcher	Houston, TX

TEP Meetings

CORE held its first TEP meeting on March 3, 2023, a meeting at which the PSSM development background and status were presented. The PSSM team held its second TEP meeting on March 17, 2023 (see Appendix B for the TEP meeting schedule). This summary report contains a summary of the two TEP meetings.

TEP meetings follow a structured format consisting of the presentation of CORE's measure development activities, as well as CORE's proposed approach, followed by an open discussion by the TEP members.

First TEP Meeting Overview

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the measure background and proposed approach to the PSSM.

During the first TEP meeting, CORE provided an update about the development activities that CORE has conducted so far and solicited the TEP's feedback on the measure concept and proposed approach, as well as the proposed measure domains and associated statements.

The following bullets represent a **high-level summary** of what was presented and discussed during the first TEP meeting. For further details, please see Appendix C.

Measure Background and Status

- CORE Presentation on the Measure Background, the Logic Model, and Measure Concept
- CORE presented their approach to developing the structural measure, the logic model, and the timeline.
- CORE shared the guiding principles for development of the measure:
    - Comprehensive, but parsimonious;
    - Explicit;
    - High standards;
    - Evidence-based;
    - Equity embedded throughout; and
    - Patient-centered.
- TEP Feedback:
    - A TEP member suggested that clear examples for what is necessary for hospitals to meet each element be provided.

Measure Domains

- CORE Presentation of the Patient Safety Structural Measure Domains
- CORE presented the eight measure domains in the initial draft measure specifications.
    - Domain 1: Strategic Planning & Organizational Policy
    - Domain 2: Leadership Commitment to Eliminating Preventable Harm
    - Domain 3: Surveillance & Investigation
    - Domain 4: Accountability & Transparency
    - Domain 5: Measuring & Improving Performance
    - Domain 6: Patient & Family Engagement
    - Domain 7: Resources, Environment & Technology
    - Domain 8: Workforce Safety
- CORE asked TEP members the following three questions:
    - Do the domains (i.e., 8 categories) capture the most important elements for advancing patient safety?
    - Are there gaps in the domains?
    - Do you think any of the domains are more or less important than others?
- TEP Feedback:

- Several TEP members highlighted the importance of Accountability & Transparency (Domain 4). A TEP member suggested that the statements in this domain include implementation of "Just Culture." A TEP member suggested quality improvement (QI) is part of accountability but may need to be explicitly called out.
- Several TEP members noted the importance of Patient & Family Engagement (Domain 6). Another TEP member recommended that it be listed first.
- One TEP member advocated for Leadership (Domain 2) at the top of the list.
- A TEP member noted that they would like to see the word "Learning" added to Domain 3: "Surveillance, Investigation, and Learning." Several TEP members noted that the term "investigation" (Domain 3) can sound threatening; alternative recommendations included "fact finding" or "analysis."
- Several TEP members made some suggestions for combining domains:
    - Some TEP members suggested that Domains 4 and 6 could be combined.
    - Several TEP members agreed that concepts in Domains 3 and 5 are related.
    - One TEP member suggested folding Domain 3 into Domain 4.
    - Two TEP members noted Domain 2 and Domain 4 are dependent on one another and could be combined.
    - One TEP member suggested combining Domain 1 and Domain 7.
    - A TEP member noted that Surveillance & Measurement could just as easily be paired as could Investigation & Improvement.
    - Other TEP members disagreed with combining domains and thought hospitals will be able to see more clearly what they need to focus on with distinct categories.
- TEP members made additional suggestions for the measure:
    - A TEP member would like to see "standardization of care," and two TEP members recommended explicitly stating communication.
    - Several TEP members noted the importance of governance; one TEP member suggested it be explicitly included within at least one statement.
    - Two TEP members noted that culture should be a standalone domain. Another TEP member suggested that culture could be addressed within Domain 3: Surveillance & Investigation.
    - A TEP member noted the impact of traveling physicians/nurses on adverse safety events and suggested reflecting this within these domains.
    - Two TEP members stated the importance of patient safety teams collaborating with other groups including supply chains and other organizational stakeholders.
    - Several TEP members suggested equity must be emphasized throughout the measure. A TEP member suggested making equity its own domain.
    - A TEP member cited the importance of proactivity in terms of mitigating risks, so errors do not occur, suggesting it may belong in Domain 3.
    - One TEP member recommended embedding Social Drivers of Health (SDOH), bias, and discrimination into RCA and Patient Family Advisory

Councils (PFACs) membership criteria to ensure that members are representative of the communities they serve.
    - A TEP member suggested adding workflow and processes of care.
    - Another TEP member call out the synergy between domains.
    - A TEP member proposed the team should consider aligning this measure with the National Action Plan.

Workforce Safety

- Ms. Apton reviewed key considerations about the "Workforce Safety" domain. She noted that there is wide agreement that workforce safety is integral to patient safety. CORE seeks input on whether to consolidate these topics.
- TEP Feedback:
    - TEP members spoke to the importance of workforce safety to patient safety, but there was not consensus on inclusion of workforce safety as a domain in the measure.
    - Several TEP members voiced concern about including workforce safety in a patient safety measure:
        - Several TEP members noted potential dilution of the focus on patient safety and operationalizing patient safety.
        - A TEP member said that including workforce safety in the PSSM likely has more drawbacks than benefits.
    - A TEP member noted potentially untapped synergies, but that there is a downside to not giving workforce safety the focus it deserves.
- Several TEP members suggested that workforce safety may need its own structural and cultural measurement.
- Two TEP members noted that if it is going to take a long time for a standalone workforce safety measure, including workforce safety in this measure would be important.
- A TEP member noted that they do not think workforce safety detracts from patient safety, and that ignoring workforce safety allows the issues to persist.
    - A TEP member stated that there has not been enough attention to workforce safety.
    - A TEP member agreed it should be included as its own domain.
    - Other TEP members thought it was important to include, but not as a stand-alone domain.
- Several TEP members noted the importance of workforce psychological safety for reporting on patient safety.
- Other TEP member comments on workforce safety included:
    - Two TEP members noted the importance of measuring violence, both patient-to-provider and provider-to-provider.
    - A TEP member suggested certain elements of workforce safety are essential to patient safety, including psychological safety and staff burnout.
    - A TEP member commented that workforce equity is part of psychological safety. They suggested equity within patient safety might require a dedicated discussion.

- A TEP member noted it is culturally easier to report a patient behavioral event than direct-to-patient harm, and that organizations need to be pushed toward a culture that reports the hard stuff too.

Second TEP Meeting Overview

Prior to the second TEP meeting, TEP members received meeting materials outlining discussion questions and topics.

The following bullets represent a **high-level summary** of what was presented and discussed during the second TEP meeting. For further details, please see Appendix F.

CORE presented five topics for discussion seeking TEP feedback listed below:

1. "Zero Preventable Harm"
2. Equity
3. Domain 7: Resources, Environment & Technology
4. Key Terms: High-reliability organization (HRO) practices and Just Culture
5. Workforce Safety: Proposed solution and poll question

Zero Preventable Harm

- CORE Presentation of Topic 1: "Zero Preventable Harm" Language
  - CORE noted controversy around stating "zero preventable harm" as the aim for hospitals and asked for further input.
- TEP Feedback:
  - TEP members noted that this language states what many believe is an unattainable goal, which is demoralizing to hospital staff.
  - Other TEP members felt strongly that this should be the aim and should be stated.
  - TEP members suggested framing in terms of "toward the elimination of preventable harm" to retain the aspiration while recognizing it is a process.
  - Another TEP member suggested acknowledging "zero preventable harm" as an aspiration or "state of mind" which is how the World Health Organization uses this phrase.
  - Other TEP members agreed it may be appropriate to provide options to hospitals on how to use this language (e.g., eliminating vs. striving for zero preventable harm).

Equity

- CORE Presentation of Topic 2: Equity
  - CORE acknowledged the importance of appropriately embedding equity into this measure, while not being duplicative of the Hospital Commitment to Health Equity measure and asked if there were additional specific suggestions for incorporating equity.
- TEP Feedback:

    - TEP members expressed an interest in asking hospitals to segment safety culture survey data by social and demographic characteristics.
    - Another TEP member underscored the role of access in achieving equity, and CORE concurred but stated it is out of the purview of this measure to address access to care.

