Environmental Scan on Targeting Improvements in Patient Safety Through Alternative Payment Models

June 10, 2026

This environmental scan was prepared at the request of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as background information to assist the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in preparing for a theme-based discussion on Targeting Improvements in Patient Safety through Alternative Payment Models. This environmental scan provides background on patient safety; causes of patient safety errors; mitigation factors for patient safety errors; measurement of patient safety; and value-based care efforts to promote patient safety. Appendices include tables detailing features of select submitted PTAC proposals.[i]

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List of Acronyms

AAMC	Association of American Medical Colleges
ABMS	American Board of Medical Specialties
ADE	Adverse drug event
AE	Adverse event
AHRQ	Agency for Healthcare Research and Quality
APCD	All-Payer Claims Database
APM	Alternative Payment Model
ASC	Ambulatory Surgery Center
ASPE	Assistant Secretary for Planning and Evaluation
BCMA	Barcode medication administration
BPCI-A	Bundled Payments for Care Improvement Advanced
CAH	Critical Access Hospital
CAUTI	Catheter-associated urinary tract infection
CDC	Centers for Disease Control and Prevention
CDS	Clinical decision support
CfCs	Conditions for Coverage
CLABSI	Central line-associated bloodstream infection
CLIA	Clinical Laboratory Improvement Amendment
CMS	Centers for Medicare & Medicaid Services
CoPs	Conditions of Participation
CPOE	Computerized Provider Order Entry
CQS	Composite Quality Score
CUSP	Comprehensive Unit-based Safety Program
DVT	Deep vein thrombosis
ECOS	Errors of Care Omission Survey
eCQM	Electronic clinical quality measure
EHR	Electronic health record
FDA	Food & Drug Administration
FFS	Fee-for-service
HAC	Hospital-Acquired Condition
HAI	Healthcare-associated infection
HEDIS	Healthcare Effectiveness Data and Information Set
HEN	Hospital Engagement Network
HHS	Health and Human Services
HIIN	Hospital Improvement Innovation Network
HITECH	Health Information Technology for Economic and Clinical Health
HRRP	Hospital Readmissions Reduction Program
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
I-PASS	Illness severity, Patient summary, Action list, Situation awareness, Synthesis
IPPS	Inpatient prospective payment system
IQR	Inpatient Quality Reporting
ISMP	Institute for Safe Medication Practices
MA	Medicare Advantage

MACRA	Medicare Access and Children's Health Insurance Program Reauthorization Act
MA-PD	Medicare Advantage Prescription Drug
MCAT	Medical College Admission Test
MERP	Medication Errors Reporting Program
MIPS	Merit-based Incentive Payment System
MISSCARE	Missed Nursing Care
NQF	National Quality Forum
NCQA	National Committee for Quality Assurance
NHSN	National Healthcare Safety Network
NPSD	Network of Patient Safety Databases
NSC	National Steering Committee for Patient Safety
OECD	Organisation for Economic Co-operation and Development
OIG	Office of Inspector General
ONC	Office of the National Coordinator for Health Information Technology
OPSS	Opioid Prescriber Safety & Support
OQR	Outpatient Quality Reporting
PA-PSRS	Pennsylvania Patient Safety Reporting System
PCDT	Preliminary Comments Development Team
PCHQR	PPS Exempt Cancer Hospital Quality Reporting
PE	Pulmonary embolism
PfP	Partnership for Patients
PFPM	Physician-focused payment model
PPS	Prospective Payment System
PREM	Patient-reported experience measure
PRT	Preliminary Review Team
PSI	Patient Safety Indicator
PSLL	Patient Safety Learning Laboratory
PSO	Patient Safety Organization
PSQIA	Patient Safety and Quality Improvement Act of 2005
PTAC	Physician-Focused Payment Model Technical Advisory Committee
QHP	Qualified Health Plan
QI	Quality improvement
QIN-QIO	Quality Innovation Network-Quality Improvement Organization
QIO	Quality Improvement Organization
QIS	Quality Improvement Strategy
QRS	Quality Rating System
QSRS	Quality and Safety Review System
REH	Rural Emergency Hospital
RFI	Request for Input
RTS	Report to the Secretary
SAFER	Safety Assurance Factors for EHR Resilience
SAQ	Safety Attitudes Questionnaire
SBAR	Situation, Background, Assessment, Recommendation
SCIP	Surgical Care Improvement Program
SME	Subject matter expert
SOPS	Surveys on Patient Safety Culture

SRE	Serious reportable event
STEEEP	Safe, Timely, Effective, Efficient, Equitable, Patient-centered care
TCOC	Total cost of care
TEAM	Transforming Episode Accountability Model
TeamSTEPPS	Team Strategies and Tools to Enhance Performance and Patient Safety
TJC	The Joint Commission
U.S.	United States
VBP	Value-Based Purchasing
VERP	Vaccine Errors Reporting Program
VTE	Venous thromboembolism
WHO	World Health Organization

I. Introduction and Purpose

Under the bipartisan Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) of 2015, Congress significantly changed Medicare fee-for-service (FFS) physician payment methods. The law also specifically encouraged the development of Alternative Payment Models (APMs) known as physician-focused payment models (PFPMs) and created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to review stakeholder-submitted PFPM proposals and make comments and recommendations on them to the Secretary of Health and Human Services (HHS; "the Secretary").

Since its inception, PTAC has received 36 proposals for PFPMs from a diverse set of physician payment stakeholders, including professional associations, health systems, academic groups, public health agencies, and individual providers.[ii] PTAC evaluates the PFPM proposals based on the extent to which they meet the Secretary's 10 regulatory criteria for PFPMs (specified in federal regulations at 42 CFR § 414.1465). Among the 36 proposals that were submitted to PTAC between 2016 and 2025, including 28 proposals that PTAC has deliberated and voted on during public meetings, nearly all of the proposals address patient safety. Committee members found that 23 of the 28 proposals met Criterion 9 (Patient Safety).

Given the increased emphasis on developing larger, population-based APMs that encourage accountable care relationships, PTAC has conducted several theme-based discussions between 2020 and early 2026 that have examined care delivery and payment issues as they relate to value-based care and APMs. A key theme that has emerged during these theme-based discussions is patient safety. Relevant topics identified for investigation in this environmental scan are:

- Background on patient safety;
- Causes of patient safety errors;
- Mitigation factors for patient safety errors;
- Measurement of patient safety; and
- Value-based care efforts to promote patient safety.

This environmental scan provides PTAC members with background information and context reflecting expert perspectives on issues related to targeting improvements in patient safety through APMs. The environmental scan is expected to help PTAC members review strategies in proposals previously submitted to the Committee. In addition, the environmental scan can inform the Committee's review of future proposals and future comments and recommendations that Committee members may submit to the Secretary relating to targeting improvements in patient safety through APMs.

Committee members will have a summary of relevant information from PTAC's review of proposals from previous submitters and findings from relevant literature, selected Centers for Medicare & Medicaid (CMS) Innovation Center models, and other CMS programs, state models, and demonstrations.

[ii] The 36 proposals submitted to PTAC represent an unduplicated count (i.e., proposals with multiple submissions are counted only once) of the number of proposals that have been voted and deliberated on by the Committee (28) and the number of proposals that have been withdrawn by stakeholders (eight, including one proposal that was withdrawn prior to any review by the Committee).

Section II provides key highlights of the findings from the environmental scan. Section III describes the research questions and methods used in the environmental scan. Subsequent sections provide background on patient safety (Section IV); causes of patient safety errors (Section V); mitigation factors for patient safety errors (Section VI); measurement of patient safety (Section VII); value-based care efforts to promote patient safety (Section VIII); relevant features in previously submitted proposals (Section IX); and areas where additional information is needed (Section X). Additionally, a list of abbreviations can be found at the beginning of the environmental scan, following the Table of Contents.

II. Key Highlights

The following section provides important definitions and highlights key findings from this environmental scan on targeting improvements in patient safety through APMs.

II.A. Definitions

PTAC formed the following working definition for patient safety:

- Freedom from errors that could cause patient harm during the delivery of health care. Errors may be either errors of commission, in which an incorrect action was taken, or errors of omission, in which a correct action was not taken.

This definition will likely continue to evolve as the Committee collects additional information from stakeholders.

II.B. Key Findings

Below are the key findings from the different sections covered in this environmental scan.

Background on Patient Safety

Safe care is one of six health care quality domains in the Institute of Medicine's (IOM's) STEEEP (Safe, Timely, Effective, Efficient, Equitable, Patient-centered care) framework.[1] IOM's *To Err Is Human: Building a Safer Health System* published in 1999 laid the foundation for prioritizing a national focus on patient safety.[2] Since the report's publication, many different strategies and interventions have been developed and implemented to prevent medical errors across health care settings.

Despite the development of these strategies and interventions following the publication of the IOM's report, progress in preventing medical errors has been slow and, in some cases, has stalled.[3,4] There are multiple potential reasons why the rates of patient harm have not substantially improved since the IOM report's publication nearly three decades ago, including competing priorities, inadequate metrics, staffing shortages, and a lack of transparency around performance.[5]

Different system-level approaches may help reinvigorate national progress in preventing medical errors, such as establishing a unified national approach to improve patient safety and further involving individual federal agencies, such as CMS, to support efforts to encourage progress with improving patient safety.[6,7]

Patient safety errors can be classified broadly as either errors of commission (i.e., errors that occur when an incorrect action was taken) or errors of omission (i.e., errors that occur when a correct action

was not taken). Although a large proportion of the research on patient safety has focused on errors of commission, research shows that errors of omission represent a larger proportion—approximately 96 percent—of medical errors.[8] Specific types of patient safety errors—which can be errors of commission or omission—are medication errors; diagnostic errors; laboratory and test errors; surgery and procedure errors; healthcare-associated infections (HAIs); patient falls; pressure injuries; equipment, device, and technology errors; and communication, handoff, and follow-through errors.

Patients can experience injury or harm from undergoing medical procedures, treatment, or care. This type of harm is called an adverse event (AE). Some adverse events are controllable, such that the harm could have been prevented if appropriate medical care was delivered. Controllable adverse events are of particular interest as a patient safety outcome because these types of events result from medical errors and can be avoided.

Globally, over 50 percent of all adverse events are controllable.[9,10] In the U.S., 43 percent of adverse events experienced by hospitalized Medicare beneficiaries in October 2018 could have been prevented by delivering better care.[11] Medication-related adverse events are among the most prevalent types of controllable adverse events, affecting approximately one in 20 patients worldwide.[12] Patient falls are also common, as 700,000 to one million hospitalized patients fall in the U.S. each year.[13] Globally, 24 percent of controllable adverse events are related to non-drug-related treatment incidents, 23 percent are related to non-surgical procedures and to surgical procedures, 16 percent are related to diagnosis-related incidents, and 16 percent are related to health care infections.[14]

The direct cost of controllable adverse events is estimated to be nearly 9 percent of health expenditures, translating to approximately $606 billion annually across Organisation for Economic Co-operation and Development (OECD) countries.[15] In the U.S., controllable medical errors cost $17.1 billion in 2008, reflecting almost 1 percent of the $2.4 trillion spent on health care the same year.[16]

Different organizations are responsible for providing oversight, technical assistance, and research, as well as monitoring patient safety errors. The World Health Organization (WHO) provides global patient safety oversight. Federal agencies, including CMS, the Agency for Healthcare Research and Quality (AHRQ), the Food & Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and HHS Office of Inspector General (OIG) provide regulatory oversight, technical assistance, support, and research on patient safety. The Joint Commission (TJC), National Quality Forum (NQF), National Committee for Quality Assurance (NCQA), and American Board of Medical Specialties (ABMS) accredit health care organizations and set standards for patient safety. The Leapfrog Group, Institute for Healthcare Improvement (IHI), Patient Safety Organizations (PSOs), and Emergency Care Research Institute (ECRI) and the Institute for Safe Medication Practices (ISMP) serve as watchdog and advisory groups focused on patient safety.

Causes of Patient Safety Errors

Different factors contribute to patient safety errors, including system and process-related factors, human factors, organizational and environmental factors, and technology and data-related factors.

- System and process-related factors that contribute to patient safety errors include communication breakdowns and poor adherence to protocols, procedures, and workflows.

- Human factors that contribute to patient safety errors include burnout and fatigue, high cognitive load and interruptions, and certain characteristics of providers (e.g., level of experience).
- Organizational and environmental factors that contribute to patient safety errors include organizational culture, organizational leadership and supervision, resource and staffing constraints, and environmental factors.
- Technology and data-related factors that contribute to patient safety errors include burden and usability issues; an overdependence on technology; and issues with access, availability, and accuracy of patient health data.

Mitigation Factors for Patient Safety Errors

Interventions that mitigate or prevent patient safety errors are standardized protocols and training, effective care coordination, enhanced communication, patient and family engagement, technology and data analytics, and a culture of safety. Examples of standardized protocols and training include the use of checklists and simulation-based training. Different strategies exist to improve care coordination, many of which focus on improving communication between providers and between providers and patients. There are many different tools available to improve communication, including Situation, Background, Assessment, Recommendation (SBAR); Illness Severity, Patient Summary, Action List, Situation Awareness & Contingency Planning, Synthesis by Receiver (I-PASS); and closed-loop communication. Patient and family engagement has an important role in patient safety as it encourages having patients and families be active partners in their health care journey. Regarding the role of technology and data in patient safety, electronic health records (EHRs) and clinical decision support (CDS) systems, medication safety technologies, human factors and systems engineering, data analytics and predictive modeling, monitoring and alarm systems, and safety event reporting systems have contributed to reducing patient safety errors. A culture of safety is critical to promote patient safety. A culture of patient safety is an environment that encourages clinicians, patients, and families to speak up when they observe potential problems that may need to be addressed, gives them confidence that reporting problems can lead to improvements, and ensures that they will be treated fairly when errors occur.[17]

Measurement of Patient Safety

Patient safety measures are a subset domain of a broader set of health care quality (STEEEP) measures. As with other quality measures, patient safety may be measured using structure measures (i.e., the health system or culture around patient safety), process measures (how safely care is delivered), and outcome measures (occurrence of adverse events and failure to rescue, as well as never events).[18]

Structure measures of patient safety assess the extent to which a health care system has the culture, capacity, and resources in place to maintain or improve safety and provide high-quality care. Examples of structure measures of patient safety are the Safety Attitudes Questionnaire (SAQ), CMS' new Patient Safety Structural Measure, and root cause analysis.

Process measures of patient safety focus on adherence to safety standards and evidence-based care. These measures focus on specific actions rather than the outcome of the actions. Examples of process

measures of patient safety are the Errors of Care Omission Survey (ECOS) and the Missed Nursing Care (MISSCARE) Survey.

Outcome measures of patient safety assess the incidence of adverse events and never events. Commonly used outcome measures include AHRQ's Patient Safety Indicators (PSIs), a collection of safety-focused measures used in acute care settings. These indicators allow health care organizations to identify safety issues related to operations, procedures, and childbirth to target quality improvement efforts. Additional examples of outcome measures are adverse drug events and measures of failure to rescue.

Patients and their caregivers can be engaged to identify and report patient safety concerns, adverse events, and near misses.[19,20] Patient-reported data can complement provider-reported safety data; identify unique safety incidents that are not detected by clinicians, medical record reviews, or captured in existing patient safety incident reporting systems; and highlight system-level vulnerabilities (e.g., insufficient staffing, organizational barriers to safer care).[21,22,23,24] Despite the value of patient and caregiver-reported safety data, there is a current lack of systematic integration of the data into existing reporting systems, potentially limiting the impact patient-reported safety data can have on safety improvement efforts and patient safety outcomes.[25]

Electronic clinical quality measures (eCQMs) automate calculation of patient safety measures, shifting from manually collected data to using electronic data extracted from EHRs and health IT systems. Currently, the CDC's National Healthcare Safety Network (NHSN) is building on eCQMs by developing electronic, automated measures called digital quality measures (dQMs) that use sources beyond EHRs (e.g., wearable devices, patient-reported data, case management systems) in an interoperable system.[26,27] NHSN dQMs use Healthcare Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) that promote standardization and data interoperability. These measures are intended to decrease reporting burden on providers, improve the quality of data collected by the NHSN, and allow real-time patient safety surveillance.

Value-Based Care Efforts to Promote Patient Safety

There are many value-based care efforts aimed at directly improving patient safety or improving patient safety as a part of an overall quality strategy. CMS has led 13 programs or models, eight of which have linked patient safety performance to payment. These initiatives either focus specifically on patient safety or involve improving quality and include patient safety measures. CMS also administers the Overall Hospital Quality Star Rating (Overall Star Rating) for hospitals. Beginning in 2026, hospitals that score in the lowest quartile for the safety of care measure group will be eligible to receive only a maximum of four stars. Starting in 2027, these hospitals in the lowest quartile will receive an automatic one-star deduction.[28,29]

CMS is also involved in promoting safety among commercial payers, particularly those payers who offer insurance products for Medicare beneficiaries. Within the Medicare Advantage (MA) program, CMS has implemented two programs, the MA and Part D Star Ratings, and Quality Improvement (QI) programs, to address quality and patient safety. CMS has also imposed requirements to implement patient safety processes within the federal/state marketplace exchange plans.

Commercial health plans also have the ability to improve patient safety. Most commercial insurers implement policies and procedures; display patient safety resources on websites; provide quality ratings for providers based on patient outcomes, safety, and cost effectiveness; and establish detailed medication safety programs to monitor medication use.

Relevant Features in Previously Submitted Proposals

Among the 36 proposals that were submitted to PTAC between 2016 and 2025, including 28 proposals that PTAC deliberated on during public meetings, Committee members found that 23 of the 28 proposals met Criterion 9 (Patient Safety). More information about these 23 proposals can be found in **Appendix B**.

III. Research Approach

This section provides a brief review of the research questions and methods that were used in developing this environmental scan.

III.A. Research Questions

Working closely with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) staff and with input from a subset of Committee members known as a Preliminary Comments Development Team (PCDT),[iii] the following research questions were developed to inform this environmental scan:

- What types of medical errors occur that compromise patient safety (e.g., missed care; unnecessary tests and procedures; hospital-acquired infections; overutilization; readmissions; and medication, diagnostic, and procedural errors)?
- What are current trends in the prevalence and cost of adverse events?
- What are the factors, causes, and challenges to patient safety?
- What are strategies or tools that can be used to reduce medical errors and increase patient safety, including the role of technology/artificial intelligence (AI) and data analytics?
- How do select models/programs incentivize patient safety (e.g., Hospital-Acquired Condition [HAC] Reduction Program, Hospital Value-Based Purchasing [VBP] Program, Merit-based Incentive Payment System [MIPS] quality measures)?
- How are patient safety measures tied to financial incentives and/or penalties?
- How can patient safety and high-quality care be incentivized in APMs (e.g., safety holdbacks or non-payment, no-bill rule for repairs, diagnostic safety bonus)?
- How can financial incentives be used while also ensuring that unintended consequences (e.g., stinting on care, cherry-picking, early discharge) do not occur?
- What are opportunities to engage providers to help reduce adverse events and improve patient safety? What solutions or insights can patients provide on improving patient safety?
- How can patient protections (e.g., consumer rights, appeals process, transparency) be used to reduce adverse events and errors and improve patient safety?

[iii] A Preliminary Comments Development Team (PCDT) comprised two Committee members: Soujanya (Chinni) Pulluru, MD (Lead); and Terry (Lee) Mills, MD, MMM.

- What are ways in which APMs can effectively promote patient safety (e.g., models that target adherence to checklists and infection prevention protocols, incentivize meeting certain safety benchmarks)?
- What are challenges with measuring patient safety?
- What are opportunities to improve the measurement of patient safety?
- What is the composition or balance of measures needed?
- What gaps exist currently in patient safety measures?
- How can patient-reported data be used more effectively to capture patient safety measures?
- What are approaches for setting appropriate benchmarks and baselines for patient safety measures?
- How can AI/machine learning be used to identify and reduce potential medical errors?
- What are opportunities to address barriers to integrating AI/technology that aids in improving patient safety?
- What are potential payment sources for integrating AI/technology to aid in improving patient safety?
- What are approaches to integrate AI predictive models into the provider workflow to aid in the identification of potential medical errors?
- What are ways in which AI/machine learning can be used to develop patient safety metrics?
- What are the future vision and next steps for using APMs to improve patient safety?

These primary research questions, organized by the environmental scan section, are provided in **Appendix A.**

III.B. Research Methods

The environmental scan includes information gathered from a targeted review of the literature, an analysis of previous PTAC proposals, and an analysis of select value-based CMS programs and Innovation Center models.

This environmental scan was specifically focused on five pertinent topics: background on patient safety; causes of patient safety errors; mitigation factors for patient safety errors; measurement of patient safety; and value-based care efforts to promote patient safety.

The analysis of select PTAC proposals (**Appendix B**) included a review of past proposals, PTAC reports to the Secretary, and content available in other PTAC process documents (e.g., public meeting minutes, Preliminary Review Team [PRT] reports).

IV. Background on Patient Safety

Patient safety errors are a prevalent and costly challenge in the U.S. health care system. The IOM's *To Err Is Human: Building a Safer Health System* published in 1999 spearheaded the focus on patient safety and helped establish dedicated research funding on the topic.[30] The report focused attention on the significant mortality (as many as 98,000 deaths annually) resulting from preventable medical errors occurring in U.S. hospitals and outlined a national agenda for prioritizing a safer health care system. Many strategies and interventions to prevent patient safety errors have been developed and adopted since the report's publication.[31]

Despite the development of these strategies and interventions following the publication of the IOM's report, progress in preventing medical errors has been slow and, in some cases, has stalled.[32,33] There are multiple potential reasons why the rates of patient harm have not substantially improved since the IOM report's publication nearly three decades ago:[34]

- Health care systems often have competing priorities with patient safety.[35] A lack of integration between competing priorities can slow progress on patient safety.
- Safety metrics alone may not be adequate to guide change.[36] Focusing exclusively on safety metrics can divert attention away from managing risks.
- Motivation to change may be impacted by a lack of transparency about performance and safety errors.[37]
- Safety reporting systems often use retrospective reporting rather than prospective or real-time measurement and tracking, making it difficult to track risks and make meaningful improvements to care.[38]
- Many health care organizations are challenged by staffing issues, such as staffing shortages, a lack of training, and burnout.[39]
- A weak economic and business case for systemic patient safety change may hinder progress in preventing medical errors.[40]

Different system-level approaches may help reinvigorate national progress in preventing medical errors. Establishing a unified national approach to improving patient safety could help drive accountability and measurable progress.[41] For example, establishing a national entity such as a Patient Safety Coordinator within the White House that mandates interagency coordination could drive system-level changes. In addition, creating a National Patient Safety Team that supports public-private partnerships could further encourage system-level improvements. This type of federal leadership would not only help to achieve system transformation but also could support the widespread adoption of new approaches that show promise in preventing medical errors, such as the use of AI and large language models.

In addition to coordinated federal leadership efforts, individual federal agencies can also support efforts to further encourage progress with improving patient safety. For example, CMS' payment policies in value-based care programs can emphasize prevention of medical errors. CMS has recently started linking hospital payment to reporting through its new Patient Safety Structural Measure focused on patient safety culture.[42] CMS could also consider adjusting the way financial rewards and penalties are determined in its existing payment programs to ensure hospitals continue to be incentivized to improve patient safety performance.[43] To ensure programs adequately capture safety performance, CMS could consider broadening the list of harm events used in its payment programs, as lists used in current programs may not sufficiently capture the wide range of patient harm.[44] Additionally, enforcing annual public reporting of patient safety errors and making safety performance public can also help promote progress in preventing medical errors.[45]

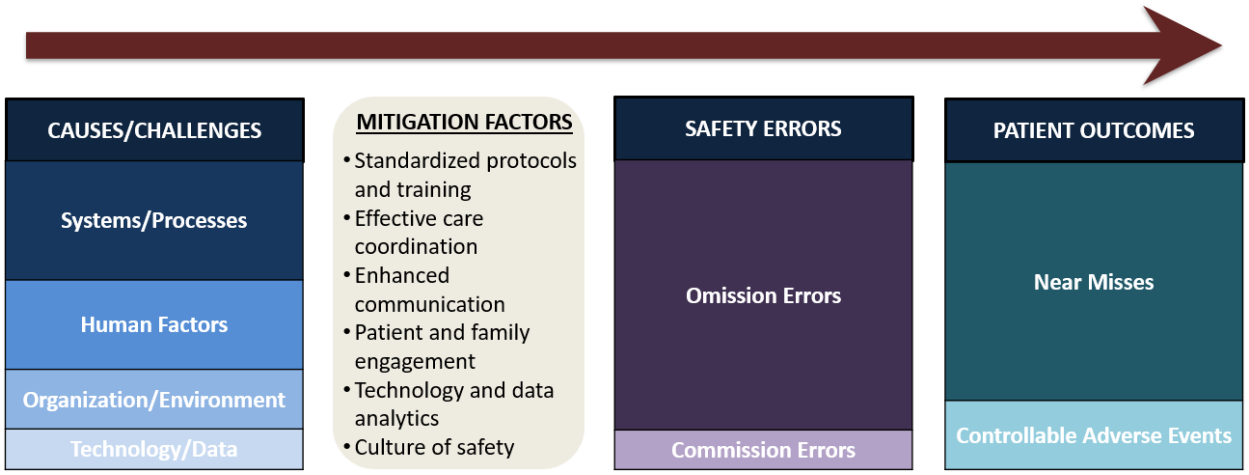
Safe care is one of six health care quality domains in the IOM's STEEEP framework.[46] As such, patient safety is a sub-domain of health care quality.

PTAC is using the following working definition for patient safety:

- Freedom from errors that could cause patient harm during the delivery of health care. Errors may be either errors of commission, in which an incorrect action was taken, or errors of omission, in which a correct action was not taken.

Exhibit 1 presents a conceptual diagram for patient safety. There are multiple reasons why medical errors might occur, including systems and processes-related factors, human factors, organizational and environmental factors, and technology and data-related factors; moreover, errors are often the result of combinations of these factors. Patient safety errors can be prevented and mitigated through various strategies and tools, including using standardized protocols and training, effectively coordinating care, enhancing communication, engaging patients and families, improving technology and data analytics, and promoting a culture of safety. Even with these mitigation factors, patient safety errors still occur. These errors can be either errors of commission (i.e., performing the wrong act) or errors of omission (i.e., failing to perform the right act). The outcome of a patient safety error is either an adverse event that harms the patient or a near miss.

Exhibit 1. Patient Safety Conceptual Diagram



Note: The size of the causes, errors, and outcomes bars approximate the variation in frequency that specific causes are experienced and the frequency of different types of errors and safety-related outcomes.

The sections that follow describe different types of patient safety errors; outcomes of patient safety errors; trends in patient safety errors, including the prevalence and costs associated with medical errors; and organizations involved in monitoring patient safety errors. Causes of patient safety errors and mitigation factors for patient safety errors will be discussed in subsequent sections of the e-scan.

IV.A. Types of Patient Safety Errors

Patient safety errors can be broadly classified as either errors of commission (i.e., errors that occur when an incorrect action was taken) or errors of omission (i.e., errors that occur when a correct action was not taken).

Errors of commission occur when the wrong action was taken — for example, a physician ordering a medication for a patient who has a documented allergy to the medication. A large proportion of the research on patient safety has focused on errors of commission, particularly errors of commission that

occur within hospital settings. However, research shows that errors of commission reflect only about 4 percent of medical errors. Errors of omission represent a far larger proportion—approximately 96 percent—of medical errors and occur across both inpatient and outpatient settings.[47] Errors of omission involve failure to take the correct action, such as failing to prescribe a medication for a patient who would likely benefit from it. Despite their prevalence, errors of omission and their consequences tend to be more difficult to identify and track compared with errors of commission, contributing to the limited amount of research on errors of omission.[48]

In a study of inpatient and outpatient health records within the Veterans Affairs (VA) health care system, the most common types of errors of omission identified were:

- Inadequacies in diagnostic testing (34 percent), such as not conducting a stress test for a patient with coronary artery disease and a new onset of chest pain;
- Obtaining insufficient information during patient histories and physicals (25 percent), such as not conducting a cardiac exam for a patient with lower extremity edema; and
- Not providing patients with needed medications (21 percent), such as not prescribing anti-platelet agent to a patient with a previous lacunar stroke.[49]

Interviews with physicians and nurse practitioners identified several common types of errors of omission that occur in primary care settings:

- Omitting patient education, such as not providing medication education, diet education, or physical activity recommendations;
- Lack of patient follow-up, such as not following up with a patient about their test results or referrals;
- Not providing family and caregiver support or addressing social well-being; and
- Not addressing patients' mental health needs, such as not screening for depression.[50]

Several categories of patient safety errors exist, and each category may contain both errors of commission and errors of omission:

- Medication errors, such as administering the wrong medication or incorrect dose of medication (commission), failing to document a patient's drug allergy (omission), or failing to prescribe a needed medication (omission);
- Diagnostic errors, such as misdiagnosing a health condition (commission), delaying diagnosis of a health condition (omission), or failing to follow up regarding abnormal test results (omission);
- Laboratory and test errors, such as ordering the wrong test (commission) or failing to order a lab test (omission);
- Surgery and procedure errors, such as wrong-site surgeries (commission), wrong-procedure surgeries (commission), or postoperative complications related to poor preparation (omission);
- HAIs, such as infections acquired through improper hand hygiene (omission), catheter-associated urinary tract infections (CAUTIs; commission), or central line-associated bloodstream infections (CLABSI; commission);
- Patient falls, such as falls due to inadequate monitoring (omission) or environmental hazards (e.g., wet floors; commission);

- Pressure injuries, such as placing the patient in an improper position (commission), failure to reposition immobile patients (omission), or delayed identification of early signs of pressure injury (omission);
- Equipment, device, and technology errors, such as malfunctioning medical equipment (commission) or not acting on a critical test because the EHR system failed to alert the clinician (omission); and
- Communication, handoff, and follow-through errors, such as taking incorrect actions due to misunderstood verbal orders (commission) or not following up with patients in need of screening tests (omission).[51,52]

IV.B. Outcomes of Patient Safety Errors

Research demonstrates that patients can experience significant injury or harm resulting directly from medical procedures, treatment, or care.[53] This type of harm is called an adverse event and may be permanent or temporary, vary in degree of severity, and, in extreme cases, result in death. Some adverse events are controllable and result from medical error, meaning that the patient harm could have been prevented if appropriate medical care—following established standards and practices—had been delivered. However, in other cases, adverse events are not under the control of the health care system. Examples of non-controllable adverse events include patient biology (e.g., a patient has a previously unknown drug reaction), environmental factors (e.g., an earthquake that causes a patient to fall and be injured), or inherent risks with medical care (e.g., sudden cardiac arrest during surgery for a patient with no prior cardiac disease).

Controllable adverse events are of particular interest as a patient safety outcome because they result from medical errors and could be avoided. More commonly, patient safety errors result in near misses, where an adverse event is avoided by chance or early detection, but patients were exposed to unsafe situations that are indiscernible from those that can lead to controllable adverse events.[54]

Controllable Adverse Events

There are three types of controllable adverse events: preventable adverse events, ameliorable adverse events, and negligent adverse events. Preventable adverse events are avoidable events that occurred due to error or failure to act.[55] Ameliorable adverse events are nonpreventable events that could have been less harmful or severe if the patient had received different care.[56] Negligent adverse events are events that occurred due to the delivery of substandard care.[57] Consequences from each of these types of adverse events may include the need for patients to undergo additional monitoring, treatment, hospitalization, or extended hospital stays.[58] Additionally, these adverse events can lead to long-term disability, decreased mental or physical health, decreased quality of life, and in some cases, death.[59]

Sentinel events are those adverse events that lead to severe temporary harm, permanent harm, or death. Examples of sentinel events include falls, wrong surgery (i.e., wrong implant, procedure, patient, or site), delay in treatment (e.g., misdiagnosis, missed diagnosis, delay in care), unintended retention of a foreign object (e.g., sponge, fragments, needle), fire/burns, or severe maternal morbidity. Although sentinel events may be noncontrollable adverse events, they often are controllable and rooted in preventable causes. By the nature of their severity, sentinel events typically trigger an investigation to identify and correct any underlying systemic issues that may have caused the event. TJC's 2024 Annual

Review of sentinel event data indicated that 1,575 sentinel events were reported from January 1 through December 31, 2024.[60] Patient falls were the most commonly reported sentinel event (49 percent). Approximately 21 percent of reported sentinel events were associated with the outcome of death.

