

Measure Information and Justification Form

Project Title: Patient Safety Structural Measure

Date:

Information included is current on 08/19/2024.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) contracted Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) to develop a hospital-based structural measure focused on patient safety. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Base Period. The contract number HHSM-75FCMC18D0042, task order HHSM-75FCMC24F0042.

Measure Name/Title

Patient Safety Structural Measure.

1. Descriptive Information

1.1 Measure Type

Identify a measure type from the list. Patient-reported outcome-based performance measures (PRO-PMs) include health-related quality of life, functional status, symptom burden, and health-related behavior. For composite measures, please also identify the measure type of the components.

- process
- outcome
- PRO-PM
- cost /resource use
- efficiency
- structure
- intermediate outcome
- population health
- composite
 - process
 - outcome
 - other
- other

1.2 Brief Description of Measure

The Patient Safety Structural Measure is an attestation-based measure that assesses whether hospitals demonstrate having a structure and culture that prioritizes patient safety. The Patient Safety Structural Measure includes five domains, each containing multiple statements that aim to capture the most

salient structural and cultural elements of patient safety. This measure is designed to identify hospitals that practice a systems-based approach to safety, as demonstrated by: leaders who prioritize and champion safety; a diverse group of patients and families meaningfully engaged as partners in safety; practices indicative of a culture of safety; and continuous learning and improvement. The Patient Safety Structural Measure is informed by *Safer Together: The National Action Plan to Advance Patient Safety*, developed by the National Steering Committee for Patient Safety convened by the Institute for Healthcare Improvement (IHI), as well as scientific evidence from existing patient safety literature and detailed input from patient safety experts, advocates, and patients.¹

1.3 If Paired or Grouped

Provide the reason why you must report the measure with other measures to interpret results appropriately.

N/A

2. [Measure Specifications](#) 

These items follow the CMS requirements for measure submission and provide information required for measure evaluation.

2.1 Measure-Specific Webpage

Provide a Uniform Resource Locator (URL) link, if available, to a webpage where you can obtain current, detailed specifications, including code lists, risk adjustment model details, and supplemental materials. Do not enter a URL linking to a home page or to general information. If no URL is available, indicate N/A.

N/A

2.2 If this is an electronic clinical quality measure (eCQM)

If not an eCQM, state N/A.

If an eCQM, attach the zipped output from the Measure Authoring Tool (MAT) and Bonnie testing results, when testing complete. Use the specification fields from the online form for the plain language description of the specifications.

N/A

2.3 Data Dictionary, Code Table, or Value Sets.

Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). The preferred file format is either .xls or .csv. If not used, contact CMS for further directions.

N/A

2.4 For an instrument-based measure

If not an instrument-based measure, indicate N/A.

Attach copy of the instrument, if available

Indicate the responder (i.e., patient, family or other caregiver, clinician).

N/A

Instructions

2.5 Updates since last submission

If this is the first submission, state N/A.

Are there changes to the specifications since the last updates/submission? If yes, update the specifications in 2.1 and 2.6-2.24 and explain the reasons for the changes.

Briefly describe any changes to the measure specifications since the last endorsement date, if CBE-endorsed, and explain the reasons for the changes.

N/A

2.6 Numerator Statement

Briefly describe the measure focus or what the measure measures about the target population—cases from the target population with the target process, condition, or event based on the evidence.

For example:

Patients in the target population who received/had [measure focus] {during [time frame]} if different from the target population.

Do not include the rationale for the measure.

For outcome measures, state the measured outcome. Describe calculation of the risk-adjusted outcome later in the calculation algorithm.

The hospital outcome is defined by the five patient safety domains, each containing multiple statements. A hospital must positively attest to all statements within a domain to receive one point for that domain, for a total of 0 – 5 total points for the outcome (1 point for each of 5 patient safety domains). The five domains defining the numerator are: Domain 1: Leadership Commitment to Eliminating Preventable Harm; Domain 2: Strategic Planning & Organizational Policy; Domain 3: Culture of Safety & Learning Health System; Domain 4: Accountability & Transparency; and Domain 5: Patient & Family Engagement.

2.7 Numerator Details

Include all information necessary to identify and calculate the cases from the target population with the target process, condition, event, or outcome. Provide definitions and specific data collection items and responses. For measures based on a coded data set, identify the code set, the specific codes, and the code descriptors. If the list of codes and descriptors exceeds one page, provide the list in a Microsoft Excel or .csv file in the format listed in 2.3.

For outcome measures, describe how to identify and count the observed outcome. The calculation algorithm should also describe how to calculate the risk adjustment.

Provide the time period for measure data aggregation (e.g., 12 months, 3 years, another specified look-back period).

Affirmative attestation to all statements within a domain will be required for the hospital to receive a point for the domain. At one point per domain, hospitals affirmatively attesting to all statements will receive the maximum five points. Hospitals participating in the Hospital Inpatient Quality Reporting (IQR) Program and the Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting

(PCHQR) Program would complete attestation during the CMS-specified time period. The five domains and associated statements for each domain include:

Domain 1: Leadership Commitment to Eliminating Preventable Harm

The senior leadership and governing board at hospitals set the tone for commitment to patient safety. They must be accountable for patient safety outcomes and ensure that patient safety is the highest priority for the hospital. While the hospital leadership and the governing board may convene a board committee dedicated to patient safety, the most senior governing board must oversee all safety activities and hold the organizational leadership accountable for outcomes. Patient safety should be central to all strategic, financial, and operational decisions.

Please attest whether your hospital engages in the following activities. Select all that apply (note: affirmative attestation of all statements within a domain is required for the hospital to receive a point for the domain).

- A. Our hospital senior governing board prioritizes safety as a core value, holds hospital leadership accountable for patient safety, and includes patient safety metrics to inform annual leadership performance reviews and compensation.
- B. Our hospital leaders, including C-suite executives, place patient safety as a core institutional value. One or more C-suite leaders oversee a system-wide assessment on safety (examples provided in the Attestation Guide)², and the execution of patient safety initiatives and operations, with specific improvement plans and metrics. These plans and metrics are widely shared across the hospital and governing board.
- C. Our hospital governing board, in collaboration with leadership, ensures adequate resources to support patient safety (such as equipment, training, systems, personnel, and technology).
- D. Reporting on patient and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) accounts for at least 20% of the regular board agenda and discussion time for senior governing board meetings.
- E. C-suite executives and individuals on the governing board are notified within 3 business days of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm.

Domain 2: Strategic Planning & Organizational Policy

Hospitals must leverage strategic planning and organizational policies to demonstrate a commitment to safety as a core value. The use of written policies and protocols that demonstrate patient safety is a priority and identify goals, metrics, and practices to advance progress, is foundational to creating an accountable and transparent organization. Hospitals should acknowledge the ultimate goal of zero preventable harm, even while recognizing that this goal may not be currently attainable and requires a continual process of improvement and commitment. Patient safety and equity in care are inextricable, and therefore equity, with the goal of safety for all individuals, must be embedded in safety planning, goal-setting, policy, and processes.

