AHRQ's Patient Safety Indicators (PSIs): Recommendations to Update the PSIs

Prepared for:

Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ)

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Notice

Executive Summary

The Agency for Healthcare Research and Quality (AHRQ) Quality Indicators (QI) program first developed the Patient Safety Indicators (PSIs) more than 20 years ago to equip providers with better information about the patients they serve by identifying preventable harms "that patients experience as a result of exposure to the healthcare system and that are likely amenable to prevention."[1] AHRQ recognized a need to update the PSIs to capture the evolving forms of preventable harm occurring across a wider range of healthcare settings. Historically, Patient Safety Indicators (PSIs) have provided important insight into potentially avoidable safety events across healthcare settings. CMS is strategically transitioning away from PSIs as the primary tool for patient safety reporting, reflecting a broader move toward digital measurement and real-time safety monitoring, which provides more actionable, precise, and timely data to improve patient safety. At the same time, collaboration with federal partners and input from the public and stakeholders contributes to a better understanding of safety events, and PSIs continue to inform considerations around measure alignment, harmonization, and emerging patient safety priorities. Given the importance of collaboration to improve safety, AHRQ and CMS contracted with MITRE, the operator of the Health Federally Funded Research and Development Center (FFRDC), to develop recommendations to update the PSIs as this work remains an important foundation to inform considerations for measure alignment, harmonization, and emerging priorities.

MITRE conducted a targeted environmental scan of patient safety literature, collected input from the public, and convened a panel of patient safety and measurement experts. Using the scan, MITRE developed a framework to discuss potential opportunities for refining, retiring, or developing new PSIs, and used that to collect input from members of the public through a listening session and via email, and to validate the recommendations with the expert panel. The framework grouped the discussion into categories of diagnostic safety events, adverse drug or blood product events, healthcare-associated infections (HAIs), healthcare-associated conditions (HACs), patient environment harm, and mortality. Using this approach, MITRE consolidated the recommendations that promote alignment of safety event data collection and analysis across federal agencies, reduce patient and provider reporting burden, and improve outcomes for patients.

The recommendations for the evolution of PSIs are:

1. Review existing PSIs to eliminate overlap with other federal safety measures, such as those from the CDC, which will help streamline reporting and reduce provider burden.
2. Expand PSIs to Ambulatory Surgery Centers (ASCs) and develop measures for perioperative care in this setting, as increasingly complex procedures are being performed in ASCs.
3. Broaden maternal and neonatal safety measures to care settings beyond the hospital, such as birthing centers, and develop perinatal safety indicators to better quantify preventable harms for these populations.
4. Continue efforts to identify data sources for measures of preventable harm from diagnostic errors, including in behavioral health.

The effort to update PSIs generated significant engagement from the public, signaling the importance of PSIs to industry and as part of the federal safety ecosystem. As the patient safety landscape continues to evolve, AHRQ will drive advancements that have downstream impacts on the future of PSIs and other quality indicators. AHRQ and its federal partners can continue to evolve the use of PSIs to promote a safe, reliable, and patient-centered healthcare system, including potentially:

- Advancing data collection on preventable harms occurring in new and emerging care settings, such as hospital-at-home, freestanding EDs, and urgent care centers, or patient harm that may result from the use of new technologies, such as telehealth and artificial intelligence (AI).

- Developing and harmonizing definitions in patient safety to accurately measure and compare safety outcomes, leading to effective quality improvement and policy decisions.
- Identifying measures of preventable harm during care transitions which is a heightened period of vulnerability for patients and a current gap in measurement efforts.
- Examining opportunities to collect patient-reported experience and outcome data for use in measurement, including advance directives and goals of care, allowing for valuable insights into the effectiveness and safety from the patient's perspective.

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1 Overview

The Agency for Healthcare Research and Quality (AHRQ) Quality Indicators (QI) program first developed the Patient Safety Indicators (PSIs) more than 20 years ago to equip providers with better information about the patients they serve by 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 provides software that allows users to calculate observed and risk-adjusted QIs 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]

While measures addressing preventable harm have historically focused on acute care settings, harms to patients occur across the healthcare system including in ambulatory, long-term, and community-based care settings. It is important that PSIs continue to evolve alongside the changing patient safety landscape to address harms that contribute to chronic disease prevalence, such as missed early diagnoses, and harms that disproportionately affect vulnerable populations, such as individuals with cognitive impairment or behavioral health conditions. Addressing preventable harm is especially important for patients with chronic conditions because these individuals often require ongoing medical care, have frequent interactions with healthcare systems, and experience complex treatment regimens, all of which increase the potential for harm.

In collaboration with AHRQ, the Centers for Medicare & Medicaid Services (CMS) engaged the MITRE-operated Health Federally Funded Research and Development Center (FFRDC) to support the development of recommendations for future updates to AHRQ's PSIs. While PSIs have provided important insights into potentially avoidable safety events, CMS is strategically transitioning away from PSIs as the primary tool for patient safety reporting. This shift reflects a broader move toward digital measurement and real-time safety monitoring, which provides more actionable, precise, and timely data to improve patient safety. At the same time, PSIs remain an important foundation and discussions about their evolution can inform further considerations around measure alignment, harmonization, and emerging patient safety priorities. These recommendations build on these concepts to promote alignment of safety event data collection and analysis across federal agencies, reduce patient and provider reporting burden, and improve outcomes for patients. This report outlines the process used to develop these recommendations.

2 Purpose and Approach

This analysis seeks to develop recommendations for future updates to the PSIs and align patient safety measurement efforts by:

1. Identifying high-priority areas for improvement in patient safety;
2. Supporting CMS and AHRQ decision-making for future stakeholder engagement and PSI development; and
3. Enhancing alignment with HHS patient-safety priorities to improve efficiency and maximize impact on clinical outcomes.

Section 2 describes the process to identify potential opportunities to update PSIs and the public input received to refine the opportunities. Section 3 details the environmental scan findings and

measurement opportunities, public input received through comments and written submissions, and input from multistakeholder convenings. Section 4 provides the final recommendations for updates to PSIs.

2.1 Establishing a Guiding Framework

A review of established frameworks from key healthcare quality and safety initiatives, as well as elements from other patient safety measure sets, formed the basis for the framework used to develop measurement opportunities. Sources included but were not limited to:

- To Err is Human[2];
- Crossing the Quality Chasm[3];
- CMS Meaningful Measures 2.0 (MM2.0), specifically the Cascade of Measures for Safety[4];
- AHRQ's National Healthcare Quality and Disparities report[5];
- National Quality Forum Serious Reportable Events, formerly known as "Never Events" (2024)[6];
- AHRQ Common Formats for Event Reporting[7]; and
- AHRQ Network of Patient Safety Databases event categories.[8]

A comprehensive analysis mapping the six preventable harm objectives listed in the MM2.0 Cascade of Measures for Safety to the other resources revealed that these objectives encompass most preventable harm concepts across frameworks. Appendix A outlines this analysis. Therefore, as the most recent and comprehensive safety framework that builds upon prior frameworks while providing a structured approach, utilizing the six objectives from MM2.0 as the initial framework supports alignment in data collection and analysis, enables systematic gap identification, and ensures consistency with CMS's broader quality measurement modernization strategy.

2.2 Developing Domains and Working Descriptions

The six preventable harm objectives guided the development of domains to categorize preventable harms and descriptions ensure consistent assignment. The six domains and descriptions are:

- **Diagnostic Safety Events:** Includes failure to establish an accurate and timely explanation of the patient's health problem(s) or to communicate that explanation to the patient.
- **Adverse Drug or Blood Product Events:** Includes harms resulting from preventable errors in the administration of medications or blood products.
- **Healthcare-Associated Infections (HAIs):** Includes infections arising during healthcare delivery.
- **Healthcare-Associated Conditions (HACs):** Includes preventable harms not addressed in other domains arising from specific actions or inactions taken during provision of healthcare services.
- **Patient Environment Harm:** Includes harms caused by errors in the healthcare environment.
- **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.

2.3 Environmental Scan

A targeted environmental scan of patient safety literature and state reporting programs identified potential preventable harms. The scan covered the following areas (see Appendix B for more detail):

- Settings: Ambulatory, Home Health, Hospice, Hospital Inpatient, Psychiatric Facility, Rehabilitation Facility, Skilled Nursing Facility/Nursing Home
- Populations: Infant, Child, Young Adult, Adult, Older Adults
- Priority Areas: Health Information Technology (HIT), Artificial Intelligence (AI), Telehealth, Radiology, Failure to Rescue, Care Transitions, Maternal, Behavioral Health
- State Safety Reporting Programs: Reportable Adverse Events (California),[9] Quality in Healthcare Program Adverse Event Reporting (Connecticut),[10] Sentinel Event Registry (Nevada),[11] and Patient Safety Reporting System (Pennsylvania)[12]

The environmental scan identified over 300 potential types of preventable harm from more than 200 sources, which MITRE used to refine the framework and provide example opportunities for measurement. The environmental scan findings are presented by domain and highlight trends in preventable harm identified in the literature for further consideration. The measurement opportunities identified through the environmental scan were intended to stimulate further input from the public and multistakeholder groups and were not intended to be comprehensive.

2.4 Framework and Taxonomy for Opportunities

The framework, shown in Figure 1, visualizes opportunities to expand PSIs within the domains outlined in section 2.2. The stages of care – prevention, diagnosis, treatment, and outcomes – span all domains, ensuring the framework reflects the full spectrum of a patient's care journey and focuses on outcomes important to patients. Subdomains, derived from existing frameworks and research, represents logical groupings of preventable harm within each domain. The framework divides subdomains into two groups: those with and those without related PSIs. The gaps, particularly in subdomains without related PSIs, point to potential opportunities for PSI development or refinement.