Some sentinel events are never events. Never events are very serious preventable events that should never happen in health care. Never events may result in death or significant disability. The NQF designates never events as serious reportable events (SREs) and has identified 29 such events that are serious, largely preventable, and potentially a sign of problems within a health care organization's safety systems.[61] The most common types of never events are performing a surgery on the wrong body part, performing the wrong surgical procedure, leaving a foreign object in a patient after surgery, and performing surgery on the wrong patient.[62] Never events are less common than other sentinel events. For example, Minnesota has had a mandatory SRE reporting system in place for hospitals and ambulatory surgical centers since 2003, and an average of 100 to 150 never events are reported annually.[63,64]

Near Misses

Near misses, also called close calls or potential adverse events, are situations or events where errors occur but the errors do not result in patient harm or injury due to chance or early detection.[65] Patient injury is avoided in these cases either due to variation in patient responses (e.g., a patient receives a medication they are allergic to but does not have an allergic reaction) or due to chance intervention (e.g., a nurse happens to notice that a physician placed an order in the wrong patient chart). These types of situations or events are indistinguishable from controllable adverse events except for the outcome.[66]

A large proportion of the research on patient safety has focused on controllable adverse events. Among patient outcomes caused by medical errors, 13 to 29 percent are controllable adverse events. The remaining outcomes caused by patient safety errors are near misses.[67]

IV.C. Trends in Patient Safety Errors

Since the publication of the IOM's 1999 report, significant work has been done to improve patient safety, particularly in the inpatient setting. This work has included efforts to reduce HACs, including HAIs, surgical errors, patient falls, and improve communication among health care teams and patients. Exhibit 2 summarizes examples of key efforts focused on improving patient safety.

Exhibit 2. Examples of Key Patient Safety Efforts

Agency/Organization	Year	Focus of Initiative	Result of Initiative
AHRQ's Comprehensive Unit-based Safety Program (CUSP)[68]	Early 2000s	• A checklist of evidence-based practices to prevent HAIs	• Rate of central line-associated bloodstream infection reduced by 41% in over 1,000 intensive care units • Rate of catheter-associated urinary tract infection reduced by 30% in over 700 hospital non-intensive care units

Agency/Organization	Year	Focus of Initiative	Result of Initiative
			• Rate of surgical site infection reduced in hospitals by 25 to 40%
AHRQ's Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)[69]	2006	• An evidence- and team-based training program that provides organizations with tools to improve communication skills and teamwork among health care teams and patients	• Improved patient satisfaction, staff perceptions of teamwork, staff perceptions of communication, and clarity of roles within health care teams • Reduced controllable medical errors • Successfully implemented across settings (hospitals, primary care offices, long-term care facilities)
WHO's Safe Surgery Saves Lives[70]	2007	• A 19-item Surgical Safety Checklist to reduce surgical errors	• Rate of hospital death reduced from 1.5% before the checklist was introduced to 0.8%[71] • Reduced inpatient complications from occurring in 11% of patients before the checklist was introduced to occurring in 7.0% of patients
The 5 Ps of Nursing[72]	2007	• A purposeful rounding strategy for nurses to reduce falls • During rounding, nurses assess patients' pain, position, potty or personal hygiene, periphery, and pump	• Rate of patient falls reduced from 4 falls per 1,000 patients to 2 falls per 1,000 patients

Evidence suggests that several areas in patient care are safer now than they were in the past. Between 2010 and 2019, the occurrence rates have declined for HAIs and adverse drug events.[73] Adverse events after a procedure for patients admitted to the hospital for acute myocardial infarction, heart failure, pneumonia, and major surgical procedures also declined between 2010 and 2019. Additionally, central line infections and venous thromboembolism substantially declined between 2006 and 2013.[74]

Since the IOM's report was published nearly three decades ago, there have been new and emerging patient safety priority areas. These include addressing issues related to diagnostic errors (e.g., developing standards for accuracy and timeliness of results), focusing on improving safety in outpatient settings, and addressing safety issues introduced by the use of health information technologies (health IT).[75]

Despite the increased attention to patient safety spurred by the IOM's 1999 report, the prevalence of adverse events remains high across health care settings. The subsequent sections summarize the prevalence and costs of adverse events. These estimates should be interpreted with the understanding that they vary widely in the literature, potentially due to methodological factors such as the use of different analytic methods (e.g., data include administrative data, chart review, patient report, or multimethod) and use of different definitions for safety events and harms. Some of the studies were

published in the early 2000s, highlighting a need for updated research. It can also be difficult to determine whether some adverse events were preventable.[76] Prevalence and costs also vary depending on clinical settings and geographic areas of focus. Additionally, some types of patient safety errors (e.g., diagnostic errors and delays, preventable patient falls in non-hospital settings, and medication errors in non-hospitals settings) cannot be easily identified using claims data. Estimating the direct costs for such errors can be difficult.[77]

Prevalence of Patient Safety Errors

This section describes the prevalence of all adverse events—both controllable and uncontrollable. Additionally, this section describes differences in the prevalence of controllable adverse events by certain patient subpopulations. Prevalence rates differ by race and ethnicity, health insurance status, age, complexity of care, and chronic disease.

Prevalence of all adverse events. Patient safety literature commonly does not make a distinction between controllable and uncontrollable adverse events and instead refers to all adverse events—controllable and uncontrollable. Globally, more than one in 10 patients experience a controllable or uncontrollable adverse event across health care settings.[78,79] A systematic review and meta-analysis of adverse events in hospital settings across 25 countries estimated 8.6 hospital adverse events per 100 patient admissions, where one in 12 hospital patients experience at least one adverse event.[80] At the U.S. state level, evidence from 11 hospitals in Massachusetts indicated that at least one adverse event was identified in 24 percent of hospital admissions in 2018.[81] Across 11 outpatient sites in the state, 7 percent of patients had at least one adverse event in 2018.[82]

In the United States, approximately 25 percent of Medicare beneficiaries hospitalized in October 2018 experienced an adverse event.[83] Almost three-quarters (74 percent) of these adverse events contributed to or independently resulted in a longer hospital stay, an increase in the level of care needed, or a subsequent admission to the hospital. Fewer of the adverse events resulted in permanent harm (10 percent), required lifesaving intervention (7 percent), or resulted in death (10 percent). More recent results from an analysis of Quality and Safety Review System (QSRS) data—which captures both controllable and uncontrollable adverse events among Medicare beneficiaries—showed that the proportion of Medicare patients who experienced at least one adverse event per hospital stay decreased from 7 percent in 2021 to 5 percent in 2023.[84]Among hospitalized Medicare beneficiaries in October 2018, medication-related adverse events (43 percent) were the most common, followed by adverse events related to patient care (23 percent), such as pressure injuries, skin tears, and falls; those related to procedures or surgeries (22 percent), such as hypotension, excessive bleeding, embolisms, and cerebrovascular accidents; and infections (11 percent), such as respiratory infection, surgical site infection, and thrush.[85]

At the state level, in Pennsylvania, 256,679 total harm reports were submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2022, of which 9,741 reports were serious events.[86] Hospitals had 27.5 reports per 1,000 patient days while ambulatory surgical facilities had 9.4 reports per 1,000 surgical encounters.

Prevalence of controllable adverse events. Globally, more than 50 percent of all adverse events are considered preventable.[87,88] A systematic review and meta-analysis of multinational studies found that

more than half of all adverse events (53 percent) in inpatient settings are preventable.[89] Approximately 12 percent of preventable harm leads to death or permanent disability worldwide.[90]

In the United States, a medical record review conducted by physicians found that approximately 43 percent of adverse events experienced by hospitalized Medicare beneficiaries in October 2018 could have been prevented through better care, while 56 percent of the events may not have been preventable due to the complexity of patients' health conditions or care.[91]

A study of 11 hospitals in Massachusetts found that 23 percent of adverse events occurring in 2018 were controllable.[92] These events occurred in 7 percent of all admissions. Across 11 outpatient sites in the state, 23 percent of adverse events identified were controllable,[93] and 2 percent of patients in the outpatient settings had at least one controllable adverse event.

Adverse events related to medication are among the most prevalent types of controllable adverse events, affecting approximately one in 20 patients worldwide.[94] This was confirmed to be true in both inpatient and outpatient settings in Massachusetts.[95,96] Patient falls are also common, where, each year, 700,000 to one million hospitalized patients fall and nearly half of nursing home residents fall in the United States.[97] Additional global evidence shows that non-drug-related treatment incidents (24 percent) are among the most common types of preventable harm, followed by events related to procedures (23 percent), surgical procedures (23 percent), diagnosis (16 percent), and health care infections (16 percent).[98]

Specialized health care settings, including intensive care, emergency, and surgical units, have the highest rates of preventable harm.[99] In addition, half of harm that occurs in long-term care settings is considered preventable.[100] Although there is limited evidence on preventable adverse events in primary care settings, the research that does exist shows that only 3 percent of patients receiving care in these settings experience preventable harm.[101] Meanwhile, there is a dearth of research on the prevalence of patient harm within mental health settings.[102]

Prevalence of controllable adverse events, by patient subpopulations. Some subpopulations are more likely to experience controllable adverse events relative to the general population. Prevalence rates vary by race and ethnicity, distance traveled to the hospital, health insurance status, age, complexity of care, and chronic disease.

One study showed that hospitalized African American and Asian/Pacific Islander patients were more likely to experience pressure ulcers, postoperative hemorrhages or hematomas, and postoperative pulmonary embolisms (PEs) or deep vein thrombosis (DVT) relative to white patients in 2009.[103] The same study showed that Hispanic/Latino patients were more likely to experience postoperative physio metabolic derangement and accidental puncture/laceration relative to white patients.

Patients who travel greater distances to the hospital may be at greater risk for adverse events. Hospital discharge data from 2005 show that, relative to patients who traveled less than 50 miles to the hospital, patients who traveled 51 to 120 miles to the hospital had 7 percent higher odds of experiencing an adverse event, and patients who traveled more than 120 miles to the hospital had 9 percent higher odds of experiencing an adverse event.[104]

The prevalence of controllable adverse events also differs by insurance status. Relative to patients with private insurance, patients with Medicaid were more likely to experience pressure ulcers, postoperative physiological metabolic derangement, postoperative respiratory failure, postoperative wound dehiscence, and death among surgeries.[105] Both patients with Medicaid and those who were uninsured had a greater likelihood of postoperative PE or DVT relative to patients with private insurance.

The prevalence of adverse events may also differ by age group. Adult patients over the age of 65 years are more likely to experience controllable adverse events relative to patients under the age of 65 years. Specifically, older patients are more likely to experience controllable events related to medical procedures, adverse drug events, and falls relative to younger patients.[106] One reason why older adults may be more likely to experience controllable adverse events is due to the elevated complexity of their care. Older patients may take more medications, receive more procedures, and have longer lengths of stays in hospitals relative to younger patients, all of which can increase a patient's exposure and the amount of time they are at risk for experiencing controllable adverse events.[107]

Patients with chronic conditions may be at greater risk for certain types of safety errors. Within the VA health care system, errors of omission were particularly prevalent among patients with chronic conditions.[108] More specifically, patients with diabetes may experience the greatest number of errors of omission. Certain comorbid conditions—congestive heart failure, pulmonary circulatory disease, metastatic cancer, coagulopathy, weight loss, and fluid/electrolyte disorder—each put patients at higher risk of experiencing an adverse event during their hospital stay in 2005.[109] Illness severity at admission also increased patients' risk of experiencing an adverse event during their hospital stay in 2005.[110] Among hospitalized patients with cardiovascular diseases, patients who took more drugs and had multimorbidity were more likely to experience drug-drug interactions, a type of preventable adverse drug event, relative to patients who took fewer drugs and did not have multimorbidity.[111] There may also be variation in the prevalence of controllable adverse events for patients with different types of cancer. Sixteen percent of patients with cancer experienced at least one controllable adverse event in 2012.[112] Among all adverse events, 32 percent were considered controllable, translating to 0.73 events per 1,000 patient days. These patients were more likely to experience controllable adverse events in inpatient settings (approximately 32 per 1,000 inpatient days) relative to outpatient settings (less than one per 1,000 outpatient days). The prevalence of controllable adverse events differed by the type of cancer treated, where patients with lung cancer experienced the greatest proportion of controllable adverse events, followed by patients with colorectal cancer and breast cancer.

Additional research is needed to understand variations in the prevalence of adverse events across different subpopulations, particularly populations with mental health disorders and cognitive impairments.[113]

Underreporting of adverse events. Many adverse events — including controllable and uncontrollable adverse events — go unreported. Hospitals may not capture nearly half (49 percent) of adverse events for the reasons described below:[114]

- 46 percent of the missed events were not captured because hospital staff did not consider the events to be harm events.
- 20 percent of the missed events were not captured because the events were difficult to differentiate from the patients' underlying diseases.

- 16 percent of the missed events were not captured because the events did not meet the hospitals' criteria for reporting the events.

Evidence on the global, national, regional, and state prevalence rates of adverse events is summarized in **Appendix C**.

Direct and Indirect Costs of Patient Safety Errors

Patient safety events can result in direct (medical) costs, as well as indirect (non-medical) costs. Indirect costs may include lost productivity due to prolonged illness or disability, reduced workforce participation, early retirement due to acute illness, and decreased income.[115] The sections below describe the direct and indirect costs of all adverse events (controllable and uncontrollable), controllable adverse events, and the controllable adverse events that are most costly.

Costs of all adverse events. In developed counties, the direct cost of all medical-related harm is estimated to be nearly 13 percent of health expenditures, translating to approximately $878 billion annually across OECD countries.[116] The WHO reported that the gross world product could have been 15 percent higher had unsafe patient care been eliminated in 2000.[117] Regarding indirect costs of all adverse events, in 2006, societies would have been willing to pay from $393 billion to $958 billion to avoid injuries and deaths caused by adverse events.[118]

Approximately 23 percent of Medicare patients who were hospitalized in October 2018 and experienced a controllable or uncontrollable adverse event required additional treatment that resulted in greater Medicare costs.[119] In October 2018, Medicare spent approximately $520 million on inpatient prospective payment system (IPPS) costs from controllable and uncontrollable patient harm events, reflecting 2 to 8 percent of Medicare IPPS expenditures during that timeframe. Additionally, Medicare spent approximately $281 million on hospital costs associated with controllable and uncontrollable harm events to non-IPPS patients in October 2018.[120]

Costs of controllable adverse events. The direct cost of controllable medical-related harm is estimated to be nearly 9 percent of health expenditures, amounting to approximately $606 billion annually across OECD countries.[121] In the United States, an analysis of claims data estimated that measurable, controllable medical errors cost $17.1 billion in 2008, reflecting almost 1 percent of the $2.4 trillion spent on health care the same year.[122] In Massachusetts, one study showed that controllable medical errors accounted for over $617 million in excess health insurance claims in 2013.[123] There are also administrative costs to medical errors, as the average administrative cost of investigating and reporting one serious reportable event was $8,029 in 2013.[124]

Patient harm is associated with indirect costs, which are likely to exceed the direct costs.[125] One study estimated that indirect costs of medical errors in 2008 were estimated to be $1.4 billion due to increased mortality rates and $1.1 billion due to lost productivity.[126] Patients, families, and caregivers can experience financial impacts from medical errors, some of which may include lost productivity due to prolonged illness or disability; reduced workforce participation, missed time at work, leaving a job, or decreased income; and additional household expenses.[127,128,129] Medical errors can also lead to a loss of trust in the health care system and avoidance in receiving care.[130]

Costs of controllable adverse events vary by patient subpopulation. In 2005, the mean incremental hospital cost to treat patients who experienced adverse events was typically higher for patients with at least one comorbidity ($27,644) compared with patients without a comorbid condition ($17,249).[131] However, the mean incremental hospital cost to treat patients who experienced adverse events may not continue to grow substantially with an increasing number of comorbidities. For example, patients with two comorbidities who experienced an adverse event had an incremental mean cost of $29,290, and patients with three comorbidities who experienced an adverse event had an incremental mean cost of $31,686.[132] Controlling for the number of comorbidities, patients with greater illness severity at admission also had higher mean incremental hospital costs associated with adverse events in 2005.[133]

Costs of adverse events may unevenly impact socially and economically disadvantaged patients. Evidence suggests that socially and economically disadvantaged communities are more likely not only to experience harm but also to be disproportionately impacted by the indirect costs of harm.[134]

Most costly types of controllable adverse events. Nationally, across inpatient and outpatient settings, postoperative infections and pressure ulcers were among the most frequent and most costly types of medical errors in 2008.[135] Within inpatient settings in multiple states, hospital-acquired urinary tract infections ($2.5 billion), venous thromboembolisms ($678.7 million), and catheter-related bloodstream infections ($196.1 million) were among the costliest controllable harms incurred during index hospital stays in 2009 to 2011.[136] Never events, such as pressure ulcers, objects left in the body, and blood type incompatibility, cost $3.7 billion nationally in 2008, reflecting 22 percent of the total cost of medical errors the same year.[137]

In 2016, AHRQ used a meta-analytic design to estimate the incremental costs of infectious and non-infectious HACs to the hospital for inpatient stays.[138] Results indicated that infectious HACs were associated with higher incremental costs relative to non-infectious HACs. The most expensive infectious HACs were CLABSI ($48,108) and ventilator-associated pneumonia ($47,238), while the least expensive infectious HACs were CAUTI ($13,793) and C. difficile infections ($17,260). Venous thromboembolism ($17,367) and pressure ulcers ($14,506) were the most expensive non-infectious HACs. The incremental costs of hospital-acquired adverse drug events and falls were $5,746 and $6,694, respectively.

In Massachusetts, the most common and costly errors in 2013 included pressure ulcers, postoperative infections, infection and inflammatory reaction due to internal prosthetic device implant and graft, accidental puncture or laceration during a procedure, medical treatment-induced abnormally low blood pressure, substances causing adverse effects in therapeutic use, and abnormal collection of blood complicating a procedure.[139]

Evidence on the direct and indirect costs of patient safety errors is summarized in **Appendix D**.

IV.D. Organizations Responsible for Monitoring Patient Safety Errors

Different organizations provide patient safety oversight, monitor patient safety events, conduct research on patient safety, set standards, and provide safety guidance and technical assistance. Some organizations require safety event reporting, compliance with safety standards, or certification for participating in a program; in contrast, these activities are voluntary for other organizations.

Global Oversight

The WHO supports patient safety by establishing global safety standards, developing evidence-based guidelines and resources (e.g., the Surgical Safety Checklist, a 19-item tool designed to prevent surgical errors), and facilitating initiatives such as the Global Patient Safety Action Plan 2021–2030.[140,141] The Global Patient Safety Action Plan 2021–2030 provides a framework for countries to develop their own national action plans to reduce controllable adverse events and promote alignment across instruments for improving patient safety across different clinical programs.[142] The plan provides a list of actions that governments, organizations, and health care facilities can adopt to improve patient safety.

Federal Regulatory Oversight, Technical Assistance, and Research

Several federal agencies are responsible for providing regulatory oversight, technical assistance, and research on patient safety in the United States, including HHS OIG, CMS, FDA, CDC, and AHRQ.

Federal agencies provide regulatory oversight on patient safety. HHS OIG provides federal oversight, audits, and enforcement across federal health programs. Additionally, OIG monitors adverse events across health care settings, conducts national incidence studies, evaluates hospital reporting practices, and provides recommendations to improve safety. OIG has developed two adverse event toolkits to provide methodological guidance for hospitals and researchers to identify and measure patient harm events in medical records.[143] Additionally, OIG supports other HHS agencies with determining the impact of harm events in federal programs. OIG published the first national incidence rate of adverse events (controllable and noncontrollable) experienced by Medicare beneficiaries in 2010 and released an update of the national incidence rate in 2022.

The Social Security Act (the Act) mandates that the federal government develop minimum health and safety standards for providers participating in the Medicare and Medicaid programs. HHS designated CMS to administer these standards.[144] To do so, CMS administers Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) for Medicare and Medicaid providers, setting requirements for acceptable quality in health care entities and serving as the foundation for improving quality and safety for beneficiaries. For example, hospitals must be compliant with applicable federal laws related to health and safety of patients and must have a governing body that ensures that services are provided in a safe manner.[145] Health care organizations must meet these quality and safety standards to be reimbursed for providing care to Medicare beneficiaries.

To addition to providing regulatory oversight, CMS supports transparency of patient safety by publicly reporting hospital quality and safety information through Care Compare on Medicare.gov.[146,147] Care Compare is a web-based tool that presents performance data for Medicare-certified hospitals, including acute care hospitals, Critical Access Hospitals (CAHs), and Rural Emergency Hospitals (REHs). Performance data presented on Care Compare include the hospital's overall star rating, which is based on how well the hospital performs in different areas of quality, including safety of care and specifically in potentially preventable injury and complications due to care provided during patients' hospitalizations. The tool allows patients to compare the performance of a health care provider with the performance of other providers in their state and across the nation. CMS also promotes accountability for patient safety through payment models and programs, described in detail in *Section VIII. Value-Based Care Efforts to Promote Patient Safety*.

In collaboration with the FDA and CDC, CMS regulates laboratory testing through the Clinical Laboratory Improvement Amendments (CLIA) program.[148] CLIA promotes the quality of clinical laboratory testing

for over 320,000 entities by setting quality standards that ensure that test results are accurate, reliable, and timely. Compliance with CLIA regulations is mandatory for all non-research-related laboratory testing; clinical laboratories must have the appropriate certificate before they can accept samples for testing. The stringency of CLIA regulations depends on the complexity of the test method, where more stringent requirements are applied to more complicated test methods.[149] Laboratories that perform moderate to high complexity tests are required to participate in proficiency testing—an approach that assesses laboratories' performance and the accuracy and reliability of their tests.[150] While CMS issues laboratory certificates, monitors laboratory performance on proficiency testing, and enforces regulatory compliance, the FDA categorizes tests based on test complexity, and the CDC conducts laboratory quality improvement research and develops technical standards and laboratory practice guidelines.[151]

The FDA regulates the manufacturing, marketing, and distribution of prescription and over-the-counter medicines, medical devices (e.g., diabetes glucose testing kits, hearing aids), and biologics (e.g., blood/plasma derivatives, gene therapies) to ensure that they are effective and safe.[152] Drugs and devices must have FDA approval before marketing. The FDA reviews products for approval, monitors products for risks once they are on the market, and issues safety recalls and alerts. The FDA's medical product safety reporting program for health professionals and patients—MedWatch—allows the public to report safety issues, which can inform the FDA's safety alerts for FDA-regulated products.[153]

The CDC leads patient safety efforts to prevent HAIs by managing the nation's largest HAI reporting system—the National Healthcare Safety Network (NHSN).[154] NHSN data are used to identify safety concerns and track progress of prevention efforts. Facilities report HAI data to CMS via the NHSN as part of CMS' quality reporting programs, and these data are used by CMS to determine performance incentives. Additionally, many states use the NHSN as the system for mandated reporting.[155]

AHRQ is the primary federal agency that conducts patient safety research and develops patient safety tools, resources, and measures. In collaboration with CMS, AHRQ developed the QSRS to track hospital adverse events.[156] The QSRS is a data collection and analysis system designed to capture the occurrence of controllable and noncontrollable adverse events (e.g., falls, hospital-acquired infections, medication events) among Medicare FFS and MA beneficiaries during stays in acute care hospitals that participate in the IPPS. QSRS data are manually extracted from inpatient records by human abstractors. Efforts are currently underway to automate the data extraction process using AI. In 2020, the QSRS replaced the Medicare Patient Safety Monitoring System (MPSMS), which was developed by CMS in 2001 to monitor and track adverse events among Medicare beneficiaries in inpatient settings.[157]

Under the Patient Safety and Quality Improvement Act of 2005 (PSQIA), AHRQ maintains the Network of Patient Safety Databases (NPSD) to collect, identify, track, and analyze non-identifiable adverse events (controllable and noncontrollable) at the national level. Using patient safety data submitted by PSOs, the NPSD provides evidence-based resources, including dashboards, chartbooks, and other informational tools, to health care providers, PSOs, and others to help mitigate safety risks and reduce harm across the country.[158] Additional information on PSOs can be found in the *Watchdog and Advisory Groups* section below. Details on different ways AHRQ has supported organizations with mitigating patient safety errors (e.g., providing training tools and resources) are in section *VI. Mitigation Factors for Patient Safety Errors*.

Accrediting and Standards Setting

Several organizations are responsible for accrediting and setting standards for patient safety, including TJC, NQF, NCQA, and ABMS.

TJC is a nonprofit organization that accredits different types of health care organizations—including hospitals, ambulatory health care facilities, laboratories, Critical Access Hospitals, rural health clinics, nursing care centers, and assisted living communities—using evidence-based standards that are focused on performance improvement strategies to promote patient safety and quality of care.[159,160] These standards cover multiple domains necessary for the delivery of safe care, such as standards for the provision of care, treatment, and services; leadership; medical staff; the physical environment; national performance goals; and performance improvement.[161] For example, standards for performance improvement include having a quality assessment and performance improvement program, collecting data, and analyzing data. Standards for the physical environment include protecting occupants during periods of construction and having a water management program that addresses Legionella and other waterborne pathogens. Organizations that achieve accreditation from TJC are thought to have made a commitment to provide high-quality care. TJC's Hospital Accreditation Program has been in existence for over 60 years. Approximately 82 percent of hospitals in the United States, including Critical Access Hospitals, are accredited by TJC.[162] TJC also evaluates and provides education to organizations to improve business operations and offers resources to support health care organizations with tracking their compliance and patient safety.[163]

TJC also monitors sentinel events, or serious, unexpected occurrences involving death, permanent harm, or severe temporary harm.[164] Although these events can include noncontrollable adverse events, most reported sentinel events are controllable adverse events. TJC instituted its own formal Sentinel Event Policy in 1996 to support health care organizations with improving patient safety. Health care organizations accredited by TJC voluntarily report sentinel events to TJC, which then collaborates with the organizations to address and prevent these types of serious events from occurring again. Reporting such events is thought to not only increase transparency but also promote a culture of safety in health care organizations. TJC maintains a Sentinel Event Database comprised of lessons learned from sentinel events.[165]

The NQF is a nonprofit organization that supports patient safety and quality by working with stakeholders to establish consensus-based national safety and quality improvement standards and practices.[166] NQF's work aims to address key measurement and reporting issues identified by stakeholders, including issues related to measurement processes that are fragmented, burdensome, and costly. Through its Focus on HARM (Harmonizing Accountability in Reporting and Monitoring) patient safety initiative, which aims to reduce preventable harm, NFQ is developing a new, unified, consensus-based list of SREs.[167] The list aims to modernize the criteria for what is considered a SRE, standardize patient safety event definitions, and align reporting standards across accountability systems.

NQF has partnered with TJC on multiple initiatives. For example, NQF and TJC are collaborating on the Focus on HARM initiative to align definitions for SREs and sentinel events. Additionally, NQF and TJC have partnered to launch a new Outcomes-Driven Certification program that includes outcomes-focused measure sets that aim to engage patients and support providers with improving patient safety and care experiences.[168] The certification will allow organizations to compare their performance with other organizations and learn from each other.

NCQA is a nonprofit organization focused on improving quality of care. NCQA promotes patient safety through its voluntary Health Plan Accreditation program that assesses health plans' structure and process, clinical performance, and patient experience.[169] Twenty-seven states require this accreditation for health plans serving the states' Medicaid populations.[170] Additionally, NCQA oversees the Healthcare Effectiveness Data and Information Set (HEDIS), a performance measurement tool that is used by many health plans. HEDIS includes over 90 quality measures, some of which assess patient safety, such as a measure of potentially harmful drug-drug interactions in older adults. HEDIS quality measures span across six domains: effectiveness of care, access/availability of care, experience of care, utilization and risk adjustment utilization, health plan descriptive information, and measures reported using electronic clinical data systems.[171] States and the federal government use HEDIS to support patients with making informed choices when selecting a health plan.[172]

The ABMS supports patient safety by setting standards for board certification that integrates patient safety education into board certification exams.[173] Board certification improves patient care by applying professional and educational standards for physician specialists. Other medical groups similarly promote patient safety. For example, the Association of American Medical Colleges (AAMC)—an organization that represents accredited medical schools and oversees the Medical College Admission Test (MCAT) exam—coordinates a certification program that trains clinical faculty to teach patient safety and quality improvement.[174] The AAMC also develops quality improvement and patient safety competencies that set safety expectations for medical students, residents, and physicians.

Watchdog and Advisory Groups

There are several watchdog and advisory groups focused on patient safety, including the Leapfrog Group, IHI, PSOs, and ECRI and the ISMP.

The Leapfrog Group is a national organization that collects, analyzes, and publishes information on quality and safety. The Leapfrog Group supports patient safety through two initiatives.[175] First, the Leapfrog Hospital Survey and Ambulatory Surgery Center (ASC) Survey are voluntary surveys that collect and publicly report on hospitals' and ASCs' quality, safety, and efficiency. Over 2,400 hospitals submit a Leapfrog Hospital Survey each year.[176] Second, the Leapfrog Hospital Safety Grade assigns general acute care hospitals across the nation letter grades based on their patient safety record. Hospitals must have sufficient safety data available to receive a letter grade. Grades are based on 32 evidence-based structure, process, and outcome measures of patient safety, including the CMS Medicare Patient Safety Indicator (PSI) 90 Patient Safety and Adverse Events composite (described in more detail in section *VII. Measurement of Patient Safety*).[177] Such transparency in quality and patient safety can promote accountability and improvement across the health care system and is strongly desired by patients and their families.[178] Patients and family members can use a web-based tool to find the overall letter grade, as well as additional safety-related information for the hospitals located in their area. Both initiatives support patients with identifying safe and high-value care.

The IHI is a nonprofit organization that uses a systems approach to improve patient safety through interactive and asynchronous educational courses and free evidence-based resources and tools (e.g., white papers, publications, videos). IHI also convenes stakeholder groups as part of initiatives to improve patient safety and quality. For example, IHI convened the National Steering Committee for Patient Safety (NSC) as a collaboration among 27 health care organizations to develop approaches for

improving and sustaining safety across health care settings.[179] IHI then leveraged insights from the NSC and other stakeholder groups to create the National Action Plan to Advance Patient Safety. This plan provides guidance and actionable recommendations for health care leaders, organizations, and associations to reduce harm across the continuum of care.[180] Additionally, in January 2024, IHI convened an expert panel to identify areas where generative AI can enhance and threaten patient safety and provide recommendations to mitigate safety risks.[181]

AHRQ oversees PSOs under PSQIA.[182] PSOs allow providers to voluntarily submit patient safety events without fear of retribution or legal discovery. By collecting, analyzing, and aggregating patient safety data at local, regional, and national levels, PSOs generate insights on the causes of patient safety events and offer a secure environment to reduce risks in patient care. Additionally, PSOs work with and offer feedback and resources to providers to promote learning and reduce harm. By carrying out these responsibilities, PSOs serve as a national learning system that helps improve safety culture and reduce the occurrence of patient harm.

