AHRQ's Patient Safety Indicators: Gap Analysis and Update Opportunities

Interim Report
May 2025

Purpose

This document summarizes a recent gap analysis conducted on AHRQ's Patient Safety Indicators (PSI), highlighting gap areas within domains and subdomains that AHRQ could address by refining existing PSIs or developing new PSIs. These gap areas will be shared with the public for discussion in an upcoming listening session.

Funding

This work was funded by AHRQ through Interagency Agreement IA24-182 with CMS and conducted by The MITRE Corporation under contract number 75FCMC23D0004/75FCMC24F0220. Approved for Public Release; Distribution Unlimited. Public Release Case Number 25-1187.

Disclaimer

The statements and opinions expressed in this paper are solely of the authors and do not represent any official position of the AHRQ, the Department of Health and Human Services, or the U.S. Government.

Questions or Concerns

Comments about the contents of this document may be directed to patientsafety@mitre.org through June 2025.

Technical assistance for the AHRQ's Patient Safety Indicators including general questions or comments of existing measures may be directed to qisupport@ahrq.hhs.gov.

Table of Contents

List of Figures

List of Tables

Purpose

This document summarizes a recent gap analysis conducted on AHRQ's Patient Safety Indicators (PSI), highlighting gap areas within domains and subdomains that AHRQ could address by refining existing PSIs or developing new PSIs. These gap areas will be shared with the public for discussion in an upcoming listening session.

Identifying, Measuring, and Mitigating Preventable Harm using AHRQ's PSIs

The AHRQ Quality Indicators (QI) program first developed the PSIs over 20 years ago to equip providers with better information about the patients they serve through identifying preventable harms "that patients experience as a result of exposure to the healthcare system and that are likely amenable to prevention."[1] AHRQ's QI program uses Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID), which include all-payer inpatient hospital discharge records, to produce measures of potentially preventable harm, including the PSIs. AHRQ releases annual software that allows users to calculate observed and risk-adjusted quality measures using their own data. AHRQ's annual software update process includes minor to significant updates to existing PSIs, which are commonly leveraged by states and hospital associations to assess potential quality improvement opportunities.[1] It is important that PSIs maintain transparency and evolve alongside the changing patient safety landscape, particularly by expanding to focus on root causes of chronic diseases, such as greater upstream focus on harm prevention through reducing missed diagnoses of conditions in their early stages that may ultimately lead to chronic disease.

While measures addressing preventable harm have historically focused on acute care, harms to patients occur across the healthcare system including in ambulatory, long-term, and community-based care settings. Addressing preventable harm is especially important for patients with chronic conditions because these individuals often require ongoing medical care, frequent interactions with healthcare systems, and complex treatment regimens that all increase the potential to experience harm. Additionally, a health system that focuses on disease prevention will by and large, have lower preventable harm than other systems. In 2024, the National Quality Forum launched the Focus on HARM Initiative to update its Serious Reportable Events list to reflect current healthcare delivery settings and modalities.[2] The Centers for Medicare and Medicaid Services also highlights safety as a goal within their Meaningful Measure 2.0 framework, an initiative launched to address measurement gaps, reduce burden, and increase

[1] Agency for Healthcare Research and Quality. (2003). Guide to patient safety indicators. https://qualityindicators.ahrq.gov/downloads/modules/psi/v31/psi_guide_v31.pdf

[2] National Quality Forum. (2024, Apr 04). *NQF to Update and Harmonize Serious Adverse Event Reporting Criteria Essential to Protect Patients From Preventable Harm*. https://www.qualityforum.org/News_And_Resources/Press_Releases/2024/NQF_to_Update_and_Harmonize_Serious_Adverse_Event_Reporting_Criteria_Essential_to_Protect_Patients_From_Preventable_Harm.aspx

efficiency across the agency.[3] Given the changes in patient care and available measurement tools over recent years, AHRQ seeks to comprehensively update and modernize the PSIs to better reflect the preventable harm landscape across healthcare settings.

Methods of Identifying Gap Areas

To identify potential gaps in the current PSIs, we reviewed existing safety frameworks to identify common domains of preventable harms; conducted an environmental scan to define new harms within these domains and/or new subdomains; and created a conceptual framework (see Figure 1 below) mapping domains and subdomains to PSIs.