Domain 7: Resources, Environment & Technology

- CORE Presentation of Topic 3: Domain 7: Resources, Environment & Technology
    - CORE outlined challenges of the existing Domain 7, "Resources, Environment and Technology," including the feasibility and specificity of the statements, and proposed integrating key statements into other domains.
- TEP Feedback:
    - TEP members agreed with CORE's proposed solution to remove Domain 7 as a standalone domain and integrate essential statements into other domains.
    - TEP members agreed on the importance of specific technologies, including computerized physician order entry, barcode medication administration, and alarm management.
    - Other suggestions include the importance of addressing data and informatics infrastructure, training, and workflow analyses.

High-Reliability Organization Practices and Just Culture

- CORE Presentation of Topic 4: Key Terms: High-Reliability Organization (HRO) practices and Just Culture
    - CORE noted the importance of including statements that meaningfully assess HRO practices and just culture and asked the TEP for input.
- TEP Feedback:
    - TEP members noted the statements should be specific and reflect key best practices of HROs.
    - TEP members agreed on including statement(s) that demonstrate a "preoccupation with failure," a key principle of HROs.
    - TEP members suggested that CORE leverage existing resources from CMS and National Quality Forum on safety culture assessments.

Workforce Safety

- CORE Presentation of Topic 5: Workforce Safety
    - CORE provided a recap of feedback on workforce safety from the first TEP meeting and the survey, which indicated that this topic is integral to patient safety but also distinct.
    - CORE proposed a solution to omit workforce safety as a discrete domain, and integrate key elements into other domains, as appropriate.
- TEP Feedback:
    - Some TEP members felt it should be included in the measure, while others disagreed. 10/12 TEP members agreed with this solution.

Next Steps

- TEP feedback on the PSSM will inform the final measure specifications. CORE will work with CMS to determine next steps for measure development, including further engagement with the TEP.

Appendix A. CORE Measure Development Team

Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Role
Katie Apton, MPH	Team Lead
Sarah Attanasio, MS, ATC	Project Coordinator
Katie Balestracci, PhD, MSW	Associate Director
Sheila Eckenrode, MA, BSN	Subject Matter Expert
Samantha Mancuso, MPH	Research Support
Kerry McDowell, M.Phil.Ed., M.S.Ed.	Project Manager
Lisa Suter, MD	Contract Director of Quality Measurement Programs
Mariel Thottam, MS, BCBA	Stakeholder Engagement Lead
Roisin Healy, BA	Stakeholder Engagement Coordinator
Rachelle Zribi, BA	Stakeholder Engagement Subject Matter Expert

Appendix B. TEP Call Schedule

TEP Meeting #1

Friday, March 3, 2023 — 12:00–2:00PM EST (Zoom Teleconference)

TEP Meeting #2

Friday, March 17, 2023 – 2:00—4:00PM EST (Zoom Teleconference)

Appendix C. Detailed Summary of TEP Meeting #1

Patient Safety Structural Measure (PSSM) Technical Expert Panel (TEP) Meeting #1 Minutes

Friday, March 3, 2023, 12:00–2:00 PM ET

Participants:

- **Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE):** Katie Apton, Sarah Attanasio, Katie Balestracci, Darinka (Daka) Djordjevic, Sheila Eckenrode, Roisin Healy, Erin Joyce, Stephanie Lambert (X4), Kerry McDowell, Samantha Mancuso, Lisa Suter, Mariel Thottam, Rachelle Zribi-Williams
- **Technical Expert Panel (TEP) Participants:** Susan Attel, Rosie Bartel, Kristin Bryant, Elizabeth (Beth) Daley-Ullem, Melissa (Missy) Danforth, Steven Faust, Thomas (Tom) Gallagher, Tejal Gandhi, Elham Ghonim, Kendra Gustafson, Martin (Marty) Hatlie, Carole Hemmelgarn, John James, Soojin Jun, Stephanie Mercado, MaryBeth Nance, Brett Powell, Edward Seferian, Hardeep Singh
- **Centers for Medicaid & Medicare Services (CMS):** Stephanie Clark, Melissa Hager, Vinitha Meyyur, Michelle Schreiber, Ngozi Uzokwe

Executive Summary

- The purpose of the first TEP meeting was to educate the TEP on the PSSM background and development approach. The TEP was invited to provide input on the proposed measure domains and statements.
- The TEP shared several considerations for the new structural measure, including general feedback about the measure concept, specific feedback on the proposed domains, and input about whether and how to include workforce safety in the measure, as it impacts patient safety.
- TEP members were generally appreciative of the concept of implementing a hospital-based structural measure to advance patient safety but there was not clear consensus about the domains and statements to be included.
- Additional TEP feedback on the proposed measure domains will be collected using a survey; presentation of survey results and additional discussion will occur at the second TEP meeting.

TEP Action Items:

- TEP members were asked to complete the Patient Safety Structural Measure TEP Survey following the meeting; responses submitted by March 8th, 2023, will be used to develop the March 17th, 2023, TEP Meeting #2 agenda.
- TEP members were invited to email safetystructuralmeasure@yale.edu with any additional comments and suggestions.

The materials within this document do not represent final measure specifications for the PSSM.

CORE Action Items:

- CORE will provide TEP members with brief information that they may communicate publicly about this work.
- CORE will send the Patient Safety Structural Measure TEP Survey link to the TEP following the meeting.
- CORE will send the agenda and meeting materials for TEP Meeting #2 by March 15th, 2023.
- CORE will convene TEP Meeting #2 on March 17th, 2023.
- CORE will distribute meeting summaries for TEP Meeting #1 and TEP Meeting #2, for TEP review, following the second TEP meeting.
- CORE will provide a TEP Debrief Survey following the second TEP meeting to allow TEP members to provide feedback on their experiences during both TEP meetings.

Detailed Discussion Summary

Welcome & Introductions

- Ms. Mariel Thottam welcomed the TEP members and reminded them of the confidentiality of today's discussion.
- Dr. Katie Balestracci welcomed the meeting participants and provided background information about the project objective and the TEP composition. She introduced Dr. Michelle Schreiber, the Deputy Director of the Center for Clinical Standards and Quality (CCSQ) and Director of the Quality Measurement and Value-Based Incentives Group (QMVIG) at CMS, as well as a primary physician with over 25 years of clinical experience.
- Dr. Schreiber noted CMS's commitment to including patient-safety advocates, patients, caregivers, and provider experts as is reflected in this TEP's composition and discussed the objective of the TEP, which is to develop a hospital-based structural measure for patient safety, to drive action and improvement in patient safety, and advance hospital progress toward zero preventable harm. She suggested in addition to a Patient Safety Structural Measure (PSSM), that there is also a need to ensure the quality infrastructure to support patient safety is in place.
- In developing the new PSSM, the TEP has an opportunity to create the measure based on what they think is important, and while there is no limit to the number of elements, a measure with too many elements is likely to receive pushback due to reporting burden; she recommended including evidence-based elements and balancing the burden, while ensuring the patient voice is reflected.
- There are many elements that might be considered for the measures, including communication and resolution programs; data that are collected; and voluntary reporting to the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Organization (PSO) program and the Network of Patient Safety Databases.
- CORE has done research to identify potential elements and the TEP will have opportunities to comment on and shape the measure. Patient safety is a fundamental

issue in healthcare. We can't have quality or equity without safety, and we do not want a system that is equitably unsafe.

- The concept of patient safety, including zero preventable harm, is likely to be advanced by the President's Council of Advisors on Science and Technology (PCAST), and we do not yet know what their recommendations will be. This topic is prominent within the CMS Quality Strategy, as well.
- Ms. Thottam reviewed the meeting agenda and reviewed CMS funding of this work. She reviewed the goal for the TEP, to solicit insight and suggestions to ensure development of a PSSM that is representative of and responsive to multiple perspectives (patients, caregivers, families, hospitals, clinicians, researchers, and other experts), and drives evidence-based action and improvement in patient safety to advance progress toward zero preventable harm.
- Ms. Thottam facilitated the introduction of TEP members, requesting TEP members state their name, affiliation, and role (including affiliation updates); conflicts of interest; and their reason for participating in this work. She reminded participants that TEP members represent themselves and not their nominating organizations.
- In the meeting chat, Dr. Schreiber welcomed the TEP members on behalf of CMS and thanked them for sharing their personal stories and for their contributions to this TEP.

Review and Approval of TEP Charter

- Ms. Thottam reviewed the TEP Charter; TEP members reported no concerns and the TEP Charter was unanimously approved.
- A TEP Member asked if there is a script/paragraph TEP members can use if they are asked about the TEP. They have received questions from the press.
- **Action item:** CORE will provide TEP members with brief information that they may communicate publicly about this work.
- Ms. Thottam reviewed the ground rules for the discussion.