ECRI and the ISMP is a single PSO certified by AHRQ. The PSO collects and analyzes safety events and develops tools that promote understanding of unsafe conditions, help to improve safety protocols, support a culture of safety, and improve outcomes through different collaborative modes of learning including coaching, education, and peer-to-peer learning.[183] The PSO also supports consumers and health care practitioners with reporting medication and vaccine errors through the ISMP National Medication Errors Reporting Program (ISMP MERP) and ISMP National Vaccine Errors Reporting Program (ISMP VERP).[184]

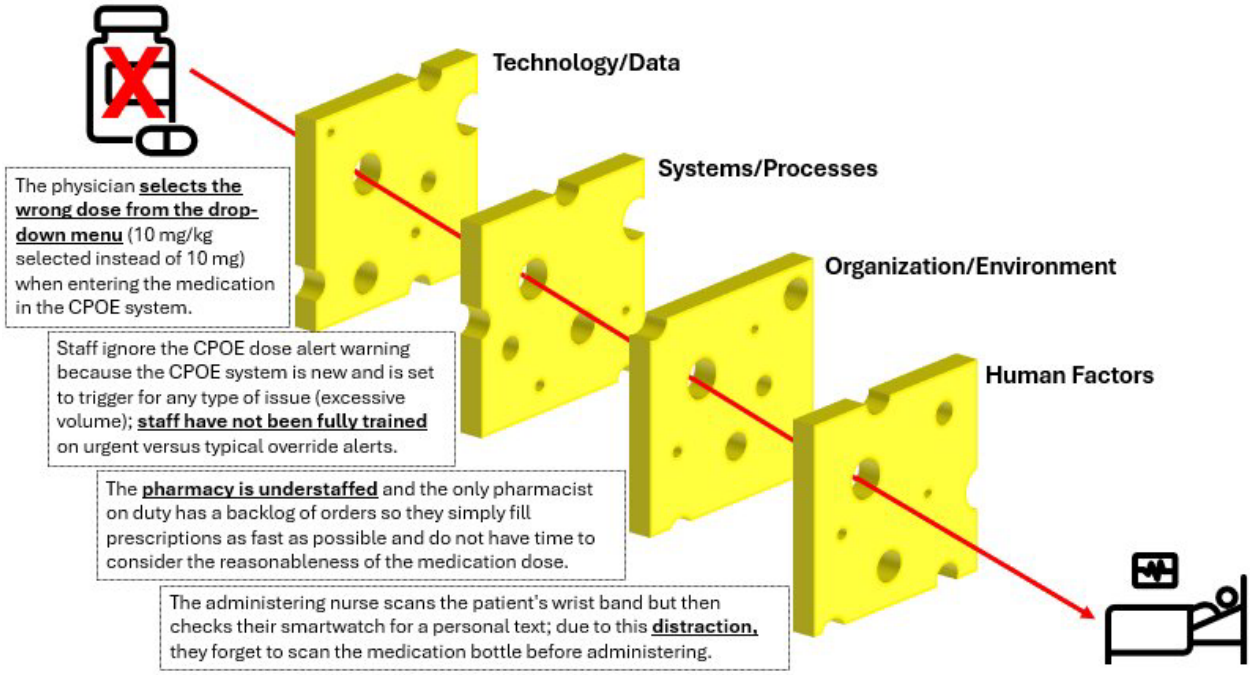
Regulatory and accreditation agencies have not prioritized outpatient safety to the same degree as inpatient safety, and patient safety research related to outpatient settings is limited.[185] Many patient safety strategies developed for inpatient settings may not be applicable or appropriate for outpatient care.

V. Causes of Patient Safety Errors

Patient safety errors can result from several different types of factors: system and process-related factors, human factors, organizational and environmental factors, and technology and data-related factors. System and process-related factors contribute to the greatest number of patient safety errors.[186] However, safety errors are often the result of more than one contributory factor.[187]

The Swiss cheese model of patient harm explains how different types of errors can lead to patient harm. While barriers (cheese slices) prevent errors from occurring, gaps in those barriers (holes in the cheese) allow mistakes to slip through.[188,189] When a series of gaps occurs across barriers, the result is a patient error. Exhibit 3 provides an example of how multiple mistakes in an inpatient setting can lead to the administration of the wrong dose of medication.

Exhibit 3. Swiss Cheese Model of Patient Harm for an Inpatient Medication Error



The main causes of patient safety errors differ by health care setting. Within hospital settings, human factors, system and process factors (e.g., communication failures), and organizational and environmental factors (e.g., equipment and supply errors, issues with management of staff and staffing levels) are among the most frequently reported factors that contributed to patient safety errors.[190] Within primary care settings, system and process factors (e.g., communication errors) and human factors are among the most frequently reported factors that contributed to patient safety errors.[191]

V.A. System and Process-Related Factors

System and process-related factors can contribute to patient safety errors. These factors can include the absence of clearly defined protocols, procedures, and workflows; and communication breakdowns.[192]

Protocols, Procedures, and Workflows

Clinical protocols, procedures, and workflows influence how health care teams make decisions and execute tasks. Health care organizations maintain many clinical protocols with defined procedures to ensure the delivery of safe care that complies with care standards.[193] These protocols and procedures must be regularly reviewed and updated, as needed, to align with external changes, such as new regulations or equipment updates.[194]

The failure to establish, implement, or adhere to medical protocols and procedures can impact the delivery of safe care. Research shows that checklists—which standardize medical procedures, support adherence to established protocols, and reduce variation in the delivery of care—can reduce patient safety errors. For example, a randomized controlled trial showed that a checklist designed for physicians treating patients with heart failure improved the quality of care (measured by the proportion of patients taking evidence-based prescription medications that manage cardiovascular conditions) and reduced

readmission rates for patients admitted with heart failure.[195] The checklist included items related to prescribing evidence-based medications, providing heart failure education and counseling, and reviewing follow-up information at discharge.

Inadequate protocols and procedures can also impact the reporting of patient safety events. For example, ineffective reporting tools, a lack of standardized reporting criteria, and inadequate feedback or follow-up after adverse events occur can contribute to the underreporting of patient safety events.[196]

In addition to protocols and procedures, clinical workflows can influence patient safety. Workflows are operational tasks clinicians and staff implement to facilitate the delivery of efficient, standardized care. A lack of well-defined workflows can increase the risk of patient safety errors.[197] For example, one study found that despite having access to EHR tools for tracking patients' tests, clinicians and staff did not always use the tools because the responsibility for overseeing and managing the tools was not clearly defined or sufficiently staffed.[198]

Communication Breakdowns

Effective communication is a key component to promoting patient safety, particularly safety during handoffs, discharge, and the exchange of medical orders or test results. Communication breakdowns that occur between health care providers (e.g., managing handoffs or transitions of care) and between health care providers and patients (e.g., communicating test results) can lead to patient harm.[199] Evidence indicates that communication failures contribute to approximately 14 percent of patient safety incidents in primary care settings.[200] A lack of communication and collaboration among health care providers can also contribute to the underreporting of adverse events.[201] A questionnaire administered to nurses highlighted the importance of collaboration and teamwork in promoting patient safety.[202] The study found that organizations with poor communication channels restricted communication among multidisciplinary staff and contributed to safety events.

Communication failures can also be an intermediary cause of patient safety errors, or the result of one or more of the other factors that contribute to patient safety errors discussed in this section. Communication failures can also stem from human factors (described in the next section). For example, communication breakdowns can be driven by poor documentation practices, a lack of standardized procedures (e.g., procedures for executing effective transitions of care), and organizational cultures that do not encourage transparency and open communication.[203] Clinicians and staff report that a lack of health IT interoperability contributes to communication breakdowns and care coordination issues.[204]

Evidence indicates that a system-level approach is necessary to improve patient safety, as individuals working within a system cannot improve systemic issues alone.[205]

V.B. Human Factors

Human factors reflect the relationship between people and the systems in which they work.[206] Despite recognition that system-level forces drive safety errors, human factors are considered a common cause of patient safety errors.[207,208] One study found that human factors are a contributing factor in approximately 30 percent of patient safety incidents in primary care settings.[209] Burnout and fatigue, mistakes stemming from high cognitive load and interruptions, and certain characteristics of providers, including their level of experience, can contribute to medical errors.

Burnout and Fatigue

Clinicians provide care within highly complex systems that are susceptible to error, delivering services amid insufficient support and increasing workloads and administrative demands. Complex systems and evolving environments can place systemic stress on providers, contributing to burnout, fatigue, and frustration—all of which can hinder a provider's ability to conduct tasks appropriately and result in patient harm.[210,211] For example, triage nurses in emergency departments (EDs) report that burnout and fatigue are important factors in safely triaging patients.[212] Among nursing students and interns who reported making a medication error, 81 percent endorsed fatigue as a contributing factor.[213] Health care providers who have made preventable medical errors may experience heightened anxiety and reduced confidence in their performance and skills.[214]

High Cognitive Load and Interruptions

Mistakes can occur due to cognitive load. Cognitive load occurs when an individual's working memory is overburdened. This overburden can decrease an individual's ability to process information and effectively execute performance-based tasks.[215] For example, information overload in the EHR—including duplicated information in patient charts, an overabundance of clinically irrelevant information in the EHR such as data necessary for billing but not clinical care, and excessive alerting—can increase physician cognitive load and the risk for medical errors.[216] Additionally, frequent interruptions (e.g., by staff, phone calls, patients, and family members) can affect the delivery of safe care to patients.[217] Sixty-four percent of nursing students and interns reported distractions as a contributing factor for making medication errors.[218]

Level of Experience

Provider characteristics, including level of experience, can be associated with patient safety. Experience may be particularly relevant in some health care settings. Within EDs, triage nurses' clinical and practical skills, capabilities, and experience can affect decision-making in the triage process and the accuracy of patient assessments.[219] Evidence indicates that triage nurses with more experience triaging patients may have better patient safety.[220]

V.C. Organizational and Environmental Factors

Organizational and environmental factors—including organizational patient safety culture, organizational leadership and supervision, resource and staffing constraints, and environmental factors—can contribute to patient safety errors.

Organizational Patient Safety Culture

Organizational patient safety culture—the extent to which an organization promotes patient safety—is a key factor influencing patient safety.[221] This organizational patient safety culture reflects the values, beliefs, and norms that are shared among clinicians and staff and can impact their behaviors.[222] Research shows a relationship between blame culture—where individuals are personally blamed for medical errors—and inadequate communication, medical errors, and hindered patient safety.[223] Although its negative impacts are generally recognized, some approaches that organizations use to sanction providers may contribute to blame culture.[224] For example, providers may choose to not report medical errors if they fear that they will be punished for the errors.[225] By not speaking up when errors

occur, systemic problems can persist, and the health care organization cannot learn from the errors.[226] Additionally, patient safety culture is influenced by hierarchical structures within an organization, which can have a negative impact on patient care.[227] For example, hierarchical structures can hinder organizational learning, which is key to enhancing patient safety.

Evidence shows that psychosocial work environments and culture are strongly related to patient complications and controllable safety errors. For example, work environments that value transparency are more likely to report adverse events.[228] Despite its importance to patient safety, patient safety culture is often considered difficult to change but must be considered when making changes within a health care environment.[229]

Organizational Leadership and Supervision

Organizational leadership establish and drive system-level priorities and processes that support a culture of safety.[230] Health care leaders are often responsible for facilitating changes that promote health care quality.[231] For example, leadership can support staffing levels and ensure that educational resources are provided to staff.[232] Evidence indicates that poor leadership and high rates of turnover in leadership may be related to compromised patient safety.[233]

Supervision among health care providers can also influence patient safety. One study showed that triage nurses who received mentorship and peer support from more experienced nurses improved patient safety.[234] Patient safety champions who oversee safety issues and provide training on safety can have an important role in supporting clinicians' understanding of patient safety.[235]

Interdisciplinary collaboration, such as collaboration among physicians from different medical specialties or collaboration among clinicians with different medical training and credentials (e.g., physicians, nurse managers, and medical directors), can promote safe patient care delivery, transparency, and perceptions of patient safety.[236] For example, collaboration between neonatology and obstetrics can improve patient safety.[237] Although inadequate interdisciplinary collaboration may lead to more adverse events, many health care organizations do not facilitate this type of collaboration.[238] Commonly, clinicians must come to an agreement on how they will work together to ensure that interdisciplinary collaborations take place.

Resource and Staffing Constraints

Resource limitations and staffing shortages can contribute to patient safety errors.[239] Evidence shows that staffing shortages (e.g., an insufficient number of staff relative to the number of patients in EDs) can prolong patients' waiting times and reduce the quality of care.[240] A lack of staff, time, and funding can also contribute to the underreporting of adverse events.[241]

Workloads and the amount of time health care providers have with patients can also impact patient safety. Research shows that a clinician's perception that they lack time to comprehensively review a patient's health information before a clinical encounter can contribute to safety errors.[242] Over 90 percent of nursing students and interns who reported making medication errors identified a high workload and shift instability as contributing factors.[243] One study showed that patient safety in EDs improves when triage nurses have more time for patient assessment.[244]

Environmental Factors

The physical environment in hospital units and patient rooms, such as room layout, level of noise, and lighting, can influence patient safety. These factors can impact clinicians' ability to deliver safe care. For example, the size and layout of certain health care facilities may put clinicians at increased risk for interruptions, cognitive overload, and fatigue which can in turn impact team members' ability to see one another and their communication.[245] These factors can also directly impact patients. For example, patient risk for falls may be associated with the layout of patient rooms, including whether room design requires sharp turns, or whether rooms have inadequate lighting, limited room for visitors, or low-quality flooring.[246]

Clinicians who deliver care in multiple health care settings with different physical environments or procedural standards may be at increased risk for safety errors. Fifty-six percent of nursing students and interns reported that working in more than one health care facility could increase risk of making medication errors due to inconsistencies in these areas across facilities.[247]

V.D. Technology and Data-Related Factors

Although technology and technology-enabled data can reduce the risk of patient safety errors (described in more detail in *Section VI. Mitigation Factors for Patient Safety Errors*), they can also introduce new types of patient safety errors. These include burden and usability issues, overdependence on technology, and issues with access, availability, and accuracy of patient health data.

Burden and Usability Issues

Research shows multiple ways technology increases burden on end-users, ultimately contributing to medical errors. These include burdensome methods for electronic documentation, EHR usability issues, and technology-related workflow complexities.[248] With respect to electronic patient orders, complex data entry forms can lead to mistakes.[249] Increased use of EHRs and digital technology may require clinicians to enter patient data into multiple systems, increasing both the opportunity for error and provider burden.[250] Systems that auto-populate some fields as a default and have difficult-to-use interfaces lead to medication errors. Difficulty locating patient information in the system may lead some clinicians to make decisions without necessary patient information.[251] Inadequate EHR messaging inboxes and notifications can also make it difficult for providers to track communications among the care team and make clinical decisions.[252]

EHR usability issues sometimes lead to unsafe workarounds. For example, if it is difficult to share data with other providers within an EHR system, clinicians may use copy-paste to share notes, which can lead to errors where inaccurate information is forwarded. Furthermore, systems may incentivize providers to enter an overabundance of patient information, burying important details about a patient in the health record.[253,254] Clinicians can also experience alert fatigue, where systems produce so many alerts of varying criticality that the most important alerts related to laboratory or medication orders may be overlooked due to desensitization.[255]

Overdependence on Technology

Errors can occur when assumptions are made that technologies always function as expected.[256] Completely trusting the information provided by a system can lead to unintended consequences for

safety.[257] For example, clinicians may have a false perception that they will be alerted by the technology displaying a patient's health information if any of the information is incorrect.

One emerging field in health care is AI. AI has the potential to improve patient safety by, for example, detecting and predicting sepsis, pressure ulcers, and adverse drug events (see section *VI. Mitigation Factors for Patient Safety Errors* for more information on how AI can improve patient safety). However, AI also has the potential to contribute to patient harm. Several studies identified risks involved with adapting AI tools in health care.

First, AI tools, especially those providing clinical decision support (e.g., diagnosis and treatment recommendations), may produce incorrect or incomplete results.[258,259] For example, a widely adopted AI system designed to detect patients with sepsis identified only 183 of 2,552 patients (7 percent) with sepsis, which contributed to delayed antibiotic administration.[260] Inaccuracies with AI tools could be due to flaws in the design of the tools or incorrect/incomplete medical record information being fed into the tools. AI tools need to be validated, and validation processes for complex patient situations are still being developed.[261,262]

Second, humans may over-rely on AI tools. Human review and sign-off on AI tools (e.g., documentation creation, diagnosis assignment) will still be needed to ensure that the tool worked correctly and is performing its intended purpose.[263] Processes need to be created to ensure that humans are accurately testing the AI tools to ensure that they are operating correctly.

Third, AI tools may be programmed using data that may not be representative of all races, genders, populations, geographic areas, and other defining characteristics. This can result in erroneous outcomes or overestimations/underestimations in certain patient populations or areas.[264,265]

Lastly, although not directly related to patient safety, using AI tools has the potential to depersonalize care. Many listening tools and digital scribes include only conversation between the provider and patient that is specific to their health care and exclude informal or casual conversations.[266] However, these informal conversations are often what creates connections between the provider and patient and help build patient-centered care. It is important to develop AI tools that balance the collection of critical patient health information with personal and social information.

Issues with Data Access, Availability, and Accuracy of Patient Health Data

Data access, availability, and accuracy are important for ensuring the delivery of safe care.[267] For example, incomplete patient information such as incomplete information on drug allergies can lead to giving a patient the wrong medication. One study showed that missing or incorrect data in patients' medical charts was a contributing factor in approximately 6 percent of patient safety incidents in primary care settings.[268]

A lack of patient record interoperability can have important implications for patient safety. Clinicians and staff report that challenges with accessing patient data, when providers treating the patient do not all use the same EHR, can affect patient safety. For example, interoperability issues can contribute to missed, delayed, or incorrect diagnoses, as well as breakdowns in communication and care coordination.[269]

VI. Mitigation Factors for Patient Safety Errors

Different interventions can help mitigate or prevent patient safety errors. These interventions are standardized protocols and training, effective care coordination, enhanced communication, patient and family engagement, technology and data analytics, and culture of patient safety. Federal agencies such as AHRQ have devoted substantial time and resources to prevent and mitigate patient safety errors.

VI.A. Standardized Protocols and Training

Standardized protocols, including checklists, can improve patient safety by helping clinicians ensure the delivery of consistent and comprehensive care. In addition, training tools and resources, including simulation-based training, can help clinicians and staff develop their clinical skills and improve quality of care.

Standardized Checklists

Checklists are organized lists of items or steps that should be considered or completed for a given task. Checklists can improve patient safety and quality outcomes by promoting the use of consistent procedures and helping clinicians manage both the volume and complexity of cases. Additionally, checklists give clinicians and staff confidence that a process was accurately and comprehensively completed. In health care, checklists are used in both routine and emergency situations.[270] Checklists are commonly developed for surgical procedures and are used in operating rooms to prevent operative and postoperative errors. However, checklists have also been developed to improve hospital discharges, patient transfers, and patient care in intensive care units.[271]

Some checklists are completed by a single clinician or health care team member.[272] For example, the pre-anesthesia checkout procedures are checklists commonly completed by anesthetists or trained anesthesia technicians to ensure that the anesthesia machine is working properly.[273] One pre-anesthesia checklist may be completed on a daily basis; checklist items may include verifying the availability of required monitors and alarms, verifying that the piped gas pressures are at the appropriate levels, and performing breathing system pressure and leak testing. A second pre-anesthesia checklist may be completed in between cases; checklist items may be a subset of the items on the checklist completed daily. Pre-anesthesia checkout procedures are intended to reduce both adverse events and near misses.[274] Evidence shows that pre-anesthesia checklists can be completed relatively quickly, help to identify potential issues (e.g., non-functional suction) during the pre-anesthetic preparation period, and reduce the incidence of non-routine events (e.g., oxygen sensor failure alarm on anesthesia machine, intravenous catheter misplaced during induction requiring replacement).[275]

Some checklists are completed by two or more health care team members. For example, the central line insertion care team checklist is commonly completed by two people; the first person (e.g., a nurse) reads the list of items on the checklist aloud, and the clinician who inserted the line states whether each item was addressed.[276] The purpose of this checklist is to prevent central line-associated infections. One study examined the implementation of a paper central line insertion checklist in a 16-bed intensive care unit of a medical center.[277] Results showed that the checklist reduced the central line-associated infection rate from 6.13 one month prior to implementation of the checklist to 0.00 two months following the implementation of the checklist.

The "5 Ps of Nursing" is another checklist that can be completed by multiple team members (typically nurses) who regularly check on patients in hospital settings. This checklist was developed to prevent falls. It includes a set of five best practices to be completed each time a nurse visits a patient.[278] The 5 Ps include checking the patient's pain, position, potty or personal hygiene, periphery, and pump. Following the 5 Ps while regularly checking in on patients can help nurses proactively approach patient care and efficiently address patients' needs.[279] Evidence indicates that use of the tool in health care settings has successfully reduced the rate of patient falls from four falls per 1,000 patients to two falls per 1,000 patients.[280]

Surgical safety checklists are often completed in group settings by surgical teams in operating rooms.[281] Prior to the induction of anesthesia, a team member (e.g., nurse, anesthetist, or surgeon) may confirm the patient's identity, whether the patient has a known allergy, and the type and site of surgery. The surgeon may also confirm with the circulating nurse that the necessary equipment is present and list any critical safety steps the team should anticipate during the surgery (e.g., anticipated blood loss). Before the patient leaves the operating room, the nurse may confirm the completion of instrument and sponge counts and that any specimens were labeled. Use of one widely adopted surgical checklist, the WHO Surgical Safety Checklist, was found to reduce the incidence of surgery-related complications by one-third and reduce the incidence of inpatient death by more than 40 percent across eight cities around the world.[282]

Some checklists use a flowchart design to support clinicians with complex decision-making, particularly in critical situations.[283] Providers may use these checklists to choose different options within a flowchart to inform decisions related to identifying an optimal pathway. An example of this type of checklist is the difficult airway algorithm. These checklists help clinicians consider all contingencies that may occur during intubation. In cases with difficult airways, a leader on the health care team may communicate team members' roles and instruct the team on how to secure the airway based on the progression of the flowchart. Such tools have been found to reduce clinicians' decision-making time, increase procedural success rates, and improve non-technical skills (e.g., crisis management, teamwork).[284]

The effectiveness of a checklist depends on multiple factors, including its thoroughness, acceptance by staff, and the patient safety culture within the organization.[285]

Simulation-Based Training

Simulation as a form of training can be used to improve clinical skills and gain experience with responding to high-risk situations without exposing patients to risk.[286] Additionally, this form of training is used to promote patient safety by improving the ability of multidisciplinary teams and non-clinical staff to manage acute or emergent situations.[287] Since 2000, AHRQ has supported 163 patient safety projects that used simulation-based methods to reduce preventable harm and improve the delivery of care.[288] The majority of projects aimed to address working conditions, workforce, and environmental factors (83 percent), followed by communication (33 percent), complications (29 percent), and clinical process/procedures (27 percent).

Common methods used for simulation-based training include the use of:

- Part-task trainers, or life-like simulations, which may include anatomically correct devices to help with improving clinical skills;

- Full-body manikins, which can be used to teach a range of skills, such as completing physical exams or performing complex clinical responses; and
- Standardized or simulated patients, which are trained actors posing as patients to help teach basic skills, such as taking a patient history.[289]

Recent advancements in technology have allowed for more sophisticated simulation-based training methods. For example, virtual reality can be used to allow learners to interact with each other and with patients in highly realistic clinical environments.[290]

One study assessed the impact of a scenario-based simulation training developed for nurses in emergency medicine, intensive care units, and general care units[291] using different training scenarios based on each nurse's clinical focus (e.g., abdominal trauma for nurses who worked in the ED, sepsis for nurses who worked in general care units). The training reduced serious medication event error rates from an average of 2.50 events per month to an average of 0.86 events per month, translating to an estimated cost impact of $90,000 to $130,000 per year.

Training Tools and Resources

Many training tools and resources have been developed to promote patient safety across health care settings. For example, through a collaboration with the Department of Defense, AHRQ developed Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS). TeamSTEPPS includes a set of training tools to help clinicians improve teamwork and communication skills to reduce risks to patient safety.[292] TeamSTEPPS has adapted core patient safety strategies to work in primary care and long-term care settings. Evidence shows that the program improves communication, including clinician attitudes related to communication, leadership, teamwork skills, and mutual support.[293] The program has also reduced preventable medical errors.

Also developed by AHRQ, the Comprehensive Unit-Based Safety Program (CUSP) Toolkit provides training resources to strengthen collaboration among physicians, nurses, and other members of the clinical care team. The CUSP Toolkit integrates evidence-based clinical practices with principles from the science of safety to enhance a care unit's ability to identify and resolve safety concerns. Developed by clinicians, the Toolkit is both modular and customizable to meet the needs of individual care units.

Each module contains educational materials and practical resources to facilitate unit-level improvement, including detailed facilitator guides with step-by-step instructions, presentation slides, implementation tools, and instructional videos.[294] As previously mentioned, CUSP has been found to reduce the rate of central line-associated bloodstream infection by 41 percent in over 1,000 intensive care units, reduce the rate of catheter-associated urinary tract infection by 30 percent in over 700 hospital non-intensive care units, and reduce the rate of surgical site infection in hospitals by 25 to 40 percent.[295]

CMS' Quality Improvement Organization (QIO) program also has a component dedicated to improving safety. QIOs are comprised of health experts who help health care organizations improve quality and safety of care for Medicare beneficiaries.[296] QIOs collaborate with health care providers to conduct case review, implement evidence-based practices, and improve health care quality. The QIO program is carried out through multiple initiatives focused on different aspects of quality improvement. The Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) and Opioid Prescriber Safety & Support (OPSS) initiatives specifically support patient safety. QIN-QIOs work with hospitals, nursing

homes, and physician offices to improve patient safety by providing technical assistance and resources, customized training and education, data analytics support, and intervention recommendations.[297] The OPSS educates eligible providers on safe opioid prescribing practices and non-opioid pain management therapies.

For example, one QIN-QIO serving Alabama, Florida, Georgia, Kentucky, Louisiana, North Carolina, and Tennessee provides patient safety-related technical assistance and support to nursing homes. This work has included providing technical assistance to nursing homes to raise awareness of safety strategies, such as hand hygiene to reduce hospitalizations due to Clostridioides Difficile.[298] The QIN-QIO also shared resources and training on drug safety for nursing home staff to reduce adverse drug events.

VI.B. Effective Care Coordination

The coordination of a patient's care across multiple health care providers can impact patient safety. A lack of communication and coordination among the providers involved in a patient's care can lead to fragmented care and increased risk of safety errors. Teamwork focused on coordination, care management, medication management, health IT-enabled coordination, and patient-centered medical homes are broad strategies that support care coordination.[299] Across these broad strategies, specific activities can be performed to facilitate care coordination, such as sharing information among other providers concerned with the patient's care, assisting with transitions of care, creating proactive care plans, assessing a patient's needs and goals, supporting a patient with their self-management-related goals, and linking a patient with community resources.

Between 2000 and 2024, AHRQ supported 47 different patient safety projects focused on enhancing care coordination across the U.S.[300] Over half (55 percent) of the care coordination projects focused on improving communication, including communication during handoffs for patients transitioning between care settings. Over one-third (36 percent) of the projects used quality improvement strategies to improve care coordination, and 30 percent of the projects used human factors/systems engineering approaches to improve care coordination. The AHRQ-funded projects aimed to improve care coordination to reduce diagnostic and/or procedural errors; workforce, working conditions, and environmental factors; medication safety; and HACs and complications.[301]

For example, one AHRQ-funded project assessed the influence of teamwork among physicians who provide care during a surgical episode on the quality of costs of care. Results showed that health systems with greater levels of physician teamwork had significantly lower rates of ED use, readmissions, mortality, and episode costs relative to health systems with lower levels of physician teamwork.[302]

VI.C. Enhanced Communication

Enhanced communication can support patient safety by ensuring that information is accurately transferred between providers and between providers and patients. Structured tools and closed-loop communication are two strategies used to enhance provider communication.

Structured tools have been developed to enhance communication among health care teams. One structured tool is Situation, Background, Assessment, Recommendation (SBAR).[303] SBAR gives providers a framework to share information about a patient's condition, including what is currently happening with the patient (situation), context and clinical background information about the patient

(background), what the provider thinks the problem might be (assessment), and what the provider plans to do to correct the issue (recommendation). One project showed that this structured handoff tool facilitated the exchange of information about warfarin management between physicians and nurses, resulting in improvements in therapeutic warfarin levels for patients in nursing homes.[304]

Another structured tool that can improve communication during transitions of care is the I-PASS.[305] I-PASS is a communication tool that structures and standardizes communication regarding patient handoffs. Providers use the tool by sharing information associated with each step of I-PASS:

- Illness Severity, such as the patient's diagnosis and anticipated discharge date;
- Patient Summary, such as medication history and current treatments;
- Action List, such as scheduled lab tests;
- Situation Awareness & Contingency Planning, such as the patient's fall risk, pain summary, and diet orders; and
- Synthesis by Receiver, which includes a summary of what was heard and an opportunity for the receiver to ask questions.[306]

One AHRQ-supported project disseminated I-PASS in hospitals and demonstrated that the tool improved the frequency of high-quality verbal and written patient summaries and reduced handoff-related adverse events by 42 percent.[307]

Closed-loop communication is another structured communication strategy that ensures that communications are clearly shared, received, and understood.[308] Closed-loop communication strategies include call-outs (to inform all team members of critical information) and check-backs (to verify that information was accurately exchanged), which are described below.

A call-out is a communication technique used to simultaneously inform all team members of critical information.[309] This strategy is commonly used in hospital settings and emergency situations, such as when a patient has an adverse reaction to sedation during a procedure. If a patient has an adverse reaction to sedation, a call-out might include information about the patient's condition and necessary next steps. By announcing essential information to all individuals involved in the situation, call-outs help create shared awareness and facilitate coordinated team responses.

A check-back, or repeat-back, is a structured communication technique designed to verify that information was accurately exchanged among team members.[310] Check-backs involve the receiver of information repeating the information back to the sender in their own words to verify understanding. This approach can be used to ensure that messages are successfully communicated across team members, as well as to patients. For example, a check-back can be used to verify a patient's receipt of care instructions. This approach supports shared understanding and alignment within the care team and with patients.

Since 2000, AHRQ has supported 62 patient safety projects focused on improving communication between health care projects.[311] The majority of the projects (77 percent) used education and training as the main strategy to improve communication. SBAR, I-PASS, and closed-loop communication can each improve communication and are included in the communication module of AHRQ's TeamSTEPPS program to ensure that critical information is not missed or misunderstood. Evidence indicates that clinicians' perceptions of communication—including communication and feedback about safety errors

and communication openness—improved upon completion of the TeamSTEPPS training program.[312] In addition to using these communication strategies, establishing relationships among staff and clearly defining staff roles and expectations can improve communication and reduce the risk of patient harm.[313]

VI.D. Patient and Family Engagement

Patient and family engagement, which considers patients and families as active partners in health care, is an important patient safety strategy. Evidence suggests that patients who are more engaged in their care have diminished risk of receiving unsafe care. For example, a systematic review examined the impact of patient and family engagement on medication safety.[314] Results from six of the 11 studies included in the systematic review showed that patient and family engagement had significant improvements on at least one medication safety outcome, such as adverse events, medication accuracy, inappropriate use of medications, and medication errors, including near misses.

Since 2000, AHRQ has supported 71 patient safety projects focused on increasing patient and family engagement.[315] The vast majority of projects (86 percent) focused on enhancing communication, followed by enhancing education and training (39 percent) to improve patient safety. AHRQ's Guide to Patient and Family Engagement in Hospital Quality and Safety is an evidence-based resource that promotes collaboration among clinicians, patients, and families. The guide outlines four strategies to encourage patient and family engagement in hospital settings:

- Supporting patients and families to participate as advisors;
- Facilitating communication among patients, families, clinicians, and hospital staff starting from the point of admission;
- Promoting safe care continuity and handoffs by including patients and families in nurses' change of shift reports; and
- Including patients and families in discharge planning throughout the patient's hospital stay to prepare for the patient's transition from hospital to home.[316]

Another AHRQ resource, the Questions are the Answer initiative, aims to improve communication between clinicians and patients.[317] The initiative provides patients with tips on how to be more involved in their health care before, during, and after their appointments. For example, the resource gives patients questions to consider asking if they need a test performed, such as what the test is for, whether there are any side effects from the test, and how they will receive the results from the test.[318] Additionally, the Questions are the Answer initiative encourages the use of notepads in medical waiting rooms for patients to list the top three questions they want to remember to ask during their appointment, such as questions about medications or medical tests.[319]

VI.E. Technology and Data Analytics

Technology and data provide new opportunities to reduce errors, enhance communication between providers and patients, and support timely, evidence-based decisions. Technology and data-focused strategies contribute to safety in multiple domains: EHRs and clinical decision support (CDS) software, medication safety technologies, human factors and systems engineering approaches, data analytics and predictive modeling, surveillance monitoring and alert functions, and event reporting functions.