Please attest whether your hospital engages in the following activities. Select all that apply (note: affirmative attestation of all statements within a domain is required for the hospital to receive a point for the domain).

Instructions

- A. Our hospital has a strategic plan that publicly shares its commitment to patient safety as a core value and outlines specific safety goals and associated metrics, including the goal of “zero preventable harm.”
- B. Our hospital safety goals include the use of metrics to identify and address disparities in safety outcomes based on the patient characteristics determined by the hospital to be most important to health care outcomes for the specific populations served.
- C. Our hospital has implemented written policies and protocols to cultivate a just culture that balances no-blame and appropriate accountability and reflects the distinction between human error, at-risk behavior, and reckless behavior.³
- D. Our hospital requires implementation of a patient safety curriculum and competencies for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors.
- E. Our hospital has an action plan for workforce safety with improvement activities, metrics and trends that address issues such as slips/trips/falls prevention, safe patient handling, exposures, sharps injuries, violence prevention, fire/electrical safety, and psychological safety.
- F. Our hospital purchases medications by utilizing contracting provisions that promote supply chain resiliency, including multi-year contracts with volume guarantees and stringent “failure to supply” clauses, either directly with vendors or indirectly through wholesalers or Group Purchasing Organizations.
- G. Our hospital has policies and procedures to respond to medication shortages and outages, including ensuring continuity of pharmaceutical services to meet patient needs during emergencies for a minimum of 7 days.

Domain 3: Culture of Safety & Learning Health System

Hospitals must integrate a suite of evidence-based practices and protocols that are fundamental to cultivating a hospital culture that prioritizes safety and establishes a learning system both within and across hospitals. These practices focus on actively seeking and harnessing information to develop a proactive, hospital-wide approach to optimizing safety and eliminating preventable harm. Hospitals must establish an integrated infrastructure (that is, people and systems working collaboratively) and foster psychological safety among staff to effectively and reliably implement these practices.

Please attest whether your hospital engages in the following activities. Select all that apply (note: affirmative attestation of all statements within a domain is required for the hospital to receive a point for the domain).

- A. Our hospital conducts a hospital-wide culture of safety survey using a validated instrument annually, or every two years with pulse surveys on target units during non-survey years. Results are shared with the governing board and hospital staff, and used to inform unit-based interventions to reduce harm.
- B. Our hospital has a dedicated team that conducts event analysis of serious safety events using an evidence-based approach, such as the National Patient Safety Foundation’s Root Cause Analysis and Action (RCA2).⁴
- C. Our hospital has a patient safety metrics dashboard and uses external benchmarks (such as CMS Star Ratings or other national databases) to monitor performance and inform improvement activities on safety events (such as: medication errors, surgical/procedural harm, falls, pressure injuries, diagnostic errors, and healthcare-associated infections).
- D. Our hospital implements a minimum of 4 of the following high reliability practices:

Instructions

- Tiered and escalating (e.g., unit, department, facility, system) safety huddles at least 5 days a week, with one day being a weekend, that include key clinical and non-clinical (e.g., lab, housekeeping, security) units and leaders, with a method in place for follow-up on issues identified.
 - Hospital leaders participate in monthly rounding for safety on all units, with C-suite executives rounding at least quarterly, with a method in place for follow-up on issues identified.
 - A data infrastructure to measure safety, based on patient safety evidence (e.g., systematic reviews, national guidelines) and data from the electronic medical record that enables identification and tracking of serious safety events and precursor events. These data are shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.
 - Technologies, including a computerized physician order entry system and a barcode medication administration system, that promote safety and standardization of care using evidence-based practices.
 - The use of a defined improvement method (or hybrid of proven methods), such as Lean, Six Sigma, Plan-Do-Study-Act, and/or high reliability frameworks.
 - Team communication and collaboration training of all staff.
 - The use of human factors engineering principles in selection and design of devices, equipment, and processes.
- E. Our hospital participates in large-scale learning network(s) for patient safety improvement (such as national or state safety improvement collaboratives), shares data on safety events and outcomes with these network(s) and has implemented at least one best practice from the network or collaborative.

Domain 4: Accountability & Transparency

Accountability for outcomes, as well as transparency around safety events and performance, represent the cornerstones of a culture of safety. For hospital leaders, clinical and non-clinical staff, patients, and families to learn from safety events and prevent harm, there must exist a culture that promotes event reporting without fear or hesitation, and safety data collection and analysis with the free flow of information.

Please attest whether your hospital engages in the following activities. Select all that apply (note: affirmative attestation of all statements within a domain is required for the hospital to receive a point for the domain).

- A. Our hospital has a confidential safety reporting system that allows staff to report patient safety events, near misses, precursor events, unsafe conditions, and other concerns, and prompts a feedback loop to those who report.
- B. Our hospital voluntarily works with a Patient Safety Organization listed by the Agency for Healthcare Research and Quality (AHRQ)⁵ to carry out patient safety activities as described in 42 CFR 3.20, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system.
- C. Patient safety metrics are tracked and reported to all clinical and non-clinical staff and made public in hospital units (e.g., displayed on units so that staff, patients, families, and visitors can see).

Instructions

- D. Our hospital has a defined, evidence-based communication and resolution program reliably implemented after harm events, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit⁶, that contains the following elements:
- Harm event identification
 - Open and ongoing communication with patients and families about the harm event
 - Event investigation, prevention, and learning
 - Care-for-the-caregiver
 - Financial and non-financial reconciliation
 - Patient-family engagement and on-going support
- E. Our hospital uses standard measures to track the performance of our communication and resolution program and reports these measures to the governing board at least quarterly.

Domain 5: Patient & Family Engagement

The effective and equitable engagement of patients, families, and caregivers is essential to safer, better care. Hospitals must embed patients, families, and caregivers as co-producers of safety and health through meaningful involvement in safety activities, quality improvement, and oversight.

Please attest whether your hospital engages in the following activities. Select all that apply (note: affirmative attestation of all statements within a domain is required for the hospital to receive a point for the domain).

- A. Our hospital has a Patient and Family Advisory Council that ensures patient, family, caregiver, and community input to safety-related activities, including representation at board meetings, consultation on safety goal-setting and metrics, and participation in safety improvement initiatives.
- B. Our hospital's Patient and Family Advisory Council includes patients and caregivers of patients who are diverse and representative of the patient population.
- C. Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally- and linguistically-appropriate as well as submit comments for potential correction to their record.
- D. Our hospital incorporates patient and caregiver input about patient safety events or issues (such as patient submission of safety events, safety signals from patient complaints or other patient safety experience data, patient reports of discrimination).
- E. Our hospital supports the presence of family and other designated persons (as defined by the patient) as essential members of a safe care team and encourages engagement in activities such as bedside rounding and shift reporting, discharge planning, and visitation 24 hours a day, as feasible.