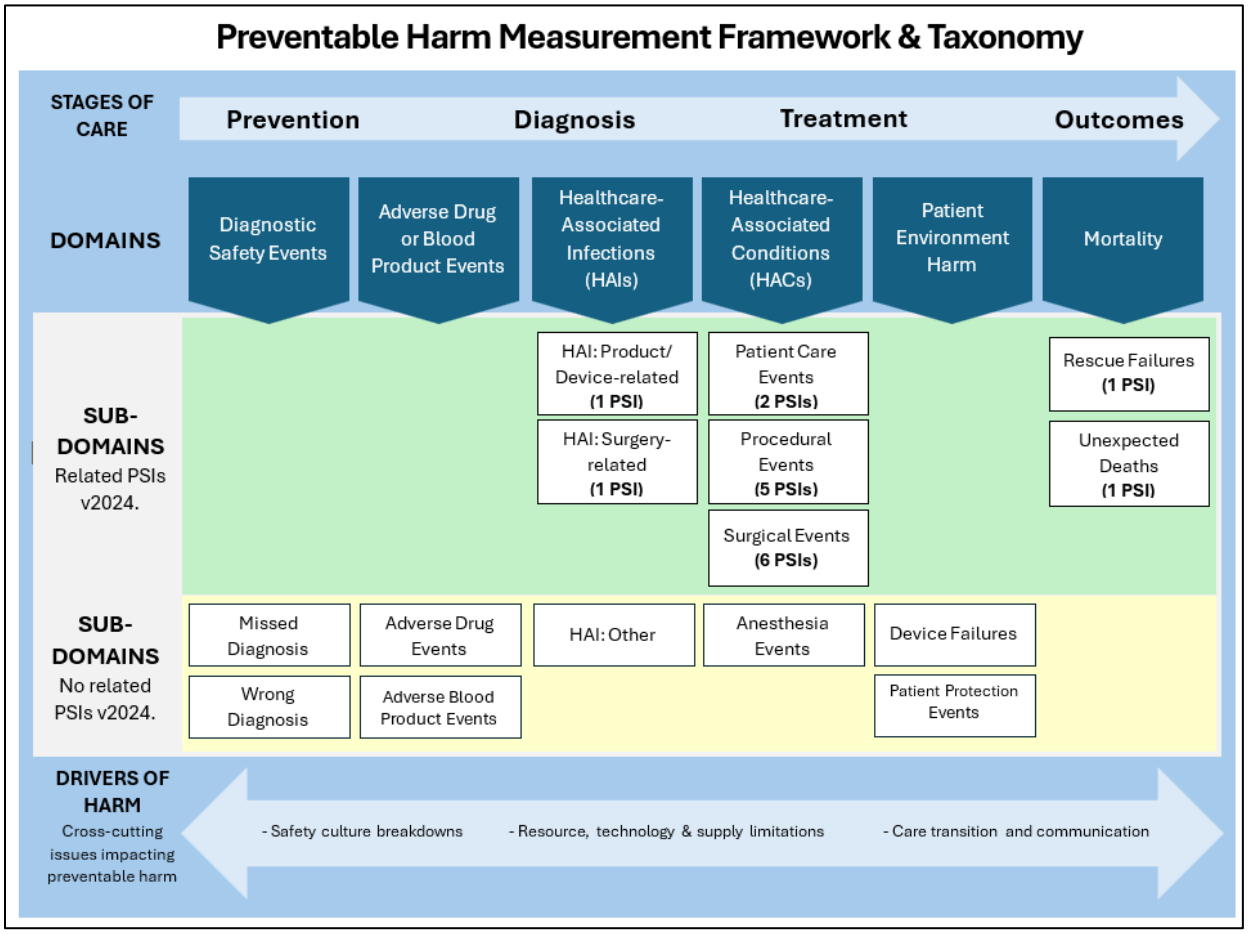

Figure 1: Visual representation of domains and subdomains mapped to PSI

A review of existing safety frameworks and research, including 'To Err is Human' and AHRQ's 'Common Format for Event Reporting,' identified six common domains of preventable harms (below). To the extent practical, these domains were also mapped across stages of care, including prevention, diagnosis, treatment, and outcomes. The six domains include:

[3] Centers for Medicare and Medicaid Services. (2024). *Meaningful Measures 2.0: Moving to Measure Prioritization and Modernization*. https://www.cms.gov/medicare/quality/cms-national-quality-strategy/meaningful-measures-20-moving-measure-reduction-modernization