Electronic Health Records and Clinical Decision Support Systems

An earlier section of this environmental scan described how adoption of technology such as EHRs can contribute to new patient safety risks. At the same time, EHRs, including EHRs with embedded CDS systems, can help promote safe patient care. Relative to the use of paper records, EHRs improve the accessibility and continuity of patient health information. By centralizing patients' medical histories, test results, and treatment plans, EHRs can promote more effective communication among providers, reduce the risk of patient safety errors such as medication and diagnostic errors, and support safer clinical decision-making.[320]

CDS systems are digital tools designed to inform clinical decision-making about patient care, including diagnosis and treatment. Often embedded within EHRs, CDS tools provide clinicians with real-time, patient-specific information through different formats and channels, such as order sets, clinical guidelines, and patient summary dashboards.[321] CDS tools also commonly use electronic alerts and reminders to support clinicians with identifying potential risks, such as deviations from best practices, and drug interactions or allergies, before harm occurs. These alerts and reminders can prevent both acts of commission (e.g., ordering a medication to which the patient has a known allergy) and acts of omission (e.g., failing to order prophylaxis of deep venous thrombosis for a patient who underwent surgery).[322] More recently, CDS systems have leveraged AI technologies to predict patient outcomes and recommend potential treatments.[323] For example, AI has the potential to improve CDS systems by filtering alerts to reduce alert fatigue among clinicians.

As described previously, use of EHRs can have unintended consequences, such as usability challenges, that increase safety risks. Resources have been developed to support health care organizations with safely integrating EHRs into workflows. The Office of the National Coordinator for Health Information Technology (ONC) developed the Safety Assurance Factors for EHR Resilience (SAFER) Guides to promote safe use of EHRs.[324] The SAFER Guides are an EHR-related self-assessment for clinicians to evaluate the safety and effectiveness of their use of EHR practices, identify areas vulnerable to safety errors, and develop solutions to reduce the risk of errors.[325] The SAFER Guides include recommended practices to optimize safe use of EHRs. For example, recommended practices cover topics on processes to safely deliver test results to the correct provider, communication processes for referrals and discharges, and processes that should be in place in the event that the EHR has a hardware or software failure.[326] CMS requires the use of SAFER Guides as part of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.[327]

Medication Safety Technologies

Specific technological innovations have been developed to improve medication safety. E-prescribing is one such technology that improves medication safety. E-prescribing allows prescribers to electronically send prescription orders from the point of care directly to a pharmacy.[328] The technology is primarily used in outpatient settings.

Relative to e-prescribing, computerized provider order entry (CPOE) systems are broader systems that allow clinicians to electronically send all types of orders (e.g., medications, diagnostic tests, procedures) directly to the recipient, such as the pharmacy.[329] Inpatient and outpatient adoption of CPOE systems increased rapidly following the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009.[330] By requiring structured electronic entry, CPOE systems can prevent errors related to ambiguous documentation (e.g., unclear acronyms), reduce confusion between

medications with similar names, eliminate issues related to illegible handwriting (e.g., for prescriptions), and allow faster transmission of orders to the pharmacy.[331] Evidence shows that CPOE decreased the risk of medication errors and adverse drug events compared with no electronic prescribing strategy or less sophisticated prescribing strategies in inpatient, outpatient, and intensive care settings.[332]

CPOE is commonly integrated into EHRs and paired with CDS systems to further enhance patient safety through automated safety checks, such as drug interaction alerts.[333] One meta-analysis found that, relative to using a paper-based order, using CPOE for a prescription drug order reduced the likelihood of an error by close to 48 percent.[334] Despite its potential advantages in supporting safety, CPOE may also have unintended consequences -- for example, by adding new work for clinicians and creating new workflows.[335]

Another technology developed to reduce medication errors is barcode medication administration (BCMA), which is commonly used in combination with CPOE and automated dispensing devices. BCMA reduces medication transcription and administration errors by electronically verifying a patient's identification, drug, dose, and route at the patient's bedside.[336] For example, a clinician may scan a bar code on their identification badge, on the patient's wristband, and on the medication to be administered. The data are then sent to an electronic system that generates warnings or approvals and documents the administration of the medication in an electronic record. Evidence shows that the implementation of BCMA with electronic medication administration record technology improved medication administration accuracy rates in hospitals.[337] Medication administration accuracy rates improved even more when wrong-time errors were excluded from the analysis. Additional research is needed to understand the impact of BCMA on timing-related medication errors where medications are administered to the patient too early or too late, as evidence on the technology's role in reducing these errors is mixed.[338]

Since 2000, AHRQ has supported 137 patient safety projects focused on improving medication safety.[339] Nearly three-quarters (74 percent) of the projects used technology as the main strategy to improve medication safety.

Human Factors and Systems Engineering Approaches

Human factors and systems engineering is a field that aims to enhance the interaction between people, technology, and work environments. In the context of health care, this field applies what is known about providers' behavior, skills, and limitations to the design of safe and effective medical tools and technologies (e.g., surgical instruments, hospital beds, CPOE systems) and tasks (e.g., ordering or administering medications, performing surgery).[340]

Between 2000 and 2024, AHRQ supported 127 patient safety projects associated with human factors and systems engineering.[341] Most projects (58 percent) used technological approaches to improve patient safety. One such approach is using human-technology interaction and user interface design principles to improve how clinicians interact with technology. For example, one current patient safety project supported by AHRQ is assessing how EHR interface design and useability among nurses in critical care settings influences perceived missed nursing care and medication errors with the goal of developing solutions that reduce EHR burden and safety errors.[342]

Patient Safety Learning Laboratories (PSLLs) are comprised of multidisciplinary teams that apply a human factors and systems engineering approach to address patient safety challenges related to the physical environment, technological factors, and clinical workflow processes. For example, one PSLL project supported by AHRQ developed the Smart Agent, a pump designed to semi-autonomously administer intravenous insulin to patients in intensive care units. The Smart Agent not only improved accuracy and efficiency of administering intravenous insulin to patients but also reduced workloads for clinical staff.[343]

Data Analytics and Predictive Modeling

Recent advancements in data analytics and predictive modeling provide new opportunities to improve patient safety. Data analytics and predictive modeling apply mathematical approaches to medical data to create predictions, inform medical decision-making, and ultimately improve care.[344] For example, predictive analytics can project which patients have a high risk of future hospitalization or predict future clinical values, such as bone mineral metabolism for patients. This data-driven approach allows clinicians to know which patients may need additional care or intervention.

AI uses large amounts of historical and real-time data to help predict and prevent errors and to detect errors early to avoid adverse events.[345,346] For example, AI can generate real-time predictions of HAI risk to prompt intervention before an infection occurs, identify patients at high risk for venous thromboembolism, use sensor data for early detection of pressure ulcers, use data in a patient's EHR to predict fall risk at the point of care, and predict surgical complications (e.g., blood loss, the need for prolonged postoperative intubation, postoperative mortality).[347] AI technologies have also reduced diagnostic errors by supporting the interpretation of imaging.[348]

Although clinical data, such as laboratory tests and imaging, can easily be used to prevent patient harm, much of the available clinical data are unstructured or inconsistent.[349] To reduce patient harm, continued efforts are needed to ensure the quality of data used for advanced analytics leveraging AI or other technologies. Additionally, there may be opportunities for emerging data sources, such as data from sensor technologies, patient-reported information, genomic data, and even social media data, to enhance the prediction of risk and allow for early detection and intervention.[350]

Surveillance Monitoring and Alert Functions

Surveillance monitoring is a relatively new strategy commonly used in general hospital settings to address failure to rescue—or the inability to prevent death in a patient who developed a treatable complication—and other acute events, such as cardiac arrest. Using sensors, such as pulse oximetry, this technology continuously monitors patient vital signs and notifies clinicians when changes occur, which could indicate complications or deteriorations.[351] By generating real-time information about the patient's condition, surveillance monitoring systems can detect changes in vital signs, improve clinicians' response times to acute events, and reduce the likelihood of serious harm.[352]

One relatively new patient safety surveillance model, the Safety Evaluation and Networked Tracking for Real-Time Yield (SENTRY), operates in real-time and across the ED care continuum to promote early detection of risks, rapid intervention, and coordinated improvements.[353] To detect safety risks, the model collects safety signals from multiple sources, such as incident reports, performance metrics, patient feedback, and clinical reviews. Safety events are then evaluated by experts using a structured

rubric to determine the severity of the safety events, their contributing factors, and opportunities for improvement. A root-cause analysis is often conducted for safety events determined to be serious. Safety events are stored in a centralized repository that serves as a living surveillance system to support the identification of recurring problems over time and real-time learning. The SENTRY model has the potential to transform surveillance into an ongoing learning process that drives workflow redesign, policy updates, and clinical decision-making.

In addition to reducing adverse events, evidence indicates that patient safety monitoring systems can facilitate tracking and reporting of adverse events and contribute to a culture of safety within health care organizations.[354] There may be future opportunities to apply surveillance monitoring approaches outside of inpatient settings to remotely monitor patients while they are at home to prevent deterioration.[355]

Event Reporting Functions

Patient safety event reporting systems help to document patient safety events. Although these web-based systems can receive information directly from EHRs, the systems rely on the individuals—such as nurses, physicians, and pharmacists—who were involved in a safety event to voluntarily report detailed information about the event.[356] Some voluntary safety event reporting systems are confidential in that the identity of the reporter is known but legal protection is provided, except in cases where misconduct or criminal acts occur.[357] Other voluntary safety event reporting systems are completely anonymous where the reporter and the patient cannot be identified. Given that these safety event reporting systems rely on voluntary reporting, reported events likely do not comprehensively capture all safety events.

VI.F. Culture of Patient Safety

Promoting a culture of safety has a positive impact on patient care. A culture of safety is an environment that encourages clinicians, patients, and families to speak up when they observe potential problems that may need to be addressed, gives them confidence that reporting problems can lead to improvements, and ensures that they will be treated fairly when errors occur.[358] As described previously, patient safety culture reflects the values, beliefs, and norms that are shared among clinicians and staff within a health care organization; these shared values, beliefs, and norms can impact their actions.[359] Safety culture can help clinicians feel supported and be more engaged in delivering care.[360]

AHRQ coordinates the Surveys on Patient Safety Culture (SOPS) Program that seeks to understand, measure, and improve patient safety culture. For the program, AHRQ develops SOPS surveys that assess safety culture, conducts research on patient safety culture, develops materials to improve patient safety culture, and hosts voluntary databases for health care organizations to track change in their safety culture.[361]

AHRQ SOPS surveys are designed to allow health care organizations to assess how their clinicians and staff perceive the organization's safety culture. SOPS surveys have been developed for five different health care settings: hospitals, nursing homes, ambulatory surgery centers, medical offices, and community pharmacies. The SOPS survey designed for hospitals—the SOPS Hospital Survey—assesses safety culture from the perspective of hospital providers and staff. Hospitals can voluntarily submit their safety culture data to AHRQ's SOPS Hospital Database to compare their results with similar types of

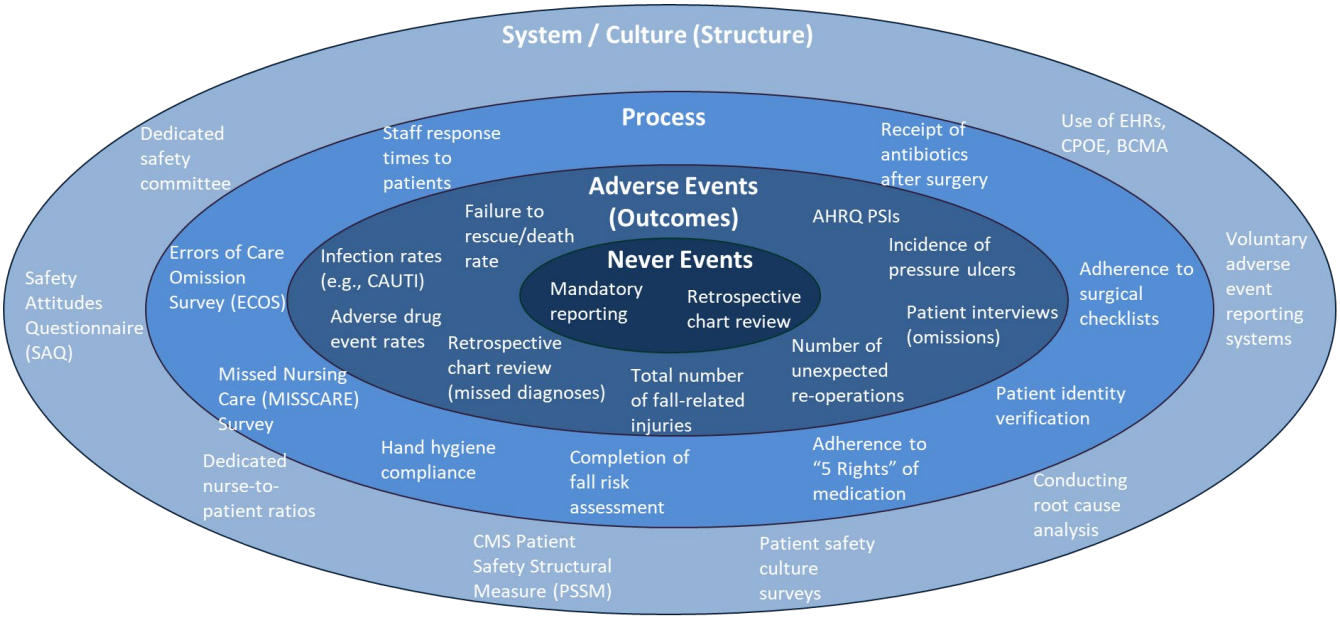
hospitals and track change over time.[362] Thousands of U.S. hospitals have reported their safety culture data. Among hospitals taking part in the TeamSTEPPS training program, clinicians' scores on the SOPS Hospital Survey improved. These improvements reflected enhancements in clinicians' perceptions of teamwork and mutual support, among other domains.[363]

To date, many different interventions have been developed and implemented to help mitigate or prevent patient safety errors. To continue to reduce preventable medical errors, additional work is needed to design and assess new safety interventions, develop standard definitions, develop standard safety training for clinical professionals across health care settings, and ensure that harm rates are publicly reported.[364,365]

VII. Measurement of Patient Safety

Patient safety measures are a subset domain of a broader set of health care quality (STEEEP) measures. As with other quality measures, patient safety measures can include structure, process, and outcome measures. In particular, structure measures of patient safety (i.e., the health system or culture around patient safety) may include measures such as staffing ratios, attitudes regarding patient safety, and use of technology to promote safety. Patient safety process measures focus on how care is delivered and include use of checklists and other processes. Finally patient safety outcome measures include occurrence of adverse events and failure to rescue, as well as never events. Exhibit 4 illustrates these three types of patient safety measures with specific examples provided.

Exhibit 4. Patient Safety Measures Conceptual Diagram



Patient safety can be measured in multiple ways, such as examining clinical information in retrospective chart review; using voluntary error reporting systems to identify errors that providers perceive as important; using surveillance monitoring to identify patients at risk for adverse events; analyzing administrative data to identify and track adverse events over time; analyzing EHR data to assess the quality of care delivered; and collecting patient-reported data, which may capture certain types of errors

that are not easily collected using other strategies (e.g., provider communication errors).[366] In recent years, electronic clinical quality measures, or eCQMs, have emerged as a way to automate calculation of patient safety measures, shifting from manually collected data to electronic data. In particular, eCQMs are quality measures that use electronic data extracted from EHRs and health IT systems. eCQMs can be structure, process, and outcome measures.

VII.A. Structure Measures of Patient Safety

Structure measures of patient safety assess the extent to which a health care system has the culture, capacity, and resources in place to maintain or improve safety and provide high-quality care. Examples of structure measures of patient safety, described in detail below, are the Safety Attitudes Questionnaire (SAQ), Patient Safety Structural Measure, and root cause analysis. Additional examples of commonly used structural patient safety measures are the ratio of providers to patients, whether the organization uses safety technologies such as CPOE and BCMA, and the availability of reporting systems for safety errors.

The SAQ assesses patient safety culture. This measure is completed by frontline health care workers to assess their attitudes regarding different patient safety issues. The measure has 60 items across multiple scales:

- Teamwork climate, which assesses perceptions of the quality of collaboration between personnel (e.g., extent to which the respondent believes physicians and nurses work together);
- Job satisfaction, which assesses positive perceptions about the work experience (e.g., extent to which the respondent likes their job);
- Perceptions of management, which assesses approval of managerial action (e.g., extent to which the respondent believes management supports their daily efforts);
- Safety climate, which assesses perceptions of an organizational commitment to safety (e.g., extent to which the respondent would feel safe being treated at the facility);
- Working conditions, which assesses perceptions of quality of the work environment and support (e.g., extent to which the respondent believes staffing levels are sufficient to manage the number of patients); and
- Stress recognition, which assesses the acknowledgement of how performance is influenced by work-related stressors (e.g., extent to which the respondent believes their performance is impaired due to an excessive workload).[367]

The SAQ has been adapted for use in intensive care units, operating rooms, inpatient settings, and ambulatory clinics.[368] Some institutions administer the measure annually to benchmark their patient safety climate against other units within the institution and against themselves to identify areas in need of improvement.

In August 2024, CMS released a new Patient Safety Structural Measure, a single measure focused on hospital implementation strategies to improve safety systems and culture.[369] Hospitals complete the measure to attest how the hospitals' strategies and practices promote patient safety systems and cultures in multiple statements across five domains:

- Leadership commitment to eliminating preventable harm;

- Strategic planning and organizational policy;
- Culture of safety and learning health systems;
- Accountability and transparency; and
- Patient and family engagement.

All acute care hospitals participating in CMS' Hospital Inpatient Quality Reporting (IQR) Program and PPS Exempt Cancer Hospital Quality Reporting (PCHQR) program must attest how the hospitals' strategies and practices promote patient safety systems and cultures. Annual reporting for CMS' Patient Safety Structural Measure began in calendar year (CY) 2025, and the pay-for-reporting incentive for the first year will be reflected in the hospitals' fiscal year (FY) 2027 payment determinations. Hospitals that do not report the measure will experience a reduction in their annual Medicare payment. When all statements within a single domain are attested in the affirmative, hospitals will receive one point for the domain (with total scores ranging from 0–5). CMS will publish hospitals' scores on Care Compare starting in 2026.[370]

Root cause analysis is a widely used retrospective method that assesses serious adverse events. This method uses a systems approach to identify underlying factors within health care systems (e.g., staffing, management, work environment) that increase the likelihood of patient safety errors. By using a systems approach, root cause analysis avoids placing blame exclusively on individuals for patient safety errors. Generally, this method involves record review, participant interviews, and analysis of the events leading up the error. The goal of root cause analysis is to identify and address issues within health care systems that contribute to safety errors to prevent future patient safety errors from occurring again.[371]

VII.B. Process Measures of Patient Safety

Process measures of patient safety focus on adherence to safety standards and evidence-based care. Described below are two examples of process measures of patient safety: the ECOS and the MISSCARE Survey. However, other commonly used patient safety process measures include completion of fall risk assessments, staff response times to patients, and adherence to postoperative checklists.

The ECOS is unique in that it is currently the only tool to measure omission errors (i.e., errors that occur when a correct action was not taken) in primary care. It is a self-report tool created for use by primary care providers and nurse practitioners, and asks providers to report how often (on a five-point scale ranging from "very frequently" to "never") critical patient care tasks were performed for an average week. The tool consists of 31 items divided into four main categories: 1) self-management support, which aims to measure provider-led education and interventions to improve patient confidence; 2) follow-up, which measures the ability of the provider to follow up with patients about treatment, tests, and referrals; 3) emotional health support, which measures how often the provider supports the patient and caregivers and discusses emotional concerns; and 4) care integration, which measures the degree that care is integrated for a given patient across all providers.[372]

The MISSCARE Survey aims to improve patient outcomes and hospital compliance by identifying omissions in nursing care.[373] Specifically, the measure systematically identifies which tasks are frequently missed (e.g., medication effectiveness assessments, timely patient education) and the underlying causes of the missed tasks (e.g., labor shortages, poor communication).

VII.C. Outcome Measures of Patient Safety

Outcome measures of patient safety assess the incidence of adverse events and never events. Patient-reported measures of patient safety can help identify safety concerns, adverse events, and near misses.

Adverse Events

Commonly used measures of adverse events are AHRQ's Patient Safety Indicators (PSIs), measures of adverse drug events, and measures of failure to rescue.

AHRQ developed the PSIs to assess potentially preventable safety events in acute care settings using administrative data.[374] There are 26 PSIs, including 18 provider-level indicators. These indicators allow health care organizations to identify safety issues related to operations, procedures, and childbirth to know where to target quality improvement efforts. Examples of PSIs include pressure ulcer rate (PSI 03), central venous catheter-related blood stream infection rate (PSI 07), postoperative sepsis rate (PSI 13), and birth trauma rate-injury to neonate (PSI 17).

PSIs are used to share valuable information about hospitals' performance with patients, caregivers, and purchasers. For example, select PSIs account for a large proportion of a hospital's letter grade in the Leapfrog Hospital Safety Grade.[375] Additionally, Healthgrades uses AHRQ PSIs (e.g., pressure ulcer rate, postoperative sepsis rate, retained surgical item or unretrieved device fragment count) to determine annual patient safety ratings for hospitals and identify which hospitals are eligible for the Patient Safety Excellence Award—a national recognition for hospitals that perform in the top 10 percent of the nation in terms of having the lowest incidences of 13 serious, preventable patient safety events during hospital stays.[376] Four hundred thirty-eight hospitals across 40 states received this award in 2026.[377]

CMS uses a subset of AHRQ's PSIs to evaluate hospital quality and tie performance to Medicare reimbursement penalties and rewards. For example, CMS developed the Patient Safety and Adverse Events Composite (CMS PSI 90), a composite measure comprised of a subset of AHRQ's PSIs.[378] This composite measure assesses patient safety across multiple indicators (e.g., pressure ulcer rate, in-hospital fall with hip fracture rate, postoperative sepsis rate), tracks performance over time, and allows hospital-level comparisons. The CMS PSI 90 is used in different CMS models and programs to promote safety, such as the Bundled Payments for Care Improvement Advanced (BPCI-A) Model's Composite Quality Score (CQS) and the Hospital-Acquired Condition (HAC) Reduction Program (see section *VIII. Value-Based Care Efforts to Promote Patient Safety* for more information).[379,380]

Adverse drug events (ADEs) are another frequently used patient safety outcome measure. ADEs are commonly measured using the rate of ADEs per 1,000 doses and the percent of admissions with an ADE.[381] ADEs are typically identified using retrospective reviews of patient records using triggers, or clues, that help to identify potential drug events.[382] Additionally, health care professionals and patients are encouraged to report serious ADEs, such as ADEs that are fatal, life-threatening, debilitating, or require prolonged hospitalization, to MedWatch, a voluntary reporting program established by the FDA.[383]

Failure to rescue is a measure of a hospital's ability to identify and treat complications before they result in patient death.[384] One example of a failure to rescue measure is CMS' recently adopted Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-rescue) claims-

based measure. This measure assesses the rate of in-hospital deaths among surgical patients who experience serious, treatable complications that result in death.[385]

Never Events

Never events are commonly measured using the NQF-developed list of SREs. Retrospective chart review is considered the gold standard for identifying never events. Never events are measured using the NQF-developed list of 28 largely preventable SREs.[386] NQF's list of SREs standardizes reporting of serious events, which typically involve death or patient harm that requires intervention or impairs activities of daily living. NQF's SREs are grouped into four main categories:

- Procedural events, such as a surgery or other invasive procedure that was performed at the wrong site or on the wrong patient;
- Product/device events, such as use of contaminated drugs;
- Patient protection events, such as discharging a patient without decision-making capacity to someone other than an authorized person or entity; and
- Care provision events, such as patient harm associated with an intravascular air embolism.[387]

Starting in January 2027, all hospitals accredited by TJC will begin voluntarily reporting NQF's list of SREs to TJC.[388] Some states have mandatory SRE reporting requirements. For example, in Massachusetts, hospitals and ambulatory surgery centers must report SREs (using NQF's list of SREs) to the Massachusetts Department of Public Health.[389]

One ongoing challenge in the measurement of patient safety involves achieving reliable measurement that allows comparisons of cases among providers. AHRQ developed the Common Formats to standardize the way near misses and patient safety events are reported and analyzed for certain health care settings such as hospitals.[390] For example, the Common Formats provide standard definitions for patient falls, medication errors, and infections. By providing uniform data elements and collection methods, the Common Formats aim to facilitate the aggregation of data into the NPSD.[391] The Common Formats reflect one step toward achieving a universal framework for measuring patient safety.

Patient-Reported Safety Measures

There is growing recognition of the importance of engaging patients and their caregivers in identifying and reporting patient safety concerns, adverse events, and near misses.[392,393] Because patients and providers may have different perspectives on safety incidents, patient-reported safety data can broaden the understanding of patient harm and complement provider-reported safety data to inform patient safety improvement efforts.[394] Patients and their caregivers may identify unique safety incidents that are not detected by clinicians, identified in medical record reviews, or captured in existing patient safety incident reporting systems.[395,396] For example, patients and families may report their observations of the care team that could contribute to safety incidents, such as interpersonal issues, breakdowns in communication, or failures in care coordination, as well as other safety concerns such as environmental hazards.[397,398] In addition, patient-reported safety concerns may highlight system-level vulnerabilities, such as insufficient staffing or organizational barriers to safer care.[399] Collecting patient-reported measures of safety promotes a patient-centered approach to care.[400]

A variety of methods can be used to collect patient- and caregiver-reported safety concerns, such as mobile applications, online portals, paper forms, hotlines, and interviews.[401] One study demonstrated that a mobile health tool—the Family Input for Quality and Safety—successfully captured hospitalized patients' safety concerns in real-time.[402] The anonymous safety reports were reviewed during weekly huddles among the hospital unit to inform safety improvement efforts, such as improvements in the unit's communication.[403] Allowing anonymous reporting is important in the collection of safety concerns; some patients may not report safety concerns due to fear of retaliation from the care team or concern with being labeled as a difficult patient.[404] Another study showed that qualitative feedback provided in free text questions of patient-reported experience measures (PREMs), such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, can help identify diagnostic safety issues.[405] For example, patients commonly described their concerns about the accuracy and timeliness of their diagnoses and reported breakdowns in providers' communication about the diagnoses.[406]

Despite growing recognition of the value of patient and caregiver-reported safety data, there is a lack of systematic integration of patient and caregiver-reported data into existing reporting systems. This lack of integration into existing reporting systems limits the impact patient-reported safety data can have on safety improvement efforts and patient safety outcomes.[407] As a result, health care organizations may miss opportunities to synthesize patient-generated safety data alongside provider-generated safety data to drive systemwide improvements.[408] Additional research is needed to understand best practices for incorporating patient and caregiver-reported safety data into system improvement efforts.[409]

VII.D. Electronic Clinical Quality Measures (eCQMs) and Digital Quality Measures (dQMs)

Electronic clinical quality measures, or eCQMs, are quality measures that use electronic data extracted from EHRs and health IT systems. Multiple entities use eCQMs, such as public and commercial payers and private organizations (e.g., TJC). eCQMs can be structure, process, and outcome measures and serve the purpose of calculating measures directly in digital systems. Examples include pressure injuries and opioid-related adverse events. Reporting these measures is important for promoting patient safety, as eCQMs provide a standardized way to track performance over time and ensure that providers meet certain quality standards.[410]

CMS' eCQMs assess patient safety, population/public health, clinical process/effectiveness, care coordination, efficient use of health care resources, and patient and family engagement.[411] Two examples of CMS programs that use eCQMs are CMS' Hospital Inpatient Quality Reporting (IQR) and Medicare Promoting Interoperability Programs. For these CMS programs, hospitals are required to report five patient safety eCQMs selected by CMS and three self-selected eCQMs. The required eCQMs selected by CMS are Safe Use of Opioids–Concurrent Prescribing, Cesarean Birth, Severe Obstetric Complications, Hospital Harm–Severe Hypoglycemia, and Hospital Harm–Severe Hyperglycemia.[412] In addition to the CMS-selected eCQMs, hospitals must report three of the following self-selected eCQMs:

- Hospital Harm-Opioid Related Adverse Events;
- Hospital Harm-Acute Kidney Injury;
- Hospital Harm-Pressure Injury;
- Hospital Harm-Falls with Injury;
- Hospital Harm-Postoperative Respiratory Failure;
- Global Malnutrition Composite Score;

- Venous Thromboembolism Prophylaxis;
- Intensive Care Unit Venous Thromboembolism Prophylaxis;
- Discharged on Antithrombotic Therapy;
- Anticoagulation Therapy for Atrial Fibrillation/Flutter;
- Antithrombotic Therapy By End of Hospital Day 2; and
  Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults.[413]

Currently, the CDC's NHSN is developing electronic, automated measures called digital quality measures (dQMs).[414] NHSN dQMs include measures of patient safety, quality reporting, and public health preparedness and response. dQMs build on eCQMs, which are a subset of dQMs, by transitioning from using EHR-only data extraction to using sources beyond EHRs (e.g., wearable devices, patient-reported data, case management systems) in an interoperable system.[415] dQMs use Healthcare Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) that promote standardization and data interoperability. These measures are intended to decrease reporting burden on providers, improve the quality of data collected by the NHSN, and allow real-time patient safety surveillance. Additionally, the measures allow for patient-level risk adjustment because the data are reported at the patient level. Example patient safety dQMs in development are hypoglycemia; hyperglycemia; respiratory pathogen surveillance; and healthcare facility onset, antibiotic treated Clostridioides difficile infection.[416]

VIII. Value-Based Care Efforts to Promote Patient Safety

There are many value-based care efforts aimed at directly improving patient safety, or improving patient safety as a part of an overall quality strategy, largely originating within CMS. CMS-led patient safety programs and initiatives primarily have been developed at the hospital or practice level. Commercial health plans also have the ability to improve patient safety. Most commercial insurers implement policies and procedures; display patient safety resources on websites; provide quality ratings for providers based on patient outcomes, safety, and cost effectiveness; and establish detailed medication safety programs to monitor medication use.

VIII.A. Select CMS Patient Safety Programs and Initiatives

CMS has undertaken several quality initiatives either aimed at patient safety or including patient safety components over the course of the last two decades. This environmental scan summarizes 13 such programs; eight of these programs link patient safety performance to payment (Exhibit 5). These initiatives either focus specifically on patient safety, such as improving surgical infectious complication rates or preventable hospital-acquired conditions (e.g., Surgical Improvement Program [SCIP], Partnership for Patients [PfP], HAC Reduction Program), or involve improving quality and include patient safety measures as part of their overall quality initiative (e.g., MIPS).

Linking performance to payment can come in the form of additional/bonus payments, as well as penalties. The Hospital Value-Based Purchasing (VBP) Program provides incentives to hospitals for reducing adverse events. In contrast, the HAC Reduction Program reduces payments to hospitals in the worst-performing quartile on HAC measures. The BPCI-A Model adjusts payments both positively and negatively based on participants' composite quality scores.

Some programs have shown promising improvements in outcomes. For example, the Premier Hospital Quality Incentive Demonstration reported that quality scores increased almost 19 percent from 2003 to 2006. The Hospital Readmissions Reduction Program (HRRP) showed reductions in readmission rates, and the BPCI-A Model resulted in net Medicare savings in its fourth year.