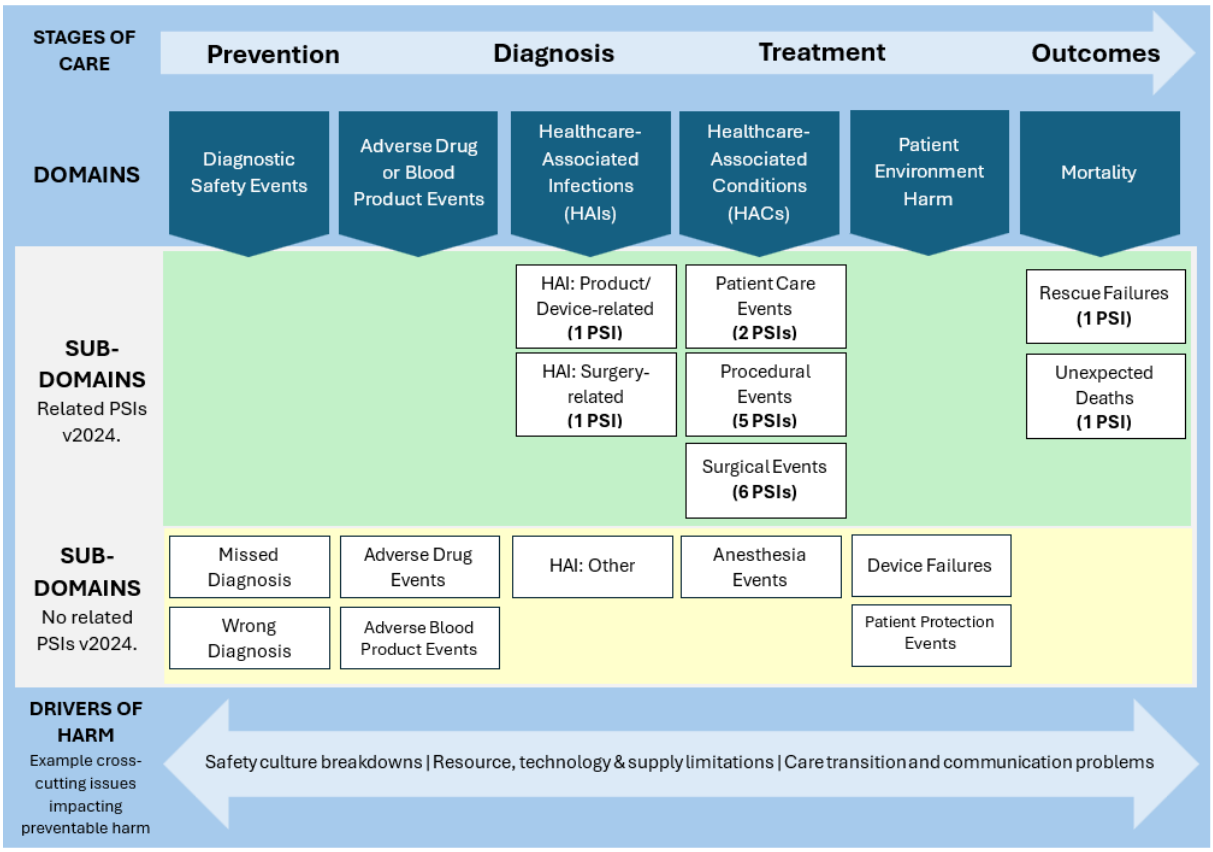

Figure 1. Preliminary Preventable Harm Measurement Framework

Figure 1 also highlights examples of cross-cutting drivers of harm, such as safety culture breakdowns, resource limitations, and communication problems, which capture external factors beyond direct patient care interactions that contribute to harm across the healthcare system. While these drivers are critical for identifying root causes of safety problems, the framework excludes them from consideration as new PSIs because they are not direct harms.

A taxonomy mapping the subdomains listed above to additional preventable harm measures and data revealed considerations and potential issues when recommending a subdomain as a measurement opportunity. Additional details on the taxonomy mapping can be found in Appendix C.

2.5 Public Input

Stakeholders from patient and patient advocacy groups, healthcare organizations, clinicians, patient safety experts, trade associations, health plans, and state and local health departments provided input on opportunities to measure preventable harm. The written public input period ran from May 7, 2025, through June 30, 2025, and began with a listening session to review the opportunities for measurement of preventable harm. The content posted for public input can be found in Appendix D. Areas highlighted for consideration included:

1. **Domain Additions/Modifications:** Adding or modifying domains or subdomains in the Patient Harm Measurement Framework & Taxonomy to better support PSIs updates.
2. **Prioritization of Gaps**: Identifying gaps in domains or subdomains that are more critical to address than others.

    a. **Data Availability** for each gap area (e.g., electronic health record (EHR) data, patient experience data, AI tools).
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 track improvements in preventing harm.
6. **Patient Experience**: Aligning clinical outcomes with improved patient experiences.

The listening session and public input period generated 213 comments. Each comment was categorized by domain or area for consideration, representing overarching themes. Summarized public input is outlined by domain (see Appendix E for the analysis of public input).

2.6 Multi-Stakeholder Group Discussion

A Multi-Stakeholder Group (MSG) convened on July 30, 2025, to refine and prioritize recommendations to update the PSIs. The MSG comprised of 14 members: four providers from health systems, three MDs from state health organizations, two patient advocates, two consensus-based entity representatives, two PhD researchers, and one payer representative. Viewpoints from across the U.S. were represented, ranging from small healthcare organizations to larger healthcare systems. Additionally, five liaisons representing additional patient safety focused organizations and a representative from Centers for Disease Control and Prevention (CDC) attended the convening to observe and provide additional feedback to AHRQ.

Prior to the convening, MSG members completed pre-work to prioritize domains for discussion. MITRE framed the discussion around priority topics synthesized from the environmental scan measurement opportunities, public input, and pre-work. The three-hour long convening's priority topics are summarized by domain.

3 Domain Opportunities for PSI Development

3.1 Diagnostic Safety Events

3.1.1 Environmental Scan Findings

Diagnostic safety is likely to impact most people at least once in their lifetime, and an estimated 12 million Americans experience a diagnostic error annually.[13] Approximately half of serious harms caused by diagnostic error relate to 15 diseases, and improving diagnosis of the top five – stroke, sepsis, pneumonia, venous thromboembolism (VTE), and lung cancer – represents an opportunity to significantly reduce harm.[14]

Research on reducing diagnostic errors mainly focuses on avoiding **wrong diagnoses** or **missed diagnoses**, including delayed diagnoses. These types of diagnostic errors may be particularly problematic for certain populations, including individuals with mental health challenges,[13] those with chronic diseases or older adults with cognitive impairment,[15] or youth at risk of suicide.[16] Despite many

national efforts to reduce diagnostic error, diagnosis in mental health is not well represented in this ongoing work.[17] Advances in technology, such as AI, virtual visits, or patient portals, may inadvertently contribute to miscommunication and misdiagnosis.[18]

Evidence suggests that some diagnostic errors may be prevented, including through the use of clinical laboratory stewardship programs[19] or improved laboratory testing processes.[20] Reductions in wrong diagnosis are possible,[13] and enhanced diagnostic tools and protocols can reduce missed diagnosis at certain points in care. Examples include protocols and bundled interventions for skin biopsies[21]; guidance to avoid overuse of cardiac telemetry[22]; electronic trigger tools to flag errors in the health record[18]; and cognitive training for behavioral health providers.[17]

3.1.2 Environmental Scan Measurement Opportunities

Currently, PSIs do not specifically address the diagnostic safety domain. Efforts to address diagnostic error in behavioral health, especially for youth, may be warranted. Missed lab, imaging, or other test results that lead to delayed or missed diagnoses, as well as inappropriate follow-up care, could be examined. Proxy measures, such as late-stage diagnosis, could be evaluated for their accuracy in reflecting true missed diagnoses. Consideration could also be given to developing measures that address diagnostic safety for the top five diseases associated with diagnostic errors.

It may be difficult to categorize a wrong diagnosis as an error versus an unusual presentation or progression of a disease. It may also be important to assess the role of technology in influencing rates of wrong diagnoses. Evaluating whether current measurement approaches are adequate to define and assess wrong diagnoses with sufficient accuracy may be warranted.

3.1.3 Public Input

Many commenters noted potential operational challenges in capturing a missed or wrong diagnoses, including time frames, thresholds, and clinical judgment considerations. Additional operational challenges include the inability to measure errors in outpatient settings, as many PSIs are specified for inpatient care; differences in diagnoses made by generalists versus specialists; and difficulties in capturing diagnostic errors through ICD-10 codes and billing documents. There are also specific considerations for rural communities, such as limited access to imaging, and patient unwillingness to pursue further care. With psychiatric disorders in particular, patients may experience symptoms that are insufficient for a diagnosis, but over time develop a more complete set of symptoms consistent with a diagnosis. This would not necessarily be considered an error, but could retrospectively be considered a late diagnosis.

3.1.4 MSG Discussion

This conversation focused on ways AHRQ can leverage non-claims-based data to develop a PSI.

A few members emphasized the importance of communicating diagnoses and proposed measuring the time between posting results in the patient portal and follow up as a potential data source. Others suggested using multiple data sources to determine missed or incorrect diagnoses, particularly looking at diagnoses over time, and discussed lab data as a supplement to claims data. Some members discussed using AI to more effectively analyze existing data, particularly diagnostic imaging results.