2.8 Denominator Statement

Provide a narrative description of the broadest population (based on the evidence) for which the target process, condition, event, or outcome is applicable. Include the time period for measure data aggregation, if different from the numerator.

Example

Patient [age] with [condition] in [setting] during [time frame]

For outcome measures, state the target population for the outcome. The calculation algorithm should also describe how to calculate the risk adjustment.

The denominator for each facility is 5 domains.

2.9 Denominator Details

Provide all definitions and instructions needed to identify and calculate the target population/denominator (e.g., definitions, time period for data collection, specific data collection items/responses, codes/value sets). For measures based on a coded data set, identify the code set, the specific codes, descriptors, definitions, and specific data collection items as appropriate. (If the list of codes and descriptors exceeds one page, provide the list in an .xls or .csv file in the format listed in 2.3.)

For outcome measures, describe how to identify the target population. The calculation algorithm should also describe how to calculate the risk adjustment.

There is no target population. The unit of measurement for this structural measure is the hospital.

2.10 Denominator Exclusions

If no denominator exclusions, state N/A and skip to 2.12.

Identify patients in the target population who should not receive the process (i.e., medical treatment), or are not eligible for the outcome for some other reason, particularly if their inclusion may bias results. Exclusions should be evidence-based. If no denominator exclusions, indicate N/A and skip to 3.12.

Example

Patients in the [target population] who [have some additional characteristic, condition, procedure]

N/A

2.11 Denominator Exclusion Details

Provide all information needed to identify and calculate exclusions from the denominator (e.g., definitions and/or specific data collection items and responses). For measures based on a coded data set, identify the code set, specific codes, descriptors, definitions, and specific data collection items for the codes as appropriate. Provide lists of individual codes with descriptors exceeding one page in an .xls or .csv file in the required format listed in 2.3.

There are no denominator exclusions.

2.12 Type of Score

- count: 0 – 5 total points (1 point for each of 5 patient safety domains)
- rate/proportion
- ratio
- categorical (e.g., yes or no)
- continuous variable (CV) (e.g., an average)
- composite/scale
- other (specify) Categorical (rating scale/score)

2.13 Interpretation of Score

Instructions

Provide an interpretation classifying whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score.

[Better quality is associated with a higher score.](#)

2.14 Risk Adjustment Type

Select the risk adjustment type. Provide specifications for risk stratification in 2.15 and for the statistical model in 2.16-2.17.

- no risk adjustment or risk stratification
- stratification by risk category/subgroup
- statistical risk model
- other

2.15 Stratification Details/Variables

Provide instructions for calculating the measure by category (e.g., age), including the stratification variables, all codes, logic, definitions, specific data collection items/responses, and the risk model covariate and coefficients for the clinically adjusted version of the measure, when appropriate. Provide lists of individual codes with descriptors exceeding one page in an .xls or .csv file in the required format listed in 2.3.

[N/A](#)

2.16 Calculation Algorithm/Measure Logic

Describe the sequence of steps necessary to calculate the measure score, including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; time period of data; and any other calculations.

You may provide a diagram of the calculation algorithm/measure logic at a measure-specific webpage URL identified in 2.1 or in an appendix.

[A hospital must positively attest to all statements within a domain to receive one point for that domain, for a total of 0 – 5 total points for the outcome \(1 point for each of 5 patient safety domains\). The five domains defining the numerator are: Domain 1: Leadership Commitment to Eliminating Preventable Harm; Domain 2: Strategic Planning & Organizational Policy; Domain 3: Culture of Safety & Learning Health System; Domain 4: Accountability & Transparency; and Domain 5: Patient & Family Engagement.](#)

2.17 Sampling

If the measure is based on a sample or survey, provide instructions for obtaining the sample and conducting the survey, along with minimum response rate required. If the measure is an instrument-based quality measure (e.g., PRO-PM), identify whether (and how) to allow proxy responses.

[N/A](#)

2.18 Survey/Patient-Reported Data

If the measure is not based on a survey or instrument, state N/A.

Instructions

If the measure is based on a survey or instrument, provide instructions for data collection and guidance on the minimum response rate. If the measure is a PRO-PM, specify how to report the calculation of response rates with quality measure results.

Specify how to handle missing data (e.g., imputation, delete case). This item is a requirement for composite measures and PRO-PMs.

N/A

2.19 Data Source

Indicate all sources for which the measure developer specified and tested. Provide testing for all sources of data specified and intended for measure implementation. If using different data sources for the numerator and denominator, indicate “numerator” or “denominator” with each source.

- administrative data
- claims data
- paper patient medical records
- electronic patient medical records
- electronic clinical data
- registries
- standardized patient assessments
- patient-reported data and surveys
- non-medical data
- other—describe in 2.20 Data Source or Collection Instrument (immediately below)

2.20 Data Source or Collection Instrument

Identify the specific data source/data collection instrument (e.g., name of database, clinical registry, collection instrument). If the measure is instrument-based (e.g., PRO-PM), identify the specific tools/instruments used to collect the measure information and standard methods, modes, and languages of administration.

The data source for the Patient Safety Structural Measure is self-attestation by hospitals participating in the Hospital Inpatient Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program.

2.21 Data Source or Collection Instrument (Reference)

Provide the reference for the data source or collection instrument. Attach a copy or specify the URL.

N/A

2.22 Level of Analysis

Indicate only the levels for which the measure developer specified and tested.

- individual clinician
- group/practice
- hospital/facility/agency
- health plan
- accountable care organization

Instructions

- geographic population
- other (specify) [Click or tap here to enter text.](#)

2.23 Care Setting

Indicate only the settings for which the measure developer specified and tested.

- ambulatory surgery center
- clinician office/clinic
- outpatient rehabilitation
- urgent care – ambulatory
- behavioral health: inpatient
- behavioral health: outpatient
- dialysis facility
- emergency medical services/ambulance
- emergency department
- home health
- hospice
- hospital
- hospital: critical care
- hospital: acute care facility
- imaging facility
- laboratory
- pharmacy
- nursing home/skilled nursing facility (SNF)
- inpatient rehabilitation facility (IRF)
- long-term acute care
- birthing center
- no applicable care setting
- other (specify) [Click or tap here to enter text.](#)

2.24 Composite Measure

This section is for additional specifications as needed. Use it for aggregation and weighting rules or calculation of individual quality measures.

N/A

3. [Importance](#) 

3.1 Evidence to Support the Measure Focus (for reference only)

The measure focus is evidence-based, demonstrated as

- *a health outcome with a rationale supporting the relationship of the health outcome to processes or structures of care*
- *an intermediate outcome with a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence the measured intermediate outcome leads to a desired health outcome*

- a patient-reported measure with evidence the measured aspects of care are those valued by patients and for which the patient is the best and/or only source of information, or the patient experience with care is correlated with desired outcomes
- efficiency measure with evidence for the quality component implied in experience with care; measures of efficiency combine the concepts of resource use and quality

Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events compared with zero are appropriate outcomes for public reporting and quality improvement.