Exhibit 5. CMS Patient Safety Programs and Initiatives That Link Performance to Payment

Program	Year	Description	Results
Premier Hospital Quality Incentive Demonstration[417,418]	2003	CMS and Premier (national organization of nonprofit hospitals) partnered to **award bonus payments** to hospitals **providing high quality of care** in several clinical areas (e.g., acute myocardial infarction, heart failure, coronary artery bypass graft).	Quality scores **increased** almost 19% from 2003 to 2006.
Surgical Care Improvement Program (SCIP)[419]	2003	CMS and CDC partnered to **improve surgical infectious complication rates** by measuring and reporting on several infection-prevention process-of-care measures.	High performance on SCIP measures **has not been associated** with improved clinical outcomes.
Hospital Value-Based Purchasing (VBP) Program[420,421]	2012	CMS **redistributes 2% Medicare payment withholds as value-based incentives** to hospitals based on performance; the program uses performance measures used for the Hospital Inpatient Quality Reporting (IQR) Program, and includes **incentives for reducing adverse events** and adopting evidence-based care standards and protocols.	**No impact** on patient outcomes; safety-net hospitals **performed worse** on quality and cost measures compared to non-safety-net hospitals.
Hospital Readmissions Reduction Program (HRRP)[422,423]	2012	CMS applies a **payment reduction for hospitals with excess readmissions** for select conditions (acute myocardial infarction [AMI], coronary artery bypass graft [CABG] surgery, chronic obstructive pulmonary disease [COPD], heart failure, pneumonia, hip/knee surgery); goal to improve communication and care coordination and reduce avoidable readmissions.	Readmission rates **decreased**, especially for AMI, heart failure, and pneumonia.
Hospital-Acquired Condition (HAC) Reduction Program[424,425]	2014	CMS **reduces payments to hospital in the worst-performing quartile** on measures of HACs; HAC scores are based on a composite and five HAI measures.	**Did not improve** patient outcomes; risk adjustment not done appropriately, leading to unfair penalties for teaching hospitals and hospitals treating disadvantaged patients

Program	Year	Description	Results
Merit-Based Incentive Payment System (MIPS)[426,427]	2017	CMS bases **payment to providers on performance across four categories** (quality, cost, improvement activities, and promoting interoperability); four quality measures are collected through administrative claims by CMS, and participants must report to CMS on six additional quality measures; **patient safety is a MIPS high priority category** (e.g., % of patients with history of falls who have a documented plan of care for falls; % of patients with a surgical site infection).	Safety-net specialists were **more than 30% likely to receive positive payment adjustments** compared to non-safety-net specialists; MIPS incentives are substantially lower than the estimated administrative costs for physicians.
Bundled Payments for Care Improvement Advanced (BPCI-A)[428,429,430]	2018	Model participants are responsible for **coordinating patient care across all providers** for a given patient; participants must report on two measures: all-cause hospital readmission and advance care plan, and up to two additional measures; model **includes specific patient safety measures**, such as PSI-90 (composite) and complication rate.	Did not result in savings to Medicare in first three years of inception; **resulted in net savings** to Medicare in model year 4
Transforming Episode Accountability Model (TEAM)[431]	2026	Acute care hospitals will **coordinate care for certain surgical procedures** (lower extremity joint replacement, surgical hip femur fracture treatment, spinal fusion, coronary artery bypass graft, and major bowel procedures) from day of surgery to 30 days post-hospitalization; participants will **report on certain patient safety measures**, including PSI-90 (composite), hospital-wide readmissions, surgical complications, mortality, falls with injury, failure to rescue.	No results yet

Five of the 13 CMS patient safety programs summarized in this environmental scan do not link performance to payment (Exhibit 6). These programs also either focus specifically on patient safety or involve improving quality and include patient safety measures as part of their overall quality initiative. Two programs, the Hospital Inpatient Quality Reporting (IQR) and the Hospital Outpatient Quality Reporting (OQR) Programs, require reporting on quality measures, including patient safety measures, and withhold payments if hospitals do not meet reporting requirements. However, payments are not withheld based on performance and are withheld only if hospitals fail to report quality measures.

Two programs showed improvements in outcomes. PfP reported an almost 9 percent reduction in harm rates and approximately $4 billion in estimated cost savings for 2011 to 2012. The QIN-QIO showed a 13 percent drop in HAC rates, resulting in an estimated $7.7 billion in cost savings from 2014 to 2017.

Exhibit 6. CMS Patient Safety Programs and Initiatives That Do Not Link Performance to Payment

Program	Start Year	Description	Results
Hospital Inpatient Quality Reporting (IQR) Program[432,433]	2004	CMS requires hospitals to **annually report on quality measures**, including specific patient safety measures (e.g., death rate among surgical inpatients with complications, new Patient Safety Structural Measure); hospitals are subject to a **payment reduction** (25%) if they **do not meet reporting requirements**; serves as the foundation for other value-based programs (e.g., HRRP, HAC Reduction Program).	Public reporting of hospital performance on CMS Care Compare
Home Health Care Quality Improvement National Campaign[434,435]	2007	Initiated by CMS, home health agencies (HHAs) engaged in a national campaign along with other stakeholders (e.g., CMS staff, QIO leaders, home care leaders) to **gather and implement best practices** (e.g., hospitalization risk assessments, emergency care planning, medication management) and HHA success stories to **reduce avoidable acute care hospitalizations.**	Participating HHAs acute care hospitalization rate **slightly improved,** while non-participating HHAs rate worsened.
Hospital Outpatient Quality Reporting (OQR) Program[436,437]	2009	CMS requires short-term acute hospitals to **annually report on quality measures** specific to outpatient care, emergency department, and surgical procedures, including patient safety measures (e.g., hospital visit within 7 days of hospital outpatient surgery); hospitals are subject to a **payment reduction** (2%) if they **do not meet reporting requirements.**	Public reporting of hospital performance on CMS Care Compare
Partnership for Patients (PfP)[438]	2011	Two objectives: 1) federal and private organizations worked together to **develop policy to reduce preventable HACs;** and 2) Hospital Engagement Networks (HENs) **provided hospitals with technical assistance to implement best practices.**	Almost **9% reduction** in harm rates; approximately **$4 billion in estimated cost savings** for 2011-2012
Quality Improvement Network-Quality Improvement	2014	Partnership for Patients integrated with QIN-QIO in 2016; HENs, renamed to Hospital Improvement Innovation Networks (HIINs), **provided hospitals with best practices to reduce harm.**	HACs rate **dropped 13%**; about **$7.7 billion in estimated cost savings** for 2014-2017

Program	Start Year	Description	Results
Organization (QIN-QIO)[439,440]			

CMS also administers the Overall Hospital Quality Star Rating (Overall Star Rating) for hospitals. Based on a weighted summary of five measure groups (mortality, safety of care, readmission, patient experience, and timely and effective care), hospitals receive a cumulative star rating of one through five stars. The Overall Star Rating is derived using data reported by hospitals through the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program. In 2025, about eight percent of hospitals nationwide received an Overall Star Rating of one star, and 10 percent of hospitals received five stars.[441] Beginning in 2026, hospitals that score in the lowest quartile for the safety of care measure group will be eligible to receive only a maximum of four stars. Starting in 2027, these hospitals in the lowest quartile will receive an automatic one-star deduction.[442,443]

CMS is also involved in promoting safety among commercial payers, particularly those payers who offer insurance products for Medicare beneficiaries. Within the Medicare Advantage (MA) program, CMS has implemented two programs to address quality and patient safety: the MA and Part D Star Ratings, and QI programs.

CMS implemented the MA and Part D Star Ratings to rate plans on a score of one to five stars based on plan quality and member experience. MA Prescription Drug (MA-PD) plans are rated on up to 43 performance measures, MA-only plans are rated on up to 33 measures, and prescription drug plans are rated on up to 12 measures. Patient safety measures are included, such as reducing the risk of falling and medication adherence. Star Ratings are provided to help ensure that MA and prescription drug plans deliver high-quality and comprehensive coverage and can also be used by beneficiaries when choosing a health plan to fit their health care needs.[444,445]

Additionally, CMS requires MA organizations to create QI programs to improve patient health outcomes and the overall quality of care for MA beneficiaries.[446] CMS identified seven domains to support QI program requirements: safer patient care, patient-centered care, effective care coordination, effective prevention and treatment, promotion of healthy living, effective communication, and improving affordability. The safer patient care domain includes medication events, healthcare-associated infections, and other preventable conditions and provides examples of efforts that could address these areas (e.g., medication reconciliation, infection control, provider education, compliance with standards of care).[447]

For marketplace exchange plans, CMS has imposed requirements to implement patient safety processes. The CMS Health Insurance Marketplace Quality Initiatives (MQIs), established by the Affordable Care Act (ACA), include four programs—Marketplace Quality Rating System (QRS), Qualified Health Plan Enrollee Experience Survey, Quality Improvement Strategy (QIS), and patient safety standards—that all plans operating in federal or state-run health insurance marketplaces, referred to as Qualified Health Plans (QHPs), are required to implement. The patient safety standards initiative mandates QHPs to verify that the hospitals they contract with meet patient safety standards and implement a patient safety program that monitors for adverse events, engages patients and caregivers, improves care coordination, and decreases patient harm risk.[448,449]

VIII.B. Commercial Health Plan Patient Safety Initiatives

Private payers are also moving toward value-based care arrangements to promote quality and patient safety. One payer, Elevance Health, has implemented the Quality-In-Sights: Hospital Incentive Program (Q-HIP) where acute care hospitals receive bonus payments for meeting quality targets. Eighty percent of the overall score is based on patient safety measures, and the remaining 20 percent consists of patient experience measures.[450]

Most payers have implemented policies and procedures to promote patient safety and have made available several patient safety resources on their websites. Most payers also provide quality ratings for providers based on patient outcomes, safety, and cost effectiveness. Additionally, many payers have established detailed medication safety programs to monitor medication use, especially for patients seeing multiple providers.

IX. Relevant Features in Previously Submitted Proposals

This section summarizes findings from an analysis of components in previously submitted PTAC proposals that are relevant to patient safety. Among the 36 proposals that were submitted to PTAC between 2016 and 2025, including 28 proposals that PTAC deliberated on during public meetings, Committee members found that 23 of the 28 proposals met Criterion 9 (Patient Safety).

The clinical focus of these 23 proposals varied. More than half (13 proposals) focused on episode-based care (e.g., oncology, chronic obstructive pulmonary disease, Crohn's disease). For the remaining 10 proposals:

- Two proposals focused on primary care;
- Two proposals addressed inpatient services in the home setting;
- Two proposals focused on serious illness and palliative care;
- Two proposals focused on emergency medicine;
- One proposal addressed coordination across primary and specialty care services; and
- One proposal focused on frequently hospitalized patients.

Proposals also varied in their approaches to address patient safety. Several proposals included quality measures specific to patient safety. For example, common patient safety measures for these proposals were surgery complications, hospital-acquired affections, pressure ulcers, falls with injury, adverse drug events, and potentially avoidable adverse events. However, nine proposals did not mention specific patient safety measures and only referenced other quality measures, such as advance care plans, hospital admissions/readmissions, and patient experience measures. Beyond including or not including specific patient safety measures, some proposals suggested additional approaches. For example, two proposals planned to regularly review organization safety standards to ensure participant adherence. One proposal described a compliance hotline where patients can formally report patient safety concerns and issues.

Appendix B includes additional information about the 23 proposals.

X. Areas Where Additional Information is Needed

This section includes a summary of some areas where additional information may be needed to guide future research on improving patient safety in APMs and value-based care. **Appendix E** further describes areas that may be better addressed outside of the literature (e.g., through external stakeholder or subject matter expert input).

- Additional research is needed to assess patient safety in outpatient settings. Regulatory and accreditation agencies have not prioritized outpatient safety to the same degree as inpatient safety. This research can help shape the development of APMs or value-based care models that promote patient safety.
- To continue to reduce preventable medical errors, additional work is needed to design and assess new safety interventions, develop standard definitions, develop standard safety training for clinical professionals across health care settings, ensure that harm rates are publicly reported, address new technology-induced safety errors and potential risks of using AI in clinical decision-making, establish metrics that can be extracted from EHRs, and develop valid and reliable measures of patient safety. This research will also help aid in the development of value-based care models and patient safety performance measures to use across these models.
- More work is needed to understand the impact of BCMA on timing-related medication errors where medications are administered to the patient too early or too late.
- Updated data assessing the prevalence and cost of preventable adverse events in the United States are needed.
- Additional research is needed to understand variations in the prevalence of adverse events across different subpopulations, particularly populations with mental health disorders and cognitive impairments.

Appendix A. Research Questions by Environmental Scan Section

Section	Research Questions
Section IV. Background on Patient Safety	• What types of medical errors occur that compromise patient safety (e.g., missed care; unnecessary tests and procedures; hospital-acquired infections; overutilization; readmissions; and medication, diagnostic, and procedural errors)? • What are current trends in the prevalence and cost of adverse events?
Section V. Causes of Patient Safety Errors	• What are the factors, causes, and challenges to patient safety?
Section VI. Mitigation Factors for Patient Safety Errors	• What are strategies or tools that can be used to reduce medical errors and increase patient safety, including the role of technology/AI and data analytics? • What are opportunities to engage providers to help reduce adverse events and improve patient safety? • What solutions or insights can patients provide on improving patient safety? • How can patient protections (e.g., consumer rights, appeals process, transparency) be used to reduce adverse events and errors and improve patient safety? • What are opportunities to address barriers to integrating AI/technology that aids in improving patient safety? • What are potential payment sources for integrating AI/technology to aid in improving patient safety? • How can AI/machine learning be used to identify and reduce potential medical errors? • What are approaches to integrate AI predictive models into the provider workflow to aid in the identification of potential medical errors? • What are ways in which AI/machine learning can be used to develop patient safety metrics?
Section VII. Measurement of Patient Safety	• What are challenges with measuring patient safety? • What are opportunities to improve the measurement of patient safety? • What is the composition or balance of measures needed? • What gaps exist currently in patient safety measures? • How can patient-reported data be used more effectively to capture patient safety measures? • What are approaches for setting appropriate benchmarks and baselines for patient safety measures?
Section VIII. Value-Based Care Efforts to Promote Patient Safety	• What are ways in which APMs can effectively promote patient safety (e.g., models that target adherence to checklists and infection prevention protocols, incentivize meeting certain safety benchmarks)? • How do select models/programs incentivize patient safety (e.g., Hospital-Acquired Condition [HAC] Reduction Program, Hospital Value-Based Purchasing [VBP] Program, Merit-based Incentive Payment System [MIPS] quality measures)? • How are patient safety measures tied to financial incentives and/or penalties? • How can patient safety and high-quality care be incentivized in APMs (e.g., safety holdbacks or non-payment, no-bill rule for repairs, diagnostic safety bonus)? • How can financial incentives be used while also ensuring that unintended consequences (e.g., stinting on care, cherry-picking, early discharge) do not occur? • What are the future vision and next steps for using APMs to improve patient safety?

Appendix B. Summary of Relevant Components for Proposals Reviewed by PTAC that Met Criterion 9 (Patient Safety)

Overview of Methodology Used to Review the Proposals

The following information was reviewed for each submitter's proposal, where available: proposal and related documents, Preliminary Review Team (PRT) Report, and Report to the Secretary (RTS). Information found in these materials was used to summarize the proposals' main design features, including payment methodology, how payment is adjusted for performance, and approaches to address patient safety.

Among the 36 proposals that were submitted to PTAC between 2016 and 2025, including 28 proposals that PTAC has deliberated and voted on during public meetings, nearly all of the proposals address patient safety. Committee members found that 23 of the 28 proposals met Criterion 9 (Patient Safety).

Findings from the review of these 23 proposals are summarized in the following table.

Exhibit B1. Characteristics of PTAC PFPM Proposals that Met Criterion 9 (Patient Safety)

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American Academy of Family Physicians (AAFP) *(Provider association and specialty society)* **Advanced Primary Care: A Foundational Alternative Payment Model (APC-APM) for Delivering Patient-Centered, Longitudinal, and Coordinated Care** Recommended for limited-scale testing, 12/19/2017	**Clinical Focus**: Primary Care **Providers**: Physicians with a primary specialty in family medicine, general practice, geriatric medicine, pediatric medicine, or internal medicine **Setting**: Primary care practices **Patient Population:** Medicare FFS beneficiaries	**Overall Model Design Features**: APC-APM builds on concepts tested through Comprehensive Primary Care (CPC) and CPC+ models. Primary care medical homes (PCMHs) work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange. **Financial Methodology**: Capitated per-beneficiary-per-month (PBPM) with shared risk options for accountability **How Payment is Adjusted for Performance**: Participants assume performance risk. APMs that meet or exceed agreed-upon benchmarks retain incentive payment. Failure to meet benchmarks would involve repaying all or part of the incentive payment. **Approaches to Address Patient Safety**: Entities would be required to report on selected quality measures from the Core Quality Measures Collaborative's PCMH/ACO/Primary Care Core Set that are tied to payment. However, the proposal does not mention specific patient safety measures. The authors also state that the model would support patient safety by making the primary attribution method be patient choice. Patients may leave the model at any time.
American Academy of Hospice and Palliative Medicine (AAHPM) *(Provider association/specialty society)* **Patient and Caregiver Support for Serious Illness (PACSSI)** Recommended for limited-scale testing, 3/26/2018	**Clinical Focus:** Serious illness and palliative care **Providers:** Palliative care teams (PCT) **Setting:** Inpatient; outpatient; other palliative care settings **Patient Population:** Patients with serious illness	**Overall Model Design Features:** PACSSI proposes palliative care medical home services for high-need patients not yet eligible or not wanting hospice care. **Financial Methodology:** Monthly care management payments adjusted based on geographic location and site of care. There are two tracks: Track 1 – payment incentives and Track 2 – shared savings and shared risk. **How Payment is Adjusted for Performance:** Payments would be adjusted based on performance on quality and spending. **Approaches to Address Patient Safety:** Participants would be required to report on two quality measures regarding hospice election rates, patient-reported surveys, and certain processes of care. These measures would be linked to payment.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American College of Allergy, Asthma & Immunology (ACAAI) *(Provider association/specialty society)* **Patient-Centered Asthma Care Payment (PCACP)** Referred for other attention by HHS, 6/22/2020	**Clinical Focus:** Asthma care **Providers:** Allergists, immunologists, pulmonologists, primary care providers (PCPs), other providers **Setting:** Emergency department **Patient Population:** Patients with asthma and asthma-like symptoms	**Overall Model Design Features:** Supports asthma specialists, PCPs, and other providers to coordinate treatment of patients with asthma **Financial Methodology:** Bundled payments based on the severity of patient symptoms **How Payment is Adjusted for Performance:** Asthma Care Teams receive the default payment level for each patient if the team scored "good" on all performance measures; payments are increased or decreased (up to +/-5% to increase over time to +/-9%) if team scored "high" or "low" on some performance measures. **Approaches to Address Patient Safety:** Quality standards must be met to receive full bundled payments. However, the proposal does not list specific patient safety measures. The authors also mention providing patient education about proper use of medications.
American College of Emergency Physicians (ACEP) (*Provider association/specialty society*) Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions Recommended for implementation, 9/6/2018	**Clinical Focus**: Emergency medicine **Providers**: Emergency medicine physicians and advanced practice professionals **Setting**: Hospital EDs **Patient Population**: Medicare FFS beneficiaries presenting in the ED	**Overall Model Design Features**: AUCM aims to coordinate care post-discharge from the ED. Several elements are adapted from the Comprehensive Care for Joint Replacement (CJR) and the BPCI Advanced Models. **Financial Methodology**: Episode-based, bundled payment; if spending for eligible and attributed episodes is less than the bundled payment target price, the participant is eligible for a positive reconciliation payment; if it is more, the participant will have to reimburse CMS. Also includes payment waivers for ED acute care transition services, telehealth services, and post-discharge home visits. **How Payment is Adjusted for Performance**: A composite quality score, including post-ED event rates and patient safety measures, determines whether participants are eligible for a reconciliation payment or if repayment to Medicare is warranted. **Approaches to Address Patient Safety:** Specific patient safety measures will be required, such as for post-discharge falls, adverse drug events, and post-surgery complications, and will be tied directly to payment.
American College of Physicians-National Committee for Quality Assurance (ACP-NCQA)	**Clinical Focus**: Improved coordination in primary and specialty care practices **Providers**: Primary and specialty care practitioners	**Overall Model Design Features**: The model builds on the CPC+, PCMHs, and patient-centered specialty practice (PCSP) concepts. **Financial Methodology**: Participants receive a monthly PBPM care coordination fee and a retrospective positive or negative payment adjustment. Track 1 includes fee-

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
(Provider association and specialty society/other) The "Medical Neighborhood" Advanced Alternative Payment Model (AAPM) (Revised Version) Recommended for testing to inform payment model development, 9/15/2020	**Setting**: Primary and specialty care practices **Patient Population**: Medicare FFS beneficiaries with multiple chronic conditions	for-service payments, while Track 2 has a reduced fee-for-service payment and a comprehensive specialty care payment (CSCP). **How Payment is Adjusted for Performance**: Performance-based payment adjustment is based on spending relative to a financial benchmark, adjusted for performance on quality and utilization metrics. **Approaches to Address Patient Safety:** NCQA would regularly review PCSP standards and rescind PCSP status if the review identified a patient safety threat. The model would include various patient experience measures, as well as National Healthcare Safety Network measures to detect if patients acquired methicillin-resistant Staphylococcus aureus **(**MRSA) bacteria and/or other HAIs when in the hospital.
The American College of Surgeons (ACS) *(Provider association/specialty society)* The ACS–Brandeis Advanced Alternative Payment Model Recommended for limited-scale testing, 4/11/2017	**Clinical Focus**: Cross-clinical focus with sets of procedural episodes of care **Providers**: Single or multispecialty practices and groups of small provider practices **Setting**: Inpatient, outpatient, ambulatory **Patient Population**: Medicare FFS beneficiaries from over 100+ conditions or procedures	**Overall Model Design Features**: Focused on procedural episodes, leveraging the Episode Grouper for Medicare (EGM) software developed by CMS and Brandeis University, the model is based on shared accountability, integration, and care coordination. **Financial Methodology**: Retrospective payment that compares episode target prices to the actual cost of the care provided **How Payment is Adjusted for Performance**: Performance (e.g., unacceptable, acceptable, good, excellent) determines the shared savings retained by the APM entity or the amount to repay CMS for losses. **Approaches to Address Patient Safety:** ACS proposed to monitor and compare care levels and outcomes across participants to identify participants with potential gaps in care that may be indicative of delayed or missed care. The authors also suggested creating a potentially avoidable adverse event measure.
American Society of Clinical Oncology (ASCO) *(Provider association/specialty society)* Patient-Centered Oncology Payment Model (PCOP)	**Clinical Focus:** Oncology **Providers:** Clinicians, including hematologists and oncologists **Setting:** Oncology specialty practices	**Overall Model Design Features**: The model proposes to create PCOP communities that include several providers, payers, and other entities to provide high-quality, coordinated care. **Financial Methodology**: Providers receive three payments: monthly care management payments (CMPs), performance incentive payments (PIPs), and adjustments to FFS reimbursement. A portion of the CMP will be allocated to a PIP. PIPs will be positively or negatively adjusted based on provider success in adherence to clinical treatment pathways, quality metrics, and cost reduction. There are two

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Recommended for testing to inform payment model development, 9/15/2020	**Patient Population:** Oncology practice patients	tracks: Track 1 participants continue to receive FFS reimbursement in addition to the CMPs; Track 2 participants participate in the Consolidated Payments for Oncology Care (CPOC) where practices can bundle 50% or 100% of the value of specified services. 10% of the amount bundled will be subject to the same performance adjustment as PIPs times a 1.4 multiplier. **How Payment is Adjusted for Performance**: If providers do not meet minimum expectations, CMP and PIP amounts may be suspended, and providers will need to develop an improvement plan. **Approaches to Address Patient Safety:** Entities would be required to follow ASCO's Quality Oncology Practice Initiative (QOPI) safety standards for chemotherapy administration. Entities must also have a process for implementing follow-up visits and tests as the authors cite failure to follow up as an important patient safety issue.
Avera Health (*Regional/local multispecialty practice or health system*) Intensive Care Management in Skilled Nursing Facility Alternative Payment Model (ICM SNF APM) Recommended for implementation, 3/27/2018	**Clinical Focus**: Geriatric primary care for residents in long-term care **Providers**: Geriatric care teams that include geriatricians, PCPs, nurses, social workers, pharmacists **Setting:** Skilled nursing homes and long-term care facilities **Patient Population**: Medicare FFS beneficiaries in skilled nursing homes or long-term care facilities	**Overall Model Design Features**: Provides access to a geriatrician-led care team through telemedicine; provides geriatric care management and management of care transitions; and mentors and trains long-term care staff **Financial Methodology**: One-time payment for new admission care and a PBPM payment for post-admission care. Two payment method options are proposed for the model: 1) a *performance-based payment* adjusted on quality performance; and 2) a *shared savings model* with an annual financial reconciliation. **How Payment is Adjusted for Performance**: In the *performance-based payment* option, payments are adjusted positively or negatively by the ability to meet performance criteria. **Approaches to Address Patient Safety:** The model would require patient safety metrics, such as percentage of patients who had a catheter left in their bladder, who were physically restrained, who fell and sustained a major injury, or who have pressure ulcers. Entities must be above the 50th percentile or not decrease more than 5% per year for at least eight of the 13 required measures or they will be removed from the model.
Coalition to Transform Advanced Care (C-TAC) (*Coalition*)	**Clinical Focus**: Advanced illness, palliative care, end-of-life care **Providers**: PCPs, specialists	**Overall Model Design Features**: An interdisciplinary care team implements the ACM care delivery services.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model Recommended for limited-scale testing, 3/26/2018	**Setting**: Hospitals, health systems, hospices, home health **Patient Population**: Medicare FFS beneficiaries with advanced illness in the last year of life	**Financial Methodology**: A non-tiered PMPM payment with downside risk for total cost of care (TCOC) and an upside bonus for quality, subject to maximum payment and loss amounts **How Payment is Adjusted for Performance**: Pay-for-quality structure, where participants are eligible for a quality-based bonus funded by shared savings and determined by performance measure performance **Approaches to Address Patient Safety:** The model proposes to address patient safety by offering care coordination approaches and monitoring quality measures. However, the proposal does not include specific patient safety measures.
Dialyze Direct *(Regional/local single specialty practice)* APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities Recommended for attention, 9/6/2018	**Clinical Focus:** End-stage renal disease (ESRD) **Providers:** Nephrologists **Setting:** SNFs **Patient Population:** Geriatric dialysis patients residing in SNFs	**Overall Model Design Features:** Nephrologists provide ESRD beneficiaries that reside in SNFs with home hemodialysis services **Financial Methodology:** Bundled payment model with ability to receive shared savings, as well as a one-time additional payment for efforts related to educating patients on the benefits of on-site staff-assisted home dialysis in the nursing home **How Payment is Adjusted for Performance:** N/A **Approaches to Address Patient Safety:** Complications of transportation, such as falls or fractures that occur, would be a measure. The authors mention that they would perform a study to accurately develop other measures that pertain specifically to the ESRD population that resides in SNFs, which is known to have a higher prevalence of comorbidities, be older, and be more frail.
Hackensack Meridian Health and Cota, Inc. (HMH/Cota) *(Regional/local multispecialty practice or health system; Device/technology company)* Oncology Bundled Payment Program Using CNA-Guided Care Recommended for limited-scale testing, 9/8/2017	**Clinical Focus:** Oncology **Providers:** Clinicians with admitting privileges in the Hackensack Meridian Health (HMH) health system **Setting:** HMH health system that includes hospitals, home health, rehabilitation clinics, skilled nursing facilities, and mental health facilities	**Overall Model Design Features:** This is an oncology bundled payment model in which care choices are modulated by the prior outcomes of similar patients from real-world data. This process is called Cota Nodal Address (CNA) guided care. **Financial Methodology:** Prospective payment is provided to HMH for patients participating in the model. HMH bears the risk of bundled payments and distributes payments to physicians. **How Payment is Adjusted for Performance:** Compensation is, in part, incentive-based and determined by the achievement of clinical quality and patient satisfaction outcomes.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
	Patient Population: Medicare patients with breast, colon, rectal, or lung cancer attributed to clinicians in the HMH health system	**Approaches to Address Patient Safety:** HMH performed analysis and learned that patients who see their doctors before starting chemotherapy treatment have fewer occurrences of toxicity compared to those patients who do not see their provider or see their provider not right before starting chemotherapy. There are also several patient safety measures included, such as biopsy review completed within 48 hours, documentation of post-operation vomiting and pain scores, presence of pressure sores, monitoring for infections, and falls/falls with injury.
Johns Hopkins School of Nursing and the Stanford Clinical Excellence Research Center (Hopkins/Stanford) *(Academic institution)* CAPABLE Provider Focused Model Recommended for testing as specified in PTAC comments, 9/6/19	**Clinical Focus:** Chronic conditions and functional limitations **Providers:** Interdisciplinary team of an occupational therapist, registered nurses, and a handy worker **Setting:** Home and community-based settings **Patient Population:** Medicare FFS beneficiaries with at least two chronic conditions and difficulty with at least one activity of daily living	**Overall Model Design Features**: A time-limited intervention performed by an interdisciplinary team to target specific functional goals, perform limited home repairs and modifications, and address common geriatric concerns **Financial Methodology:** Partial bundled payment with partial upside, moving toward a fully capitated model of care **How Payment is Adjusted for Performance:** A bonus for meeting quality metrics would be awarded. **Approaches to Address Patient Safety:** The authors highlighted that the CAPABLE Model is a patient safety approach because it aims to improve the ability for older adults to take care of themselves at home. It has been approved by the National Council on Aging as a fall prevention program. The model would include metrics such as home hazard or fall risk.
Illinois Gastroenterology Group and SonarMD, LLC (IGG/SonarMD) *(Regional/local single specialty practice; Device/technology company)* Project Sonar Recommended for limited-scale testing, 4/10/2017	**Clinical Focus**: Chronic disease (Crohn's disease) **Providers**: Specialty physicians **Setting**: Outpatient settings and specialty care practices **Patient Population**: Medicare FFS beneficiaries	**Overall Model Design Features**: The model integrates evidence-based medicine with proactive patient engagement. It allows physicians to participate in chronic disease management that is not triggered by a surgical procedure or on an inpatient or outpatient basis. **Financial Methodology**: Add-on PBPM payment with two-sided risk, plus a payment to support remote monitoring **How Payment is Adjusted for Performance**: Payments would be adjusted based on quality and financial performance. **Approaches to Address Patient Safety:** Project Sonar references patient engagement to aid in decreasing patient safety concerns.
Innovative Oncology Business Solutions, Inc.	**Clinical Focus**: Oncology	**Overall Model Design Features**: Builds off the Community Oncology Medical Home (COME HOME) CMS Innovation Center project

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
(IOBS) *(For-profit corporation)* Making Accountable Sustainable Oncology Networks (MASON) Referred for further development and Implementation, 12/10/2018	**Providers**: Oncologists, surgeons, PCPs, pathologists, radiologists **Setting**: Oncology practices **Patient Population**: Medicare FFS beneficiaries	**Financial Methodology**: Determined by the oncology payment category (OPC), consisting of FFS payments for physician visits, imaging, lab, radiation therapy, surgery; infusion with a facility fee; ambulatory payment classifications (APCs) for hospital outpatient care; diagnosis-related groups (DRGs) for inpatient care; and the PCOP for medical home infrastructure **How Payment is Adjusted for Performance**: 2% of the OPC, which includes all expenses related to cancer care except drugs, is reserved for a quality pool. If quality measures are not met, the 2% is not rewarded. **Approaches to Address Patient Safety:** COME HOME, the program this model builds from, measured patients who went to different care sites than expected (e.g., office instead of ED) and found that patients experienced no harm when visiting the doctor's office versus the ED.
Large Urology Group Practice Association (LUGPA) *(Provider association and specialty society)* LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer Not recommended, 2/28/18	**Clinical Focus:** Urology/Oncology (treatment of prostate cancer) **Providers:** Eligible professionals (including urologists) at large and small urology and multispecialty practices **Setting:** Large and small urology and multispecialty practices **Patient population:** Newly diagnosed prostate cancer patients with localized disease	**Overall Model Design Features**: The model aims to identify those newly diagnosed prostate cancer patients with low-risk localized disease to receive active surveillance rather than active intervention. **Financial Methodology**: An episode-based payment that would retrospectively compare actual initial episode spending against a target amount **How Payment is Adjusted for Performance**: Participants earn performance-based payments or owe performance-based repayments based on the number of quality performance targets achieved/exceeded. **Approaches to Address Patient Safety:** LUGPA proposes several quality measures, such as biopsy follow-up and avoidance of overuse of bone scan. However, the proposal does not list specific patient safety measures.
Icahn School of Medicine at Mount Sinai (Mount Sinai) (*Academic institution*) "HaH-Plus" (Hospital at Home-Plus): Provider-Focused Payment Model	**Clinical Focus**: Inpatient services in the home setting **Providers**: Physicians and HaH-Plus providers, including nurse practitioners, registered nurses, social workers, and physical, occupational, and speech therapists	**Overall Model Design Features**: Multidisciplinary care around an acute care event to reduce complications and readmissions **Financial Methodology**: Bundled payment covering the acute episode and an additional 30 days of transition services. Two components are in the payment model: 1) a new DRG-like HaH-Plus payment to substitute for the acute inpatient payment to the hospital and attending physician; and 2) the potential for a performance-based