The MSG also discussed specific populations and settings. They supported examining opportunities to incorporate diagnostic safety into future PSI measurement, particularly for **infants and older adults**. For

infants, MSG members noted concerns about missed diagnoses (e.g., infections) and overtreatment due to incorrect diagnoses. One member provided the example of missed diagnoses for neonatal ischemic encephalopathy, which could lead to catastrophic outcomes. For complex older adults, opportunities included improving time to diagnosis and treatment for acute stroke, addressing overuse of diagnostic tests (e.g., unnecessary antimicrobial prescribing for asymptomatic bacteriuria, overuse of C. Diff testing), acute coronary events in the Emergency Department (ED), laboratory testing for chronic conditions, and consistent screening for polypharmacy across care settings.

The MSG also supported more closely examining safety risks in **behavioral health**, particularly for adolescents, young adults, and the maternal population. One MSG member emphasized the importance of tracking maternal mortality, including both acute conditions (e.g., hemorrhage or severe hypertension) and long-term complications.

3.2 Adverse Drug or Blood Product Event

3.2.1 Environmental Scan Findings

Adverse events arising from errors in the administration of drugs or blood products are a risk to individuals regardless of age or care setting. In the U.S., medication errors harm an estimated 1.5 million patients per year and lead to 400,000 adverse events.[23] The impact of medication events is projected into the billions of dollars.[24]

Adverse drug events (ADEs) may include medication errors, drug-drug interactions, and medication reactions, with errors and delays in administration[25] posing safety risks in inpatient, post-acute, and outpatient/ambulatory care.[26,27,28,29,30] **Adverse blood product events** related to adverse reactions during transfusions are largely preventable and may lead to blood product wastage and can result in patient harm.31 While relatively few items were identified about blood product events in the environmental scan, these errors can sometimes lead to serious harm.

Increased attention to events occurring within pediatric and older adult populations may be warranted. Children are at particular risk for safety events related to vaccines, sedatives, and allergen therapies, and allergen immunotherapy medication errors can cause significant harm.[32] For older and help-dependent individuals, the use of multiple medications also poses safety risks for drug-to-drug interactions.[33]

Interventions such as clear orders for proper medication titration,[34] specialized connectors to prevent misconnection,s[35],\ regularly updating medication histories for high-risk patients,[36] use of barcodes, and use of oral syringes instead of cups can reduce medication errors[18] and offer potential opportunities to reduce adverse drug events. Patients also report that improved provider communication about medications is needed,[37] and providing language services may be helpful in reducing safety events.[18] Software programs may significantly improve efficiency, accuracy, and consistency [38,39,40,18] in tracking and reducing medication errors.[42] Clinical decision support tools that trigger alerts may be useful for preventing drug allergy interactions.[43] Better guidance for pediatric vaccine use is needed, including recommendations for storing “look-alike” vaccines and proper temperature maintenance.[44] Anticoagulation stewardship may reduce adverse events, as anticoagulants (along with opioids and hypoglycemics) are most associated with serious events in outpatient settings.[36,45]

3.2.2 Environmental Scan Measurement Opportunities

Currently, PSIs do not specifically address adverse drug or blood product events, but other measures sets do address some aspects of adverse drug events, such the Healthcare Effectiveness Data and Information Set (HEDIS), which includes measures related to the use of high-risk medications and polypharmacy in older adults.[46] To address high-risk populations, special attention to the needs of older and younger populations and those who depend on others for help may be warranted. Improved linkages between EHR and clinical data may provide technological advances to aid in the measurement of adverse drug event harms, and measures to address transfusion events may be considered.

Given the large number of findings from the environmental scan and the frequency of medication errors, this PSI gap may warrant further exploration. Additional subdomains could be developed for different types of ADEs, but it is unclear if this is needed given that key interventions, such as improved medication reconciliation, may address multiple types of adverse drug events.

3.2.3 Public Input

One commenter noted that not all adverse reactions to medication or blood products are necessarily preventable and asked for additional details on defining adverse reactions. One commenter suggested a process measure for identifying preventable harms, rather than an outcome measure that may penalize a provider for an ADE that is not necessarily preventable. One comment suggested focusing on serious ADEs, as there are frequently minor reactions and reporting those would be a reporting burden. Some comments noted that ADEs are often only known if patients report them, so a patient reporting mechanism would be required for formal reporting to federal agencies. A few comments highlighted the distinction between medication errors and ADEs, and one asked about risks associated with geriatric or age-related inappropriate or high-risk medications. There were no comments related to blood product events.

3.2.4 MSG Discussion

This conversation focused on AHRQ's potential to overcome data limitations related to developing a PSI for ADEs. Blood product events were not the primary area of discussion.

MSG members generally supported PSI development for ADEs. MSG members noted the importance of **clearly defining an ADE**, particularly those that are preventable, as non-preventable adverse reactions should not be considered a safety event. Suggested definitions should include a distinction between medication errors and preventable adverse reactions and may also focus on "high-alert" medications (e.g., opioids, anticoagulants, insulin). One MSG member supported focusing on ADEs in pediatric populations.

MSG members discussed the **lack of data within claims** to effectively track ADEs. For example, medication reconciliation, wrong dose, and excessive dose do not appear in claims data. A few MSG members emphasized fragmentation of care as a root cause driving the inability to track ADEs. One MSG member noted that pharmacy data is not transmitted to health system EHRs unless a retail pharmacy is embedded within the health system, so asking patients to report preventable ADEs may be the only feasible way to comprehensively measure them. Another member added that Veterans Affairs (VA) pharmacies may not have visibility into patient prescriptions issued through Medicare or in the community, and tracking across systems would be an ideal way to develop a comprehensive PSI. Finally, one MSG member noted that because many ADEs occur in outpatient settings, ADEs often are not captured until patients arrive in the ED with medication error-related events.

3.3 Healthcare Associated Infections

3.3.1 Environmental Scan Findings

Approximately one in 31 patients and one in 43 nursing home residents in the U.S. contract at least one infection associated with their healthcare daily.[47] HAIs are the second most common outpatient adverse safety event.[29] While HAIs continue to pose risks to patient safety, CDC has reported that infection rates have generally returned to pre-2020 levels in acute care hospitals.[47]

HAIs can be **product- or device-related**, such as catheter-associated urinary tract infections, which account for approximately 40 percent of nosocomial infections,[48] or they can be **surgery-related**, such as surgical site infections (SSI), which are most common in cardiovascular and colorectal surgeries.[49] Some infections may **not be related to products, devices, or surgery**, such as Clostridioides difficile (C. diff) infection, which is the most frequent HAI, accounting for 56 percent of reported HAIs,[50] or non-ventilator acquired pneumonia, which occurs in one of every 100 hospitalized patients.[51] Some infections, including those mentioned above, as well as sepsis, which is severe and costly,[52] may stem from a variety of etiologies.

Active surveillance is helpful for managing the spread of infection.[53] For example, Pennsylvania monitors patient-safety events for hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities,[12] and CDC has introduced monitoring for hospital-onset bacteremia and fungemia as an indication of an HAI infection.[54] Traditional preventive efforts, such as antimicrobial prophylaxis, hand hygiene, and decontamination, remain important,[55] while emerging AI tools may also be helpful for diagnostics, monitoring, sterility assurance,[56] and risk prevention.[57]

3.3.2 Environmental Scan Measurement Opportunities

Current PSIs address central venous catheter-related bloodstream infection rate (PSI 07) and postoperative sepsis rate (PSI 13). While sepsis is prevalent in maternal health, the AHRQ Maternal Health Indicators (MHI) address hospital maternal morbidity and mortality, which includes sepsis. New PSIs could be developed to measure other common HAIs, such as C. diff, ventilator- and non-ventilator-associated pneumonia, hospital-onset bacteremia and fungemia, catheter-associated urinary tract infections, or SSIs among cardiovascular and colorectal surgeries. However, CDC's National Healthcare Safety Network (NHSN) offers providers extensive support in tracking and measuring HAIs. Of note, definitions and risk of infection from multidrug-resistant organisms and C. diff may vary by location and population.

3.3.3 Public Input

A few commenters suggested minor updates to subdomain classification, including HAI examples of product- or device-related HAIs and HAIs not related to product, devices, or surgery. One comment suggested an additional subdomain focused on HAIs associated with antibiotic use or overuse. One commenter suggested a broader indicator of HAIs that would give a more holistic view of HAI prevention effectiveness without duplication.

3.3.4 MSG Discussion

The convening focused on the duplication of PSIs with NHSN measures.

MSG members discussed whether current PSIs in this area should be retired or refined, noting duplication of HAI-related PSI measures with measures used by the NHSN. Some MSG members supported **retiring PSI 07: Central Venous Catheter-Related Bloodstream Infection Rate**, due to duplication and administrative burden, noting that all states are expected to have access to this NHSN data. MSG members generally supported maintaining PSI 13: Postoperative Sepsis Rate as it is distinct from general sepsis and has no direct analogue in the NHSN program. There was some support for expanding PSI 13 to include ambulatory surgery centers (ASCs). One MSG member supported maintaining PSIs so they remain accessible for stratification. Finally, one MSG member supported a PSI on hospital-wide infections for high-risk pathogens (e.g., Carbapenem-Resistant Enterobacterales [CRE], Candida auris [C. auris]), particularly for emerging threats that can be proactively addressed by understanding incidence.