- **Diagnostic Safety Events:** Failure to establish an accurate and timely explanation of the patient's health problem(s) or communicate that explanation to the patient.
- **Adverse Drug or Blood Product Events:** Includes harms from preventable errors in administration of medications or blood products, such as providing the wrong drug or blood product intended for a patient, inadvertently administering the wrong dose or amount of a drug or blood product, or giving a drug or blood product to a patient with a known contraindication to the drug or blood product.
- **Healthcare-Associated Infections (HAIs):** Includes patient infections that arise during healthcare delivery, including catheter-associated urinary tract infection (CAUTI), bloodstream infections (e.g., central-line-associated bloodstream infection (CLABSI)), surgical site infection (SSI), and ventilator-associated pneumonia (VAP).
- **Healthcare-Associated Complications (HACs):** Includes preventable harms not addressed in other domains that occur as a result of specific actions or inactions taken during provision of healthcare services, such as patient falls, pressure injuries, venous thromboembolism, accidental punctures or lacerations, or surgical errors.
- **Patient Environment Harm:** Includes harms caused by errors within the healthcare environment, such as malfunctioning devices, contaminated air or water in healthcare facilities, or misdelivery of necessary medical equipment.
- **Mortality:** Includes patient deaths in a healthcare setting that are unexpected based on their occurrence in groups with low risk of mortality and/or due to inadequate provision of appropriate healthcare interventions, such as failure to rescue patients with treatable complications.

Following the identification of common domains, an environmental scan[4] of the patient safety literature considered the need for harm measurement in the following settings, special populations, and priority areas:

- Settings
    - Ambulatory, Home Health, Hospice, Hospital Inpatient, Outpatient, Psychiatric Facility, Rehabilitation Facility, Skilled Nursing Facility/Nursing Home
- Special Populations
    - Child, Young Adult, Older Adults, Maternal, Behavioral Health
- Priority Areas
    - Health Information Technology, Artificial Intelligence, Telehealth, Radiology, Failure to Rescue, Care Transitions

The environmental scan informed updates to the domains and the creation of subdomains to provide additional structure within each domain. The subdomains were mapped to the current PSIs, categories of the National Quality Forum's 2011 Serious Reportable Events, and examples of other relevant safety measures. This mapping revealed gaps in subdomains that were considered as a measurement opportunity.

[4] The scan included peer reviewed and grey literature as well as a sample of state reporting program requirements.

Measurement Gaps

Table 1 below provides a mapping of PSIs to the identified domains and subdomains to demonstrate where measurement gaps may exist. Many subdomains do not currently have PSIs to measure preventable harms, and new PSIs may be considered to address these gaps. There are also subdomains with PSIs that are currently specified for inpatient settings only. Refinement of existing PSIs could be considered to include other settings and populations. Examples of preventable harms from the environmental scan that could potentially be measured through PSIs are provided for each subdomain; these examples are not intended to be exhaustive. Appendix A details measurement opportunities within each subdomain intended to provide examples of how PSIs may address the gaps shown in **Table 1**.

Table 1.

Domains and Subdomains with v2024 PSIs and preventable harm examples.

Domain	Subdomain	v2024 PSIs	Examples of Other Preventable Harms
1. Diagnostic Safety Events	**1A. Missed Diagnosis**	None	Missed or delayed behavioral health diagnosis
1. Diagnostic Safety Events	**1B. Wrong Diagnosis**	None	Misdiagnosis of sepsis
2. Adverse Drug or Blood Product Events	**2A. Adverse Drug Event**	None	Medication errors, drug-drug interactions, reactions to medication
2. Adverse Drug or Blood Product Events	**2B. Adverse Blood Product Event**	None	Adverse reaction to a blood transfusion
3. HAIs	**3A. HAIs Not Related to Product/Devices or Surgery**	None	C. diff or other nosocomial infections due to lack of proper hand hygiene
3. HAIs	**3B. Product/Device-Related**	PSI 07: Central Venous Catheter-Related Blood Stream Infection Rate	Catheter-associated urinary tract infections
3. HAIs	**3C. Surgery-Related**	PSI 13: Post-Operative Sepsis Rate	Surgical site infections
4. HACs	**4A. Anesthesia Events**	None	Oversedation; post-operative delirium
4. HACs	**4B. Patient Care Events**	PSI 03: Pressure Ulcer Rate PSI 08: In-Hospital Fall-Associated Fracture Rate	Venous thromboembolism