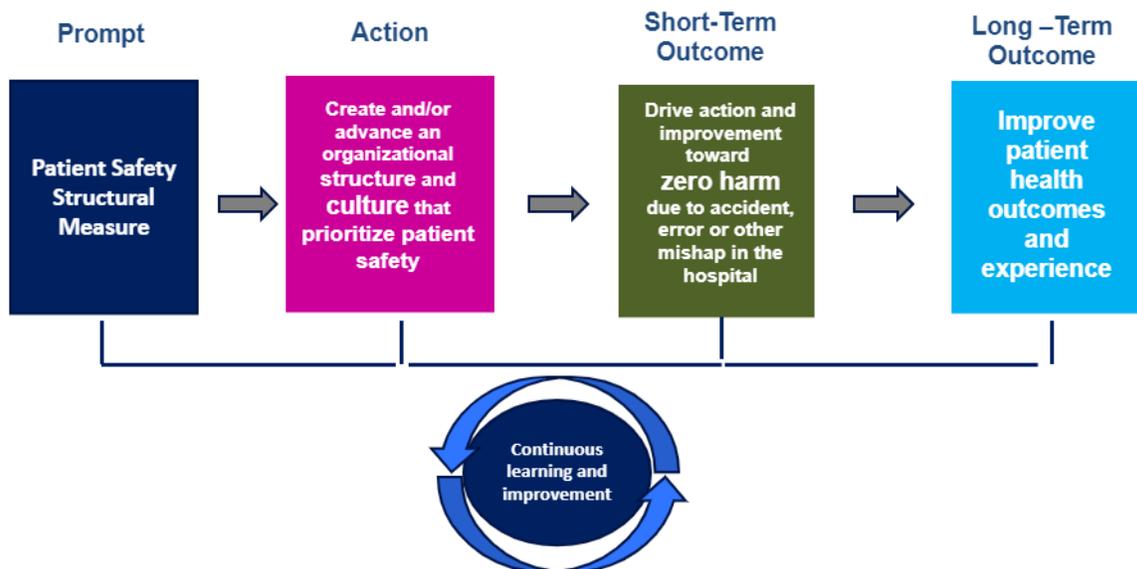
The preferred systems for grading the evidence are the [United States Preventive Services Task Force \(USPSTF\)](#)  grading definitions and methods, or [Grading of Recommendation, Assessment, Development, and Evaluation \(GRADE\)](#)  guidelines.

3.1.1 Logic Model

Briefly state or diagram the steps between the health care structures and processes (e.g., interventions, services) and the patient’s health outcome(s). General, non-technical audiences should easily understand the relationships in the diagram. Indicate the structure, process, or outcome for measurement.

Figure 1 below depicts the Conceptual Model outlining the framework of the measure. CMS requested a Patient Safety Structural Measure, to create and/or advance an organizational structure and culture that prioritizes patient safety. The short-term outcome of the measure is to drive action and improvement toward zero preventable harm due to accident, error or other mishaps in the hospitals and the long-term outcome is to improve patient health outcomes and experience.

Figure 1: Conceptual Model of the Patient Safety Structural Measure.



3.1.2 Value and Meaningfulness

If this is a patient-reported measure, provide evidence the target population values the measured outcome, process, or structure and finds it meaningful. Describe how and from whom you obtained input.

Instructions

****RESPOND TO ONLY ONE OF THE NEXT THREE SECTIONS - EITHER 3.1.3, 3.1.4, or 3.1.5 ****

3.1.3 Empirical Data (for outcome measures) – as applicable

Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one health care structure, process, intervention, or service.

3.1.4 Systematic Review of the Evidence (for intermediate outcome, process, or structure quality measures, include those that are instrument-based) – as applicable

What is the source of the systematic review of the body of evidence supporting the quality measure? A systematic review is a scientific investigation focusing on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar, but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (Institute of Medicine, 2011)

- Clinical Practice Guideline recommendation (with evidence review)
- USPSTF recommendation
- Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, [AHRQ Evidence-based Practice Centers](#))
- Other

For each systematic review, populate the table. Make as many copies of the table as needed to accommodate each systematic review.

<p>Source of Systematic Review (SR)</p> <ul style="list-style-type: none"> • Title • Author • Date • Citation, including page number • Uniform Resource Locator (URL) 	
Quote the guideline or recommendation verbatim about the process, structure, or intermediate outcome for measurement. If not a guideline, summarize the conclusions from the SR.	
Grade assigned to the evidence associated with the recommendation with the definition of the grade.	
Provide all other grades and definitions from the evidence grading system.	
Grade assigned to the recommendation with definition of the grade.	
Provide all other grades and definitions from the recommendation grading system.	
<p>Body of evidence</p> <ul style="list-style-type: none"> • Quantity – how many studies? • Quality – what types of studies? 	
Estimates of benefit and consistency across studies.	
What were the harms identified?	
Identify any new studies conducted since the initial SR. Do the new studies change the conclusions from the initial SR?	

Instructions

3.1.5 Other Source of Evidence – as applicable

If source of evidence is not from a clinical practice guideline, USPSTF, or SR, describe the evidence on which quality measure is based.

The sources of evidence are varied, and include evidence-based recommendations, guidance and reports on patient safety, and hospital requirements and standards.

3.1.5.1 Briefly Synthesize the Evidence

A list of references without a summary is not acceptable.

The landmark reports *To Err is Human*⁷ and *Crossing the Quality Chasm*⁸ surfaced major deficits in health care quality and safety. These reports resulted in widespread awareness of the alarming prevalence of patient harm and spurred improvements in the field. However, preventable harm to patients in the clinical setting resulting in significant morbidity and mortality remains common. In 2016, an article published in *BMJ* estimated that medical error is the third leading cause of death in the U.S.⁹

Effective measurement is paramount to monitoring harm events, identifying key gaps, and tracking progress toward safer, more reliable care. There are a number of outcome and process measures in use targeting specific incidents (e.g., central line associated bloodstream infections, adverse events associated with medication and diagnostic errors). While these metrics are important to capture, they each represent a single data point within the broad and complex domain of patient safety. The systems approach to patient safety maintains that errors and accidents in medical care are generally not due to an individual's mistake but rather a reflection of system-level failures.¹⁰ There is strong alignment among patient safety experts to shift to a more holistic, proactive, systems-based approach to patient safety.^{1,11,12,13,14,15}

3.1.5.2 Process Used to Identify the Evidence

Identify guideline recommendation number and/or page number and quote verbatim the specific guideline recommendation.

N/A

3.1.5.3 Citation(s) for the Evidence

Grade assigned to the quoted recommendation with definition of the grade.

N/A

3.2 Performance Gap – Opportunity for Improvement

3.2.1 Rationale

Briefly explain the rationale for this measure (i.e., benefits or improvements in quality envisioned by use of this measure).