3.4 Healthcare Associated Conditions

3.4.1 Environmental Scan Findings

As a domain, HACs encompass a wide array of safety events that result from the delivery of healthcare services. Together, surgical and procedural events are the third most common source of patient harm among outpatients, behind adverse drug events and HAIs.[29]

Commonly referenced **surgical events** include retained surgical items, which were the third most frequently reported event in 2021[58]; hospital-acquired acute kidney injury[59]; and perioperative hyperthermia.[60] Examples of **procedural events** mentioned in the literature include undetected needle dislodgement or bloodline separation in hemodialysis, which can lead to death[22]; unplanned extubation in pediatric populations, which is associated with extended ventilator support[61]; and difficulties with in-home infusion therapy and parenteral nutrition as individuals with complex care needs are increasingly being managed in the home.[62]

Patient care events include harms that occur during routine patient care, such as falls and pressure ulcers, which are particularly common among long-term care residents with mobility issues,[63,64,30,65] post-intensive care syndrome[18] VTE, which is associated with mortality and higher costs of care; and maternal VTE, which accounts for almost 15 percent of maternal mortality.[66]

Examples of harm related to **anesthesia events** include oversedation[18]; perioperative hyperglycemia[67]; complexities of anesthesia management in children[68]; and post-operative delirium, more common in aging populations.[69,70,71,72] Because anesthesia is administered for surgeries and procedures, it is identified as a separate domain in this framework.

The literature references many examples of interventions to prevent HACs, including bundles for skin care to reduce pressure ulcers[73,18] checklists to aid intubation and prevent ventilator-associated pneumonia[39,66,74]; use of report cards to improve surgical outcomes[65] and best practices, such as use of regional anesthesia for aging populations[75] and in ambulatory surgery for obstructive sleep apnea.[76] Recommendations for minimum volume standards have been made for certain procedures, including bariatric surgery; carotid endarterectomy; esophageal, lung, and pancreatic resections; open aortic procedures; mitral valve repair and replacement; and rectal cancer surgery.[77]

3.4.2 Environmental Scan Measurement Opportunities

Currently, PSIs address many HACs, including pressure ulcers (PSI 03), retained surgical items or unretrieved device fragments (PSI 05), iatrogenic pneumothorax rate (PSI 06), in-hospital fall with hip fracture (PSI 08), perioperative hemorrhage or hematoma rate (PSI 09), postoperative physiologic and metabolic derangement rate (PSI 10), postoperative respiratory failure rate (PSI 11), perioperative pulmonary embolism or deep vein thrombosis rate (PSI 12), postoperative wound dehiscence (PSI 14), accidental puncture or laceration (PSI 15), birth trauma injury to neonate (PSI 17), and two obstetric trauma measures (PSI 18 and 19).

Since the current PSIs are specified only for the inpatient setting, the opportunity to expand the specifications of several measures to different settings may be warranted. This is particularly relevant for measures related to falls and pressure ulcers given their prevalence in the long-term care setting. Additional surgical or procedural outcomes may also present an opportunity for measurement, but consideration should be given to whether HACs with a long-term outcome horizon are feasible for measurement and for the implementation of effective interventions. Opportunities for PSI expansion may include PSIs for anesthesia and perioperative care, with both referenced across inpatient and ambulatory care settings and across populations. While the anesthesia-related HAC subdomain is intended to signal a potential gap area, relevant measurements could potentially be captured under the surgery- or procedure-related HAC subdomains.

Many concepts covered under this domain are specific to certain conditions, specialties, or subpopulations and consideration is needed for the desired level of specificity of the PSIs. Measures specific to certain subpopulations could be included as PSIs or referred for incorporation in other Quality Indicator Sets, such as the MHI or the Pediatric Quality Indicators. Finally, the use of advanced tools and devices that may mitigate HAC risks could be a topic for further discussion.

3.4.3 Public Input

One commenter suggested examining vascular access harm, as some hospitals are requiring peripheral access devices to be used instead of central venous catheters, which the commenter notes has resulted in a broad range of serious adverse events. A few comments asked for clarification of the approach to tracking anesthesia events, including whether they would be built into a composite. One comment suggested considering PSI measures of preventable harm due to insufficient perioperative glycemic monitoring.

3.4.4 MSG Discussion

The convening focused on PSIs related to anesthesia-specific conditions, perioperative measures, and the potential to expand existing PSIs to outpatient settings, specifically surgical measures to ASCs.

The members expressed significant support for developing or specifying PSIs for **ASCs** given both the increased volume of procedures and increased complexity of procedures in this setting. MSG members identified the major factors warranting measure development, specifically the lack of comparable quality oversight of ASCs relative to hospitals, and the lack of resources and technology (e.g., EHRs) within ASCs. Several MSG members noted that CMS is proposing to add many procedures to the ASC Covered Procedures List and remove procedures from the Inpatient-Only list, which is likely to increase the types of procedures performed in ASCs. One member noted that there are currently a handful of CMS outcome measures within the Ambulatory Surgery Center Quality Reporting Program that include

wrong site, wrong procedure, and wrong person events. MSG members also expressed that there may be low uptake of NHSN's ASC modules leading to a lack of data availability on NHSN outcome measures.

MSG members generally supported perioperative **anesthesia events** as an area for PSI measure development, particularly for catastrophic events. Members noted wrong-route injection events as potential areas of focus. One member pointed out that there is a risk of overreporting and cited the example of the hospital eCQM using naloxone reversal outside the operating room as a measure of opioid-related adverse events when it is very commonly used in non-overdose situations. Despite support for a measure in this space, one MSG member noted that a previous PSI for complications of anesthesia was retired in part due to low incidence.

Several MSG members supported consideration of PSI measure development in other settings, including **infusion centers, hospital-at-home, and birthing centers**. For infusion centers and hospital-at-home settings, MSG members suggested looking at frequency of rehospitalization as a potential indicator. Regarding birthing centers, some MSG members agreed that levels of oversight similar to those in hospitals should be applied.

3.5 Patient Environment Harm

3.5.1 Environmental Scan Findings

The rapid increase in the use of healthcare technology raises the question of whether harm resulting from **device failure** is an important area for measurement. Aging equipment, such as that used in radiology, risks malfunction or breakdown, which may pose safety risks to patients and staff.[78] Electrosurgical devices used during head and neck surgery are the most common cause of surgical fires.[79] Burns also occur due to use of light sources such as scopes.[80] As more patients receive home-based care, devices originally intended for use in a clinical environment may present risks of harm to users who are not properly skilled in operating the devices.[62] Home dialysis machines require significant patient training to be used safely.[81] Communication gaps about recalls and defects can also present a danger,[22] and while technology-related safety risks are similar across primary and community-based care, they are less well understood in community-based settings.[82]

Studies are mixed in terms of the effects of EHR use on patient safety, with some finding no impact[83] and others linking EHR use to medication errors, diagnostic errors, and cybersecurity threats.[84] As underlying contributors to patient harm across many domains and subdomains, HIT, AI, and telehealth are not included under a distinct domain, as they are not harms in and of themselves. However, consideration of how to address harms arising from increased use of technology will likely require further exploration.

Patient protection events primarily reflect risks to vulnerable populations, including nursing home residents and individuals with mental health diagnoses. Examples of potential harms include those resulting from restraint use, seclusion, and patient elopement,[12] as well as visitor or caregiver noncompliance with safety precautions.[85] Increased use of remote care may warrant further consideration as well, with research emerging on chronic disease and risk areas, such as rehabilitation for stroke patients delivered via telehealth.[86]

3.5.2 Environmental Scan Measurement Opportunities

Currently, PSIs do not address the patient environment domain. Given the increased use of technology across inpatient and outpatient settings, long-term opportunities for PSI expansion could explore the ability to identify preventable harms related to the use of medical equipment across care settings. Additionally, new data sources within devices or EHRs may provide insight into device-related preventable harm. Similarly, patient protection events present an opportunity for further exploration, particularly for vulnerable populations and during care transitions.

It may be challenging to attribute harms to adverse events associated with device or technology malfunction as opposed to human error. Some types of harm may be difficult to determine due to competing goals of care, such as balancing the risk of potential harm from physical restraints with the high risk of falls. Current measurement may not be sufficiently advanced to accurately attribute specific harms to patient protection deficiencies, such as insufficient staffing or training in healthcare environments.

3.5.3 Public Input

Some commenters supported PSIs for device-related events (e.g., device malfunctions), though other comments questioned potential redundancy with HACs that may have similar device-related measures. One comment supported patient protection events as a priority in psychiatric hospitals and related facilities, particularly in cases of patient-on-patient aggression or protection from self-harm incidents. One commenter questioned the potential to appropriately measure equipment not delivered to a patient's home. For example, if a delivery company is at fault, this may not be captured through ICD-10 codes. Several commenters suggested a broader discussion on safety culture, communication, and care transitions, particularly for individuals with chronic conditions. Some commenters highlighted care transitions as a priority, but raised operational considerations (e.g., how to report accountability for transitions and lack of access to primary care leading to ED visits). One commenter suggested researching an adequate discharge planning indicator to incorporate standards of discharge planning and coordination of care. Finally, a few commenters suggested examining end-of-life discussions and goals of care planning in ambulatory settings.

3.5.4 MSG Discussion

The members reviewed the potential to include several preventable harm topics, such as end-of-life, infant and maternal health, chronic conditions, frailty, and post-acute care/long-term care. MSG members voted in real time to discuss two topics: (1) preventable harm due to communication/transition issues, and (2) telehealth/remote patient monitoring.

MSG members generally supported exploring PSI measure development for **care transitions**, including potentially aligning with CMS's Patient Safety Structural Measure; focusing on **transparency and communication** (e.g., regarding adverse events, discharge planning and care instructions, exposure to an infectious outbreak in a healthcare facility); assessing and addressing social determinants of health (e.g., housing, economic, transportation issues); and emphasizing cultural competency. MSG members also described challenges created by different types of care transitions (e.g., between facilities, within facilities, and between ambulance transport and EDs).

Despite support, the MSG noted that these issues are broad and inherently complex, and one MSG member noted that a hospital may not be able to control the entire spectrum of issues that may arise. One MSG member suggested beginning with a framework to capture the multitude of issues. Another

recommended that the PSI should collect enough data to be statistically predictive of high-risk areas related to care transitions.