Domain	Subdomain	v2024 PSIs	Examples of Other Preventable Harms
4. HACs	**4C. Procedural Events**	PSI 06: Iatrogenic Pneumothorax Rate PSI 15: Abdominopelvic Accidental Puncture or Laceration Rate PSI 17: Birth Trauma Rate - Injury to Neonate PSI 18: Obstetric Trauma Rate - Vaginal Delivery with Instrument PSI 19: Obstetric Trauma Rate - Vaginal Delivery without Instrument	Improper placement or dislodgement of needle or feeding tube; unplanned extubation; enteral tubing misconnection
4. HACs	**4D. Surgical Events**	PSI 05: Retained Surgical Item or Unretrieved Device Fragment Count PSI 09: Postoperative Hemorrhage or Hematoma Rate PSI 10: Postoperative Acute Kidney Injury Requiring Dialysis Rate PSI 11: Postoperative Respiratory Failure Rate PSI 12: Perioperative PE/DVT Rate PSI 14: Postoperative Wound Dehiscence Rate	Perioperative hypothermia; adverse surgical events due to lack of procedure volume of high-risk surgeries, such as for bariatric surgery, carotid endarterectomy.
5. Patient Environment Harm	**5A. Device Failures**	None	Injury caused by malfunctioning device
5. Patient Environment Harm	**5B. Patient Protection Events**	None	Medically necessary equipment not delivered to the home following discharge; Legionella in hospital water system
6. Mortality	**6A. Rescue Failures**	PSI 04: Death Rate Among Surgical Inpatients with Serious Treatable Conditions	Death rate among non-surgical patients with serious treatable conditions
6. Mortality	**6B. Unexpected Deaths**	PSI 02: Death Rate in Low-Mortality DRGs	Death of a low-risk maternity care patient; death of full-term newborn

Considerations

We are considering several areas of improvement, including potential expansion of PSIs to new care settings and populations. It is critical to consider how PSIs can address emerging patient safety challenges, including the following issues:

1. **Domain Additions/Modifications:** Potential additions or modifications to the Patient Harm Measurement Framework & Taxonomy domains or subdomains to better support updates to the PSIs.

2. **Prioritization of Gaps:** Identifying gaps in domains or subdomains that are more critical to address than others.
    a. **Data Availability:** The availability of data (e.g., EHR data, patient experience data, AI tools) for each gap area.
3. **Mitigating Unintended Consequences:** Reducing unintended side effects from updating or adding PSIs including balancing the burden of data collection and measurement with leveraging the PSIs to prevent harm.
4. **Specific vs. Broad Measures:** Balancing PSI measure specificity with the ability to identify actionable measures of preventable harm versus the ability to apply a measure across diverse healthcare settings.
5. **Measurement of Effectiveness Over Time:** Ensuring that new or updated PSIs measure improvements in preventing harm.
6. **Patient Experience:** Aligning clinical outcomes with improving patient experiences.

Appendix A

Opportunities to address the gaps identified above in Table 1 may include expansion of existing PSIs to other settings and populations as well as the development of new PSIs to address preventable harms where PSIs do not currently exist. Opportunities identified in Table 2 for preventable harms met the following criteria:

- Preventable harms that have either a high degree of severity or prevalence, or
- Preventable harms for which intervention(s) exists but is/are thought to be underutilized

Table 2.

Measurement Opportunities

Domain	Subdomain	Measurement Opportunity
Domain #1: Diagnostic Safety Event	Missed Diagnosis	**Opportunity #1—Consider New Measures of Diagnostic Excellence**: Potential areas may include missed labs, imaging, or other test results that delay proper diagnosis or follow up.
Domain #1: Diagnostic Safety Event	Wrong Diagnosis	**Opportunity #2: Leverage Different Data to Identify Wrong Diagnosis with Sufficient Accuracy:** Potential gap area may include behavioral health (particularly for youth).
Domain #2: Drug or Blood Product Event	Adverse Drug Event	**Opportunity #3: Consider Developing New Measures for Adverse Drug Events Using Claims Data:** Consider new PSIs in the near-term with available claims data to identify adverse drug events in older adults, young adults, or general antibiotic overuse. **Opportunity #4: Consider Improved Use of Technology for Future PSI Measurement of Adverse Drug Events:** Consider linking EHR and clinical data, including through the use of artificial intelligence (AI), in the long-term to identify adverse drug event related harms.
Domain #2: Drug or Blood Product Event	Adverse Blood Product Event	**Opportunity #5: Consider Developing New Measure for Blood Product Events, Particularly in Outpatient Settings:** Consider new PSIs in the near-term to address blood product events in outpatient settings.
Domain #3: HAIs	HAIs Not Related to Product/Devices or Surgery	**Opportunity #6: Consider Developing New Measures for Common HAIs:** New PSIs could be developed to measure several additional HAIs, including: • Clostridioides difficile (C. Diff) in the near-term • Ventilator-associated (VAP) and nonventilator-associated (NVHAP) pneumonia in the near-term • Hospital-onset bacteremia and fungemia in the long-term **Opportunity #7: Consider Measurement of HAIs Using New Data Sources:** New data sources may be helpful for diagnosis, monitoring, and sterility assurance.