If the measure is a composite, a combination of component measure scores, all-or-none, or any-or-none, describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually. Describe the area of quality measured, component measures, and the relationship of the component measure to the overall composite and to each other (whether reflective or formative model used to develop this measure, and

whether components are correlated. Describe how the aggregation and weighting of the components measures are consistent with the stated quality construct and rationale.

The Patient Safety Structural Measure comprises a compilation of attestation statements that aim to capture the most salient, systems-oriented actions to advance patient safety. These statements are intended to exemplify hospital approach to a culture of safety and leadership commitment to transparency, accountability, patient and family engagement, and continuous learning and improvement.

3.2.2 Performance Scores

Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. Include the mean, standard deviation, minimum, maximum, interquartile range, and scores by decile. Describe the data source, including number of measured entities, number of patients, dates of data, and, if a sample, characteristics that the entities include. Also use this information to address the subcriterion on improvement in 6.1.1.

The testing plan, approved by CMS, is to conduct testing following initial implementation of the measure, with the benefit of nationally representative data. No testing has been conducted to date.

3.2.3 Summary of Data Indicating Opportunity

If there is no or limited performance data in 3.2.2 on the measure as specified, provide a summary of data from the literature indicating opportunity for improvement or overall, less-than-optimal performance on the specific focus of measurement. Include citations.

Despite improvements in patient safety, preventable harm to patients in the clinical setting resulting in significant morbidity and mortality remains common. In 2016, an article published in BMJ estimated that medical error is the third leading cause of death in the U.S.⁹ The systems approach to patient safety maintains that errors and accidents in medical care are generally not due to an individual's mistake but rather a reflection of system-level failures.¹⁰ There is strong consensus among patient safety experts to shift to a more holistic, proactive, systems-based approach to patient safety.^{1,12,13,14,15,16} The Patient Safety Structural Measure will be designed to function as a prompt to hospitals to implement specific, evidence-based practices for improving patient safety.

3.2.4 Equity/Disparities

Provide data on how the measure, as specified, addresses disparities—current and over time—by population group (e.g., race or ethnicity, gender, age, insurance status, socioeconomic factors, and disability). Describe the data source, including number of measured entities, number of patients, and dates of the data. If the data are from a sample, include characteristics of the entities. What is the impacted demographic and what component is the measure addressing and how? For measures showing high levels of performance (i.e., topped out), disparities data may demonstrate an opportunity for improvement/gap in care for certain subpopulations. Also use this information to address the subcriterion on improvement in 6.1.1.

The Patient Safety Structural Measure addresses equity in attestation measure statements within measure domains, for hospital response. As a hospital structural measure, for which the hospital is the unit of analysis, there are no patient-level outcomes nor patient-level data to be analyzed.

3.2.5 If no or limited equity/disparities data, provide summary of data.

If there are no or limited data on disparities reported from the measure as specified in 3.2.2, provide a summary of data from the literature addressing disparities in care on the specific focus of measurement and include citations. The summary is not necessary if you provided performance data in 3.2.2.

There are well-documented disparities in patient outcomes based on race, ethnicity, and other social and demographic characteristics. Equity and safety are considered to be two separate dimensions of care quality that are inextricable – care cannot be safe if it is inequitable. The existing research on disparities in the incidence of patient safety events is limited but indicates, for example, that compared to White patients, Black patients experience higher rates of hospital-acquired infections and injuries during surgery.^{16,17,18}

3.3 [Harmonization](#)

If this measure conceptually addresses either the same measure focus or the same target population as other measure(s), are the measure specifications harmonized to the extent possible?

If there is not complete harmonization of the measure specifications, identify the differences, rationale, and impact on interpretability and data collection burden.

N/A

3.3.1 Related and Competing Measures

If a measure meets other criteria and there are related measures (either the same measure focus or target population) or competing measures (both the same measure focus and same target population), you compared the measures to address harmonization and/or selection of the best measure.

There are no competing measures.

3.3.1.1 Relation to Other Measures

Are there related measures or competing measures?

yes

no

If there are related measures (i.e., conceptually related by same measure focus or same target population) or competing measures (i.e., same measure focus and same target population), list the title of all related and/or competing measures and list the CMS CBE number, if applicable.

3.3.1.2 Competing Measures

If this measure conceptually addresses the same measure focus and the same target population as other measure(s), describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality), or provide a rationale for the additive value of endorsing an additional measure. Provide analyses when possible.

There are no competing measures.

4. [Scientific Acceptability](#)

4.1 What is the Source of Data Used for Testing?

Measure specified to use data sources must be consistent with data sources entered in 2.19.

Instructions

The data source for the Patient Safety Structural Measure is self-attestation by hospitals participating in the Hospital Inpatient Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program.

Measure tested with data from

- abstracted from paper record
- administrative/management
- claims
- instrument-based
- assessment
- clinical database/registry
- abstracted from electronic health records (EHRs)
- electronic clinical quality measure (eCQM) Health Quality Measure Format (HQMF) implemented in EHRs/health information technology
- other (specify) No testing has been conducted to date. Will be tested with hospital-provided self-attestation data.

4.2 Identify the Specific Dataset

If using an existing dataset, identify the dataset. The dataset used for testing must be consistent with the measure specifications for target population and measured entities (e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home Minimum Data Set [MDS] home health Outcome and Assessment Information Set [OASIS], clinical registry).

N/A

4.3 Testing Data

4.3.1 What Are the Dates of the Data Used in Testing?

Enter the date range for the testing data.

N/A

4.3.2 What Levels of Analysis Did the Measure Developer Test?

Provide testing for all levels specified and intended for measure implementation (e.g., individual clinician, hospital, health plan).

N/A

Measure specified to measure performance of *(must be consistent with data sources entered in 2.19)*

- individual clinician
- group/practice
- hospital/facility/agency
- health plan
- accountable care organization
- geographic population
- other (specify) Click or tap here to enter text.

Measure tested at level of

- individual clinician
- group/practice
- hospital/facility/agency
- health plan
- accountable care organization
- geographic population
- other (specify) [Click or tap here to enter text.](#)

4.3.3 How Many and Which Measured Entities Were Included in the Testing and Analysis?

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if using a sample, describe the selection criteria for inclusion in the sample.

[Testing with national data planned. No testing has been conducted to date.](#)

4.3.4 How Many and Which Patients Were Included in the Testing and Analysis?

Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if using a sample, describe the selection criteria for patient inclusion in the sample. If there is a minimum case count used for testing, reflect the minimum in the specifications.

[N/A; the measure will not assess patients.](#)

4.3.5 Sample Differences, if applicable

If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusion, risk adjustment), identify how the data or sample differ for each aspect of testing reported.