The MSG discussed several issues related to **telehealth** access, including appropriate support for patients with limited English proficiency, digital literacy, and the digital divide (e.g., bandwidth issues) and appropriateness of a telehealth visit versus in-person visit. Some MSG members supported reviewing the literature to determine specific measures that could be addressed with a PSI, including measures in both physical and mental telehealth services. One MSG member supported tracking device failures.

3.6 Mortality

3.6.1 Environmental Scan Findings

Preventable patient death continues to be an issue within the healthcare delivery system in the U.S., and it is estimated that approximately three percent of healthcare-related deaths are preventable.[87]

Failure to rescue remains a challenge identified in the literature,[88,89,90] such as with neurosurgical patients[91] and trauma patients,[92] who continue to see negative trends in failure to rescue. Specific non-surgical events or procedures associated with failure to rescue include cardiac or pulmonary arrest,[93,94,18] unrecognized esophageal intubation,[95] open abdominal aortic aneurysm repair,[96] and pancreatectomy and esophagectomy.89 The literature continues to identify high rates of **unexpected deaths** in the maternal and neonatal populations, especially among those considered low-risk.[97,98]

The rate of survival for critically ill patients in intensive care units has increased; effective rapid response systems are seen as a key intervention.[93,94,18] Additionally, facilities with higher procedure volumes see lower failure-to-rescue rates.[96,89] Safety bundles have been identified as an intervention to prevent maternal mortality,[97] as has 24/7 in-house obstetrician care.[98] Improved recognition of clinical deterioration is also seen as a key intervention to prevent failure to rescue and unexpected death.[99] Building AI into vital sign monitoring may enhance the effectiveness of such systems.[88]

3.6.2 Environmental Scan Measurement Opportunities

Current mortality-related PSIs include death rate in low-mortality diagnosis-related groups (PSI 02) and death rate among surgical inpatients with serious treatable conditions (PSI 04). These measures, along with the Maternal Health Indicators and Inpatient Quality Indicators, may sufficiently address the acute care setting; however, there may be opportunities to refine specifications to account for baseline risk factors such as frailty and to adjust for procedural volume. Other measurement opportunities may involve a more expansive view of preventable death in non-acute care settings. The feasibility and utility of broader population-based assessments of preventable deaths, such as measurement of mortality attributed to chronic diseases among younger populations, may also present an opportunity for expanding measurement. Identifying new or expanding existing PSIs may involve leveraging novel data sources, such as those within vital sign monitoring systems and AI tools.

3.6.3 Public Input

One commenter asked whether AHRQ would continue maternal mortality and morbidity measurement efforts under this domain.

3.6.4 MSG Discussion

This domain was not discussed during the MSG convening due to limited input from both the public and MSG members.

3.7 Overarching Themes

3.7.1 Public Input

Several commenters suggested the use of additional **data sources**. Some commenters supported the use of patient-reported harm, which could be gleaned from Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, complaint systems, or patient-reported outcome measures (PROMs). Many commenters acknowledged **overlap across measures**, including PSIs, CDC's NHSN, CMS's electronic clinical quality measures (eCQMs), NCQA's HEDIS ambulatory quality metrics, and patient experience surveys. Commenters suggested coordinating and/or streamlining to minimize redundancy and reduce administrative burden. Some commenters noted that PSI technical specifications may differ from similar CMS measures and others highlighted the burden of eCQMs on hospitals, particularly the cost of hiring staff to collect, extract, and validate the data.

Several commenters suggested **examining risk adjustment**. Many suggested considering the burden on non-acute care hospital settings that may have limited resources for technology and safety/quality expertise. Two commenters recommended examining additional risk adjustment for extremely ill patients and tertiary care facilities.

A few commenters noted that **sensitivity and specificity** of measures may depend on the condition in question and associated outcomes. For example, one commenter favored a highly sensitive indicator for severe sepsis that allows for false positives, as the tradeoff for false positives greatly outweighs that of false negatives.

A few commenters questioned the **effectiveness of PSIs** and noted that healthcare facilities spend extensive resources improving PSI documentation rather than focusing on harm prevention. One commenter suggested examining PSI effectiveness in addressing harms over a long period of time. Some commenters supported a mix of both process and outcome measures, including capturing implementation of evidence-based processes.

3.7.2 MSG Discussion

The convening focused on two specific topics raised during public input: new PSI data sources and expansion to new care settings

MSG members emphasized the importance of the patient voice and suggested examining existing efforts to incorporate patient perspectives in quality measure development and in leveraging patient-reported data. One MSG member suggested examining the use of advance directives or goals of care to account for patient care goals. Another suggested reviewing case studies where health systems incorporate patient perspectives and determining whether there are areas that could translate to measurement. While Patient Safety Organizations (PSOs) and Serious Reportable Events (SREs) were raised as sources of data, one MSG member noted that there are challenges with the data being voluntarily reported, as well as with subjectivity and lack of data standardization. A few MSG members suggested measuring **access to care** broadly, and acknowledged certain metrics currently being used (e.g., wait time data).

Other members suggested **expanding PSIs to additional settings**, including freestanding EDs and urgent care.

4 Recommendations

In reviewing the results of the environmental scan along with the public input and feedback received during the MSG meetings, several priorities emerged that AHRQ should consider to inform future PSI efforts. These reflect the need to address broader issues of measure alignment and harmonization across federal programs as well as more targeted measurement opportunities that are meaningful to the public and important to the field of patient safety. They also reflect opportunities that are within AHRQ's purview as a federal agency focused on patient safety research and the use of scientific evidence, tools, and data to improve quality and safety. These recommendations should be viewed in the context of transitioning toward digital measurement. These evaluations continue to honor prior PSI work while supporting the development of more modern, comprehensive, and actionable patient safety metrics across emerging care settings. While many priorities exist for patient safety, not all are amenable to measurement due to limitations in the current evidence base or data availability.

4.1 Review Existing PSIs for Overlap with Other Government Agencies' Patient Safety Measures

PSIs and the CDC's NHSN are both critical tools for monitoring and improving patient safety in healthcare settings. PSIs measure potentially avoidable safety events, including in-hospital complications and adverse events following surgeries, procedures, and childbirth, offering opportunities to enhance care delivery. NHSN, the nation's most widely used system for tracking healthcare-associated infections, provides essential data to identify problem areas, measure prevention progress, and eliminate infections. Additionally, NHSN enables healthcare facilities to monitor blood safety errors, healthcare personnel influenza vaccination rates, and adherence to infection control practices, fostering a comprehensive approach to patient safety and quality improvement. These tools, along with other reporting mechanisms, such as CMS's quality reporting programs and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey instruments, while serving different purposes contribute to the reporting burdens that providers continue to lament. Recognizing that PSIs are no longer the focal point of CMS' safety measurement strategy creates an opportunity to ease this reporting burden. MSG members discussed the overlap of HAIs in detail, discussing the value of utilizing NHSN or claims data in terms of collection burden, accuracy, and data availability for analysis.

MITRE recommends that AHRQ review existing PSIs for overlap with the patient safety measures used by other government agencies to identify opportunities to address potential redundancies and to ensure a system of measurement tools that advances patient safety while reducing burdensome reporting. This review could serve to identify when measures would be developed for which reporting system and how these systems should work together for surveillance, quality improvement, transparency and accountability to support better outcomes for patients. AHRQ should assess all measures that may be duplicative across agencies and consider retiring those that are redundant. When measures are retained despite overlap, AHRQ should clearly communicate their unique value to the public and the scientific community. The assessment of overlapping measures can help identify opportunities to retire redundant indicators, clearly communicate the unique value of retained measures, and ensure that future measurement efforts align with a more digital, data-driven approach to patient safety.

More specifically, feedback from the public and MSG recommended an evaluation of the value and reporting burden of PSI 07, Central Venous Catheter-Related Bloodstream Infection Rate, in comparison to the NHSN Bloodstream Infection Events. MSG members discussed retiring this PSI in favor of keeping the NHSN measure, which is based on data collected by infection preventionists and is thought to be more accurate. There was mixed feedback on the value of PSI 13, Postoperative Sepsis, with some advocating for maintaining its use and others suggesting the need for clarification of elective versus emergent procedure since these distinctions can affect outcomes and data interpretation. MSG members also discussed retaining PSI 13, as it provides more specific and useful information than other sepsis measures.

4.2 Expand PSIs to ASCs and Identify and/or Develop Perioperative Measures

The rapid growth of services provided in non-hospital settings, along with the shift of more medically complex patients and procedures to ASCs, may increase risk in patient safety. Many published articles highlight the need for additional research on patient safety in these settings.[101,102] Although the public did not provide specific input on expanding PSIs to ASCs, they noted the importance of expanding PSIs that are appropriate for other care settings. MSG members discussed expanding PSIs to ASCs, citing the increasing complexity and volume of procedures performed in ASCs as reasons to expand to these settings.

MITRE recommends reviewing current PSIs for their appropriateness for use in ASCs and developing or identifying measures of perioperative care. This is a critical step to address emerging patient safety concerns and to improve care quality in these increasingly utilized healthcare environments. To support this effort, AHRQ should review existing safety data related to the quality and safety of care in ASCs, including CMS's ASC Quality Reporting Program (ASCQR) and CDC's NHSN Outpatient Procedure Component. Additionally, guidelines from organizations such as the American College of Surgeons and the American Society of Anesthesiologists on in-office surgery should be considered to identify new areas for measurement.[103] In March 2025, the Medicare Payment Advisory Commission (MedPAC) identified ophthalmology and gastroenterology as the most frequently reported specialties utilizing ASCs for cataract removal, gastrointestinal endoscopy, and colonoscopy as the most frequently billed procedures.[104] Additionally, CMS is proposing to increase the types of procedures performed by ASCs through proposed changes to the inpatient-only procedure list. These may indicate specialties and procedures that have the potential for an increase in preventable harm. Other opportunities may include harms related to anesthesia use or harms that occur during perioperative care, which are relevant across both inpatient and ambulatory care settings regardless of clinical specialty.