Measure Background & Status

- Ms. Katie Apton described CORE's approach to this structural measure. She noted that CORE:
    - Used AHRQ's definition: structural measures give consumers a sense of a healthcare provider's capacity, systems, and processes to provide high-quality of care.
    - Grounded their approach to the development of the PSSM in a framework for Monitoring Patient Safety Model (Berenholtz S. and Pronovost P.) which includes Outcomes, Process, Structure, and Culture (leadership, attitudes, beliefs). CORE views the PSSM as a hybrid assessment of structure and culture.
    - Developed a conceptual (logic) model that illustrates how adoption of a PSSM measure is theorized to lead to better outcomes.
    - Conducted an Environmental Scan and Literature Review (ES/LR), cataloguing existing assessment items and recommendations, drafting of initial measure specifications, and engaging stakeholder input.
- Ms. Apton reviewed the PSSM development timeline.

- Ms. Apton noted the guiding principles for development of the PSSM, including:
    - Comprehensive, but parsimonious;
    - Explicit;
    - High standards;
    - Evidence-based;
    - Equity embedded throughout; and
    - Patient-centered.
- A TEP Member suggested adding clear examples of how hospitals can accomplish each item to the guiding principles; they noted structural measures are criticized as being so broad hospitals can always say "yes" and examples of what is necessary to meet each element would be helpful.

Key Questions & Discussion
Measure Domains

- There were facilitated discussions in each breakout room to discuss the eight recommended domains:
    - Domain 1: Strategic Planning & Organizational Policy
    - Domain 2: Leadership Commitment to Eliminating Preventable Harm
    - Domain 3: Surveillance & Investigation
    - Domain 4: Accountability & Transparency
    - Domain 5: Measuring & Improving Performance
    - Domain 6: Patient & Family Engagement
    - Domain 7: Resources, Environment & Technology
    - Domain 8: Workforce Safety
- The same three questions were posed to the TEP participants in each room:
    - Do the domains (i.e., 8 categories) capture the most important elements for advancing patient safety?
    - Are there gaps in the domains?
    - Do you think any of the domains are more or less important than others?

Question 1: Do the domains capture the most important elements for advancing patient safety? Are there gaps in the domains?

- A TEP member highlighted the importance of Accountability & Transparency (Domain 4) and Patient & Family Engagement (Domain 6). They drive the others and the more the outside is looking in, the more leadership steps up and their strategies and measurement improve.
- A TEP member would like to see the word "Learning" added to Domain 3: "Surveillance, Investigation, and Learning."
- A TEP member would like to see "standardization of care" and "communication" included and noted the importance of this for academic healthcare facilities.
- A TEP member agreed with Dr. Schreiber's statement regarding equity and to be safe we also need to be equitable. It is hard to achieve safety without some fundamental competency and support systems in the quality infrastructure. Mentioning quality is important.

- A TEP member noted what is listed first is considered most important and recommended listing Patient & Family Engagement (Domain 6) first as it is the most important.
- A TEP member agreed about emphasizing quality, and suggested quality improvement (QI) is part of Accountability but may need to be explicitly called out. It all comes back to QI, and how it is handled by healthcare organizations is important. Transparency is sometimes left out. Patients are not invited in for QI, but patients need to be at the table for the QI work.
- A TEP member stated that they think the domains look good and capture the main areas.
- A TEP member was struck that governance was not explicitly mentioned, although it is referenced under Leadership and is part of Accountability, and Patient & Family Care. While they liked that it is threaded throughout, they suggested that it be included explicitly within at least one of the statements.
- A TEP member reiterated that communication is important and recommended explicitly stating communication.
- Ms. Thottam stated she heard a general theme around transparency, communication, and patient engagement.
- Ms. Apton noted she heard that Patient & Family Engagement should move to the top, and the measure could be more explicit about concepts including Communication, Learning, and Quality.
- A TEP member suggested that culture could be addressed within Domain 3: Surveillance & Investigation.
- A TEP member noted that they are a member of inpatient quality and safety committees, and they were struck by the impact of traveling physicians/nurses on adverse safety events. The TEP member noted this to be an ongoing issue and would like to see this reflected within these domains.
- A TEP member stated the importance of patient safety teams collaborating with other groups including supply chains and other organizational stakeholders.
- Two TEP members noted that culture should be a standalone domain as it adds value to a patient safety program. It is a key element to making sure other embedded processes occur.
- A TEP member agreed about the importance of collaboration; for most facilities, the core patient safety team is small and must have robust connections that identify opportunities at all levels of the organization.
- A TEP member agreed with the importance of culture and suggested that Domain 8: Workforce Safety and Engagement could be combined. They emphasized leadership commitment and they observed there isn't a statement about governance, which is an important component. Like equity, it may be reflected throughout the other domains. They asked why this measure only discusses hospitals.
- Dr. Balestracci responded CORE specified hospitals because this measure is targeted for the Inpatient Quality Reporting (IQR) Program, which is hospital specific.

- A TEP member suggested making equity its own domain, or that it must be specifically called out because equity is not always at the top of everyone's mind.
- In the meeting chat, a TEP member suggested also considering how this intersects with the health equity structural measure that already exists.
- Dr. Balestracci requested clarification if they were recommending equity as a standalone domain.
- A TEP member suggested equity must be hard-wired throughout.
- A TEP member agreed that equity is currently not called out enough. Equity is like patient safety in that it is currently part of everyone's job, and it does not get enough emphasis.
- A TEP member asked other TEP members to define what they mean when they say equity, to clarify the concept.
- A TEP member responded they think about it through the Institutes of Medicine (IOM) and AHRQ lens of safe, timely, effective, efficient, equitable, and patient-centered care with an emphasis on individualism and catering care to the individual patient's needs.
- A TEP member cited the importance of the concept of proactivity in terms of mitigating risks, so errors do not occur. This may belong in Domain 3 and could push the field in the right direction; clear areas in safety, segmentation of reporting and culture of safety work (safety culture, root cause analysis [RCA], patient family engagement). They recommended embedding Social Drivers of Health (SDOH), bias, and discrimination into RCA and Patient Family Advisory Councils (PFACs) membership criteria to ensure that members are representative of the communities they serve. It is a "both and" situation where the CORE team must embed equity in each domain, so it does not just get relegated to the Equity team.
- Another TEP member appreciated this callout and noted this is where the "process" is very important (to make sure the process is proactive and not reactive).
- Dr. Balestracci noted she heard the importance of having equity embedded throughout, but also explicitly stated so it cannot be ignored or devalued.

Question 2: Do you think any of the domains are more or less important than others?

- A TEP member thought the proposed domains all complemented one another.
- A TEP member noted they had some difficulty with the concept of combining patient safety and workforce safety; workforce safety impacts patient safety but might not align well with the other domains and could be difficult to incorporate.
- Dr. Schreiber asked about the number of domains and wondered if eight domains seemed appropriate; it is more domains than are included in the other structural measures and she wondered if we should anticipate pushback on burden due to the number of domains.
- A TEP member noted support of the overarching importance of Domains 4 and 6; these are foundational to the other domains. They agreed with Dr. Schreiber we may be able to collapse some of the domains to a smaller number.

- A TEP member agreed that leadership is important but hard to capture. Eight domains would likely be overwhelming and combining or streamlining to support workflows would make sense for hospitals.
- A TEP member noted that they do not favor collapsing the domains and thought hospitals not achieving all elements will be able to see more clearly what they need to focus on with more distinct categories; the domains may help catalyze improvement (more like a check list). Based on the broad descriptions, hospitals will think they are already doing these things.
- A TEP member sees the affinity between Domains 4 and 6, and between Domains 3 and 5. If we collapse to a smaller number of domains, each will have more statements. They agreed it may be helpful to keep more domains to increase the level of discernment.
- A TEP member noted for Domains 3 and 5 that these concepts are intertwined. Surveillance leads to investigation which leads to improvement. Surveillance & Measurement could just as easily be paired as could Investigation & Improvement. For Workforce Safety, they asked if we are including psychological safety or workforce violence. It is up to leadership to provide transparency with respect to patient safety, but it is less clear for the workforce aspect.
- In the meeting chat, a TEP member noted Domains 3 and 5 are all part of QI.
- Ms. Apton noted CORE started with 5 domains and it increased to 8. Domains 3 and 5 have been noted as ones that could collapse. When you look at statements for Domain 3, they focus on learning and awareness of safety events whereas Domain 5 is more about QI. Domains 3, 4, and 5 were originally a single domain with ten statements; once we figure out the statements to include it may be easier to collapse them.
- A TEP member asked what conceptual model/framework was used to guide this work. They often have used a socio-technical model for patient safety work with eight dimensions.
- Ms. Apton noted CORE did not use an academic model. During the ES/LR, CORE took stock of recommendations such as the Institute for Healthcare Improvement (IHI) National Patient Safety Action Plan, which includes a self-assessment for hospitals, and then compiled evidence-based practices to inform these domains.
- The same TEP member suggested adding workflow and processes of care.
- Ms. Apton suggested workflow and processes may fall within Domain 5: Measuring & Improving Performance.
- In the meeting chat, a TEP member provided the socio-technical model they used for Patient Safety that has emphasis on technology, A New Socio-technical Model for Studying Health Information Technology in Complex Adaptive Healthcare Systems (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3120130/). They noted several domains are overlapping and workflow and processes may not be reflected. They used this model to develop Office of the National Coordinator SAFER Guides which CMS endorsed as a structural measure recently.
- A TEP member noted these domains map to the National Steering Committee that IHI and AHRQ co-chair as well as the World Health Organization (WHO) Global Patient Safety Action Plan (resources, technology, and research).