[N/A](#)

4.3.6 What Were the Social and Functional Risk Factors That Were Available and Analyzed?

Describe social and functional risk factors; for example, patient-reported data (e.g., income, education, language), proxy variables when the measured entity does not collect social and functional risk data from each patient (e.g., census tract), or patient community characteristics (e.g., percentage of vacant housing, crime rate), which do not have to be a proxy for patient-level data.

Test measures for all data sources and specified levels of analyses.

Information on scientific acceptability should be sufficient for CMS and interested parties to understand to what degree the testing results for the measure meet evaluation criteria for testing.

[N/A; this structural measure will not be risk adjusted.](#)

4.4 [Reliability Testing](#) (for reference only)

Reliability testing demonstrates measure data elements are repeatable, producing the same results a high percentage of the time when assessed in the same population in the same time period, and/or the measure score is precise. For instrument-based measures (including PRO-PMs) and composite measures, demonstrate reliability for the computed performance score.

Reliability testing applies to both the data elements and computed measure score. For composite measures, must demonstrate reliability of the computed performance score. Examples of reliability testing for data elements include inter-rater/abstractor or intra-rater/abstractor studies, internal consistency for multi-item scales, and test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

If the measure developer empirically tested for accuracy/correctness (i.e., validity) of data elements, there is no requirement for separate reliability testing of data elements. In 4.4.1, check patient/encounter level; in 4.4.2, enter “refer to section 4.5 for validity testing of data elements”; and skip 4.4.3 and 4.4.4.

4.4.1 Level of Reliability Testing

At what level of reliability was testing conducted? (check all that apply)

- patient/encounter level (data element level) (e.g., inter-abstractor reliability)
- accountable entity level (measure score level) (e.g., signal-to-noise analysis)

4.4.2 Method of Reliability Testing

Describe the method of reliability testing for each level used, as identified in 4.4.1. Do not just name the method. What type of error is it testing? Provide the statistical analysis you used.

[Testing with national data planned. No testing has been conducted to date.](#)

4.4.3 Statistical Results from Reliability Testing

What were the statistical results from reliability testing for each level, as identified in 4.4.1? Examples include percent agreement and kappa for the critical data elements, and distribution of reliability statistics from a signal-to-noise analysis. Provide reliability statistics and assessment of adequacy in the context of norms for the test conducted.

[Testing with national data planned. No testing has been conducted to date.](#)

4.4.4 Interpretation

What is your interpretation of the results in terms of demonstrating reliability? What do the results mean and what are the norms for the test conducted?

[Testing with national data planned. No testing has been conducted to date.](#)

4.5 [Validity Testing](#) (for reference only)

Validity testing demonstrates the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument-based measures, including PRO-PMs and composite measures, demonstrate validity for the computed performance score.

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to, testing hypotheses the measures scores indicate quality of care (e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method); correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related

measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate for measures not yet in a CMS program if accomplished by identified experts through a systematic and transparent process explicitly addressing whether performance scores resulting from the measure as specified and can distinguish good from poor quality. Provide/discuss the degree of consensus and any areas of disagreement.

4.5.1 Level of Validity Testing

At what level(s) of validity was testing conducted? (check all that apply)

- patient/encounter level (data element level)
- accountable entity level (measure score level)

4.5.2 Type of validity testing

Select the type or types of validity testing conducted.

- empirical validity testing
- systematic assessment of face validity of quality measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

Provide empirical validity testing at the time of maintenance review; if not possible, provide justification.

4.5.3 Method of Validity Testing

For each level tested, describe the method of validity testing and what it tests. Do not just name the method; please describe the steps and what the measure developer tested (e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected, statistical analysis used).

[Testing with national data planned. No testing has been conducted to date.](#)

4.5.4 Statistical Results from Validity Testing

Provide statistical results and assessment of adequate validity (e.g., correlation, t test).

[Testing with national data planned. No testing has been conducted to date.](#)

4.5.5 Interpretation

What is your interpretation of the results in terms of demonstrating validity? What do the results mean and what are the norms for the test conducted?

[Testing with national data planned. No testing has been conducted to date.](#)

4.6 [Exclusions Analysis](#) (for reference only)

Support exclusions by the clinical evidence and note sufficient frequency to warrant inclusion in the specifications of the measure. Examples of evidence an exclusion distorts measure results include frequency of occurrence, variability of exclusion across measured entities, and sensitivity analyses (with and without the exclusion). If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence the exclusion impacts performance on the measure; in such cases, specify the measure so the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Patient preference is not a clinical exception to eligibility and measured entities interventions may influence patient preference.

If there are no exclusions, indicate this section is not applicable and skip to 4.7.

4.6.1 Method of Testing Exclusions

Describe the method of testing the exclusions and what it tests. Do not just name the method; describe the steps and what the measure developer tested (e.g., whether the exclusions affect overall performance scores); and statistical analysis used.

N/A

4.6.2 Statistical Results from Testing Exclusions

What were the statistical results from testing the exclusions? Include overall number and percentage of individuals excluded, frequency distribution of the exclusions across measured entities, and impact on quality measure scores.

N/A

4.6.3 Interpretation

What is your interpretation of the results in terms of demonstrating there is a need for exclusions to prevent unfair distortion of performance results (i.e., the value outweighs the burden of increased data collection and analysis)? If patient preference is an exclusion, specify the measure so the effect on the performance score is transparent (e.g., scores with and without the exclusion).

N/A

4.7 Risk Adjustment or Stratification for Outcome or Resource Use Measures (for reference only)

For outcome and other measures (e.g., resource use, cost), specify an evidence-based risk adjustment strategy (e.g., risk model, risk stratification), is based on patient factors (including clinical, sociodemographic, and functional factors) influencing the measured outcome, are present at start of care, are not associated with the quality of care, and have demonstrated adequate discrimination and calibration.

Do not specify risk factors influencing outcomes as exclusions. Measure developers should consider both stratification and risk adjustment of measures by risk factors (clinical, social, functional).

If this is not applicable, describe the rationale/data support for no risk adjustment/stratification.

If the measure is not an intermediate, or health outcome, PRO-PM, or resource use measure, state not applicable and skip to 4.8.

See also the [Risk Adjustment in Quality Measurement](#)  supplemental material.

N/A

4.7.1 Method of Controlling for Differences

The method of controlling for differences in case mix is

- no risk adjustment or stratification
- statistical risk model with (specify number) risk factors

- stratification by (specify number) risk categories
- other (specify) [Click or tap here to enter text.](#)

If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

4.7.2 Rationale for Why There Is No Need for Risk Adjustment

If not risk-adjusting or stratifying an outcome or resource use measure, provide rationale and analyses to demonstrate there is no need for controlling for differences in patient characteristics (i.e., case mix) to achieve fair comparisons across measured entities.