4.3 Expand PSIs for Maternal and Neonatal Measures to Other Care Settings and Identify and/or Develop Perinatal Measures

Preventable harms that occur during pregnancy and infancy can have devastating impacts on mothers and infants, including early death. Many articles cite HACs as the most common preventable harm in this area, including estimates of 600-1,600 in-hospital newborn drops,[105] sepsis among obstetric patients,[107] severe bleeding during birth,[108] and VTE, which is estimated to account for almost 15% of maternal mortalities.[66] Research suggests that expanding hospital-based measures to birthing centers will be necessary as delivery volumes shift from hospitals to these settings.[109] Public input supports the need to focus on this population with specific requests to explore behavioral health measures for the maternal population and expanded measures for the neonatal population. The MSG discussed this topic

extensively as well, specifically related to the expansion of birthing centers and preventable harms related to diagnostic safety, including behavioral health and hypertension diagnoses.

MITRE recommends expanding PSIs for maternal and neonatal health to non-acute care settings and exploring additional perinatal and neonatal measures to address preventable harms that can occur across the course of a pregnancy, such as hemorrhage, postpartum depression, infection, drops, and other common or potentially harmful complications within a defined period before and after childbirth.

4.4 Continue to Explore Potential Data Sources to Measure Preventable Harm from Diagnostic Errors.

Preventable harm stemming from delayed, wrong, or missed diagnosis remains an important focus area in patient safety, and research continues to emphasize the need to measure diagnostic safety across the healthcare delivery system, with examples ranging from behavioral health to undetected patient decompensation, laboratory tests, and imaging. Defined as the failure to establish or communicate an accurate and timely assessment of a patient's health problem, diagnostic errors contribute to an estimated 40,000-80,000 deaths each year.[13] Research noted "diagnostic error is well understood to be a problem in mental healthcare… although few studies used clear definitions or frameworks for understanding diagnostic error in mental health."[17] "People with disabilities are also at greater risk for health disparities related to diagnostic overshadowing, i.e., an incorrect attribution of symptoms to a major diagnosis, such as a disability, rather than to a potential coexisting condition."[106] And despite progress in laboratory testing, errors continue to occur at all phases of the total testing process and are linked to more complex testing.[19]

The public continues to express substantive interest in measure development in this area despite the technical challenges associated with defining diagnostic events and the data needed to measure them. The MSG discussed this topic with great interest noting infant and older adult populations at high risk as they often rely on family or caregiver support to communicate with providers, and adolescents and maternal populations at high risk of missed behavioral health diagnoses. It was also discussed that Patient Safety Organization (PSO) data indicates lab testing as a high-risk area for diagnostic errors. Participants noted the challenge of collecting accurate and useful data to measure diagnostic events while reiterating the need to address this challenge. They discussed tracking patient lab results and resulting hospitalizations through ICD-10 codes to determine if a diagnosis was missed and test collection time to treatment time for acute stroke.

MITRE recommends that AHRQ continue its work to improve measurement of diagnostic safety and explore potential data sources for measures of preventable harm from diagnostic errors. In an RFI published in December 2024, AHRQ requested feedback on measures of diagnostic safety and has since launched the IDEAS project and a cross-federal workgroup to improve diagnostic safety and quality. Research indicates that this focus and intensity need to continue to help the industry identify and implement meaningful measures in this domain. As a complement to measurement, AHRQ should also continue to support the development and availability of resources to assist providers in identifying and reducing diagnostic safety events.

5 Future Considerations

As the patient safety landscape continues to evolve, AHRQ plays an important role in prioritizing efforts to advance research, data collection, measure development and quality improvement to ensure a

healthcare system that is safe and reliable for patients. The movement of patient safety monitoring beyond traditional inpatient settings makes it critical to advance research and measurement strategies that capture preventable harm in emerging care environments, care transitions, and via patient-reported outcomes. While PSIs provide historical context and foundational insights, the focus is shifting to digital and real-time measurement approaches that offer greater precision, reduce reporting burdens, and accelerate quality improvement efforts. These future considerations attempt to drive a continuity of learning while embracing a forward-looking strategy for patient safety.

Advance broader data collection for patient safety.

With healthcare continuing its shift beyond traditional inpatient settings, it is increasingly important to monitor and advance research on preventable harms occurring in new and emerging care environments, such as hospital-at-home, freestanding EDs, and urgent care centers, or patient harm that may result from the use of new technologies, such as telehealth and remote patient monitoring. Providers manage increasingly complex patient needs in these contexts, yet there is a notable lack of standardized measures and available data to assess patient safety and harm.[110,111] Evidence suggests that is it critical for patients to be treated in the appropriate setting to minimize preventable harm, especially as care models become more decentralized and tailored to individual needs.[111] Collecting data on patient admissions from these settings to an inpatient setting may offer a starting point for understanding inappropriate or low-quality care. By proactively tracking research in these areas, AHRQ and other stakeholders can drive toward relevant PSIs that support safe care across healthcare.

Develop and harmonize definitions in patient safety.

Consistent and clear definitions are essential to accurately measure and compare safety outcomes across different healthcare settings. Currently, variation in how federal agencies define and collect safety measures leads to confusion, duplication of effort, and challenges in data interpretation. Harmonizing definitions across the federal government will streamline data collection, reduce reporting burden, and enhance the reliability of patient safety metrics. This effort should include collaboration across agencies to align terminology, measurement criteria, and reporting standards, ensuring that stakeholders have a shared understanding of what is being measured and why. Clear, harmonized definitions will ultimately support more effective quality improvement and policy decisions.

Identify measures of preventable harm during care transitions, including discharge planning.

Care transitions - especially when patients move from the hospital back home or to other care settings - are a period of heightened vulnerability for patients. During transitions, patients are at increased risk for medication errors, misunderstandings about their follow-up care, and lapses in communication between providers, all of which can lead to harm.[112] Developing measures that specifically address these risks is crucial, as existing PSIs do not capture the unique challenges of care transitions. By identifying and tracking preventable harm during discharge planning and other transitions, healthcare organizations can target interventions to improve patient safety and reduce readmissions. This work will help fill gaps in measurement and ensure that patient safety measurement efforts extend beyond the inpatient setting.

Examine opportunities to collect patient-reported experience and outcome data for use in measurement and quality improvement.

Patient-reported outcome (PROs) measures can provide valuable insights into the effectiveness and safety of care from the patient's perspective, which can lead to the development of interventions that can improve patient safety and lead to more patient-centered care.[113] The current PSIs do not incorporate any data reported by patients and given the importance of the patient viewpoint on

identifying preventable harm, AHRQ may consider how to incorporate this data into existing or new PSIs. This work could leverage advance directives and documented goals of care as part of measurement strategies, ensuring that care aligns with patient wishes and reducing unnecessary interventions, which can lead to preventable harms. Reviewing current initiatives such as Project PIVOT, which focuses on integrating patient voices into quality improvement, can support the identification of best practices and opportunities for broader adoption.[114] Additionally, utilizing patient-reported experience measures (PREMs), such as CAHPS, can provide unique insights into patient concerns. Expanding the use of PROs and PREMs in measurement will enhance the relevance and impact of patient safety efforts.

Appendix A. Framework Domains or Elements Mapped to MM 2.0 Preventable Harm Objectives

Background

A review of established frameworks from key healthcare quality and safety initiatives and elements of other patient safety measure sets established the basis for the most appropriate framework to develop opportunities for measurement. The sources examined were:

- CMS Meaningful Measures 2.0 (MM 2.0), specifically the Cascade of Measures for Safety
- CMS Preventable Harms
- NQF Serious Reportable Event (SRE) categories from the 2024 update
- AHRQ National Healthcare Quality and Disparities Report (NHQDR) Subcategories
- AHRQ Common Formats for Event Reporting
- AHRQ Network of Patient Safety Databases (NPSD) event categories

The goal was to determine whether the Cascade of Measures Safety Priority of MM 2.0 could serve as a foundational framework that adequately captures domains found within the other frameworks.

Summary of Methods

MITRE reviewed each framework for high-level domains of preventable patient harm. While some frameworks included domains, others included only individual measures or events (referred to as elements). Across the six frameworks, MITRE identified 31 domains and 28 elements. MITRE mapped each framework's domains or elements to the six Preventable Harm objectives of the MM2.0 Cascade of Measures for Safety. The mappings are shown in Table 1 and Table 2.

Summary of Findings

MITRE analyzed these frameworks and found MM 2.0 to be comprehensive and current, built upon existing safety frameworks, and supportive of alignment of safety reporting/measurement systems. MITRE mapped 49 out of 59 framework domains or elements to the MM2.0 Cascade Safety Preventable Harm objectives.

Recommendation

MITRE recommends leveraging the Preventable Harm objectives of the Cascade of Measures for Safety to inform the environmental scan and MM2.0 more broadly as the guiding framework. MITRE will continue to make recommendations to CMS and AHRQ and iterate on the best opportunities to incorporate aspects of MM2.0 in addition to the Cascade of Measures for Safety Preventable Harm objectives. MITRE will continue to capture potential priority gap areas in patient safety that do not readily fit under this framework for further analysis and consideration as this effort progresses.