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Recommended for implementation, 9/17/2017	**Setting**: Patient homes **Patient Population**: Medicare FFS beneficiaries who have one of the 44 acute conditions	payment linked to the total Medicare spend for the entire HaH-Plus episode and the APM performance on quality metrics. **How Payment is Adjusted for Performance**: The APM entity's performance on quality metrics influences payment. **Approaches to Address Patient Safety:** The authors propose to track adverse events metrics, such as occurrence of various infections, pressure ulcers, falls, and adverse drug reactions. Furthermore, all adverse events must be reported within 24 hours of occurrence for review by a medical director, as well as an independent provider.
New York City Department of Health and Mental Hygiene (NYC DOHMH) *(Public health department)* Multi-provider, bundled episode of care payment model for treatment of chronic hepatitis C virus (HCV) using care coordination by employed physicians in hospital outpatient clinics Not recommended, 12/18/2018	**Clinical Focus**: Hepatitis C virus (HCV) **Providers**: Primary care and internal medicine physicians (infectious disease specialists, gastroenterologists) **Setting**: Hospital-based outpatient clinics **Patient Population**: Patients with HCV	**Overall Model Design Features**: The Project INSPIRE Model proposes integrated medical, behavioral, and social services for patients with HCV. **Financial Methodology**: Bundled payment with the opportunity for shared savings **How Payment is Adjusted for Performance**: Additional shared savings are awarded for being a "high-performing facility" based on their sustained virological response (SVR) score. **Approaches to Address Patient Safety:** The proposal references that patient safety is addressed through the use of a care coordinator, as well as the ability to modify shared savings rates to incentivize provider behavior and decrease potential care stinting. The proposed model does not list specific patient safety measures. It also does not include patient-reported outcome measures.
Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group Inc. (PMA) (*Regional/local single specialty practice*) The COPD and Asthma Monitoring Project (CAMP) Not recommended, 4/11/2017	**Clinical Focus:** COPD and/or asthma **Providers:** Pulmonary physicians **Setting:** Patient home **Patient Population:** COPD and asthma patients	**Overall Model Design Features**: The model proposes remote interactive monitoring for patients with COPD, asthma, and other chronic lung diseases. **Financial Methodology**: Two-sided risk arrangement that would permit CMS to recoup up-front costs first and then allow participants to share in remaining savings or losses up to a stop loss percentage amount **How Payment is Adjusted for Performance**: The proposal does not specify how quality measures would affect payment.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
		Approaches to Address Patient Safety: The proposal mentions that there will be several checks in place to ensure that patients are not neglected; however, specific details are not provided. The proposal also does not include specific patient safety measures.
Personalized Recovery Care (PRC) (*Regional/local single specialty practice*) Home Hospitalization: An Alternative Payment Model for Delivering Acute Care in the Home Recommended for implementation, 3/26/2018	**Clinical Focus**: Inpatient services in the home setting or skilled nursing facility **Providers**: Admitting physicians at facilities receiving personalized recovery care (PRC) payments; on-call physicians; recovery care coordinators **Setting**: Patient home or skilled nursing facility **Patient Population**: Commercial and Medicare Advantage patients with one of 150 acute conditions	**Overall Model Design Features**: This is a home hospitalization care model that proposes to provide inpatient hospitalization-level care and PRC at home or a skilled nursing facility for patients with certain conditions through an episodic payment arrangement. **Financial Methodology**: Bundled episode-based payment not tied to an anchor admission, replacing FFS with shared risk. Bundled payment has two components: 1) risk payment for delivering care compared to the targeted cost of care; and 2) a per-episode payment made for care provided instead of an acute care hospitalization. **How Payment is Adjusted for Performance**: To be eligible for shared savings, providers must meet or exceed benchmarks for performance measures. Participants are eligible to receive 20% of savings for each measure that meets or exceeds the benchmark. Participants receive 100% of savings if all five performance measures are met (0% if none are met). **Approaches to Address Patient Safety:** The authors cite that because the care takes place at home and not in a hospital, hospital-acquired infections and other conditions are avoided. Care coordinators would have substantial involvement and engagement with patients to ensure patient safety. The proposed model would also offer a compliance hotline number where patients can formally report patient safety concerns and issues. Specific patient safety measures are also included, such as the percentage of episodes with adverse events (e.g., pressure ulcers, falls with injury) and medication reconciliation.
Renal Physicians Association (RPA) (*Provider association and specialty society*) Incident ESRD Clinical Episode Payment Model Recommended for implementation, 12/18/2017	**Clinical Focus**: End-stage renal disease (ESRD) **Providers**: Nephrologists, PCPs **Setting**: Dialysis centers	**Overall Model Design Features**: Condition-specific, episode-of-care payment model for ESRD patients during the first six months of dialysis therapy that promotes coordination, patient choice for treatment, chronic kidney disease (CKD) patient education, quality of life, and advanced care planning **Financial Methodology**: Episode of care payment model with shared savings achieved over the entire six-month episode of care. There is also a one-time bonus payment for nephrologists to facilitate a patient receiving a kidney transplant preemptively or during the episode of care.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
	Patient Population: Medicare patients with ESRD	**How Payment is Adjusted for Performance**: Physicians' quality scores based on performance on patient-centered quality measures determine the percentage of overall shared savings the physician receives. The higher the quality score, the higher amount of shared savings received. **Approaches to Address Patient Safety:** The proposal describes that interventions, such as this proposed model, that keep patients out of the hospital improve patient safety because there is decreased risk of hospital-acquired infections. Additionally, avoiding use of hemodialysis catheters decreases risk of catheter infections. RPA also developed a kidney patient safety resource for nephrologists. The proposal references quality measures specific to the care of ESRD patients, including home dialysis percentage and patient experience measures, but does not list specific patient safety measures.
University of Chicago Medicine (UChicago) *(Academic Institution)* The Comprehensive Care Physician Payment Model (CCP-PM) Recommended for limited-scale testing, 9/7/2018	**Clinical Focus**: Frequently hospitalized patients **Providers**: Inpatient and outpatient providers **Setting**: Home care and rehabilitation **Patient Population**: Medicare beneficiaries who are at high risk for hospitalization	**Overall Model Design Features**: The model seeks to coordinate care for patients at risk for hospitalization by having one physician to provide inpatient and outpatient care. **Financial Methodology**: Add-on PBPM payment with shared risk **How Payment is Adjusted for Performance**: Providers will continue to be incentivized or penalized for quality outcome measures based on their APM or MIPS participation. **Approaches to Address Patient Safety:** The proposal describes that it ensures patient safety by reducing the transitions of care between inpatient and outpatient settings and providing coordination (e.g., one provider responsible for both inpatient and outpatient care).
The University of New Mexico Health Sciences Center (UNMHSC) (*Academic institution*) ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Emergencies	**Clinical Focus**: Cerebral emergency care; telemedicine **Providers**: Neurologists, neurosurgeons, and providers in rural and community systems **Setting**: Inpatient, outpatient, or emergency department	**Overall Model Design Features**: Rural EDs can consult neurologists via teleconsultation and assess patients' condition when they present at the hospital ED. The model aims to reduce costs in hospital transfers and ambulatory medicine. **Financial Methodology**: Additional one-time payment without shared risk **How Payment is Adjusted for Performance**: Performance is monitored but does not impact payment.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Recommended for implementation, 9/16/2019	**Patient Population**: Patients with neurological emergencies	**Approaches to Address Patient Safety:** The authors propose that there would be a process in place to verify patient identification and to obtain written consent for telemedicine. Additionally, education and resources, such as neuroscience workshops and technology education, would be provided to all clinical staff to ensure competency of staff. Model leaders would perform a systematic review to ensure that clinical guidelines are being followed.
Upstream Rehabilitation (Regional/local single specialty practice) CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients Not recommended, 5/11/2019	**Clinical Focus:** Chronic wound care **Providers:** Physical and operational therapists **Setting:** Physical and occupational therapy centers **Patient Population:** Medicare patients with chronic wounds	**Overall Model Design Features:** Physical and occupational therapists will provide chronic wound care services in outpatient therapy clinics. **Financial Methodology:** Providers would track the total cost of and time in treatment for each patient, to include wound care supplies. CMS would allow providers to be reimbursed $250 per patient for wound care supplies and to bill for advanced therapeutics (e.g., bioengineered dressings). **How Payment is Adjusted for Performance:** Claim refunded to CMS if minimum standards of improvement are not met. Clinicians can receive a 3% savings bonus for achieving average reimbursement costs below risk-adjusted thresholds. **Approaches to Address Patient Safety:** The proposal would measure rates of infection, patient level of pain, and patient satisfaction.

Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
Global Patient Safety Report 2024 (WHO)[451]	Global	• >1 in 10 patients experience harm (controllable and noncontrollable) across settings. • 50% of harm is considered preventable. • 1 in 20 patients experience preventable medication-related harm. • Preventable harm is more prevalent in specialized care settings (ICUs, EDs, surgical units) compared with general hospital and primary care settings. • >3 million deaths annually due to unsafe care	• AE: "An incident that resulted in harm to a patient" • Preventable harm: "Accepted by the community as avoidable in the particular set of circumstances"	• Patient safety survey, completed by 108 Member States from 2022-2023, covering ≈84% of global population • Synthesis of evidence in the literature (e.g., systematic reviews, meta-analyses)	• Patients of all ages in hospitals, primary care, ED, surgery, ICU, long-term care settings • Focus on low- and middle-income countries, vulnerable groups (e.g., older adults, ethnic minorities), and clinical settings at high risk for harm
Panagioti et al. (2019)[452]	Global	• 6% pooled prevalence of preventable patient harm (≈1 in 20 patients, accounting for ≈50% of total patient harm) • 12% of preventable harm was considered severe or resulted in death. • Highest prevalence of preventable harm occurs in ICUs (18%) and surgical units (10%). • 25% of preventable harm is drug-related.	• Preventable harm: harm that "occurs as a result of an identifiable modifiable cause, and its future recurrence can be avoided by reasonable adaptation to a process, or adherence to guidelines"	• Systematic review and meta-analysis of 66 observational studies reporting 70 independent samples across multiple countries	• Patients receiving care across settings: general hospitals and obstetrics, primary care, EDs, advanced hospital specialties (ICU, surgery) • Majority of studies focused on adult patients; fewer studies focused on children or older adults.
Sauro et al. (2021)[453]	Multinational (25 countries)	• 8.6 hospital AEs (controllable and noncontrollable) per 100 hospital admissions (~1 in 12 admissions) • 53% of AEs were preventable.	• AE: "negative, unintended consequences of health care"	• Systematic review and meta-analysis of 94 hospital-based studies conducted from 1961-2014 from 25 countries	• Patients in acute care hospitals • Focused on adult (pediatric-only studies excluded)

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		• 40% of AEs (controllable and noncontrollable) resulted in moderate or significant harm. • Among all AEs (controllable and noncontrollable), obstetric AEs affecting the mother were the most common AE (7.5 per 100 patient admissions), followed by drug-related AEs (4.1 per 100 patient admissions). • Occurrence of AEs (controllable and noncontrollable) changed over time (pooled estimate of 9.5 AEs per 100 admissions in the 1980s, 7.0 AEs per 100 admissions in the 2010s).			
Adverse Events Among Medicare Hospitalizations in 2021–2023 (AHRQ & CMS)[454]	National	• Weighted percentage of patients with ≥1 AE (controllable and noncontrollable) during hospitalization: – 7% in 2021 – 6% in 2022 – 5% in 2023 • Similarly, the rate of AEs (controllable and noncontrollable) per 1,000 discharges declined from 83.1 to 59.4 from 2021-2023. • Pressure injuries/ulcers, medication AEs, and HAIs accounted for ~80% of AEs across all three years.	• AE: "harm to a patient as a result of medical care or occurring within a health care setting, including the failure to provide needed care"	• Retrospective national analysis using the Quality and Safety Review System (QSRS), a data collection and analysis system designed to identify the occurrence of AEs in hospital settings	• Focused on acute care hospitals participating in IPPS (excluded VA and Department of Defense hospitals) • Patients ≥18 years old with Medicare Part A coverage (through traditional or MA)

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018 (OIG, 2022)[455]	National	• 25% of hospitalized Medicare patients experienced ≥1 AE (controllable and noncontrollable). • 43% of AEs (controllable and noncontrollable) were medication-related • 43% of AEs (controllable and noncontrollable) were considered preventable (if limited to preventable events only, overall harm rate would be 13% rather than 25%).	• Patient harm: "includes adverse events and temporary harm events" • AE: "harm to a patient as a result of medical care or in a health care setting, including the failure to provide needed care"	• Nationally representative random sample of Medicare patients with discharges from short-term acute care hospitals in October 2018 (n=770 patients from n=629 hospitals nationwide) • Two-stage retrospective medical record review: – Stage 1: Nurse screening of medical records using an OIG-modified Global Trigger Tool to flag potential harm – Stage 2: Physician review of full medical records flagged in Stage 1 to confirm harm, severity, and preventability	• Medicare beneficiaries discharged from U.S. short-term acute-care hospitals in October 2018 (excluded outpatient-only encounters and VA hospitals)
Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer (OIG, 2025)[456]	National	• 49% of patient harm events (controllable and noncontrollable) were not captured by hospitals' incident reporting or surveillance systems. • Hospitals are more likely to miss harm events resulting from surgeries or procedures (73%) compared with harm events from non-surgeries or procedures.	• Patient harm: "any undesirable clinical outcome—not caused by underlying disease—that was the result of medical care or that occurred in a health care setting, including the failure to provide needed care"	• 2023 survey to 154 hospitals where harm events occurred to determine whether those events were captured in incident reporting or surveillance systems	• Medicare beneficiaries discharged from U.S. short-term acute-care hospitals in October 2018 (excluded outpatient-only encounters and VA hospitals)

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
Eldridge et al. (2022)[457]	National	• Acute myocardial infarction declined from 218 → 139 AEs per 1,000 discharges. • Heart failure declined from 168 → 116 AEs per 1,000 discharges. • Pneumonia declined from 195 → 119 AEs per 1,000 discharges. • Major surgical procedures declined from 204 → 130 AEs per 1,000 discharges. • Rate of AEs (controllable and noncontrollable) for all other conditions remained unchanged: 70 AEs per 1,000 discharges.	• Patient safety errors: "in-hospital adverse events"	• Serial cross-sectional analysis assessed change over time in patient safety outcomes for hospitalized patients across 3,156 U.S. acute care hospitals • Used data from the Medicare Patient Safety Monitoring System (2010-2019)	• Hospitalized adult patients (≥18 years) in U.S. acute care hospitals
Hayward et al. (2005)[458]	Regional (Midwest and Western U.S.)	• 82% of patients had ≥1 error during a 13-month period. • Mean 4.7 errors per patient (mean 1.7 errors per patient with diabetes) • 96% of errors were errors of omission (underuse). • 27 of 2,917 errors were rated as highly serious, 26 of which were errors or omission.	• Medical error: "An act of commission or omission that substantively increases the risk of a medical adverse event. Errors can result from the failure of a planned action to be completed as intended (i.e., a mishap or error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning)" • Errors of commission: "misapplications or mistakes in using the ever-growing number of medical treatments"	• Retrospective cohort study where physicians reviewed complete inpatient and outpatient medical records for errors • Errors classified as errors of commission or omission	• Inpatient and outpatient care across 12 VA health care systems in two regions • Adult patients, oversample of patients with chronic (diabetes, COPD)

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
			• Errors of omission: "the potential to cause serious injury and death from inadequate treatment"		
Kepner & Jones (2023)[459]	State (Pennsylvania)	• 256,679 total harm reports were submitted in 2022 (controllable and noncontrollable). • 246,938 reports were incidents, and 9,741 reports were serious events. • Hospitals had 27.5 reports per 1,000 patient days. • Ambulatory surgical facilities had 9.4 reports per 1,000 surgical encounters.	• Incidents: "an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient" • Serious events: "an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient"	• Extracted data from the mandatory facility reporting to Pennsylvania Patient Safety Reporting System (PA-PSRS) • Counts of harm reports were calculated based on report submission date	• Patients of all ages receiving care from acute care facilities in Pennsylvania that are required to report patient safety events to the PA-PSRS
Bates et al. (2023)[460]	State (Massachusetts)	• At least one AE (controllable and noncontrollable) was identified in 24% of admissions. • 23% of AEs were preventable. • Preventable AEs occurred in 7% of all admissions.	• AEs: "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment,	• Retrospective study using a random sample of admissions from hospitals in Massachusetts in 2018	• 11 Massachusetts hospitals

Study	Scope	Prevalence of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		• The most common AEs were adverse drugs events (39% of all events), surgical or procedural events (30%), patient care events (15%), and HAIs (12%).	or hospitalization, or that results in death"	• AEs identified using the trigger method and medical record review	
Levine et al. (2024)[461]	State (Massachusetts)	• 7% of patients had at least one AE (controllable and noncontrollable). • 23% of AEs were preventable. • 2% of patients had at least one preventable AE. • The most common AEs were adverse drug events (64%), HAIs (15%), and surgical or procedural events (14%).	• AE: "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death"	• Retrospective study using a random sample of patients from outpatient sites in Massachusetts in 2018 • AEs identified using the trigger method and medical record review	• 11 Massachusetts outpatient sites

Notes. AE = adverse event; COPD = Chronic Obstructive Pulmonary Disease; ED = emergency department; HAI = healthcare-associated infections; ICU = intensive care unit; IPPS = Inpatient Prospective Payment System; MA = Medicare Advantage; VA = Veterans Affairs. National studies reflect studies conducted in the United States.

Appendix D. Direct and Indirect Costs of Patient Safety Errors

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
The Economics of Patient Safety: From Analysis to Action (OECD)[462]	Global & Multinational with emphasis on OECD countries	• Direct costs of all harm (controllable and noncontrollable): $878 billion/year (≈12.6%) across OECD countries • Direct costs of avoidable harm: $606 billion/year (≈8.7% of total health expenditure) across OECD countries	• Social costs of harm: estimated $1-2 trillion/year • Eliminating patient harm could boost global economic growth by nearly 1% per year (translating to $118 trillion between 2000 and 2020).	• Patient harm: "Any unintended and unnecessary harm resulting from, or contributed to by, health care. This includes the absence of indicated medical treatment." • AE: "An incident during care that results in patient harm"	• Review of international literature • Indirect costs assessed using human capital approach and willingness-to-pay approaches	• Settings include acute/inpatient care, primary and ambulatory care, and long-term care, with special attention to infections, medication errors, VTE, diagnostic error, falls, and pressure injuries.
Global Patient Safety Report 2024 (WHO)[463]	Global	• Some studies place the costs of harm in acute care at 2% of total health expenditure, while other studies place the aggregate burden of hospital harm from 6-12% of total health expenditure. • Annual cost of hospital-acquired VTE is $7-10 billion. • Annual cost of adverse drug events is $54 billion in OECD countries.	• Described as often exceeding direct costs, with a global societal cost estimate of $1.17 trillion per year • Indirect costs driven by lost productivity cost $1.9 billion. • For pressure ulcers, the indirect costs are $3.6 billion compared with $2.3 billion in direct costs. • The global economic cost of adult diabetes is $1.31 trillion, and about 35% ($458	• AE: "An incident that resulted in harm to a patient" • Preventable harm: "Accepted by the community as avoidable in the particular set of circumstances"	• Patient safety survey, completed by 108 Member States from 2022-2023, covering 84% of global population • Synthesis of evidence in the literature (e.g., systematic reviews, meta-analyses)	• Patients of all ages in hospitals, primary care, ED, surgery, ICU, long-term care settings • Focus on low- and middle-income countries, vulnerable groups (e.g., older adults, ethnic minorities), and clinical settings at high risk for harm

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		• Gross world product could have been 15% higher had unsafe patient care been eliminated in 2000.	billion) of these costs were indirect.			
Van Den Bos et al. (2011)[464]	National	• Annual cost of controllable medical errors that harm patients was $17.1 billion in 2008. • 10 types of controllable errors account for more than two-thirds of the total cost of errors (postoperative infection: $3.364 billion, pressure ulcer: $3.273 billion).	• Not reported	• Medical error: "a preventable adverse outcome that results from improper medical management (a mistake of commission) rather than from the progression of an illness or from lack of care (a mistake of omission). A medical error may or may not result in medical injury."	• Actuarial approach to assess the frequency and costs of medical errors in the U.S. identified using medical claims data (2000-2008)	• Nationwide sample of commercially insured and retiree patients in inpatient and outpatient settings
Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018 (OIG, 2022)[465]	National	• Medicare spent $520 million on IPPS costs associated with patient harm events (controllable and noncontrollable) in October 2018. • Medicare spent $281 million on hospital costs associated with harm (controllable and noncontrollable) for	• Not reported	• AE: "harm to a patient as a result of medical care or in a health care setting, including the failure to provide needed care" • Patient harm event: "Any harm to a patient as a result of medical care"	• Sample of 770 Medicare patients from 629 hospitals • Single-month national incidence and cost projection (October 2018)	• Medicare beneficiaries in short-term acute-care hospitals

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		non-IPPS patients in October 2018.				
Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital-Acquired Conditions (AHRQ, 2016)[466]	National	• Among preventable HACs, infectious HACs were associated with higher incremental costs relative to non-infectious HACs. • The most expensive infectious HACs were CLABSI ($48,108) and ventilator-associated pneumonia ($47,238). • Venous thromboembolism ($17,367) and pressure ulcers ($14,506) were the most expensive non-infectious HACs. • The incremental costs of hospital-acquired adverse drug events and falls were $5,746 and $6,694, respectively.	• Not reported	• Not reported	• Systematic review and meta-analysis to estimate the incremental costs of infectious and non-infectious HACs to the hospital for inpatient stays	• U.S. health care facilities
Anand et al. (2019)[467]	Multistate (12 U.S. states)	• Severe pressure ulcers increase the cost of the index stay by $26,000 to $32,000. • VTE increase the cost of the index stay by $18,000.	• Not reported	• Inpatient medical harms: “injuries to patients that occur while hospitalized”	• Compared hospital costs incurred by patients who experienced harm during their hospital stay with the costs incurred by similar patients who did not experience harm	• Adult patients admitted to acute-care hospitals (excluding rehabilitation or mental health) in 12 U.S. states • Hospital inpatient setting

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		• CAUTIs increase the cost of the index stay by $13,000. • Hospital-acquired urinary tract infections increase the cost of the index stay by $9,000. • Falls increase the cost of the index stay by $6,000.			• Used 2009 to 2011 Healthcare Cost and Utilization Project's State Inpatient Databases • Claims data from all payers	
Shreve et al. (2010)[468]	National	• Medical errors (controllable and noncontrollable) cost the U.S. $19.5 billion in 2008. Of this total: • $17 billion (87%) represents excess direct medical costs (from providing inpatient, outpatient, and prescription drug services to people impacted by errors). • The estimated average cost per medical error is $13,000.	• Medical errors (controllable and noncontrollable) cost $1.4 billion due to increased mortality rates. • Medical errors (controllable and noncontrollable) cost $1.1 billion due to lost productivity from short-term disability.	• Error: "Preventable adverse outcome of medical care that is a result of improper medical management (a mistake of commission) rather than a progression of an illness due to lack of care (a mistake of omission)"	• Claims-based actuarial analysis (2008)	• A national U.S. insured population, including commercially insured individuals and Medicare-eligible retirees • Both inpatient and outpatient health care settings
Goodman et al. (2011)[469]	National	• Not reported	• Annual social cost of all AEs in the U.S. was $393-$958 billion in 2006 (equivalent to	• AEs: "medical interventions that cause harm or injury to a patient separate from	• Synthesis of existing evidence on the incidence of AEs	• U.S. hospital patients of all ages

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
			approximately 18% to 45% of total U.S. health care spending).	the underlying medical condition"	• Economic modeling to estimate social costs of AEs	
The Financial and Human Cost of Medicare Error…and How Massachuesetts Can Lead the Way on Patient Safety (Betsy Lehman Center, 2019)[470]	State (Massachusetts)	• Controllable medical errors cost Massachusetts $617 million in excess health insurance claims in 2017 (attributable to 61,982 preventable harm events). • CLABSIs have an average $55,068 incremental cost. • Infection and inflammatory reaction due to internal prosthetic device implant and graft have an average $16,988 incremental cost. • Pressure ulcers have an average $13,195 incremental cost. • Postoperative infections have an average $11,546 incremental cost.	• Controllable medical costs lead to a loss of trust in the health care system. • People experience financial setbacks from medical errors (33% decrease in income; 50% increase in medical expenses).	• Medical error: "Sometimes when people receive medical care, mistakes are made. These mistakes sometimes result in no harm; sometimes they may result in additional or prolonged treatment, disability, or death. These types of mistakes are called medical errors."	• Used the Massachusetts All-Payer Claims Database (APCD) and Medicare claims (2013) • Adjusted costs to 2017 dollars	• Massachusetts residents of all ages • All health care settings, including hospitals, EDs, ambulatory surgery centers, and medical offices
Blanchfield et al. (2018)[471]	Single academic medical center	• Administrative cost to investigate and report 44 controllable SREs was $353,291, with an	• Not reported	• SREs: "unambiguous, largely, if not entirely, preventable, serious, and any of the	• Qualitative case study included interviewing staff and reviewing documents to examine	• Events occurred at a single academic medical center in

Study	Scope	Direct Cost of Patient Safety Events	Indirect Cost of Patient Safety Events	Definition of Safety Events	Methods to Identify Prevalence of Safety Events	Setting and/or Population of Focus
		average cost of $8,029 per SRE. • The costs ranged depending on SRE type (surgical SREs cost $9,123 per SRE, environmental SREs cost $6,653, product/device-related SREs cost $21,276).		following: adverse, indicative of a problem in a healthcare setting's safety systems, [or] important for public credibility or public accountability"	SREs occurring at an academic medical center in 2013.	Massachusetts during fiscal year 2013.

Notes: AE = adverse event; OECD = Organisation for Economic Co-operation and Development; SRE = serious reportable event; VTE = venous thromboembolism; WHO = World Health Organization. National studies reflect studies conducted in the United States.

Appendix E. Areas for Future Exploration and Research

Please note that the items listed below may be better addressed outside of the literature (e.g., through external stakeholder or subject matter expert input). They are captured here for further exploration.

- Successes and shortfalls of current programs and strategies to improve patient safety
- Insights from patients on improving patient safety
- Additional opportunities to improve the measurement of patient safety
- The use of patient-reported data to more effectively capture patient safety measures
- Approaches for setting appropriate benchmarks and baselines for patient safety measures
- Strategies to incorporate AI/machine learning to develop patient safety metrics
- Best practices to integrate AI predictive models into the provider workflow to aid in the identification of potential medical errors
- Further incentivizing patient safety and high-quality care in APMs
- Approaches to patient safety in outpatient settings
- Effectiveness of patient and family engagement on improving patient safety
- Strategies to develop valid and reliable measures, establish standard definitions, and ensure that harm rates are publicly reported
- Best practices to effectively engage patients and families
- Impact of barcode medication administration (BCMA) on timing-related medication errors
- Future vision and next steps for using APMs to improve patient safety

Appendix F. Annotated Bibliography

Abdelaziz S, Garfield S, Neves AL, Lloyd J, Norton J, van Dael J, et al. What are the unintended patient safety consequences of healthcare technologies? A qualitative study among patients, carers and healthcare providers. *BMJ Open*. 2024;14(11):e089026. https://doi.org/10.1136/bmjopen-2024-089026

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To explore unintended patient safety consequences associated with health care technologies from the perspectives of patients, caregivers, and health care providers.
Main Findings: The study found that health care technologies can introduce several unintended risks to patient safety. Five key themes emerged: unequal access to technology, increased burden on users, reduced personal interaction in care, overdependence on technology, and unclear accountability when issues arise. Participants highlighted that limited digital access and literacy can worsen disparities in care. Technologies may also increase stress for patients and providers by adding tasks. Additionally, reliance on technology may lead to incorrect assumptions that systems are always accurate, and uncertainty about responsibility for errors may create safety concerns.
Strengths/Limitations: The study included both patient/public participants and health care providers, allowing for multiple perspectives. One limitation is that the sample was limited to English-speaking participants in the United Kingdom, which may reduce applicability to other health care systems.
Generalizability to the Medicare Population: Weak; the study was based in the United Kingdom.
Methods: This qualitative study included five online focus groups with patients, caregivers, and health care providers. The study used thematic analysis to identify patterns in unintended consequences of health care technologies.

Adu G, Zuma SM. Contributory factors related to patient safety incidence: a nursing perspective. *Health SA*. 2024;29:2296. doi:10.4102/hsag.v29i0.2296

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To examine factors that contribute to patient safety incidents from the perspective of nurses working in hospital settings.
Main Findings: The study found that several organizational and knowledge-related issues contribute to patient safety incidents. Many nurses lacked a clear understanding of patient safety concepts, which affected safety practices. Communication problems within multidisciplinary teams were also identified as a key contributor, leading to breakdowns in coordination of care. In addition, poor adherence to established safety policies and protocols was common, increasing the risk of errors and adverse events. Overall, the findings suggest that gaps in training, communication, and policy implementation play an important role in patient safety incidents and should be addressed to improve quality of care.
Strengths/Limitations: This study focused on frontline nurses, providing practical insights into real-world patient safety challenges. One limitation is that the study was conducted in only two private hospitals in one region, which may limit broader generalizability.
Generalizability to the Medicare Population: Weak; the study was conducted in South Africa.
Methods: This qualitative study was conducted in two private hospitals using purposive sampling of professional nurses. The data were analyzed using thematic analysis guided by a patient safety framework.

Alizadeh-Dizaj G, Damanabi S, Hejazi ME, Raoofi S, Kalankesh LR. Implementation of patient safety monitoring systems in hospitals: a systematic review. *BMJ Health Care Inform*. 2025;32(1):e101392. doi:10.1136/bmjhci-2024-101392

Subtopic: Mitigation Factors for Patient Safety Errors

Type of Source: Journal Article

Objective: To review how patient safety monitoring systems are implemented in hospitals and assess their impact on patient safety outcomes.

Main Findings: The study found that patient safety monitoring systems are used across a variety of hospital settings, including intensive care, surgery, and emergency care. These systems track safety issues such as infections, medication errors, and procedural complications. Overall, implementation was associated with safety improvements, such as better detection of safety events, more timely alerts, and enhanced safety culture within organizations. However, the effectiveness of these systems varied depending on how they were implemented and integrated into workflows.

Strengths/Limitations: One strength of the study is its comprehensive synthesis of studies across multiple clinical settings. One limitation is the variability across studies in design and outcomes, making comparisons challenging.

Generalizability to the Medicare Population: Moderate; although not Medicare-specific, the hospital-based systems and safety domains examined are highly relevant to U.S. hospital care, including populations served by Medicare.

Methods: This systematic review was conducted using multiple databases (e.g., PubMed, EMBASE) following Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. The systematic review included 23 studies that examined implementation and outcomes of patient safety monitoring systems.

Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. *Journal of the American Medical Informatics Association*. 2008;15(5):585-600. https://doi.org/10.1197/jamia.M2667

Subtopic: Mitigation Factors for Patient Safety Errors

Type of Source: Journal Article

Objective: To evaluate the impact of electronic prescribing systems on medication errors and adverse drug events.

Main Findings: This study found that electronic prescribing systems generally reduce medication errors, with most studies showing meaningful decreases after implementation. Reductions were also observed for potential adverse drug events and actual drug-related harms, although findings were less consistent. The extent of improvement varied widely depending on system design, clinical setting, and study quality. Overall, electronic prescribing shows promise for improving medication safety, but results are not uniform across contexts.

Strengths/Limitations: One strength of the study is its inclusion of multiple study designs and settings. One limitation is that many included studies had methodological weaknesses and inconsistent reporting quality.

Generalizability to the Medicare Population: Strong; medication safety and prescribing systems are directly relevant to Medicare beneficiaries, particularly older adults.

Methods: This systematic review of controlled and pre-post studies examined electronic prescribing systems and included subgroup analyses across settings and system types.

Anand P, Kranker K, Chen AY. Estimating the hospital costs of inpatient harms. *Health Services Research*. 2019;54(1):86-96. https://doi.org/10.1111/1475-6773.13066

Subtopic: Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors

Type of Source: Journal Article

Objective: To estimate the additional hospital costs associated with inpatient medical harms and related readmissions.