- A TEP member asked about the assessment referenced in Domain 1, item 5 and whether it is referencing programmatic assessment or individual assessment (competency, knowledge, etc.).
- Ms. Apton clarified that this measure relates to individual assessment and CORE might consider adding clarifying language.
- Another TEP member commented that the last domain in the WHO framework is Synergy, which acknowledges these items do not stay in their own lanes and interact. It may be helpful to call this out within the new PSSM measure.
- Ms. Apton noted CORE could call out the interdependency among the domains.
- Dr. Balestracci noted concerns that eight domains is a lot and through this work with the TEP the CORE team is trying to determine which elements are most essential to a PSSM; the team may need to make choices to reduce burden. She encouraged participants to provide feedback on the individual statements via the survey following the call.
- A TEP Member noted Domain 2 (Leadership) and Domain 4 (Accountability) are dependent on one another and could be combined. They noted that these are the most important domains.
- A TEP member stated that Domain 4 (Accountability & Transparency) is the most important domain; they have personal experience with that not happening and observed it is still not happening. The statements might include implementation of *just culture* where it is not happening yet to ensure fair change (is it a personnel/medical provider insufficiency or a process insufficiency).
- A TEP member stated that Domains 2 and 4 are interconnected, with Domain 1 tying in as well. They noted that leadership is paramount in this and added that the National Action Plan for Patient Safety has four domains. They proposed the team should consider aligning this measure with the National Action Plan.
- In the meeting chat, another TEP member agreed that the term "leadership" is broad and that there are merits to adding governance.
- A TEP member stated the importance that this measure does not become a "well, we do this, and this fits into that." The measure needs to invoke behavior change and inspire providers to do better and if they are doing well to teach others (a stretch goal). Eight domains are a lot; they suggested specifying the weighing process. Domain 2 is a key driver to ensuring accountability. Transparency stands out as intrinsically wrapped in so the other domains can flow. Integration of patient safety silos and some kind of weighting or prioritization may be helpful.
- A TEP member noted you can do well on a domain but are deficient elsewhere (e.g., a great strategic plan and not a great culture). They like the idea of collapsing the domains and making them of equal weight.
- In the meeting chat, a TEP member supported the idea of combining some domains; they also advocated for moving Leadership (Domain 2) to the top of the list because a safety culture cannot exist without a strong and involved leadership.
- In the meeting chat, a TEP member agreed that transparency is fundamental — if you don't have that foundation of defining, tracking, and reporting harm, the entire system

and all the domains fail. Even if you have good culture scores, you really must look at whether harms are being reported. For example, if you have great culture scores but you only have 40% of your serious claims that have been reported within 24 hours in your event reporting system, there is a problem.

- A TEP member asked if this measure captures just the duration of the stay or also captures harm following discharge. They also asked if it includes errors of omission, such as in the case of smoking cessation.
- Dr. Balestracci stated that this type of measure aims to address overall structure, culture, and process, and will not measure episode-level events during or following a hospitalization, but measure whether hospitals have a structure in place to capture events.
- A TEP member noted in the meeting chat that they think Domain 3 will sound threatening — they suggested it be folded into Domain 4, and folding Domains 1 and 7 together. They commented that too often leadership says that 'safety does not pay or penalize' so the commitment to safety is variable.
- Another TEP member agreed that the term "investigation" can sound threatening. They recommended the team use the term "fact finding."
- Another TEP member recommended "Analysis" as an alternative to "Investigation."
- CORE facilitators provided high-level summarization of concepts discussed in each breakout room:
    - Ms. Thottam indicated the notes from both breakout sessions will be included in the minutes distributed following the second TEP meeting. The general feedback from room one focused on Domains 4 and 6 and included the value of keeping the eight domains.
    - Ms. Healy noted for room two, there was a lot of conversation about inclusion of equity, as its own domain or be proactive with it to ensure it is not lost in the background. Culture was also a big discussion, and a topic that may merit its own domain. Transparency & Leadership was considered a driving factor for accountability and knowing where harm is happening in facilities. There was conversation about condensing or collapsing domains and giving each domain equal weight.

Discussion 2— Workforce Safety

- Ms. Apton reviewed key considerations about the Workforce Safety domain, which addresses both physical and emotional harm to hospital staff. This could include psychological safety, environmental hazards, violence, and injury among other risks.
- She noted that there is wide agreement that workforce safety is integral to patient safety.
- CORE wants to know from the TEP members whether consolidating these topics allows proper emphasis on both topics.
- Ms. Apton noted the discussion question for this session:
    - What are the benefits and drawbacks to including the Workforce Safety Domain?

- Ms. Thottam asked if TEP members had any questions about what we mean by workforce safety.
- A TEP member noted emotional and psychological safety are paramount to a well-functioning patient safety system. They noted concerns about blurring the lines between patient safety and employee health/injury; it could dilute the focus on patient safety and operationalizing patient safety. They noted wanting it included within these measures, but encouraged the group to figure out how we can avoid the employee health space.
- A TEP member noted concerns about detracting from patient safety and thought it might be two separate things.
- A TEP member indicated ambivalence about this but thought if the workforce is not safe, patients could not be safe. There may be different approaches to address patient safety and workforce safety. Workforce safety may need its own structural and cultural measurement.
- A TEP member suggested awareness of workforce safety was valid but suggested there could be a danger of conflating the two. They noted that one informs the other, but they are also distinct and that separate conversations may give both topics their full merit.
- A TEP member noted concern about dilution of the concept. They are working on pediatric patient safety where this is a challenge. How much weight is given to it is important and they liked the idea of including psychological safety for reporting but suggests avoiding inclusion of employee benefits and noted that it is hard to know where to draw the line. They noted that employees need to be willing to step forward and report situations where harm occurs.
- A TEP member said that including workforce safety in the PSSM likely has more drawbacks than benefits.
- A TEP member noted similar discussions in his work on a hospital-level safety board; if the workforce is not safe, then hospitals cannot ensure patients will be safe, and severe errors that caused patient harm happened because the environment was not safe, and staff did not back each other up. They do not think workforce safety detracts from patient safety. Ignoring workforce safety allows the issues to persist.
- A TEP member thought it was beneficial to bring attention to workforce safety and the processes for patient safety could be applied more effectively to workplace harm events (e.g., innovative investigation strategies). They noted that there are potentially untapped synergies. However, there is a downside to not giving workforce safety the focus it deserves. This member noting leaning towards leaving it out if there is a standalone measure for workforce safety.
- A TEP member agrees with TEP members who advocate workforce safety. There has not been enough attention to workforce safety, this issue does not have the same tools for addressing the problem, and it is not given the same emphasis. It was very consciously included in the National Patient Safety Plan. If there were similar, parallel measures, the TEP member would support that; otherwise, excluding it leaves a big gap.