Table 1. MM2.0 Preventable Harm Objectives mapped to framework categories and/or elements

CMS Cascade of Measures for Safety MM2.0 Objectives	1. Reduction in healthcare-associated conditions	2. Reduction in healthcare-associated infections	3. Diagnostic excellence as it impacts safety	4. Reduction in medication error	5. Safety of the patient environment	6. Reduction in mortality from healthcare interventions
SRE Categories	Surgical or Invasive Procedure Events Product or Device Events	N/A	N/A	N/A	Environmental Events Potential Criminal Events Patient Protection Events	N/A
AHRQ NHQD Report Subcategories	Other Complications of Hospital Care Surgical Care	Healthcare-Associated Infections	Healthcare-Associated Infections	Complications of Medication Inappropriate treatment (medication)	N/A	N/A
CMS Preventable Harms	Healthcare-Acquired Complications (HAC)	Healthcare-Associated Infections	Healthcare-Associated Infections	Medication Events	Abuse & Neglect	Maternal Morbidity & Mortality
PCAST	Surgical Adverse Outcomes Pressure Injuries Deep Vein Thrombosis Pulmonary Embolus Falls	Hospital-associated infections	Hospital-associated infections	Medication Adverse Outcomes	N/A	N/A

CMS Cascade of Measures for Safety MM2.0 Objectives	1. Reduction in healthcare-associated conditions	2. Reduction in healthcare-associated infections	3. Diagnostic excellence as it impacts safety	4. Reduction in medication error	5. Safety of the patient environment	6. Reduction in mortality from healthcare interventions
AHRQ Common Formats for Event Reporting	Pressure Injury (Pressure Ulcer)(Nursing Home 1.0) Pressure Injury (Hospital 2.0), Venous Thromboembolism (Hospital 2.0), Fall (Hospital 2.0, Nursing Home 1.0) Surgery (Hospital 2.0) Anesthesia (Hospital 2.0) Biological products (Community Pharmacy 1.0), Nutritional products (Community Pharmacy 1.0), Medical foods ((Community Pharmacy 1.0), Blood or Blood Product (Hospital 2.0), Device or Medical/Surgical Supply (Hospital 2.0), Device or Medical/Surgical Supply, Including Health Information Technology (HIT)(Nursing Home 1.0)	N/A	N/A		N/A	N/A
AHRQ NPSD Event Categories	Blood or Blood Products Device or Medical/Surgical Supply Fall Pressure Ulcers Surgery or Anesthesia Venous Thromboembolism	Healthcare-Associated Infection	Healthcare-Associated Infection		N/A	N/A

Table 2. Framework categories and/or elements that did not map to MM2.0

Framework	Categories and/or elements that did not map to MM2.0
SRE Categories	Care Management Events Radiologic Events
AHRQ NHQD Report Subcategories	Birth-Related Complications Home Health Communication Supportive and Palliative Care
CMS Preventable Harms	Health Information Technology-Related Errors
AHRQ Common Formats for Event Reporting	Perinatal (Hospital 2.0) Device or Medical/Surgical Supply, Including Health Information Technology (HIT)(Nursing Home 1.0)
AHRQ NPSD Event Categories	Perinatal

Appendix B. Summary of Environmental Scan

An environmental scan identified areas for improvements related to preventable harm for a set of scoped settings, populations, and priority topics. The scan informed the patient safety domains and taxonomy and opportunities for measurement of preventable harm.

The scoped review focused on the following settings, populations, and priority topics:

- Settings: Ambulatory Surgery; Home Health; Hospice; Hospital inpatient; Outpatient; Psychiatric Facility; Rehabilitation Facility; Skilled Nursing Facility/Nursing Home
- Populations: Maternal; Pediatric; Older adults; Cognitively impaired adults
- Priority topics: Health Information Technology; AI; Care Transitions; Telehealth; Radiology; Mental health; Failure to rescue

The scan included the following categories of sources: (1) AHRQ Making Healthcare Safer (MHS) IV, (2) targeted searches of PubMed, (3) literature on patient safety available from patient safety and healthcare-related organizations, and (4) select state patient safety reporting requirements. CA, CT, NV, PA were selected for a review of current patient safety reporting requirements, based on their geographic distribution and longstanding safety reporting. Reporting requirements were cataloged if they were beyond the list of NQF's Serious Reportable Events. Table 3 describes the search methods and resulting 1,345 total sources reviewed for relevancy with a total of 226 sources deemed in scope and cataloged further based on the type of harm(s) specified.

Table 3. Summary of Sources

Source Category	Search Description	Sources Identified for Scan
MHS IV	• 17 preventable harm topics • 1 MHS IV report with 332 Patient Safety Practices	18
PubMed	• Initial search: "Patient safety" OR "Patient harm" in Title/Abstract; AND any listed setting, population, or priority term in Title/Abstract; AND prevent* or avoid* anywhere in article; NOT Covid; Published Jan. 1, 2023, through Jan. 31, 2025; Limited article types • Supplemental search 1: "Patient safety" OR "patient harm" [Mesh Major Topic]; AND prevent* or avoid* anywhere in article; published Jan. 1, 2023, through Jan. 31, 2025; Limited article types • Supplemental search 2: "Patient safety" AND Indicator* in Title/Abstract; published last 5 years; Limited article types	446
Patient Safety and Healthcare-related Organization Searches*	• Institute for Healthcare Improvement: reviewed publications and white papers tagged with patient safety. • ECRI, Press Ganey, Premier, Collaborative Healthcare Patient Safety Organization, & National Committee for Quality Assurance: searched for key term "patient safety." • NQF: searched reports for key term "patient safety." • Leapfrog: searched for key term "patient safety" and sources tagged with patient safety. • Vizient: searched for key term "improving patient safety." • The Joint Commission: reviewed all sentinel event alerts and quick safety reports. • Veterans' Health Administration: reviewed alerts and patient safety newsletter topics (public resources only). • Patient Safety Movement Foundation: reviewed all evidence-based practice reports that have not been successfully implemented by hospitals.	877
Select States (CA, CT, NV, PA)	• Patient safety reporting	4

*Limited to the past five years or current postings.

Appendix C. Summary of Taxonomy and Framework Development

The taxonomy mapped subdomains to:

1. Main Care Stage(s): diagnosis, prevention, treatment and/or outcome to ensure all care stages were covered by subdomains.
2. Topic Example(s): example preventable harms categories, including wrong drug, wrong dose, late diagnosis of chronic disease, and harm due to faulty device.
3. Related SRE(s): 2011 SRE, if applicable.
4. Related PSI(s): PSI v2024, if applicable.
5. Making Healthcare Safer Area(s): relevant chapter(s) of the 2024 Making Healthcare Safer report to understand the relevance of the subdomain to these reports.
6. Examples of Other Potentially Relevant Metric(s): other potentially relevant metrics from CDC, CMS, and other metric developers to understand the breadth of measurement in the subdomain.
7. Primary Settings: most applicable care settings to show areas for initial PSI refinement. Some subdomains were cross-setting, others mapped to Hospital/Acute care, Long-term care, or outpatient / office based surgical setting.
8. Data Sources (Preliminary): potential new data sources to identify gaps or new data sources.

A filtered taxonomy map identified subdomains with no related PSIs. The remaining 11 subdomains reviewed against the other fields and the environmental scan data revealed potential issues or points for consideration when identifying measurement opportunities (see Table 4).

Table 4. Potential Issues and Considerations for PSI Development by Subdomain

Domain(s)	Subdomain(s)	Potential Issues	Points for Consideration
All	All	Certain cross-cutting issues may apply across domains. For example, a wide range of safety impacts and outcomes may be related to mental & behavioral health issues.	Since mental and behavioral health-related safety issues can occur across different subgroups and settings (e.g., development of pediatric patient anxiety might be deemed a patient care HAC, while insufficient attention to patients with cognitive impairment may lead to a patient protection error), these types of issues could potentially be categorized as population-specific or as discrete events resulting from specific types of care (e.g., post-op delirium as a surgical HAC).
Diagnostic Error	Wrong Diagnosis	Often it may be difficult to determine the categorization of events that are truly errors (e.g., a disease may have an unusual presentation and/or evolve over time) and the role of technology (e.g., AI decision support) in influencing an increase or decrease in the rate of wrong diagnoses.	May need to evaluate whether current measurement approaches are sufficient to consistently define and assess "wrong" diagnoses with sufficient accuracy.
Diagnostic Error	Missed Diagnosis	Existing measures in this category generally tend to focus on proxies (e.g., timely transfer of patient information across settings and providers, late-stage diagnoses). It may be difficult to attribute certain cases as a healthcare error (e.g., if patient presents to the healthcare setting late in their disease process).	Consider whether proxy events are sufficient to measure missed diagnoses and if a missed diagnosis should only be counted when there is a clear mistake (e.g., lost test result) that is tied to a negative outcome (e.g., delayed treatment in a rapidly progressive disease).

Domain(s)	Subdomain(s)	Potential Issues	Points for Consideration
Drug or Blood Product Error	Adverse Blood Product Event	Relatively few items were identified about this area in the environmental scan, but errors can sometimes lead to serious harm.	Consider whether this area was already sufficiently covered by NHSN reporting.
Drug or Blood Product Error	Adverse Drug Events	Adverse drug events have been reported to be prevalent and, in some cases, lead to serious harm, with a variety of specific types of error falling under this subdomain. However, there are challenges in consistently defining what constitutes certain types of adverse drug events.	Given the large number of findings in the environmental scan and commonality of medication errors, consider whether this is a PSI gap area. More subdomains could theoretically be developed to address different types of adverse drug events, but it is unclear if this is needed given that key interventions (e.g., improved medication reconciliation) may address multiple types of adverse drug events.
HACs	Anesthesia Events	A variety of sources in the environmental scan addressed harm events targeted around anesthesia that were not clearly covered by other subdomains or existing PSIs.	A proposed anesthesia-related HAC subdomain was created to address a potential gap area, but relevant topics could potentially be lumped under other subdomains (e.g., surgery-related HACs and procedural HACs).
HACs	Patient Care Events	Some potential preventable harm outcomes are difficult to assess in the near term. For example, negative effects of excessive radiation may sometimes only be clearly present years after the initial exposure.	Consider whether HACs with a long-term outcome horizon are sufficiently feasible to be deemed a priority for PSI development based on ability to effectively measure and intervene.