4.7.3 Conceptual, Clinical, and Statistical Methods/Model

Describe the conceptual, clinical, and statistical methods and criteria used to select patient factors (i.e., clinical factors, social risk factors, or functional risk factors) used in the statistical risk model or for stratification by risk (e.g., potential factors identified in the literature and/or expert panel, regression analysis, statistical significance of $p < 0.10$, correlation of x or higher, patient factors should be present at the start of care and not related to disparities). Also, discuss any ordering of risk factor inclusion; for example, are social risk factors added after all clinical factors?

4.7.4 Conceptual Model of Impact of Social and Functional Risks

How was the conceptual model of the impact of social and functional risks of this outcome developed? Check all that apply.

- published literature
- internal data analysis
- other (specify) [Click or tap here to enter text.](#)

4.7.5 Statistical Results

Describe the statistical results of the analyses used to select risk factors.

4.7.6 Analyses and Interpretation in Selection of Social and Functional Risk Factors

Describe the analyses and interpretation resulting in the decision to select social and functional risk factors (e.g., prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects). Also, describe the impact of adjusting for risk (or not) on measured entities at high or low extremes of risk.

4.7.7 Method Used to Develop the Statistical Model or Stratification Approach

Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach. Do not just name the method; describe the steps and identify the statistical analysis you used.

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (i.e., case mix). If stratified, skip to 4.7.11.

4.7.8 Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R2)

4.7.9 Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)

4.7.10 Statistical Risk Model Calibration—Risk decile plots or calibration curves

4.7.11 Results of Risk Stratification Analysis

4.7.12 Interpretation

What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix), i.e., what do the results mean and what are the norms for the test conducted?

4.7.13 Optional Additional Testing for Risk Adjustment

While not required, this testing would provide additional support of adequacy of the risk model (e.g., testing of risk model in another data set, sensitivity analysis for missing data, other methods assessed).

4.8 Identification of Meaningful Differences in Performance (for reference only)

Data analysis of computed measure scores demonstrates methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance. With large enough sample sizes, small, statistically significant differences may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% vs. 75%) is clinically meaningful, or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 vs. \$5,025) is practically meaningful. Measures showing less-than-optimal performance may not demonstrate much variability across measured entities.

You may also describe the evidence of overall less-than-optimal performance. The intent of this section is to go beyond demonstrating a performance gap and address statistical significance, if possible.

4.8.1 Method

Describe the method for determining whether identification of statistically significant and clinically or practically meaningful differences in quality measure scores among the measured entities is possible. Do not just name the method, describe the steps and the statistical analysis you used. Do not just repeat the information provided related to performance gap in the section on importance, 3.2, Performance Gap.

Testing with national data planned. No testing has been conducted to date.

4.8.2 Statistical Results

What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in quality measure scores across measured entities? For example, was an unexpected number and percentage of entities with scores significantly varying from the mean or some benchmark? How was meaningful difference defined?

Testing with national data planned. No testing has been conducted to date.

4.8.3 Interpretation

What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? What do the results mean in terms of statistical and meaningful differences?

Testing with national data planned. No testing has been conducted to date.

4.9 Comparability of Multiple Data Sources/Methods (for reference only)

If there is only one set of specifications, skip to 4.10.

If specifying multiple data sources/methods, there is demonstration they produce comparable results.

Measure developers should direct this item to risk-adjusted measures —with or without social or functional risk factors—or to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from patient record abstraction and a different set of specifications, e.g., claims or eQMs). It does not apply to measures using more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and patient record abstraction for the numerator). There is no requirement for comparability when comparing performance scores with and without social/functional risk factors in the risk adjustment model. However, if there is no demonstration of comparability for measures with more than one set of specifications/instructions, submit the different specifications (e.g., for patient records vs. claims) as separate measures.

4.9.1 Method

Describe the method of testing conducted to demonstrate comparability of performance scores for the same entities across the different data sources or specifications. Describe the steps—do not just name a method. Provide the statistical analysis used.

4.9.2 Statistical Results

What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications (e.g., correlation, rank order)?

4.9.3 Interpretation

What is your interpretation of the results in terms of demonstrating comparability of quality measure scores for the same entities across the different data sources or specifications? What do the results mean and what are the norms for the test conducted?

4.10 Missing Data Analysis and Minimizing Bias (for reference only)

Analyze and identify the extent and distribution of missing data (or nonresponse) and demonstrate there is no bias in performance results due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

4.10.1 Method

Describe the testing method conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate there is no bias in performance results due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias. Describe the steps—do not just name a method. Provide the statistical analysis used, such as examples of evidence missing data distorts measure results include, but not limited to, frequency of occurrence and variability across measured entities.

N/A

4.10.2 Missing Data Analysis

What is the overall frequency of missing data, the distribution of missing data across measured entities, and the results from testing related to missing data (e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse)? If there is no empirical sensitivity analysis, identify the approaches considered for handling missing data and pros and cons of each.

N/A

4.10.3 Interpretation

What is your interpretation of the results in terms of demonstrating there is no bias in performance results due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias? What do the results mean in terms of supporting the selected approach for missing data, and what are the norms for the test conducted? If you did not conduct empirical analysis, provide the rationale for the selected approach for missing data.

N/A

5. [Feasibility](#)

This criterion assesses the extent to which the required data are readily available, retrievable without undue burden, and are implementable for performance measurement.

5.1 Data Elements Generated as Byproduct of Care Processes

How are the needed data elements generated to compute measure scores?

[The data source for the Patient Safety Structural Measures is self-attestation by hospitals.](#)

Data used in the measure are (check all that apply)

- generated or collected by and used by health care personnel during provision of care (e.g., blood pressure, laboratory value, diagnosis, depression score)
- coded by someone other than the person obtaining original information (e.g., Diagnosis-Related Group, International Classification of Diseases, 10th Revision, Clinical Modification/Procedure Coding System codes on claims)
- abstracted from a record by someone other than the person obtaining original information (e.g., chart abstraction for quality measure or registry)
- other (specify) Self-attestation by hospitals

5.2 Electronic Sources

5.2.1 Data Elements Electronic Availability

To what extent are the data elements needed for the measure available electronically (i.e., needed elements to compute quality measure scores are in defined, computer-readable fields)?

- All data elements are in defined fields in EHRs.
- All data elements are in defined fields in electronic claims.
- All data elements are in defined fields in electronic clinical data such as clinical registry, nursing home MDS, and home health OASIS.
- All data elements are in defined fields in a combination of electronic sources.
- Some data elements are in defined fields in electronic sources.
- No data elements are in defined fields in electronic sources.

Data are patient/family reported information; may be electronic or paper.

5.2.2 Path to Electronic Capture

If all data elements needed to compute the quality measure score are not from electronic sources, specify a credible, near-term path to electronic capture or provide a rationale for using other than electronic sources.

The Patient Safety Structural Measure assesses hospital capacity and administrative processes that advance patient safety (e.g., leadership commitment to patient safety). The measure reflects system-level practices, infrastructure, and elements of organizational culture that are not able to be feasibly captured electronically at this time.