- A TEP member suggested the need for workforce psychological safety to be able to report patient safety. The second part around violence is also important and there is overlap between patients and providers. Violence can be patient-to-provider and provider-to-provider, and there needs to be an action plan for violence and this is new. They noted there is a measure in place to address violence through regulation.
- A TEP member noted some kind of structural measure of workforce safety is needed. The issue cannot be sufficiently addressed using only a clinical lens. Operationally, public safety and security needs are put in place for this, such as adopting *just culture* principles and using RCA. This needs to be driven from the enterprise-wide foundation of culture and procedures.
- A TEP member noted that they are separate domains that overlap. They noted that the sweet spot is psychological safety so staff can speak up regarding safety. Violence in hospitals is a concern for both staff and patients. They thought a separate structural measure for workforce safety makes the most sense.
- A TEP member is concerned workforce safety is included, it might rise to the top and overshadow achievement of patient safety.
- Another TEP member noted agreement with this concern about overshadowing patient safety.
- A TEP member agreed it should be included while recognizing there is more to worker safety than what is included for patient safety. It should be in here as its own domain.
- In the meeting chat, a TEP member noted accountability and transparency is what is most important. If the workforce is not safe to report on patient safety, it is a problem and there is a threatening environment among facility staff. There are many workers that use reporting as a threat. The TEP member thinks it makes sense to include it, but maybe not as a standalone domain. They wondered if workforce safety can be part of a culture/psychological safety domain.
- A TEP member suggested this will be tough to sort out with conflicting opinions that all have merit. They align with feedback that it is synergistic, but separate and distinct. They would like to see psychological safety and culture of safety included.
- A TEP member noted appreciation for the discussion with differing opinions. They noted a link between physical workforce safety and patient safety, giving an example of a nurse worried about a back injury that might keep them from turning into a patient and result in a pressure injury, which is a patient safety issue. They can see the distinct link between physical workforce safety (in addition to psychological safety). They can see it as a standalone domain in this space and suggested it would be beneficial to see the direct link between workforce safety and patient safety.
- In the meeting chat, another TEP member agreed and noted one of the goals of this metric will be to increase public reporting by hospitals. They anticipate it would be helpful to researchers, measurement folks, and the public to see the organizations that are effectively addressing worker safety together with patient safety.
- In the meeting chat, another TEP member noted there is currently significant under-reporting of workforce violence as well as patient safety issues.

- A TEP member supported including workforce safety in some way but perhaps not as a separate domain. Workplace violence and uncivil behavior has increased and leads to burnout in the industry and less engaged employees. They also noted the impact of patient behavioral events (PBEs) on safety. Staff that are less engaged score lower on the AHRQ Patient Safety Culture survey. The link to patient safety might belong in a new culture domain. They can also see development of a structural measure specific to workplace issues including violence as being of benefit.
- In the meeting chat, another TEP member suggested there is national data that shows a very tight correlation between overall engagement and safety culture.
- A TEP member suggested certain elements of workforce safety essential to patient safety, including psychological safety and staff burnout. They noted that it is difficult to engage a burned-out workforce in system change. If workforce safety is not included as its own domain, they would like to see at least one statement to address it. It would be a glaring oversight to omit it entirely. A recent WHO report on patient safety and COVID-19 included it as a standalone section. They provided a link in the meeting chat to the WHO Report titled Implications of the COVID-19 Pandemic for Patient Safety: A Rapid Review https://www.who.int/publications/i/item/9789240055094
- A TEP member noted it is culturally easier to report a patient behavioral event than direct-to-patient harm (e.g., easier to report that a patient attacked you rather than that you gave the wrong medication). Organizations need to be pushed toward a culture that reports the hard stuff too. It is a leadership challenge to close that gap. If you are first hearing of an issue when you receive a claim, it is problematic.
- A TEP member agreed that reporting needs to occur on both physical and psychological safety of staff; and both are likely under-reported. They reinforced that physical harm can also lead to patient safety issues.
- A TEP member noted that they are undecided on this issue following an experience as a witness to a patient pulling a gun at a provider because they wanted opioid medication. They noted that the clinic did not have a good plan to get the other patients to safety and noted personally experienced emotional harm because of this violent event. They stated that all safety issues are under-reported. They noted that if it is going to take a long time to get to a standalone workforce safety measure, they suggested including workforce safety in this measure and not waiting.
- A TEP member noted the PSSM has two uses. The measure is a signal to hospitals about what they need to do to reduce patient harm and an opportunity for patients to understand the concept of patient safety better through public reporting. There is no clarity among patients about this concept and the main risks to patients need to be clarified. They noted that including workforce safety likely detracts from the main risks of errors, accidents, incidents.
- A TEP member commented that the group had not talked very much about equity. They hear from PFACs, they are seeing issues play out (i.e., a transgender employee being mistreated by other employees), and that is part of the psychological safety. They suggested equity within patient safety might require a dedicated discussion.

- Ms. Apton thanked the group for sharing their perspectives. She noted that although there is not clear consensus, this discussion helps with understanding the issues better. CORE cannot speak to how long it might take to address a separate workforce safety measure. Even though CORE plans to focus on the survey results, the team might also consider further discussion of this topic during the second TEP meeting.

Wrap Up & Next Steps

- On behalf of CORE, Ms. Thottam thanked the group for their time and valuable feedback. She noted that continued feedback was welcomed, and she encouraged TEP members to send email with additional input at any time to safetystructuralmeasure@yale.edu.
- Ms. Thottam noted TEP members will receive a survey link today following the meeting and encouraged them to respond by Wednesday, March 8th. Results of this survey will be the primary topic of the second TEP meeting that is scheduled for March 17th.
- Dr. Balestracci thanked participants for a great discussion. She clarified that the measure specifications as provided in the survey will not reflect today's discussion.
- Materials for the March 17th TEP meeting, including the planned discussion questions, will be provided on or before March 15th to allow TEP members to review it prior to the meeting.
- A meeting summary will be provided following the second TEP meeting, along with a debrief survey for TEP members to provide feedback on their experiences during both TEP meetings.

Appendix D. Patient Safety Structural Measure TEP Survey Tool

Enclosed in this survey are the draft specifications for the Patient Safety Structural Measure. These are the same draft specifications that were included in the background packet in preparation for the first TEP meeting on March 3rd. At this stage of measure development, we are focused on ensuring the most salient concepts are captured, and non-essential statements are omitted. Please complete your response by March 8th. We will synthesize your feedback and identify key issues for discussion at the second TEP meeting on March 17th.

Please note: Italicized text embedded in the survey questions denotes the need for further definition and refinement, or in some cases, specific considerations and questions. We welcome your input on these topics.

As you review, please keep in mind our 6 guiding principles:

- The measure domains and statements will be comprehensive, but parsimonious. That is, reserved for all of the most important protocols and practices.
- The specifications will be as explicit as possible so as not to be left open to interpretation.
- The measure will uphold high standards.
- The measure statements will be evidence-based and if not, guided by experts. Equity will be embedded throughout.
- The measure domains and statements will be meaningful to patients.

Thank you for your time, guidance, and insights! We are looking forward to hearing your feedback.

* 1. Please provide First and Last Name (required response)

Domain 1: Strategic Planning & Organizational Policy

A. Our hospital has a strategic plan stating specific safety goals and associated metrics.
B. Our hospital safety goals include metrics assessing disparities in safety outcomes based on social and demographic characteristics.
C. Our hospital strategic plan specifies a “zero harm” goal.
D. Our hospital has a written policy describing protocols to cultivate a just culture. [Per AHRQ, a just culture recognizes that individual practitioners should not be held accountable for system failings over which they have no control. However, in contrast to a culture that touts “no blame” as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).]
E. Our hospital’s human resources strategy requires patient safety curriculum and competencies for all hospital staff, including hospital leaders; regular

assessments of these competencies for all roles; and action plans for continuing education. [Hospital leaders refers to "c-suite" executives, board members, and trustees unless otherwise noted.]

F. Our hospital has a written policy on responding to unexpected patient safety events, including at a minimum, protocols for investigation (i.e., root cause analysis), and disclosure and apology to patients.

2. Do items in this domain capture the intent of the domain? (Yes/No)

3. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

4. Are any key concepts missing? (Yes/No)

5. If yes, please describe the key concepts that are missing.

6. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 2: Leadership Commitment to Eliminating Preventable Harm

A. Job descriptions for hospital leaders specify responsibility for patient safety.
B. One or more "c-suite" level leaders oversee execution of patient safety initiatives with specific metrics, and report outcomes to staff and patients.
C. Hospital performance on patient safety metrics inform annual performance reviews and compensation for hospital leaders.
D. Reporting on patient safety events, root cause analysis, infection outbreak, and other patient safety topics account for at least 20% of all leadership and board agendas.
E. Our hospital leaders participate in investigations of patient safety events including root cause analysis.

7. Do items in this domain capture the intent of the domain? (Yes/No)

8. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

9. Are any key concepts missing? (Yes/No)

10 If yes, please describe the key concepts that are missing.

11. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 3: Surveillance and Investigation

A. Our hospital conducts a culture of safety survey once a year using a validated instrument, and results are shared with the board and all hospital staff.