Main Findings: This study found that inpatient harms significantly increased hospital costs, with some of the most serious events (e.g., surgical site infections, pressure ulcers) adding expensive costs. Less severe harms, such as hospital-acquired infections or blood clots, also substantially increased costs, though to a lesser extent. Patients who experienced harms were also more likely to be readmitted, further increasing overall health care spending. These findings highlight the financial burden of preventable safety events.

Strengths/Limitations: A strength of the study includes its use of large, multi-state administrative data to estimate costs. One limitation is the study's reliance on claims data, which may not capture all clinical details or accurately identify every harm.

Generalizability to the Medicare Population: Strong; the study used U.S. hospital data and focused on inpatient harms that are highly relevant to Medicare beneficiaries.

Methods: This observational analysis used Healthcare Cost and Utilization Project (HCUP) data and compared costs for patients with and without inpatient harms. The analysis included 90-day readmission costs.

Baker KM, Brahier M, Penne M, Hill MA, Davis S, Gallagher WJ, et al. Using patient experience surveys to identify potential diagnostic safety breakdowns: a mixed methods study. *Journal of Patient Safety*. 2024;20(8):556-63. doi:10.1097/PTS.0000000000001283

Subtopic: Measurement of Patient Safety

Type of Source: Journal Article

Objective: To examine whether patient experience surveys can help identify problems in the diagnostic process that may lead to patient safety issues.

Main Findings: The study found that patient experience surveys can help uncover problems in the diagnostic process that may not be captured in medical records. Patients reported issues such as delays in diagnosis, poor communication, and confusion about next steps in care. The survey responses helped identify areas where the diagnostic process breaks down, especially in follow-up and information sharing. The findings suggest that patients can provide valuable insight into safety problems and that using their feedback can help improve diagnostic accuracy and care coordination.

Strengths/Limitations: A limitation is that this study relied on patient perceptions, which may not always align with clinical records or confirmed diagnostic errors.

Generalizability to the Medicare Population: Strong; issues in the diagnostic process may be common among Medicare beneficiaries, especially those with chronic conditions.

Methods: This study used a mixed-methods design by including patient survey data and qualitative analysis to identify patterns in reported diagnostic safety concerns.

Bardach NS, Stotts JR, Fiore DM, Sarkar U, Sharma AE, Boscardin WJ, et al. Family Input for Quality and Safety (FIQS): using mobile technology for in-hospital reporting from families and patients. *Journal of Hospital Medicine*. 2022;17(6):456-65. doi:10.1002/jhm.2777

Subtopic: Measurement of Patient Safety

Type of Source: Journal Article

Objective: To examine how a mobile reporting tool can be used by patients and families in the hospital to identify safety and quality concerns.
Main Findings: The study found that patients and families can help identify safety problems during hospital stays when given simple tools to report concerns. Using a mobile reporting system, participants shared issues such as communication problems, delays in care, and potential safety risks. Many of these issues may not have been captured by traditional reporting systems. The findings suggest that involving patients and families in reporting can improve awareness of safety problems and provide useful information to improve care.
Strengths/Limitations: A limitation of the approach used in the study is that it depended on patients having smartphones and required technology infrastructure that may not be available in all settings.
Generalizability to the Medicare Population: Strong; patient and family engagement is relevant to the Medicare population.
Methods: This study used a mixed-methods design to assess a mobile reporting tool that collects patient and family feedback. Reported concerns were analyzed to identify patterns in safety issues.

Basoor A, Doshi NC, Cotant JF, Saleh T, Todorov M, Choksi N, et al. Decreased readmissions and improved quality of care with the use of an inexpensive checklist in heart failure. *Congestive Heart Failure*. 2013;19(4):200-6. doi:10.1111/chf.12031

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate whether using a low-cost checklist during hospitalization and discharge improves care quality and reduces readmissions among patients with heart failure.
Main Findings: The study found that implementing a checklist significantly improved adherence to guideline-based care, including increased use of recommended medications and better dose adjustments before discharge. Patients who received care guided by the checklist had notably lower readmission rates at both 30 days and six months compared to those receiving usual care. The checklist also improved patient education, discharge planning, and follow-up arrangements, which likely contributed to better outcomes.
Strengths/Limitations: A strength of the study is its use of a low-cost intervention that can be easily implemented in clinical settings. One limitation is the small sample size and single-site design.
Generalizability to the Medicare Population: Strong; heart failure is prevalent among Medicare beneficiaries, and these interventions are high priorities for Medicare.
Methods: This comparative study focused on patients hospitalized with acute heart failure. One group received checklist-guided care, and a control group received usual care.

Bates DW, Levine D, Syrowatka A, et al. The potential of artificial intelligence to improve patient safety: a scoping review. *npj Digit Med*. 2021;4,54. https://doi.org/10.1038/s41746-021-00423-6

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To assess the potential of artificial intelligence (AI) to improve patient safety.
Main Findings: The review identified widespread use of AI in predicting and preventing patient safety events across domains such as medication errors, infections, and diagnostic issues. AI tools can analyze large and complex datasets, including information from electronic health records (EHRs) and wearable devices, to detect risks earlier and support clinical decision-making. The findings suggest AI has strong potential in areas where traditional approaches have been

less effective, such as early detection of patient deterioration and diagnostic errors. Challenges remain related to data quality, integration, and implementation in clinical settings.
Strengths/Limitations: A strength of the study is its broad scope across multiple patient safety domains. One limitation is that many included studies are early-stage or observational.
Generalizability to the Medicare Population: Moderate; AI applications in clinical care are relevant to the Medicare population.
Methods: This scoping review of published literature identified studies on AI applications for prediction, prevention, and detection of patient safety events across eight harm domains.

Bates DW, Levine DM, Salmasian H, Syrowatka A, Shahian DM, Lipsitz S, et al. The safety of inpatient health care. *New England Journal of Medicine*. 2023;388(2):142-53. doi:10.1056/NEJMsa2206117

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess how often patient harm occurs during hospital stays and evaluate the severity and preventability of these events.
Main Findings: The study found that patient safety issues remain common in hospital settings, with nearly one in four admissions involving at least one adverse event. About one-quarter of these events were considered preventable, indicating ongoing opportunities for improvement. Preventable events occurred in roughly seven percent of hospitalizations, with a smaller proportion classified as serious or life-threatening. Medication-related harms were the most frequently observed, followed by complications related to procedures, nursing care, and infections.
Strengths/Limitations: A strength of the study includes its use of detailed chart reviews across multiple hospitals. One limitation is that the study focused on hospitals in only one geographic region.
Generalizability to the Medicare Population: Strong; many of the safety issues around inpatient hospital care are relevant to Medicare beneficiaries.
Methods: The study was a retrospective cohort study of a random sample of hospital admissions across multiple hospitals.

Bates DW, Singh H. Two decades since to err is human: an assessment of progress and emerging priorities in patient safety. *Health Affairs*. 2018;37(11):1736-43. doi:10.1377/hlthaff.2018.0738

Subtopic: Background on Patient Safety; Causes of Patient Safety Errors; Mitigation Factors for Patient Safety Errors; Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To evaluate progress in patient safety since the Institute of Medicine's *To Err Is Human* report was published and identify remaining challenges and future priorities.
Main Findings: The authors report that substantial progress has been made in specific areas such as hospital-acquired infections and medication safety, with effective interventions now available. However, improvements have been inconsistent due to challenges in implementation across health care systems. New areas of concern have also emerged, including diagnostic errors, outpatient safety, and risks associated with health information technology. Overall, preventable harm remains common, and better measurement tools and data systems are needed to further advance patient safety.
Strengths/Limitations: This article provided a comprehensive synthesis of two decades of research and policy developments. One limitation of the article is that it is largely a narrative assessment rather than a formal systematic analysis.

Generalizability to the Medicare Population: Strong; the discussion is focused on the U.S. health care system and includes issues relevant to Medicare populations, such as hospital care and chronic disease management.
Methods: This narrative review and policy analysis drew on existing literature, national data, and prior research on patient safety trends.

Betsy Lehman Center for Patient Safety. The financial and human cost of medical error and how Massachusetts can lead the way on patient safety. June 2019. https://betsylehmancenterma.gov/assets/uploads/general/Cost-of-Medical-Error-Report-2019.pdf

Subtopic: Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Report
Objective: To estimate the financial and human impact of medical errors in Massachusetts and identify opportunities to improve patient safety.
Main Findings: The report found that medical errors remain a significant problem, with tens of thousands of preventable harm events occurring in a single year. These events were associated with hundreds of millions of dollars in excess health care costs. The findings also highlighted that these estimates likely undercount the true burden of medical errors, since some common errors cannot be captured in claims data. In addition to financial costs, patients and families reported lasting emotional, physical, and behavioral consequences, as well as reduced trust in the health care system. Overall, the report emphasizes that preventable harm continues to affect patients across all care settings and remains an important area for improvement.
Strengths/Limitations: A strength of the study is its use of mixed-methods data with quantitative data and patient-reported experiences. One limitation is the study's reliance on administrative claims data, which could underestimate errors that are more difficult to detect.
Generalizability to the Medicare Population: Moderate; although the study was specific to Massachusetts, the harms and drivers of costs were relevant to older adults in the Medicare population.
Methods: This mixed-methods analysis of health insurance claims data estimated medical errors and used a population survey to assess patient experiences.

Blanchfield BB, Acharya B, Mort E. The hidden cost of regulation: the administrative cost of reporting serious reportable events. *The Joint Commission Journal on Quality and Patient Safety*. 2018;44(4):212-8. https://doi.org/10.1016/j.jcjq.2017.08.006

Subtopic: Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Journal Article
Objective: To estimate the administrative costs associated with investigating and reporting serious reportable events in a hospital setting.
Main Findings: The study found that reporting requirements for serious safety events caused substantial administrative costs on health care organizations. On average, each event costs several thousand dollars in staff time and resources to investigate, document, and report. Most of the burden was related to internal investigation activities, such as root cause analysis, which accounted for the majority of total costs. Additional costs were linked to external reporting, including public disclosure requirements, which represented a meaningful portion of the overall burden.
Strengths/Limitations: A strength of the study is its detailed breakdown of administrative tasks and costs associated with safety reporting. One limitation is that the study was conducted at a

single academic medical center, which may limit how broadly the findings apply to other settings.
Generalizability to the Medicare Population: Moderate; the findings may be relevant to Medicare-funded hospitals with regulatory reporting requirements.
Methods: This qualitative case study analyzed all serious reportable events at one hospital over a defined period using staff interviews and document review.

Borycki EM, Kushniruk AW. Health technology, quality and safety in a learning health system. *Healthcare Management Forum*. 2023;36(2):79-85. doi:10.1177/08404704221139383

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To examine how health technologies influence quality and patient safety and how the technologies can be effectively integrated into a learning health system.
Main Findings: The article explained that health technologies, such as electronic health records and medical devices, can improve care by supporting data collection, enhancing decision-making, and reducing human error in clinical processes. However, these technologies can also introduce new risks, including technology-related errors and the spread of mistakes across interconnected systems. The authors emphasized that achieving a learning health system requires continuous monitoring, evaluation, and refinement of both clinical processes and the technologies.
Strengths/Limitations: A strength of the study is the conceptual framework linking technology, safety, and learning health systems. One limitation is that the study is largely theoretical and does not include quantitative data or outcomes.
Generalizability to the Medicare Population: Moderate; although the study is not focused on a specific population, the use of digital health technologies in hospital and outpatient care is applicable to the Medicare population.
Methods: This narrative review was based on existing literature and health informatics principles to describe how technology and learning health systems can help improve quality and safety.

Bowman CL, De Gorter R, Zaslow J, Fortier JH, Garber G. Identifying a list of healthcare 'never events' to effect system change: a systematic review and narrative synthesis. *BMJ Open Qual*. 2023;12(2):e002264. doi:10.1136/bmjoq-2023-002264

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To identify which patient safety events are most commonly defined as “never events” and which are considered the most preventable to support system-wide improvement.
Main Findings: The review found substantial variation in how “never events” are defined across different frameworks, which limits consistency and collaboration in patient safety efforts. Across 367 publications, the authors identified 125 distinct never events, with surgical errors, such as wrong-site surgery, wrong procedure, or retained foreign objects, appearing most frequently. Only about one-fifth of events were consistently described as completely preventable, highlighting gaps in agreement about preventability. The study suggests that focusing on a smaller, standardized set of the most serious and preventable events could improve learning, coordination, and reductions in patient harm.
Strengths/Limitations: A strength of the study is the comprehensive synthesis of literature across many frameworks. One limitation is that the findings depend on how prior studies defined “never events,” which may introduce inconsistency.

Generalizability to the Medicare Population: Strong; surgical and medication-related errors are relevant to the older adult Medicare population.
Methods: This systemic review included a narrative synthesis of published literature.

Brittain AC, Carrington JM. Organizational health and patient safety: a systematic review. *Journal of Hospital Management and Health Policy*. 2021;5. doi:10.21037/jhmhp-20-57

Subtopic: Causes of Patient Safety Errors; Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To review existing research on how organizational-level factors influence patient safety and contribute to health care errors.
Main Findings: The review found that patient safety errors are often rooted in broader organizational issues rather than isolated clinical mistakes. Key contributing factors include poor communication, weak leadership, inadequate teamwork, and unfavorable work environments. Positive mitigation factors include strong leadership support, effective interdisciplinary collaboration, and an organizational culture that prioritizes safety. Overall, improving organizational health, particularly communication and culture, is critical to reducing patient safety incidents.
Strengths/Limitations: A strength of the study is the focus on system-level causes of errors, offering a broader perspective beyond individual clinician behavior. One limitation is the variability in study quality and methodology, including inconsistent definitions of adverse events.
Generalizability to the Medicare Population: Strong; organizational factors such as communication, staffing, and care coordination are relevant to the Medicare population.
Methods: This systematic review focused on peer-reviewed literature published between 2009 and 2019 and used multiple databases. Studies were analyzed thematically to identify key organizational factors affecting patient safety.

Chaneliere M, Koehler D, Morlan T, Berra J, Colin C, Dupie I, et al. Factors contributing to patient safety incidents in primary care: a descriptive analysis of patient safety incidents in a French study using CADYA (categorization of errors in primary care). *BMC Family Practice*. 2018;19:121. doi:10.1186/s12875-018-0803-9

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To identify and describe the factors contributing to patient safety incidents in primary care focusing on human and system-level causes.
Main Findings: The study found that patient safety incidents in primary care are influenced by a combination of process, human, environmental, and technical factors. The most common contributors were issues in the care process (e.g., workflow breakdowns), followed closely by human factors such as provider and patient behaviors. Communication failures were the single most frequently identified issue. Other contributing human factors included lack of attention, stress, fatigue, and emotional strain among providers and patients. The findings suggest that improving communication, addressing workload and stress, and strengthening care processes are key strategies for reducing preventable harm in primary care settings.
Strengths/Limitations: A strength of the study is the categorization of factors using a structured framework (CADYA). One limitation is that the data are based on reported incidents from a specific national context, which may not fully represent other health care systems.

Generalizability to the Medicare Population: Moderate; although the study was conducted in France, the contributing factors are applicable to primary care settings that serve Medicare beneficiaries.
Methods: This mixed-method descriptive study analyzed reported patient safety incidents from a national primary care survey. The incidents were coded using the CADYA classification system.

Cheraghi-Sohi S, Panagioti M, Daker-White G, Giles S, Riste L, Kirk S, et al. Patient safety in marginalised groups: a narrative scoping review. *Int J Equity Health*. 2020;19(1):26. doi:10.1186/s12939-019-1103-2
Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To map and synthesize existing research on patient safety issues affecting marginalized populations and identify the factors associated with increased risk of harm.
Main Findings: The review found that marginalized populations, including racial and ethnic minorities, older adults, and individuals with low socioeconomic status, face a higher risk of patient safety incidents. These incidents are often related to medication errors, adverse outcomes, and near misses. The causes are multifactorial, involving patient-level barriers (e.g., language, cognitive limitations), provider-related factors (e.g., bias, communication gaps), and system-level issues (e.g., access to care, coordination failures). The findings suggest that improving culturally competent care, communication, and system coordination could help reduce disparities in patient safety outcomes.
Strengths/Limitations: A strength of the study is the broad scope of the review with multiple marginalized populations and a wide range of contributing factors. One limitation is the heterogeneity of the included studies.
Generalizability to the Medicare Population: Strong; many marginalized groups identified in the study, particularly older adults and individuals with lower socioeconomic status, overlap with the Medicare population.
Methods: This narrative scoping review used systematic searches across multiple databases.

Chowdhury R, Orishchak O, Mascarella MA, Aldriweesh B, Alnoury MK, Bousquet-Dion G, et al. Emergency airway management: a systematic review on the effectiveness of cognitive aids in improving outcomes and provider performance. *Clin Pract*. 2025;15(1):13. doi:10.3390/clinpract15010013
Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the effectiveness of cognitive aids (e.g., checklists, algorithms) in improving provider performance and patient outcomes during emergency airway management.
Main Findings: The review found that cognitive aids can significantly improve provider performance in high-risk airway emergencies. These tools were associated with faster decision-making, higher procedural success rates, and improved teamwork and crisis management skills. Providers using cognitive aids also reported increased confidence and reduced anxiety during emergency scenarios. The findings suggest that structured tools such as airway algorithms and visual aids help reduce errors and delays, particularly in high-stress and time-sensitive situations.
Strengths/Limitations: A strength of the study is the focus on measurable performance outcomes. Limitations include the small number of included studies and the reliance on simulation settings.
Generalizability to the Medicare Population: Moderate; although the study focused on emergency airway management, reducing errors through cognitive aids are broadly applicable to settings that treat older adults and Medicare beneficiaries.

Methods: This systematic review used multiple databases, including MEDLINE and Cochrane Library. The review included randomized trails and mixed-methods studies.

Chustecki M. Benefits and risks of AI in health care: narrative review. *Interact J Med Res*. 2024;13:e53616. doi:10.2196/53616

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the potential benefits and risks of artificial intelligence (AI) in health care, specifically ethical, safety, and regulatory considerations.
Main Findings: The review highlighted that AI has the potential to improve health care by supporting more accurate diagnoses, enhancing clinical decision-making, and increasing efficiency in care processes. However, AI introduces risks that may affect patient safety, such as errors from biased data, lack of transparency in decision-making, and overreliance on automated systems. These risks can lead to inappropriate clinical decisions if AI outputs are not carefully interpreted by clinicians.
Strengths/Limitations: A strength of the study is the comprehensive overview of the benefits, risks, ethical, and regulatory considerations. One limitation is the lack of quantitative estimates or standardized comparisons across studies.
Generalizability to the Medicare Population: Strong; the benefits and risks of AI in health care are relevant to the Medicare population.
Methods: This narrative review of peer-reviewed literature qualitatively synthesized information to identify key themes related to the benefits and risks of using AI.

Department of Health and Human Services. Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018. OEI-06-18-00400. Office of Inspector General. May 2022. https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf

Subtopic: Key Highlights; Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Report
Objective: To estimate the national incidence rate of adverse events among hospitalized Medicare beneficiaries in October 2018.
Main Findings: One quarter of hospitalized Medicare patients experienced one or more controllable and noncontrollable adverse events in short-term acute care hospitals in October 2018. Approximately 43 percent of the adverse events were medication-related events. Less than half (43 percent) of the adverse events were considered preventable.
Strengths/Limitations: Retrospective medical record reviews of adverse events may not fully capture all patient harm events. Determining the preventability of adverse events using this approach may be impacted by hindsight bias.
Generalizability to the Medicare Population: Strong; this report focused specifically on adverse events experienced by hospitalized Medicare beneficiaries.
Methods: This study included a nationally representative random sample of Medicare beneficiaries with discharges from short-term acute care hospitals in October 2018. A two-stage retrospective medical record review approach was used. In stage 1, nurses screened medical records using an Office of Inspector General (OIG)-modified Global Trigger Tool to flag potential harm. In stage 2, physicians reviewed full medical records flagged in stage 1 to confirm the harm, severity, and preventability of the adverse events.

Department of Health and Human Services. Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer. OEI-06-18-00401. Office of Inspector General. July 2025. https://oig.hhs.gov/documents/evaluation/10840/OEI-06-18-00401.pdf

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events

Type of Source: Report

Objective: To assess the extent to which hospitals' incident reporting or surveillance systems captured prior patient harm events.

Main Findings: Nearly half (49 percent) of controllable and uncontrollable patient harm events were not captured by hospitals' incident reporting or surveillance systems. Hospitals were more likely to miss harm events resulting from surgeries or procedures (73 percent) compared with harm events from non-surgeries or procedures. Of the harm events that were captured, few were investigated or resulted in improvement efforts to enhance patient safety.

Strengths/Limitations: Some hospitals that received the survey did not report whether the hospital collected specific patient harm events. Results may underestimate the rate of harm events captured by hospitals.

Generalizability to the Medicare Population: Strong; this report focused specifically on harm events experienced by hospitalized Medicare beneficiaries.

Methods: In 2023, a survey was administered to 154 short-term acute care hospitals where harm events occurred in October 2018 to determine whether those events were captured by the hospitals' incident reporting or surveillance systems.

Dixit RA, Boxley CL, Samuel S, Mohan V, Ratwani RM, Gold JA. Electronic health record use issues and diagnostic error: a scoping review and framework. *Journal of Patient Safety*. 2023;19(1):e25-30. doi:10.1097/PTS.0000000000001081

Subtopic: Causes of Patient Safety Errors

Type of Source: Journal Article

Objective: To examine how electronic health records (EHRs) can lead to diagnostic errors and to develop a framework linking EHR-related issues to stages of the diagnostic process.

Main Findings: The review found that EHR-related issues can contribute to diagnostic errors across multiple sites of care. These issues were grouped into three main categories: information gathering, clinical decision-making, and implementation and communication of the care plan. Specific contributing factors included usability problems, poor interface design, workflow disruptions, and difficulties tracking or synthesizing patient information. The findings highlight that EHRs, while designed to support care, can unintentionally introduce safety risks if they are not aligned with clinical workflows and decision-making needs.

Strengths/Limitations: A strength of the study is the development of a structured framework that connects EHR issues to specific steps in the diagnostic process. Limitations include the relatively small number of included studies and variability in study designs.

Generalizability to the Medicare Population: Strong; EHR systems are widely used in care settings that serve Medicare beneficiaries.

Methods: This scoping review of the literature examined the relationship between EHR use and diagnostic errors.

Eldridge N, Wang Y, Metersky M, Eckenrode S, Mathew J, Sonnenfeld N, et al. Trends in adverse event rates in hospitalized patients, 2010-2019. *JAMA*. 2022;328(2):173-183. doi:10.1001/jama.2022.9600

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events

Type of Source: Journal Article
Objective: To assess change in the national rate of adverse events in hospitalized patients between 2010 and 2019.
Main Findings: Between 2010 and 2019, acute myocardial infarction declined from 218 adverse events per 1,000 discharges to 139 adverse events per 1,000 discharges, heart failure declined from 168 adverse events per 1,000 discharges to 116 adverse events per 1,000 discharges, pneumonia declined from 195 adverse events per 1,000 discharges to 119 adverse events per 1,000 discharges, and major surgical procedures declined from 204 adverse events per 1,000 discharges to 130 adverse events per 1,000 discharges. The rate of controllable and noncontrollable adverse events for all other conditions remained unchanged at 70 adverse events per 1,000 discharges between 2012 and 2019.
Strengths/Limitations: One limitation of the study is that a limited subset of hospital-based adverse events were included in the analysis; the study therefore did not assess change in the rate of adverse events across all types of hospital-based adverse events. Additionally, the study did not account for differences in the prevalence of patients at risk for different types of adverse events.
Generalizability to the Medicare Population: Strong; the study used data from the Medicare Patient Safety Monitoring System, which tracks adverse events among hospitalized patients.
Methods: A serial cross-sectional analysis assessed change over time in patient safety outcomes for hospitalized patients across 3,156 U.S. acute care hospitals. The study assessed 2010 to 2019 data from the Medicare Patient Safety Monitoring System.

Esslinger E, Kevech M, Anderson D, Knowles B. Home Health Quality Improvement National Campaign: the journey and potential impact on clinical practice. *Home Healthc Nurse*. 2008;26(7):398-405. doi:10.1097/01.NHH.0000326317.94218.5a

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To provide an overview of the Home Health Quality Improvement (HHQI) National Campaign and examine its impact on improving clinical practice in home health care.
Main Findings: The article described a national quality improvement initiative aimed at reducing avoidable hospitalizations among home health patients through the adoption of evidence-based practices. The campaign emphasized multiple best practices, including improving care coordination, enhancing patient education, strengthening clinical monitoring, and standardizing care processes. These strategies were designed to address system-level gaps in care that can lead to safety issues, particularly during transitions of care. The findings suggest that structured quality improvement programs can support better clinical decision-making and reduce preventable adverse events.
Strengths/Limitations: A strength of the study is its focus on a large-scale, real-world quality improvement initiative.
Generalizability to the Medicare Population: Strong; the campaign specifically targets home health agencies serving Medicare beneficiaries.
Methods: This article provided a descriptive overview of a national quality improvement campaign.

Esslinger EE, Sun C, Wright S, Knowles B, Schade CP. The 2010–2011 Home Health Quality Improvement National Campaign. *Home Healthcare Now*. 2011;29(5):298-305. doi:10.1097/NHH.0b013e31821738e4

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article

Objective: To provide an overview of the 2010-2011 Home Health Quality Improvement (HHQI) National Campaign and its potential to improve clinical practice in home health care.
Main Findings: The article highlights how the second phase of the HHQI National Campaign expanded on earlier efforts by emphasizing collaboration across care settings and providing structured tools to support quality improvement. Key elements included educational resources, performance feedback, and best-practice intervention packages to reduce avoidable hospitalizations and improve medication management. The campaign also introduced incentives and tools to help agencies set measurable targets and track performance improvements.
Strengths/Limitations: A strength of the study is its focus on a large-scale, real-world quality improvement initiative.
Generalizability to the Medicare Population: Strong; the campaign specifically targets home health agencies serving Medicare beneficiaries.
Methods: This article provided a descriptive overview of a national quality improvement campaign and discussed enhancements introduced in 2010-2011.

Fekonja Z, Kmetec S, Fekonja U, Mlinar Reljić N, Pajnkihar M, Strnad M. Factors contributing to patient safety during triage process in the emergency department: a systematic review. *Journal of Clinical Nursing*. 2023;32(17-18):5461-77. https://doi.org/10.1111/jocn.16622

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To identify and analyze factors that influence patient safety during the triage process in the emergency department.
Main Findings: The review found that multiple factors impact patient safety during triage, including staff experience, communication quality, workload, and the use of standardized triage systems. Adequate training and clinical expertise were strongly associated with more accurate triage decisions. Clear communication among health care providers and with patients also played a key role in reducing errors. In contrast, overcrowding, time pressure, and high patient volume were linked to increased risk of misclassification and delays in care. The use of standardized guidelines and tools helped improve consistency and reduce variability in triage decisions.
Strengths/Limitations: A strength of the study is the systematic synthesis of evidence across multiple studies using Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. One limitation is the relatively small number of included studies.
Generalizability to the Medicare Population: Moderate; although the focus is on emergency department triage, the findings were relevant to older adults who may rely on emergency care.
Methods: This systematic review of literature used multiple databases (e.g., PubMed, CINAHL, Embase). Thematic analysis was conducted on the 11 included studies.

Goodman JC, Villarreal P, Jones B. The social cost of adverse medical events, and what we can do about it. *Health Affairs*. 2011;30(4):590-5. https://doi.org/10.1377/hlthaff.2010.1256

Subtopic: Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Journal Article
Objective: To estimate the annual social cost of adverse events based on what individuals are willing to pay to avoid the risk of experiencing such events.
Main Findings: The annual social cost of all adverse events in the U.S., including deaths and injuries, was $393 to $958 billion in 2006, translating to approximately 18 to 45 percent of total U.S. health care spending.

Strengths/Limitations: N/A
Generalizability to the Medicare Population: Moderate; although the study did not focus specifically on the Medicare population, the authors considered the rate of adverse events experienced by Medicare beneficiaries in their review of the literature.
Methods: The authors synthesized existing evidence on the incidence of adverse events and then conducted economic modeling to estimate the social costs of adverse events among hospitalized patients of all ages.

Hassan AE, Mohammed FA, Zakaria AM, Ibrahim IA. Evaluating the effect of TeamSTEPPS on teamwork perceptions and patient safety culture among newly graduated nurses. *BMC Nurs*. 2024;23(1):170. doi:10.1186/s12912-024-01850-y

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the impact of the TeamSTEPPS training program on teamwork perceptions and patient safety culture among newly graduated nurses.
Main Findings: The study found that participation in the TeamSTEPPS program led to meaningful improvements in nurses' perceptions of teamwork and communication. Nurses reported stronger collaboration, clearer communication, and greater confidence in team-based care following the training. The intervention also contributed to improvements in overall patient safety culture, particularly in areas such as mutual support and shared responsibility for patient outcomes. These findings suggest that structured teamwork training can help reduce errors by improving coordination and communication among clinical staff, especially for less experienced providers.
Strengths/Limitations: A strength of the study is its focus on newly graduated nurses who may be vulnerable to teamwork and communication challenges. One limitation is that the study relies on self-reported perceptions.
Generalizability to the Medicare Population: Moderate; although the study focuses on nurses rather than patients, the topics are relevant to care settings serving Medicare beneficiaries.
Methods: This quasi-experimental study used pre- and post-intervention surveys to assess changes in teamwork perceptions and patient safety culture among newly graduated nurses following TeamSTEPPS training.

Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *New England Journal of Medicine*. 2009;360(5):491-9. doi:10.1056/NEJMsa0810119

Subtopic: Background on Patient Safety; Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate whether implementing a standardized surgical safety checklist reduces complications and mortality among surgical patients.
Main Findings: The study found that the use of a structured surgical safety checklist was associated with significant reductions in both postoperative complications and mortality. Across participating sites, complications such as infections, bleeding, and anesthesia-related issues decreased after checklist implementation. Mortality rates also declined, suggesting that the checklist improved overall surgical outcomes. The intervention worked by promoting better communication, coordination, and adherence to safety steps for surgical teams.
Strengths/Limitations: A strength of the study is the large and multi-country sample. One limitation is its use of a pre-post study design without a randomized control group.

Generalizability to the Medicare Population: Strong; the study focuses on surgical care, a common health care setting for Medicare beneficiaries.
Methods: This pre-post intervention study was conducted across multiple international hospitals.

Hayward RA, Asch SM, Hogan MM, Hofer TP, Kerr EA. Sins of omission: getting too little medical care may be the greatest threat to patient safety. *Journal of General Internal Medicine*. 2005;20(8):686-91. https://doi.org/10.1111/j.1525-1497.2005.0152.x

Subtopic: Key Highlights; Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess the incidence of medical errors of commission and omission.
Main Findings: Approximately 82 percent of patients experienced at least one medical error during a 13-month period. The average number of medical errors was 4.7 errors per patient. Ninety-six percent of the errors were errors of omission. Of the 2,917 errors identified, 27 were rated as highly serious, 26 of which were errors of omission.
Strengths/Limitations: One limitation is that the study relied on medical records to identify errors of commission and omission. Errors of commission may be more difficult to detect in medical records relative to errors of omission.
Generalizability to the Medicare Population: Moderate; although the study was conducted in Department of Veterans Affairs (VA) health care systems, findings may be applicable to the Medicare population.
Methods: The study used a retrospective cohort design where physicians reviewed complete inpatient and outpatient medical records of patients at 12 VA health care systems for errors and classified the errors as errors of commission or omission.

Hebbar KB, Colman N, Williams L, Pina J, Davis L, Bost JE, et al. A quality initiative: a system-wide reduction in serious medication events through targeted simulation training. *Simulation in Healthcare*. 2018;13(5):324-30. doi:10.1097/SIH.0000000000000321

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate whether targeted simulation-based training can reduce serious medication-related events.
Main Findings: The study found that targeted simulation training was associated with a substantial reduction in serious medication events. The intervention focused on high-risk scenarios and helped staff identify and address common sources of medication error. Following implementation, there were notable improvements in team communication, adherence to safety protocols, and the ability to recognize and respond to potential medication-related risks.
Strengths/Limitations: A strength of the study is the implementation of a system-wide, simulation-based intervention in a pediatric population. One limitation is the lack of a randomized comparison group.
Generalizability to the Medicare Population: Strong; medication safety is a key concern for Medicare beneficiaries.
Methods: The Children's Simulation Center and Medication Safety Workgroup designed a two-hour, simulation-based training to support a medication administration error (MAE) bundle that included the Five Rights, MedZone, and Independent Double Check. Compliance was monitored through bedside audits over 18 months using a hospital-wide reporting system, and cost impact was estimated using national pediatric inpatient database.