5.2.3 eCQM Feasibility

If not an eCQM, state N/A.

If this is an eCQM, provide a summary of the feasibility assessment in an attached file, e.g., the [eCQM Feasibility Scorecard](#) , or make it available at a measure-specific URL.

N/A

5.3 Data Collection Strategy

5.3.1 Data Collection Strategy Difficulties (optional)

Describe difficulties as a result of testing or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, and other feasibility or implementation issues.

If the measure is instrument-based, consider the implications of burden for both individuals providing the data (e.g., patients, service recipients, respondents) and the measured entities.

N/A

5.3.2 Fees, Licensing, Other Requirements

Describe any fees, licensing, or other requirements to use any aspect of the measure as specified, such as the value or code set, the risk model, programming code, or algorithm. Please provide the fee schedule, if available. If none, state N/A.

N/A

6. [Usability and Use](#)

This criterion evaluates the extent to which intended audiences such as consumers, purchasers, measured entities, and policy makers can understand results of the measure and are likely to find them useful for decision-making. CMS expects use of CMS CBE-endorsed measures are in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to being in use for performance improvement.

6.1 Usability

6.1.1 Improvement

Instructions

Refer to data provided in 3.2, Performance Gap, but do not repeat here. Discuss or document progress on improvement, such as trends in performance results; number and percentage of people receiving high-quality health care; and geographic area and number and percentage of accountable entities and patients included.

If there was no improvement demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale describing how to use the performance results to further the goal of high-quality, efficient health care for individuals or populations.

N/A

6.1.2 Unexpected Findings

Explain any unexpected findings—positive or negative—during implementation of this measure, including unintended impacts on patients.

6.1.3 Unexpected Benefits

Explain any unexpected benefits from implementation of this measure.

6.2 Use

6.2.1 Current and Planned Use

Select all uses that apply. Identify whether the use is current or planned.

- public reporting
- public health or disease surveillance
- payment program
- regulatory and accreditation programs
- professional certification or recognition program
- quality improvement with external benchmarking to multiple organizations
- quality improvement internal to a specific organization
- not in use
- use unknown

For each current use listed, provide

- *name of the program and sponsor*
- *URL for the program (if in current use)*
- *purpose*
- *geographic area*
- *number and percentage of accountable entities and patients included*
- *level of measurement*
- *setting*

6.2.1.1 Reasons for Not Publicly Reporting or Use in Other Accountability Application

If not currently publicly reported or used in at least one other accountability application such as payment program, certification, or licensing, what are the reasons? Are there policies or actions of the measure

developer and steward or accountable entities restricting access to performance results or impede implementation?

6.2.1.2 Plan for Implementation

If not currently publicly reported or used in at least one other accountability application, provide a credible plan for implementation within the expected time frames (i.e., any accountability application within 3 years and publicly reported within 6 years of initial endorsement). Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified time frames. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

This updated Patient Safety Structural Measure (with the addition of two attestation statements to Domain 2 addressing drug shortages) is targeted for implementation in the Hospital Inpatient Quality Reporting (IQR) Program, the Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, and the Hospital Value-Based Purchasing (HVBP) Program. [The current version of the measure, prior to the addition of attestation statements addressing drug shortages, was finalized in the Fiscal Year (FY) 2025 Inpatient Prospective Payment Systems (IPPS) final rule for the IQR and PCHQR programs.]

6.2.2 Feedback on the Measure by Measured Entities or Others

6.2.2.1 Technical Assistance Provided During Development or Implementation

Describe the provision of performance results, data, and assistance with interpretation to measured entities or other users during development or implementation.

How many and which types of measured entities and/or others did you include? If you only included a sample of measured entities, describe the full population and describe the selection of the sample.

As testing has not yet been conducted, stakeholder feedback has not yet been obtained on testing results.

Stakeholder input on the development of the Patient Safety Structural Measure was extensive; almost all of the experts and patients/caregivers on the Technical Expert Panel (15 of 18) answered “Yes” when asked if this Patient Safety Structural Measure will be useful in differentiating between hospitals that are highly committed to patient safety from those that are less so, indicating strong TEP expert, patient, and caregiver support for the face validity of this measure.

6.2.2.2 Technical Assistance with Results

Describe the process(es) involved, including when/how often you provided results, what data you provided, what educational/explanatory efforts you made, etc.

N/A

6.2.2.3 Feedback on Measure Performance and Implementation

Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how you obtained feedback.

N/A

6.2.2.4 Feedback from Measured Entities

Summarize the feedback obtained from measured entities.

N/A

6.2.2.5 Feedback from Other Users

Summarize the feedback obtained from other users.

N/A

6.2.2.6 Consideration of Feedback

Describe how you considered the feedback described in 6.2.2.3 when developing or revising the measure specifications or implementation, including whether you modified the measure and why or why not.

N/A

Additional Information

Appendix

Provide supplemental materials in an appendix.

Organize all supplemental materials, such as data collection instrument or methodology reports, in one file with a table of contents or bookmarks. Indicate if material pertains to a specific MIJF item number. Provide requested information in the MIJF and any measure testing attachment(s). There is no guarantee of review of supplemental materials. Indicate whether supplemental materials are available at a measure-specific web page (URL identified in 3.1 in the MIJF), available in attached file, or no supplemental materials.

Other Additional Information

Ad.1. Working Group/Expert Panel Involved in Measure Development

List the working group/panel members' names and organizations.

Describe the members' role in measure development.

As part of its measure design process, CORE convenes stakeholders, experts, and consumer advocates who contribute direction and thoughtful input on their work and analysis. The purpose of this nationally convened Technical Expert Panel is to assemble a group with diverse perspectives and expertise to advise on conceptual, technical, and implementation considerations of this measure. The following table includes a list of members' names and organizations.

Name	Organization (if applicable) and Role	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	College Station, TX
Beth Daley-Ullem MBA	Institute for Healthcare Improvement and Patients for Patient Safety US, Patient Expert	San Juan Capistrano, CA
Melissa Danforth	The Leapfrog Group, Vice President for Healthcare Ratings	Washington, D.C.
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
Martin Hatlie, JD	Project Patient Care, President & Chief Executive Officer Patients for Patient Safety; Patient Expert	Chicago, IL

Name	Organization (if applicable) and Role	Location
Carole Hemmelgarn, MS	MedStar Health Institute for Quality and Safety, Senior Director; Caregiver Expert	Highlands Ranch, CO
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Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2. First Year of Measure Release

To be determined

Ad.3. Month and Year of Most Recent Revision

Submission to the 2024 MUC represents the most recent revision to the measure (the addition of two attestation statements to Domain 2 addressing drug shortages).

Ad.4. What is your frequency for review/update of this measure?

To be determined

Ad.5. When is your next scheduled review/update for this measure?

To be determined

Ad.6. Copyright Statement

N/A

Ad.7. Disclaimers

N/A

Ad.8. Additional Information/Comments

Nothing additional

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