Domain	Subdomain	Measurement Opportunity
Domain #3: HAIs	Product/Device-Related	**Opportunity #8: Consider Developing New Measures for Common Product/Device-Related HAIs:** New PSIs could be developed in the near-term to measure additional device-related HAIs, including catheter-associated urinary tract infections.
Domain #3: HAIs	Surgery-Related	**Opportunity #9: Consider Developing New Measures for Common Surgery-Related HAIs:** New PSIs could be developed in the near-term to measure surgery-related HAIs, including surgical site infections (SSIs), particularly associated with cardiovascular and colorectal surgeries.
Domain #4: HACs	Anesthesia Events	**Opportunity #10: Consider Developing New Measures for Anesthesia-Related Events:** In the near-term, consider development of new PSIs for anesthesia-related events across all settings and populations. **Opportunity #11: Consider Developing New Measures for Events Related to Perioperative Care:** In the near-term, consider new PSIs for events related to perioperative care, including blood and nutrition management for certain risk factors as an opportunity for PSI measurement.
Domain #4: HACs	Patient Care Events	**Opportunity #12: Consider Refining Current PSIs Measures to Capture Patient Care Events for Other Settings/ Populations**: Current PSIs are specified only in an inpatient setting. Consider expanding PSIs to other settings and populations, particularly for long-term care facilities. **Opportunity #13: Consider Refining Current PSIs to Capture Use of AI:** In the long-term, consider refining PSIs to account for the presence/absence of AI in patient care tools and devices as a factor that modifies risk of harm. Tools and devices supplemented with AI may increase harm if not properly tested and validated, but can potentially reduce preventable harm when used appropriately (e.g., improved disease detection in imaging). In the long-term, the absence of using effective AI could become a risk factor to care outcomes. **Opportunity #14: Consider Developing New Measures for VTE:** In the long-term, consider developing new measure for VTE-related events.
Domain #4: HACs	Procedural Events	**Opportunity #15: Consider Refining Current PSIs to Include Other Settings/ Populations**: Current PSIs are specified only in an inpatient setting. Consider near-term expansion of these PSIs to other settings and populations.
Domain #4: HACs	Surgery Events	**Opportunity #16: Consider Developing New Measures for Surgery-Related HACs:** Opportunities include measuring volumes of high-risk surgeries (e.g., bariatric surgery or carotid endarterectomy) successfully completed for which there is a strong volume-outcome relationship.

Domain	Subdomain	Measurement Opportunity
Domain #5: Patient Environment Harm	Device Failures	**Opportunity #17: Consider Different Types of Data for Future PSI Measurement of Device Failures:** Future long-term expansion of PSIs could consider different types of data across settings related to the use of medical devices and equipment.
Domain #5: Patient Environment Harm	Patient Protection Events	**Opportunity #18: Consider Assessment of Points of Care Transition, Particularly for Chronic Disease Outcomes for Future PSI Measurement:** Future long-term PSI expansion could consider chronology of preventable harms across points of care transition, particularly for chronic disease outcomes.
Domain #6: Mortality	Rescue Failures	**Opportunity #19: Consider Refining Current PSIs to Account for Several Factors:** There may be opportunities to account for baseline risk factors (e.g., frailty) and enhanced risk adjustment for volume of procedures. **Opportunity #20: Consider Developing New PSIs to Measure Mortality Events Using New Types of Data**: Self-report and indicators of failure to rescue events are an incomplete view. Future PSI expansion could consider new types of data using AI or patient monitoring to identify events.
Domain #6: Mortality	Unexpected Deaths	**Opportunity #21: Consider Different Data to Identify Events**: Long-term, new PSIs could include different data using AI or patient monitoring to identify events.