Domain(s)	Subdomain(s)	Potential Issues	Points for Consideration
HACs	Patient Care Events	HACs that tend to focus on a specific sub-population may sometimes relate to multiple types of harm (e.g., obstetric injuries and maternal sepsis).	Consider whether topics like obstetric harms should be predominantly captured under HAC Patient Care Events or as a separate subdomain. The preliminary approach has been to lump more than split to avoid potentially overlapping subdomains.
HAIs	Other HAI	Definitions and risk of infection from multi-drug resistant organisms and Clostridioides difficile may vary by location and population.	Consider whether NHSN measures for other HAI are sufficient or whether PSI development may be useful.
Patient Environment Harm	Patient Protection Events	Some types of harm may be more difficult to attribute due to competing risks (e.g., balancing risk of potential harm from physical restraints with fall risk)	Consider if current measurement approaches are sufficiently advanced to accurately attribute specific harm outcomes as being due to patient protection deficiencies (e.g., insufficient staffing levels) in healthcare environments.
Patient Environment Harm	Device/System Harm	It may be challenging to attribute some cases to a device or technology issue versus appropriate use of the device or application of technology by healthcare staff.	Topics like health IT, AI, and telehealth were not included as a separate subdomain since they are not harms themselves. Consider whether any special measurement considerations necessary for these types of issues within PSIs.
Mortality	Unexpected Deaths	Potential opportunities may exist to take a more expansive view of preventable deaths occurring outside the acute inpatient setting.	Consider the feasibility and utility of broader population-based assessment of preventable deaths, such as measurement of mortality attributed to chronic diseases among younger age populations.

Appendix D. Content for Public Input

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."[a] 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.[aError! Bookmark not defined.] 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.[b] 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 efficiency across the agency.[c] 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.

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

[b] 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

[c] Centers for Medicare & 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

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 2 below) mapping domains and subdomains to PSIs.

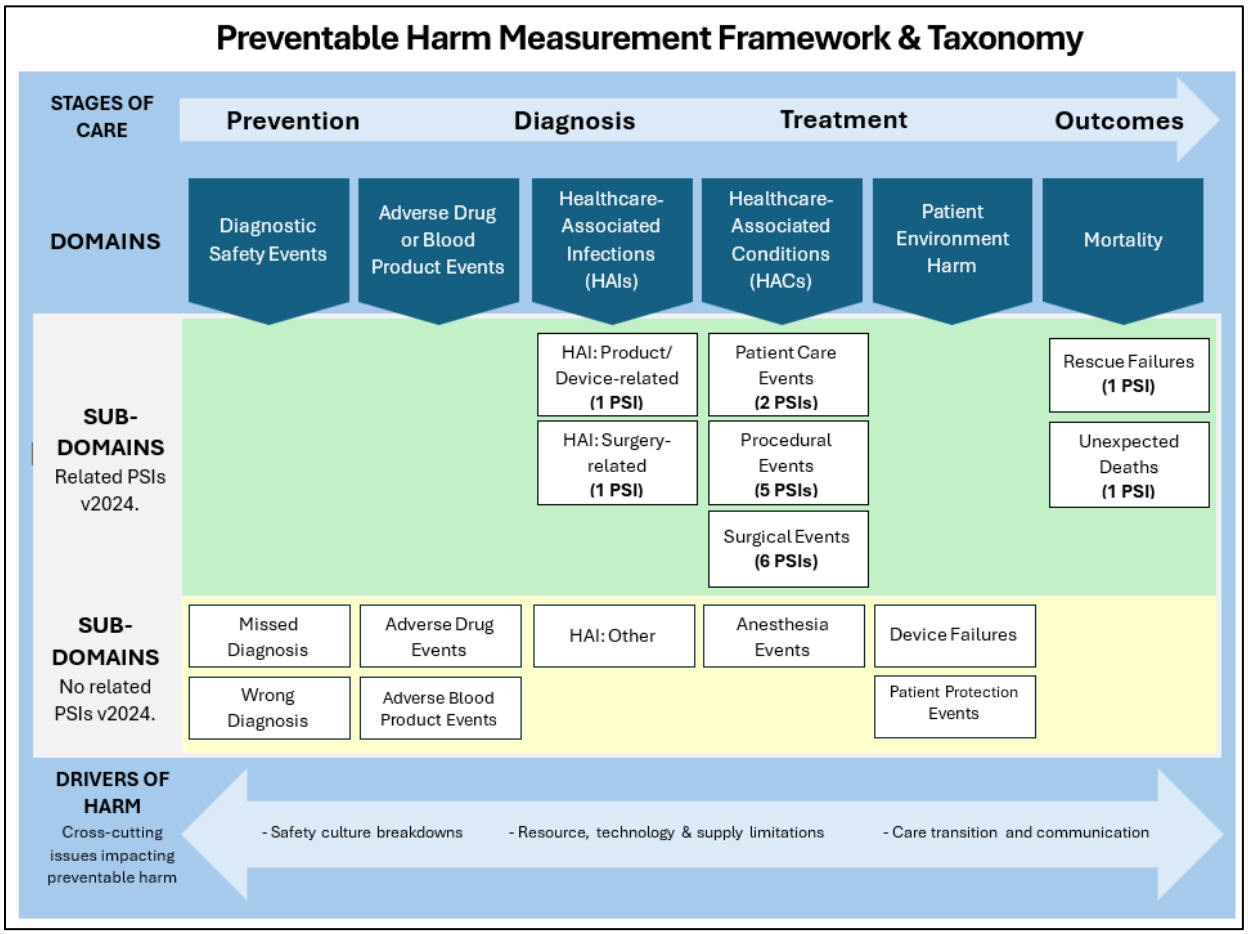

Figure 2. Visual representation of domains and subdomains mapped to PSI

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:

- **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[d] 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, AI, 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.

Measurement Gaps

Table 5 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. The measurement opportunities section details

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

measurement opportunities within each subdomain intended to provide examples of how PSIs may address the gaps shown in Table 5.

Table 5. 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

Domain	Subdomain	v2024 PSIs	Examples of Other Preventable Harms
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.

Measurement Opportunities

Opportunities to address the gaps identified above in Table 5 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 6 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 6. 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	Subdomain	Measurement Opportunity
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	Subdomain	Measurement Opportunity
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 #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	Subdomain	Measurement Opportunity
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	Subdomain	Measurement Opportunity
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 #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	Subdomain	Measurement Opportunity
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.

Appendix E. Public Input Analysis

Below outlines the 213 comments received during the public input period.

1. 213 comments were received
    a. 138 were considered in scope
        i. 41 were on diagnostic safety events
        ii. 25 were on patient environment of harm
        iii. 23 were on HAIs
        iv. 18 were on adverse drug or blood product
        v. 17 were on HACs
        vi. 11 were on mortality
        vii. 125 were overarching themes as follows:
            1. 22 were on care transitions and communications
            2. 20 were related to data
            3. 29 were related to PSIs overlapping with other quality measures
            4. 12 were related to safety culture
            5. 10 were related to the specificity of measures
            6. 9 were related to unintended consequences
            7. 6 were related to effectiveness
            8. 4 were related to resources needed to report PSIs
            9. 4 were related to the historical nature of PSI data
    b. 74 were considered out of scope
        i. 36 were out of scope as they required a straightforward response, or did not require a response (e.g., "Thank you," "Question related to availability of slides").
        ii. 34 were out of scope as they were question related to current PSI specifications, including inclusion/exclusion criteria, or numerators, denominators.
        iii. 5 were out of scope as they related to payment or accountability on quality measure (e.g., PSI used by The LeapFrog Group)
2. 53 comments were received via email and 160 comments were received via webinar Q&A functionality.

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MITRE's internal AI tool (mChat) was used in a consultative capacity to help refine portions of the draft. All AI-assisted content has been thoroughly reviewed by MITRE staff to ensure accuracy, and when appropriate, has been incorporated into the overall deliverable. This complies with MITRE's generative AI use guidelines.

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Glossary

Acronym	Definition
AHRQ	Agency for Healthcare Research and Quality (HHS)
AI	Artificial Intelligence
ASC	Ambulatory Surgery Centers
ASTP	Assistant Secretary for Technology Policy (HHS)
BMI	Body Mass Index
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CDC	Centers for Disease Control and Prevention (HHS)
CMS	Centers for Medicare & Medicaid Services (HHS)
CT	Computed Tomography
EHR	Electronic Health Record
ED	Emergency Department
FEVAR	Fenestrated Endovascular Abdominal Aortic Aneurysm Repair
FFRDC	Federally Funded Research and Development Center
HAC	Healthcare-Associated Condition
HAI	Healthcare-Associated Infection
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	U.S. Department of Health and Human Services
HIT	Health Information Technology
MHI	Maternal Health Indicators
MM2.0	Meaningful Measures 2.0 (CMS)
MSG	Multi-Stakeholder Group
NHSN	National Healthcare Safety Network
NSQIP	National Surgical Quality Improvement Project
PIV	Peripheral Intravenous Catheter
PREM	Patient-Reported Experience Measures

Acronym	Definition
PRO	Patient-Reported Outcomes
PSI	Patient Safety Indicator
SRE	Serious Reportable Events
SSI	Surgical Site Infection
VA	Veterans Affairs
VQI	Vascular Quality Initiative
VTE	Venous Thromboembolism