B. Our hospital has an anonymous reporting system that allows hospital staff, patients, and families to report patient safety events, unsafe conditions, and other concerns. [auditing or peer review component?]
C. All harm events and near misses are reported to the CEO and Board Chair immediately, and cases resulting in significant morbidity or mortality are reviewed [and evaluated?] within 24 hours.
D. Our hospital has internal and external notification protocols for reporting near misses, harm events, infection outbreaks, and unsafe conditions.
E. After a patient safety event, our hospital has a dedicated team that conducts root cause analysis using an evidence-based approach, such as the National Patient Safety Foundation's Root Cause Analysis and Action (RCA2). [auditing or peer review component?]

12. Do items in this domain capture the intent of the domain? (Yes/No)

13. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

14. Are any key concepts missing? (Yes/No)

15. If yes, please describe the key concepts that are missing.

16. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 4: Accountability and Transparency

A. Our hospital's safety goals are explicitly and publicly stated to hospital staff and patients.
B. All claims of harm events and unsafe conditions, and status of investigation, are reported at every board meeting.
C. Our hospital publicly reports on serious reportable events (i.e., "never events," e.g., surgery on wrong body part or patient) quarterly to [local, state, federal departments of health. Determine what standard is/should be for reporting].
D. Our hospital uses a core set of patient safety metrics that are tracked and reported to all staff and patients.
E. Our hospital makes a communication and resolution program, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit, available to all patients involved in safety events.
F. Patients and families are not prohibited from sharing information on safety events as a condition for disclosure or in exchange for compensation for the harm.

17. Do items in this domain capture the intent of the domain? (Yes/No)

18. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

19. Are any key concepts missing? (Yes/No)

20. If yes, please describe the key concepts that are missing.

21. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 5: Measuring & Improving Performance

A. Our hospital uses a systematic, evidence-based process improvement approach grounded in high reliability science, such as Lean, Six Sigma, or Change Management.
B. Our hospital uses data on care safety and quality to implement performance improvement initiatives that target specific types of harm.
C. Our hospital patient safety manager and Patient and Family Advisory Council participate in local, regional, or national learning network(s) (i.e., quality improvement initiatives organized by patient safety organizations, state associations, and other organizations) focused on patient safety, and we share data on safety events and outcomes with these network(s).
D. Our hospital stratifies all adverse event data by social and demographic variables such as race, ethnicity, sexual orientation, gender, age, disability status, and income, to identify disparities in harm events and advance equity in care and outcomes.

22. Do items in this domain capture the intent of the domain? (Yes/No)

23 If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

24. Are any key concepts missing? (Yes/No)

25. If yes, please describe the key concepts that are missing.

26. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 6: Patient & Family Engagement

A. Our hospital has a Patient and Family Advisory Council that ensures patient/family/caregiver/community representation in safety-related activities, including regular attendance at board meetings, safety goal-setting, and participation in patient safety committees and initiatives.
B. Our hospital's Patient and Family Advisory Council includes patients and caregivers of patients who have directly experienced a safety event.
C. All claims of harm events and unsafe conditions, and status of investigation, are reported to the Patient and Family Advisory Council.
D. Patients have full and immediate access to medical records and clinician notes via patient portals and other options such as OpenNotes. [CMS Condition of Participation for hospitals says, "within reasonable timeframe." May not be needed here.]

E. Huddles and shift changes are always completed at the patient bedside when practical and appropriate (e.g., in accordance with privacy laws, not for patients who are immunocompromised). [Refine further. More language about transitions of care, broadly?]
F. Our hospital has an open visitation policy. [Implicit, but not defined in CMS Condition of Participation for hospitals. May not be needed here]

27. Do items in this domain capture the intent of the domain? (Yes/No)

28. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

29. Are any key concepts missing? (Yes/No)

30. If yes, please describe the key concepts that are missing.

31. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Domain 7: Resources, Environment & Technology

A. Our hospital invests in technologies to promote safety (e.g., barcode medication administration solutions, Barcoding diagnostics, five-letter drug entry for medication search and selection, EHR alerts). [Instead specify technologies required to satisfy this statement?]
B. Our hospital has at least one full-time Patient Safety Manager who reports to a director or other senior leader.
C. Our hospital has at least one full-time infection preventionist.
D. Our hospital has a surveillance system to prevent and control infection outbreaks, which includes documenting transmissible pathogens in patient electronic health records.
E. Our hospital conducts weekly air and water quality assessments. [Life Safety Code requirements and/or NFP99 or 100, so may not be needed in this measure; further research and refine]
F. Environmental cleaning – ratio, scheduling, frequency. [further research and refine]
G. Nurse-to-patient ratio. [varying guidance and requirements based on setting, patient acuity e.g., ICU vs. ED. Discuss further]

32. Do items in this domain capture the intent of the domain? (Yes/No)

33. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

34. Are any key concepts missing? (Yes/No)

35. If yes, please describe the key concepts that are missing.

36. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Please note, Workforce Safety can be a discrete domain, or integrated in the other domains. If it were integrated, we made a note of an alternative domain in the list below.

Domain 8: Workplace Safety

A. Our hospital has an explicit workforce safety strategy with metrics and goals.
B. (Domain 1: Strategic Plan and Organizational Policy)
C. Our hospital has an action plan for workforce safety and includes activities for: slips/trips/falls prevention; safe patient handling; exposures; sharp injuries; violence prevention; and psychological safety. (Domain 1: Strategic Plan and Organizational Policy)
D. Our hospital employs an occupational safety expert to advise and control job hazards across all levels of the organization. (Domain 7: Resources & Technology)
E. Our hospital is in regular communication with staff about workforce safety hazards including reporting incident rates, safety stories, and activities to improve safety. (Domain 3: Surveillance & Investigation)

37. Do items in this domain capture the intent of the domain? (Yes/No)

38. If we need to eliminate statements to shorten the survey, what if any statements could be eliminated in this domain and why?

39. Are any key concepts missing? (Yes/No)

40. If yes, please describe the key concepts that are missing.

41. Provide additional input here, including any feedback on questions or considerations in italicized text, where that applies.

Thank you for sharing your input. CORE looks forward to further discussion during our next TEP meeting.

Appendix E. Patient Safety Structural Measure TEP Survey Results

Following the first TEP meeting, CORE surveyed the TEP members to collect feedback on the proposed PSSM domains and statements. Results of this survey were used by CORE to identify key issues and discussion topics for the second TEP meeting.

The survey was launched on Friday, March 3, 2023, and closed at 5:00 PM on Wednesday, March 22, 2023. CORE distributed the survey link in an email to the nineteen PSSM TEP members immediately following the first meeting of the TEP, requesting responses by close of business Wednesday, March 8, 2023. CORE elected to keep the survey open until March 22, 2023, to allow for additional responses by TEP members leading up to and following the second TEP meeting. Interim survey results were used to inform the second TEP meeting agenda.

Nineteen of nineteen (100%) of the TEP members responded to the survey. A high-level summary of the survey results is included below.

For Domain 1: Strategic Planning & Organizational Policy:

- Consider removing B, C, and E
- Consider combining:
    - A and B
    - D and E
    - D, E, and F
- Additional concepts to consider include DEI, Board engagement and oversight, and multi-disciplinary partnerships

For Domain 2: Leadership Commitment to Eliminating Preventable Harm:

- Consider removing D and E
- Additional concepts to consider include leader huddles/rounding, reporting to patients/families, and psychological safety

For Domain 3: Surveillance and Investigation:

- Consider removing E
- Consider combining B and D
- Additional concepts to consider include use data for concrete action, embed equity, anonymous/confidential reporting and protection of reporters, patient and family reporting and representation, annual audit, focus on infrastructure

For Domain 4: Accountability and Transparency:

- Consider removing: A, C, and D
- Consider combining:
    - B and D
    - C and D
    - E and F
- Additional concepts to consider include outside audit, leadership and board accountability, include safety incidents in death reporting, reporting transparency, and patient & family representation

For Domain 5: Measuring & Improving Performance:

- Consider removing C and D
- Consider combining B and D
- Additional concepts to consider include participation in existing initiatives, industry alignment of requirements like survey frequency, external benchmarking, require EHR data collection, patient & family representation, and training and implementation methods

For Domain 6: Patient & Family Engagement:

- Consider removing C, D, E, and F
- Consider combining D, E, and F
- Additional concepts to consider include equity and inclusion, align with CANDOR, pharmacist engagement, event response team, family present policy, and resident and attending physician miscommunication

For Domain 7: Resources, Environment & Technology:

- Consider removing A, B, C, E, F, and G
- Consider combining B and C
- Additional concepts to consider include train personnel on sociodemographic and SDOH data, professional certification, hygiene/PPE, and pharmacist engagement

For Domain 8: Workplace Safety:

- Consider removing A, C, and D
- Additional concepts to consider include DEI, leadership performance incentives, wellness, mental health and burnout, metrics/reporting that includes costs, direct link to patient safety, culture of safety, and protection from retaliation and harassment

Appendix F. Detailed Summary of TEP Meeting #2

Patient Safety Structural Measure (PSSM) Technical Expert Panel (TEP) Meeting #2

Friday, March 17, 2023, 2:00 PM – 4:00 PM EST

Participants:

- **Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE**): Katie Apton, Sarah Attanasio, Katie Balestracci, Darinka (Daka) Djordjevic, Sheila Eckenrode, Roisin Healy, Kerry McDowell, Samantha Mancuso, Lisa Suter, Mariel Thottam, Rachelle Zribi-Williams
- **Technical Expert Panel (TEP) Participants:** Susan Attel, Rosie Bartel, Elizabeth (Beth) Daley-Ullem, Melissa (Missy) Danforth, Steven Faust, Thomas (Tom) Gallagher, Tejal Gandhi, Elham Ghonim, Kendra Gustafson, Martin (Marty) Hatlie, Carole Hemmelgarn, John James, Soojin Jun, Stephanie Mercado, MaryBeth Nance, Brett Powell, Edward Seferian, Hardeep Singh
- **Centers for Medicaid & Medicare Services (CMS):** Stephanie Clark, Michelle Schreiber

Executive Summary

- The purpose of the second Technical Expert Panel (TEP) meeting was to gain further feedback from the TEP on the PSSM measure specifications. The TEP was invited to provide input on five controversial and high-impact topics that emerged from the survey responses:
    1. "Zero Preventable Harm"
    2. Equity
    3. Domain 7: Resources, Environment & Technology
    4. Key Terms: High-reliability organization (HRO) practices and Just Culture
    5. Workforce Safety: Proposed solution and poll question
- Additional TEP feedback on the proposed measure domains and specifications will be collected via email, and CORE will work with CMS to determine the next steps for advancing the measure.

TEP Action Items:

- TEP members were invited to email safetystructuralmeasure@yale.edu with any additional comments and suggestions following the meeting.
- TEP members were asked to complete the poll question regarding the incorporation of "Workforce Safety," if they were unable to do so during the meeting.

CORE Action Items:

- CORE will provide TEP members with a TEP Meeting Summary for meetings #1 (March 3, 2023) and #2 (March 17, 2023).

The materials within this document do not represent final measure specifications for the PSSM.

Detailed Discussion Summary

Welcome & Introductions

- Ms. Mariel Thottam welcomed the TEP members and reminded them of the confidentiality of today's discussion.
- Ms. Katie Apton welcomed the meeting participants and thanked them for their contributions thus far to the TEP discussions and the survey. She presented the decision matrix which was used by CORE to decide what to bring to the discussion today. She noted the points for discussion at the meeting would be those determined by CORE to be high impact/controversial: 1) "Zero Preventable Harm", 2) Equity, 3) Domain 7: Resources, Environment, and Technology, 4) Key Terms: High Reliability Organization practices and "Just Culture," and 5) Workforce Safety: Proposed Solution and poll question.

Key Questions & Discussion

Topic 1— "Zero Preventable Harm"

- Ms. Apton introduced the first topic of discussion: the use of the phrase "zero preventable harm." She explained that the language is controversial because it may not be attainable or may be perceived as an unattainable goal.
- She posed the following question to the TEP: considering we want PSSM to have a bold aim, should we include the phrase and if not, how do we effectively communicate a bold aim?
- She added that during the survey, one TEP member suggested reviewing the World Health Organization (WHO)'s Global Safety Action plan that describes "zero avoidable harm" as a "state of mind and a rule of engagement in the planning and delivery of health care."
- A TEP member suggested using language such as "eliminating preventable harm" which retains the meaning but gives a way to describe a journey towards the same end goal.
- A TEP member noted that there were many discussions on this topic when they helped develop the WHO's Global Safety Action Plan. They noted it can be demoralizing to providers because there will always be harm that cannot be avoided. They noted that this language could be detrimental to patient safety but suggested using it in terms of an aspirational goal and rule of engagement.
- A TEP member suggested that while there are negatives to using "zero harm", it is important to strive for this. They noted it is a vision, and that while it may not be achievable, it is important to note. They agreed with language such as "eliminating preventable harm" or "striving towards zero harm." They noted the importance of having something like this in the measure.
- A TEP member underscored that the term is "zero *preventable* harm" and that this is the right approach. There is harm that is unpreventable, but the purpose of this measure is to decrease *preventable* harm.
- A TEP member agreed with the importance of maintaining a statement of "zero preventable harm."

- A TEP member agreed with the approach of qualifying a statement on preventing harm with “eliminate” because eliminate is an attainable daily goal.
- A TEP member stated that this discussion opens the debate of what harm is preventable and what harm is not. They noted that if society cannot achieve zero harm, then maybe the next generation can. They added the overall goal is to achieve zero harm, and although it may not be attainable it does not mean that it should be removed.
- A TEP member asked for a concrete suggestion of how this topic will be addressed within the structural measure. Will the structural measure ask if it is in the hospital’s mission statement?
- Ms. Apton noted that the TEP’s discussion would directly influence the statement under domain 1 which is currently “Our hospital strategic plan specifies a “zero harm” goal.
- A TEP member proposed giving hospitals flexibility and options, whether that be “eliminating preventable harm” or “achieving zero harm” because they do not want hospitals to get stuck on this question. They said if it was a mission statement, it would be a different situation.
- Ms. Apton summarized the group's discussion, reiterating the agreement to adjust the statement to “eliminating preventable harm.” She asked if anyone disagreed.
- A TEP member suggested agreed with giving hospitals options. They noted many hospitals may already have a similar phrase in their strategic plan and this measure should not make them change it.

Topic 2: Equity

- Ms. Apton introduced the second topic of discussion, equity. She noted the team received feedback on the surveys identifying a need for a stronger emphasis on equity. She explained that there are currently two domains that explicitly address equity. In Domain 1, there is a statement that says, “Our hospital safety goals include metrics assessing disparities in safety outcomes based on social and demographic characteristics.” In Domain 5, there is a statement that says, “Our hospital stratifies all adverse event data by social and demographic variables such as race, ethnicity, sexual orientation, gender, age, disability status, and income, to identify disparities in harm events and advance equity in care and outcomes.”
- She mentioned that CMS has adopted a separate structural measure focused solely on equity, the Hospital Commitment to Health Equity Measure. She noted an embedded link in the slides to the full measure specifications. She made a note that it is relevant to include equity in this measure, but to also be mindful of duplicative statements.
- Ms. Apton posed the question to the TEP: are there other specific suggestions for better embedding equity?
- A TEP member stated that in domain 3, equity must be embedded within investigation of patient safety events.

- A TEP member noted that during the last meeting, they discussed safety culture. They expressed an interest in understanding differences in safety culture assessment responses among different groups.
- A TEP member stated one of the biggest barriers to equity is access. They asked if there should be a statement requiring hospitals to ensure access within their community. They noted a lack of insurance is a barrier to access.
- Ms. Apton noted that the team is aware of the issues of access, and that this may be out of the scope of this measure.

Topic 3: Domain 7: Resources, Environment, and Technology

- Ms. Apton introduced the third topic of discussion: Domain 7 - Resources, Environment, and Technology. She outlined the feedback the team had received through the surveys. The feedback that was received was that several statements are challenging due to feasibility. For example, small hospitals may not be able to have a full-time patient safety manager. Other feedback was that some statements may be too specific and may micromanage hospitals, in addition to there being varying local and state level regulations that impact statements like that for air and water assessments. Another piece of feedback was the need to assess informatics infrastructure of the hospitals, and capacity for patient safety data collection and information exchange within the hospital. In survey responses, TEP members also recommended that the measure not include a statement on nurse-to-patient ratio since this is a contentious issue and context-specific.
- Ms. Apton proposed to prioritize statements, integrate them into other domains, and remove this as a standalone domain. Ms. Apton presented the two discussion questions.
    - The first question was, “Is there a list of minimum essential technologies that should be included in statement A?” Statement A was “our hospital invests in technologies to promote safety.”
    - The second question was “How can we best articulate a statement on having sufficient infrastructure for data and informatics that is integrated with clinical staff?”
        - A TEP member answered the second question by referencing the National Patient Safety Goals set by The Joint Commission. They noted one required technology should be something to properly identify patients. Another technology to consider is medication barcode technology. The TEP member also noted an interest in addressing alarm fatigue and management. They noted that technology is a priority.
- A TEP member stated that they believe the measure should focus on patient safety, and not expanding to environmental safety. They also noted that currently there is a disconnect between the electronic health record (EHR) professionals and the clinical team. They stated healthcare organizations have been collecting EHR data for many years and that the data is not being used. The TEP member stressed the importance of clinicians and others working with the EHR professionals to access and learn from data.

- A TEP member referenced that the Coronavirus Aid, Relief, and Economic Security (CARES) Act requires patients be provided specific information through a patient portal or electronic health record and that some organizations are not fulfilling that requirement. The TEP member identified the technology as an important consideration to be kept. They also stated that while environmental safety is not specifically patient safety, it can directly cause patient safety events and so environmental safety should be included and considered. The TEP member also stated that many healthcare settings collect a lot of data and do not use the data.
    - A TEP member agreed to make statement A more specific. They noted that Leapfrog Group requires both Computerized Physician Order Entry (CPOE) and Bar Code Medication Administration (BCMA) because medication errors are the most common types of patient safety concerns. The TEP member noted these technologies have the capability to severely decrease medication errors. On the infrastructure and data informatics question, the TEP member stated the importance of identifying the roles of individuals that need to be involved.
- A TEP member stated the importance of training the individuals who capture the EHR data. They also noted the importance of requiring hospitals to have a patient safety officer regardless of size.
- A TEP member noted that if it is decided that the measure addresses technology, it is important the team be cautious about workarounds. They noted an interest in conducting workflow analyses. They also noted in anything data-related, checks and balances must be considered.
- Ms. Apton noted the team is planning to dissolve domain 7 and place the items into other domains.
    - A TEP member asked which domains the items would be moved into, noting the importance of maintaining the statements in the measure.
    - Ms. Apton noted that the team is not sure yet which domains, but it may be domain 3 ("Surveillance and Investigation") and 5 ("Measuring and Improving Performance").

Topic 4: Key Terms: High Reliability Organization (HRO) practices and "Just Culture"

- Ms. Apton introduced the fourth topic of discussion which was key terms. She noted that there are two key terms that will be discussed, the first is "High Reliability Organization (HRO) Practices." She noted the feedback the team received from the surveys were that all hospitals would say they use a HRO practice, so this question would be easy to endorse and thus may not be meaningful. Ms. Apton noted that high-reliability science is a conceptual pillar to patient safety. She posed the question of how the team can incorporate a statement that meaningfully assesses whether a hospital adequately demonstrates key characteristics of a HRO, and what key practices the measure should ask about.
- A TEP member responded that one of the pillars of HROs is a preoccupation with failure, noting it is important that hospitals keep failure in mind when addressing patient safety.

- A TEP member noted two important HRO features were the ability for anyone to bring a safety concern forward without retribution, and the second was 360-degree reviews which meant everyone could review their supervisors and provide feedback.
    - A TEP member agreed that the statement should be specific about what best practices are called out. She also agreed with the concept of a preoccupation with failure.
    - Two TEP members agreed regarding the specific best practices being mentioned. One TEP member suggested one method could be listing five best practices and asking hospitals to attest to doing at least two. Another TEP member also noted if this measure decides to encourage hospitals to be high reliability organizations, that may expand the scope of the measure greatly.
- A TEP member asked if the team is looking to make hospitals into HROs or if they are looking to have hospitals take on some characteristics.
    - A TEP member noted that some organizations have both a patient safety officer and a high reliability officer.
    - A TEP member suggested the use of a concrete example. They recommended asking a hospital when a safety event occurs, do they conduct certain best practices instead of asking which best practices they use.
- Ms. Apton introduced the second key term for discussion which was "just culture." Feedback from the survey described how the existence of a hospital's protocol to cultivate a *just culture* does not mean it is practiced. She asked if there was a better way to assess the presence of having or being committed to a *just culture*.
- A TEP member stated one way to estimate *just culture* is to look at the near misses and how many were reported anonymously. They noted asking hospital employees if they feel comfortable reporting near misses.
    - A TEP member agreed that one way of measuring *just culture* would be to assess near misses. They added that the measure should include language requiring hospitals to have policies that describe behavioral norms or appropriate professional conduct.
- A TEP member asked a fellow TEP member if policies about psychological safety can have an impact.
    - A TEP member noted that having a policy may not have a strong impact, but it allows for accountability when a standard is made.
    - A TEP member added that 360 reviews are a useful tool to identify if a *just culture* exists, explaining that it holds both lower-level and upper-level employees accountable.
    - A TEP member stated that asking anything policy-related cannot be a check box. It must be a demonstration because it's easy to just say yes.
- A TEP member noted everyone wants the items to be actionable and measurable.
- A TEP member stated it is important that items be actionable but also meaningful for progression to occur.

- A TEP member stated that there has been a lot written about the culture of safety, adding that it may be beneficial to build the measure off past resources like those created by CMS or the National Quality Forum (NQF).

Topic 5: Workforce Safety: A Proposed Solution and poll question

- Ms. Apton introduced the final topic of discussion: Workforce Safety. The feedback received from the surveys and TEP meeting #1 was that workforce safety is important and is tied to patient safety, but it is distinct. During TEP meeting #1, several TEP members indicated that workforce safety should be a separate measure while others felt it was important to keep it in this measure. Ms. Apton proposed a solution to remove workforce safety as a separate domain and then retain key concepts and statements and incorporate them into other domains. She stated the team will be conducting a poll to ask if the TEP agrees to the proposed solution. Ms. Thottam opened the poll.
- A TEP member shared concern regarding the last statement about workers' safety being reported to the board, noting that serious patient safety events must be reported as well.
    - A TEP member responded to another TEP member that within another domain, it is mentioned to bring patient safety events to the board. They additionally agreed that safety events must be reported to the board and added an interest in a national safety body that establishes a national standard.
- A TEP member expressed concern about other domain language and asked if other domain wording will be discussed at a later meeting.
    - Dr. Balestracci responded that there currently is not another meeting scheduled, however there may be in the future. She asked anyone who had feedback to send it via email.
- A TEP member asked what the overall vision is for the measure.
    - Dr. Michelle Schreiber from CMS responded that the initial structural measure will most likely look like the Hospital Commitment to Health Equity Structural measure, containing about five domains each with about five statements below them. She said future versions of this measure could include outcomes or could develop into a designation like the designation CMS is planning to address maternal health. She added it is not enough for the measure to ask hospitals to be committed to *just culture*, as every hospital will state they are without making improvements.
- Ms. Thottam summarized the results of the poll asking about CORE's approach to remove from the measure a domain specific to workforce safety and to incorporate key concepts and statements into other measure domains. 10 individuals agreed with the proposed solution, one voted no to agreement, and one voted for "other."

Wrap Up & Next Steps

- Ms. Apton identified the next steps of measure development. She explained that the team will be refining measure specifications and will be discussing with CMS to determine the next steps in advancing the measure, possibly through a regulatory

process. She noted the team will reach out to the TEP members within the next two to three months to provide updates on the measure status and next steps.

- A TEP member expressed admiration to the TEP and to the TEP leaders. She asked if items that were not brought to the TEP today would be brought back up in the future for discussion.
- Ms. Apton responded that the team prioritized controversial topics, but the team is still working to incorporate all feedback into the measure.
- The TEP member asked if the TEP would be reconvened.
- Ms. Apton responded that the CMS will determine if the TEP is reconvened.
- Dr. Balestracci added the team will investigate all the feedback received and will decide if there are areas the team needs more clarification from the TEP.
- A TEP member asked when additional feedback is due to the team.
- Ms. Apton asked TEP members to send additional feedback within the next two weeks.
- A TEP member stated that if the CORE team has any confusion about the TEP's feedback they should reach out to specific TEP members.
- Ms. Apton reassured the TEP member that the team will reach out if there is any confusion.
- Dr. Balestracci clarified that no subset of TEP members would be reconvened, that if further discussion was required the entire TEP would be reconvened.
- On behalf of CORE, Ms. Apton thanked the group for their time and valuable feedback. She noted that continued guidance was welcomed, and she encouraged TEP members to email with additional input at any time to safetystructuralmeasure@yale.edu.
- She noted a TEP Meeting Summary Report and Debrief survey will be distributed to the TEP via email and the team is requesting responses within two weeks of receiving the email.