Hemmelgarn C, Hatlie M, Sheridan S, Daley Ullem B. Who killed patient safety? *Journal of Patient Safety and Risk Management*. 2022;27(2):56-8. https://doi.org/10.1177/25160435221077778

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To reflect on the current state of patient safety efforts and examine why progress in reducing medical errors has been slower than expected.
Main Findings: The article indicates that progress in patient safety has stalled due to a combination of systemic challenges, including lack of accountability, fragmented efforts, and insufficient leadership commitment. The authors suggest that despite early momentum following major reports such as *To Err Is Human*, many health care organizations have struggled to sustain meaningful improvements. Contributing factors include limited transparency, inconsistent measurement of safety outcomes, and a tendency to focus on isolated interventions rather than system-wide change.
Strengths/Limitations: One limitation is that the article is a brief commentary piece and does not include empirical data or formal analysis.
Generalizability to the Medicare Population: Strong; the systemic challenges discussed are relevant to health care systems serving Medicare beneficiaries.
Methods: This commentary/editorial was based on prior literature, policy developments, and expert perspectives.

Hong YR, Nguyen O, Yadav S, Etzold E, Song J, Duncan RP, et al. Early performance of hospital value-based purchasing program in Medicare: a systematic review. *Med Care*. 2020;58(8):734-743. doi:10.1097/MLR.0000000000001354

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To assess the early effects of the Medicare Hospital Value-Based Purchasing (HVBP) program on hospital performance, including quality and patient safety outcomes.
Main Findings: The review found little to no evidence that the HVBP program improved care quality or patient outcomes. Some studies indicated small improvements in process measures, but there was little evidence of meaningful improvements in patient safety outcomes such as mortality or complications. The findings also suggested that financial incentives under the program may not have been strong enough to drive substantial changes in hospital behavior. Additionally, variation in hospital performance persisted, and there was limited evidence that the program reduced disparities in care.
Strengths/Limitations: A strength of the review is the synthesis of studies evaluating a major national policy initiative. One limitation is that the review focused on early years of the program and may not capture longer-term effects.
Generalizability to the Medicare Population: Strong; the HVBP program specifically targets Medicare hospitals and care for Medicare beneficiaries.
Methods: This systematic review of literature published between January 2013 and July 2019 evaluated the Medicare HVBP program. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines were used.

Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Washington (DC): National Academies Press (US); 1999.

Subtopic: Key Highlights; Background on Patient Safety
Type of Source: Report

Objective: To raise awareness of the importance of patient safety, explain why patient safety errors occur, and provide recommendations to reduce patient safety errors.
Main Findings: As many as 98,000 Americans die from medical errors in hospitals annually. The direct and indirect cost of preventable adverse events is between $17 billion and $29 billion nationally. Medication errors are among the most common types of patient safety errors in hospitals. Recommendations to improve patient safety include establishing a national center for patient safety, learning from errors collected through reporting systems, protecting voluntary reporting systems from legal discovery, setting performance standards for patient safety, and creating safety systems within health care organizations.
Strengths/Limitations: One strength of the report is its national focus on medical errors.
Generalizability to the Medicare Population: Moderate; although the report was not focused specifically on the Medicare population, the report focused on patient safety at a national-level and is applicable to Medicare beneficiaries.
Methods: This report included a review of findings from the literature, public testimony, a survey, input from targeted groups, and a commissioned paper.

Isaksson S, Schwarz A, Rusner M, Nordström S, Källman U. Monitoring preventable adverse events and near misses: number and type identified differ depending on method used. *Journal of Patient Safety*. 2022;18(4):325-30. doi:10.1097/PTS.0000000000000921

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To compare the number of preventable adverse events and near misses identified through different methods, including structured record review, web-based incident reporting, and daily safety briefings.
Main Findings: Structured record review identified the greatest number of preventable adverse events. Specifically, structured record review identified 19.9 preventable adverse events per 1,000 patient days while incident reporting systems identified 3.4 preventable adverse events per 1,000 patient days and daily safety briefings identified 5.4 preventable adverse events per 1,000 patient days. The methods also differed in the most common types of preventable adverse events identified. The most common types of events identified by structured record review were drug-related events, pressure ulcers, and hospital-acquired infections. The most common types of events identified by incidence reporting systems and daily safety briefings were fall injuries and pressure ulcers.
Strengths/Limitations: Incidence reporting systems and daily safety briefings rely on self-reported events, and therefore the authors could not confirm whether the reported events were preventable adverse events or near misses. Additionally, results from this study may not be generalizable to other hospitals and health care settings.
Generalizability to the Medicare Population: Moderate; the study was conducted in Sweden.
Methods: Preventable adverse events and near misses were collected from acute care hospitals' existing resources.

Jelacic S, Bowdle A, Nair BG, Togashi K, Wu C, Boorman DJ, et al. The effects of an aviation-style computerised pre-induction anaesthesia checklist on pre-anaesthetic set-up and non-routine events. *Anaesthesia*. 2019;74(9):1138-46. https://doi.org/10.1111/anae.14707

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the effects of an aviation-style computerized pre-induction anesthesia checklist on preparation and non-routine events.

Main Findings: The study found that implementing a computerized checklist improved the completeness and consistency of pre-anesthetic setup. Use of the checklist helped ensure that key safety steps were completed prior to induction, reducing the likelihood of omissions. The intervention was also associated with a decrease in non-routine events, such as equipment or preparation issues, that can disrupt procedures and introduce risk. Additionally, the checklist supported better team coordination and situational awareness.
Strengths/Limitations: A strength of the study is its use of an aviation-checklist in a real-world clinical setting.
Generalizability to the Medicare Population: Moderate; the findings are relevant to surgical care settings that frequently serve Medicare beneficiaries.
Methods: This intervention study evaluated anesthesia cases before and after implementation of a computerized checklist.

Kepner S, Jones R. Patient safety trends in 2022: an analysis of 256,679 serious events and incidents from the nation's largest event reporting database. *Patient Safety*. 2023;5(2). doi:10.33940/001c.74752

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess patient safety reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2022.
Main Findings: There were 256,679 total controllable and noncontrollable harm reports submitted in 2022. Of those reports, 9,741 were serious events that resulted in death or an unanticipated injury that required additional health care services. There was an increase in the number of serious event reports submitted to PA-PSRS in 2022. Hospitals had 27.5 reports per 1,000 patient days while ambulatory surgical facilities had 9.4 reports per 1,000 surgical encounters.
Strengths/Limitations: One strength of the study is its use of the PA-PSRS, which is one of the largest repositories of patient safety data in the U.S.
Generalizability to the Medicare Population: Moderate; this study was conducted in Pennsylvania and findings may not be generalizable outside of the state.
Methods: Data were extracted from mandatory facility reporting by acute care facilities in Pennsylvania to the PA-PSRS. Counts of harm reports were calculated based on report submission date.

Kim JM, Suarez-Cuervo C, Berger Z. et al. Evaluation of patient and family engagement strategies to improve medication safety. *Patient*. 2018;11:193-206. https://doi.org/10.1007/s40271-017-0270-8

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the effectiveness of patient and family engagement strategies to improve medication safety.
Main Findings: The review found that involving patients and their families in care can improve medication safety by identifying errors, increasing adherence, and improving communication with providers. Engagement strategies included medication reconciliation, patient education, shared decision-making, and use of patient-accessible tools.
Strengths/Limitations: A strength of the study is that it was the first systematic review to specifically evaluate patient family engagement strategies and their impact on medication safety.

Generalizability to the Medicare Population: Moderate; although nine of the 19 included studies were from outside of the U.S. medication safety is a relevant issue for Medicare beneficiaries.
Methods: This systematic review of studies examined patient and family engagement strategies related to medication safety published between 1966 through August 2016.

Kovačević M, Vezmar Kovačević S, Miljković B, Radovanović S, Stevanović P. The prevalence and preventability of potentially relevant drug-drug interactions in patients admitted for cardiovascular diseases: a cross-sectional study. *Int J Clin Pract*. 2017;71:e13005. doi:10.1111/ijcp.13005

Subtopic: Background in Patient Safety Errors
Type of Source: Journal Article
Objective: To assess the type and prevalence of potentially harmful drug-drug interactions that occur among patients with cardiovascular diseases.
Main Findings: Potential drug-drug interactions were identified in 84 percent of patients and were more common among those with polypharmacy, multiple comorbidities, longer hospital stays, and conditions such as arrhythmia or heart failure. Approximately 13 percent of the interactions were further complicated by concurrent renal or liver disease, with patients who had a history of myocardial infarction showing the highest additional risk. Strategies to reduce risk included switching medications, such as avoiding Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) or certain antibiotics. Many interactions could be monitored through vital signs and lab values, showing the value of integrating drug interaction screening tools with clinical and laboratory data.
Strengths/Limitations: A strength of the study is that it was the first study conducted to assess the prevalence and characteristics of potentially relevant drug-drug interactions for patients with cardiovascular disease, providing new insights for this high-risk population.
Generalizability to the Medicare Population: Moderate; although the study was conducted outside of the U.S., cardiovascular disease in older adults is an important issue for the Medicare population.
Methods: A cross-sectional study in the Cardiology ward of University Clinical Hospital Center in Belgrade, Serbia was conducted to identify and assess patients' potential drug-drug interactions. The study included 527 patients.

Lawton EJ, Sheetz KH, Ryan AM. Improving the Hospital-Acquired Condition Reduction Program through rulemaking. *JAMA Health Forum*. 2020;1(5):e200416. doi:10.1001/jamahealthforum.2020.0416

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To examine how the Hospital-Acquired Condition (HAC) Reduction Program could be improved through regulatory and policy changes.
Main Findings: The article indicates that the HAC Reduction Program has not consistently achieved its intended goal of improving patient safety. The authors note that the program's design may unfairly penalize certain hospitals, particularly those serving more complex or disadvantaged patient populations. The authors highlight concerns regarding measurement limitations, including reliance on administrative data that may not fully capture clinical complexity or safety performance. The authors proposed several improvements, such as refining performance measures, adjusting for patient risk more effectively, and reconsidering how penalties are applied.
Strengths/Limitations: One limitation of the study is that it is a commentary and does not include original empirical analysis.

Generalizability to the Medicare Population: Strong; the HAC Reduction Program is a Medicare policy.
Methods: This policy commentary analyzed the structure and performance of the HAC Reduction Program.

Lei Z, Naveh E. Patient safety and other priorities. *Health Affairs*. 2019;38(4):693. https://doi.org/10.1377/hlthaff.2019.00121
Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To explain why patient safety should be better integrated with other health care priorities.
Main Findings: Patient safety is more effective when it is aligned with other priorities such as cost and efficiency rather than handled on its own. The authors emphasized the value of bringing together ideas from different fields, such as health care, psychology, and operations management. Overall, the authors suggested that health care systems should consider taking a more coordinated approach that improves both processes and learning at the same time.
Strengths/Limitations: One limitation of the article is that it is a brief commentary and does not include empirical data.
Generalizability to the Medicare Population: Strong; the discussion on patient safety is relevant to the Medicare population.
Methods: This commentary drew on policy context and prior literature.

Levine DM, Syrowatka A, Salmasian H, Shahian DM, Lipsitz S, Zebrowski JP, et al. The safety of outpatient health care: review of electronic health records. *Annals of Internal Medicine*. 2024;177(6):738-48. https://doi.org/10.7326/M23-2063
Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess the number of adverse events in 11 Massachusetts outpatient hospitals.
Main Findings: Approximately 7 percent of patients had at least one controllable or noncontrollable adverse event. Twenty-three percent of adverse events were preventable, and 2 percent of patients had at least one preventable adverse event. The most common adverse events were adverse drug events (64 percent), health care-associated infections (15 percent), and surgical or procedural events (14 percent).
Strengths/Limitations: One limitation of the study is that retrospective medical record reviews can miss adverse events, delayed diagnoses, and patient-reported adverse events. In addition, the study did not consider outpatient safety associated with telemedicine.
Generalizability to the Medicare Population: Moderate; this study was conducted in Massachusetts and findings may also not be generalizable beyond the population in the northeastern U.S.
Methods: This retrospective study used a random sample of patients from outpatient sites in Massachusetts in 2018. Adverse events were identified using the trigger method and medical record review.

Lewin Group. *CMS Bundled Payments for Care Improvement Advanced Model: Year 2 Evaluation Report*. March 2021. https://www.cms.gov/priorities/innovation/data-and-reports/2021/bpci-yr2-annual-report
Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Report

Objective: To report on program year 2 of the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model.
Main Findings: The number of participating providers increased over the model's first three years, in part due to increased participation among rural and safety net hospitals. Participants reported joining the model to understand how to drive care transformation, strengthen partnerships between hospitals and physicians, achieve financial success, and build on prior experiences in other initiatives and value-based payment programs. Relative to the comparison group, participating hospitals reduced total allowed episode payments in seven of 13 clinical episodes within the first 10 months. There was no evidence that the model impacted quality of care; however, mortality decreased for three clinical episodes. The model resulted in a net loss of $158.6 million to Medicare during the first 10 months.
Strengths/Limitations: The impact estimates included only 13 clinical episodes due to insufficient sample sizes for other clinical episodes and challenges with creating sufficient comparison groups.
Generalizability to the Medicare Population: Strong; this report is an evaluation of a model that was developed by the Centers for Medicare & Medicaid Services.
Methods: A difference-in-difference design was used to estimate model impacts.

Lewin Group. *CMS Bundled Payments for Care Improvement Advanced Model. Fifth Annual Evaluation Report*. May 2024. https://www.cms.gov/priorities/innovation/data-and-reports/2024/bpci-adv-ar5

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Report
Objective: To report on results for the first year after changes were implemented in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model.
Main Findings: The number of participants decreased by 37 percent between model year 3 and model year 4. In model year 4, more than 25 percent of eligible U.S. clinicians triggered a BPCI Advanced episode. Care redesign activities transformed health care across culture, structure, process, and relationships. The model reduced total episode payments relative to the comparison group by $930 per episode. There was limited evidence showing model impacts on quality of care, patients' functional status, care experiences, and satisfaction with care. For the first time, the model resulted in net savings to the Medicare program ($464.7 million) in model year 4.
Strengths/Limitations: There were challenges with identifying sufficient counterfactuals for hospitals and physician group practices. The evaluation did not include 100 percent of BPCI Advanced model year 4 episodes. Additionally, the evaluation did not estimate the impact of all clinical episodes.
Generalizability to the Medicare Population: Strong; this report is an evaluation of a model that was developed by the Centers for Medicare & Medicaid Services.
Methods: A difference-in-difference design was used to estimate model impacts.

Lin MY, Zhang Z, Carey K, Gidwani R, Hanchate AD. Merit-Based Incentive Payment System: longitudinal performance and uneven rewards for safety-net providers over 5 years. *Health Aff Sch*. 2025;3(6):qxaf105. doi:10.1093/haschl/qxaf105

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To evaluate the performance, payment adjustments, and adjustment rates of clinicians who participated in the Medicare Merit-based Incentive Payment System (MIPS) program with a focus on differences between safety net providers (SNPs) and non-SNPs.

Main Findings: Results showed uneven rewards between SNPs and non-SNPs. Relative to non-SNPs, SNPs were more likely to receive positive payment adjustments and higher adjustment rates. However, due to MIPS' percentage-based adjustment structure, SNPs were not more likely to have higher cumulative financial rewards relative to non-SNPs. MIPS financial incentives were relatively low.
Strengths/Limitations: One limitation is that results may not be generalizable to clinicians who entered and exited the MIPS program, as the study sample was comprised of clinicians who continuously participated in the MIPS program. Given the study design, causality cannot be inferred between safety-net status and performance in the MIPS program.
Generalizability to the Medicare Population: Strong; this article was focused on a program established by the Centers for Medicare & Medicaid Services.
Methods: The analysis included five years of longitudinal data (2018-2022). Clinicians' performance was evaluated using three metrics: whether clinicians received a positive payment adjustment annually; the five-year average of payment adjustment rates; and the total amount of clinicians' payment adjustments over the five-year period.

Lipitz-Snyderman A, Pfister D, Classen D, Atoria CL, Killen A, Epstein AS, et al. Preventable and mitigable adverse events in cancer care: measuring risk and harm across the continuum. *Cancer*. 2017;123(23):4728-36. https://doi.org/10.1002/cncr.30916

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To assess adverse events among patients with cancer in inpatient and outpatient settings.
Main Findings: Three hundred and four adverse events were identified, translating to a rate of 2.3 events per 1,000 patient days. The rate of adverse events was higher in inpatient settings (91.2 per 1,000 inpatient days) compared with outpatient settings (0.9 per 1,000 outpatient days). Over one-third (34 percent) of patients experienced one or more adverse events. The rate of adverse events was lower among patients with breast cancer relative to patients with colorectal and lung cancer.
Strengths/Limitations: One limitation of the study is that the number of adverse events may be underestimated as medical records are often incomplete. Additionally, physicians' assessments of the preventability of adverse events were subjective in nature.
Generalizability to the Medicare Population: Moderate; although the study included only patients with cancer from one institution, results may be applicable to the Medicare population.
Methods: This retrospective cohort study included 400 adult patients with breast, colorectal, or lung cancer. Patients were followed for one year. Medical records and safety reporting databases were reviewed to identify adverse events.

Meslamani AZA. Underreporting of adverse drug events: a look into the extent, causes, and potential solutions. *Expert Opinion on Drug Safety*. 2023;22(5):351-354. doi:10.1080/14740338.2023.2224558

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To assess the current state of underreporting adverse drug events globally.
Main Findings: Adverse drug events are often unreported. There are multiple provider-level causes of underreporting adverse drug events, including fear-based factors (e.g., fear of punishment for reporting errors); knowledge-based factors (e.g., lack of training on reporting events); system-based factors (e.g., lack of standardized reporting criteria); and organizational-

based factors (e.g., lack of resources to support reporting). At the patient-level, personal-based factors (e.g., fear of being labeled as a difficult patient); information-based factors (e.g., lack of understanding the reporting process); and system-based factors (e.g., limited access to reporting mechanisms) can lead to underreporting adverse drug events.
Strengths/Limitations: N/A
Generalizability to the Medicare Population: Moderate; although this commentary did not focus specifically on underreporting of adverse drugs events in the U.S., the commentary may still be applicable to the Medicare population.
Methods: This article was a commentary that summarized previously published literature.

Munford LA, Armitage CJ, Webb RT, Ashcroft DM. Economic case for reducing inequities in patient safety. *BMJ Open Quality*. 2025;14(1). doi:10.1136/bmjoq-2024-003042
Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To describe the economic case for reducing inequities in patient safety globally.
Main Findings: There are inequities in the risk of adverse events by socioeconomic status, ethnicity, gender, language proficiency, and geography. Higher risk of experiencing adverse events among disadvantaged groups may lead to greater direct health care costs and indirect (non-medical) costs from adverse events. Reducing differences in patient safety inequities may improve health outcomes, increase workforce productivity, and improve public trust in the health care system. To address inequities in patient safety, there are opportunities to improve data collection and analysis, implement targeted interventions that reduce inequities, and encourage policy and system-level changes.
Strengths/Limitations: N/A
Generalizability to the Medicare Population: Moderate; although the commentary did not focus specifically on inequities in patient safety in the U.S., the commentary may still be applicable to the Medicare population.
Methods: This article was a commentary that summarized previously published literature.

Mushtaq A, Sarwar H, Ernest M, Javed R, Javed S. Assessing the prevalence and contributing factors of medication error in hospital setting. *Journal of Health, Wellness and Community Research*. 2025;3(8):e392. https://doi.org/10.61919/sddj0225
Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To estimate the prevalence and identify contributing factors of medication-related errors among nursing students and interns in hospitals.
Main Findings: Three quarters of participants reported medication errors. Excessive workloads, staff shortages, and fatigue were reported as the main factors that contributed to the medication errors. Fewer than one in five participants (18 percent) reported having confidence in reporting errors.
Strengths/Limitations: One limitation is that this study was conducted at a single hospital, limiting the generalizability of the findings to other settings. In addition, participants may have under or overestimated their experiences with medication errors.
Generalizability to the Medicare Population: Moderate; this study was conducted in Pakistan, and findings may not be generalizable to the Medicare population.
Methods: This cross-sectional observational study included 50 randomly selected nursing students and interns at a single hospital in Pakistan. Participants reported their perceptions of challenges associated with medication errors and error reporting.

Naessens JM, Campbell CR, Shah N, Berg B, Lefante JJ, Williams AR, et al. Effect of illness severity and comorbidity on patient safety and adverse events. *Am J Med Qual*. 2012;27(1):48-57. doi:10.1177/1062860611413456

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To assess the influence of patients' health status at hospital admission on the likelihood of adverse events, incremental costs associated with adverse events, and length of stay.
Main Findings: Patients' severity at admission increased the likelihood of experiencing adverse events, incremental costs, and length of stay. Results indicated that adverse event reporting could benefit from incorporating comorbidity and health status at admission. Additionally, reimbursement incentives to improve patient safety could consider adjusting for health status at admission.
Strengths/Limitations: This study was conducted within a single community, potentially limiting the generalizability of results to other communities. Because the study estimated only hospital costs and did not consider patient costs, physician services costs, or post-discharge costs, estimates of incremental costs associated with adverse events may be underestimated.
Generalizability to the Medicare Population: Strong; the study utilized Medicare cost reports to categorize patients' hospital bills.
Methods: This retrospective cross-sectional study used generalized linear models to estimate the association between severity at admission and adverse events. Adverse events were identified using Patient Safety Indicators.

Nijor S, Rallis G, Lad N, Gokcen E. Patient safety issues from information overload in electronic medical records. *J Patient Saf*. 2022;18(6):e999-e1003. doi:10.1097/PTS.0000000000001002

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To assess how information overload related to the use of electronic health records (EHRs) may impact patient safety.
Main Findings: EHRs may contribute to information overload by including excessive amounts of clinically irrelevant information, poorly displaying data, and continuously alerting clinicians. Information overload from the use of EHRs was associated with increased physician cognitive load and error rates in clinical simulations.
Strengths/Limitations: Given the study design was a literature review of 28 articles, the study may be limited by potential author bias and omissions of relevant research in the included articles.
Generalizability to the Medicare Population: Strong; this study considered literature on Medicare payment policies.
Methods: A literature review was conducted. Twenty-eight eligible articles were identified.

Organisation for Economic Co-operation and Development. Measuring patient safety: opening the black box. April 30, 2018. https://doi.org/10.1787/4a764a70-en

Subtopic: Measurement of Patient Safety
Type of Source: Report
Objective: To examine how patient safety is measured and identify ways to improve how safety data is collected and used.

Main Findings: The report explains that many patient safety problems are not fully captured by current measurement systems, making it difficult to understand the true extent of harm in health care. The report highlights gaps in how safety data are collected, especially across different settings and countries. To improve safety, the authors stress the need for better data systems, stronger reporting practices, and more consistent measures. Overall, the report suggests that improving how patient safety is measured is key to identifying problems and making meaningful improvements.
Strengths/Limitations: A strength of the study is its broad, system-level view of patient safety measurement across countries.
Generalizability to the Medicare Population: Strong; improving how patient safety is measured is relevant to the Medicare population.
Methods: This policy report was based on an analysis of existing data systems, international comparisons, and review of current approaches to measuring patient safety.

Panagioti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *BMJ*. 2019;366:l4185. http://dx.doi.org/10.1136/bmj.l4185
Subtopic: Key Highlights; Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess the global prevalence of preventable patient harm.
Main Findings: The pooled prevalence of preventable patient harm is 6 percent, translating to approximately one in 20 patients and accounting for approximately 50 percent of total patient harm. Twelve percent of preventable harm was considered severe or resulted in death. The highest prevalence of preventable harm occurred in intensive care units and surgical units. Approximately 25 percent of preventable harm was drug related.
Strengths/Limitations: One limitation is that the prevalence of preventable harm varied across studies included in the analysis. Studies were excluded from the analysis if they did not report data on preventable patient harm.
Generalizability to the Medicare Population: Moderate; although this study estimated the global prevalence of patient harm, results may be applicable to the Medicare population.
Methods: A systematic review and meta-analysis included 66 observational studies reporting 70 independent samples across multiple countries. Multiple health care settings were included in the study, including general hospitals and obstetrics, primary care, emergency departments, and advanced hospital specialties (intensive care unit, surgery).

Panagos PG, Pearlman SA. Creating a highly reliable neonatal intensive care unit through safer systems of care. *Clinics in Perinatology*. 2017;44(3):645-62. https://doi.org/10.1016/j.clp.2017.05.006
Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To describe how neonatal intensive care units (NICUs) can improve patient safety by using safer systems and more consistent care practices.
Main Findings: The article explained that improving safety in NICUs depends on having clear systems and strong teamwork. Strategies such as using checklists, improving how staff communicate, and encouraging people to speak up about mistakes can help prevent errors. The authors also emphasized that leadership support and regular training are important to keep safety practices in place. Overall, the authors suggested that using approaches from other high-risk fields can help reduce harm and improve care for newborns.

Strengths/Limitations: One limitation is that the study did not include a quantitative evaluation of the outcomes.
Generalizability to the Medicare Population: Moderate; although the study is focused on neonatal care, the safety strategies can be applied to settings serving Medicare beneficiaries.
Methods: This descriptive article was based on existing research and safety frameworks.

Pavuluri SK, Sangal RB, Venkatesh AK, van Tonder R, Sather J. SENTRY—A systems-based model for quality and safety surveillance with continuous quality improvement in emergency care. *NEJM Catalyst Innovations in Care Delivery*. 2026;7(6):CAT-25. doi:10.1056/CAT.25.0231

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To describe a new patient safety surveillance model used in emergency departments (EDs), called Safety Evaluation and Networked Tracking for Real-Time Yield (SENTRY).
Main Findings: SENTRY is a new surveillance model that supports patient safety. The model operates in real-time to promote early detection of safety risks and timely intervention. To detect safety risks, the model collects safety signals from multiple sources (e.g., incident reports, performance metrics, patient feedback). Safety events are evaluated by experts using a rubric to determine the severity of the safety events and their contributing factors. Safety events determined to be serious often undergo a root-cause analysis. Safety events are stored in a centralized repository that serves as a living surveillance system to support the identification of recurring problems over time and real-time learning.
Strengths/Limitations: One limitation of the model is its potential to contribute to alert fatigue among providers. In addition, implementing the model requires resources that may not be available in all settings, particularly smaller EDs and non-academic EDs.
Generalizability to the Medicare Population: Moderate; the model is embedded in Yale New Haven's EDs and may have limited generalizability to the Medicare population.
Methods: N/A

Poghosyan L, Norful AA, Fleck E, Bruzzese JM, Talsma A, Nannini A. Primary care providers' perspectives on errors of omission. *The Journal of the American Board of Family Medicine*. 2017;30(6):733-42. https://doi.org/10.3122/jabfm.2017.06.170161

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To understand how primary care providers view errors of omission—missed or incomplete care—and what factors contribute to these errors.
Main Findings: The study found that errors of omission are common in primary care and often happen when needed care is delayed, not completed, or overlooked. Providers identified several reasons for these errors, including heavy workloads, time constraints, poor communication, and gaps in follow-up systems. The findings suggest that missed care is often caused by system-level issues rather than individual mistakes. Strengthening communication, improving care coordination, and using better tracking systems may help reduce these types of errors.
Strengths/Limitations: A strength is that the study captured real-world perspectives from primary care providers about why missed care occurs.
Generalizability to the Medicare Population: Strong; the findings are relevant to Medicare patients due to their complex care needs and use of primary care.
Methods: This qualitative study conducted 26 interviews with primary care providers to identify themes related to causes of errors of omission.

Pozzobon LD, Rotter T, Sears K. The benefits and opportunities: engaging patients in identifying and reporting patient safety incidents. *Healthcare Management Forum*. 2024:37(4):196-201. doi:10.1177/08404704231203593

Subtopic: Measurement of Patient Safety
Type of Source: Journal Article
Objective: To examine how involving patients in identifying and reporting safety issues can improve patient safety.
Main Findings: The article emphasizes that patients can play an important role in identifying safety problems due to their firsthand experience. When patients are encouraged to speak up, they can help identify communication problems, delays, or mistakes that may not be caught by health care staff. The authors highlight that patient reporting can improve awareness of safety concerns and support better care. However, patients need clear ways to report issues and must feel comfortable doing so. Overall, engaging patients is presented as a useful way to strengthen existing safety systems.
Strengths/Limitations: A strength of the study is its focus on patient involvement as a practical and underutilized way to improve safety. A limitation of the study is that success depends on whether patients feel willing and able to report concerns.
Generalizability to the Medicare Population: Strong; engaging patients in safety is relevant for the Medicare population, who often has complex health needs.
Methods: This narrative review summarized existing research and provided examples of patient engagement in reporting safety incidents.

Quon S, Low S, Zhou S, Zheng K. Patient and family-initiated safety event reporting: a scoping review. *Patient Safety*. 2026;8(2). doi:10.33940/001c.156234

Subtopic: Measurement of Patient Safety
Type of Source: Journal Article
Objective: To examine how patients and families report safety concerns and the role these reports play in improving patient safety.
Main Findings: The review found that patients and families can identify a wide range of safety issues, including communication problems, delays in care, and mistakes that may not be captured by traditional reporting systems. The study also found that these reporting systems are not always widely used, and patients may face barriers such as lack of awareness, discomfort speaking up, or unclear reporting processes. Overall, the findings suggest that patient and family reporting can improve detection of safety issues, but systems need better support and need to encourage participation.
Strengths/Limitations: A strength of the study is its broad overview of different approaches to patient and family reporting in multiple settings. A limitation is that the studies are very different and often small or short-term, making it difficult to compare results or understand long-term impact.
Generalizability to the Medicare Population: Strong; patient and family involvement is relevant to the Medicare population.
Methods: This scoping review of published literature examined systems where patients and families report safety events.

Radley DC, Wasserman MR, Olsho LE, Shoemaker SJ, Spranca MD, Bradshaw B. Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. *Journal of the*

American Medical Informatics Association. 2013;20(3):470-6. https://doi.org/10.1136/amiajnl-2012-001241

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To assess whether the use of computerized provider order entry (CPOE) systems reduces medication errors in hospitals.
Main Findings: The study found that hospitals using CPOE systems had fewer medication errors compared to those who had not adopted these systems. The biggest improvements were observed in prescribing errors, such as incorrect doses or incomplete orders. The findings suggest that CPOE systems help standardize ordering processes and reduce mistakes caused by handwriting or manual entry. However, some types of errors were not completely eliminated, showing that technology alone cannot prevent all safety issues.
Strengths/Limitations: A strength of the study is its use of data from multiple hospitals, which strengthens the reliability of the findings.
Generalizability to the Medicare Population: Strong; medication safety in hospitals is relevant to Medicare patients.
Methods: This systemic literature review and applied random-effects meta-analysis compared medication errors that occurred in hospitals with and without CPOE systems. The authors also used national hospital survey data to estimate the extent to which these systems reduced errors.

Reynolds CS, Cunningham JL, Ng YC, Dean CL. Using a checklist to decrease central line infections in the intensive care unit. *Crit Care Nurs Q*. 2025;48(4):337-344. doi:10.1097/CNQ.0000000000000568

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To determine whether using a checklist reduces central line infections in an intensive care unit (ICU).
Main Findings: The study found that using a checklist helped reduce central line infections in the ICU. The checklist confirmed that staff followed key safety steps, such as proper hand hygiene and sterile technique when inserting and caring for central lines. It also helped improve consistency and communication among the care team. Overall, the checklist supported safer practices and led to better patient outcomes by lowering the risk of infection.
Strengths/Limitations: One limitation of the study is that it is likely based on a single setting or unit, which may limit how well the results apply to other hospitals.
Generalizability to the Medicare Population: Strong; preventing infections in hospital settings is relevant to Medicare patients.
Methods: The quality improvement study compared infection rates before and after the checklist was introduced.

Rivera AJ, Karsh BT. Human factors and systems engineering approach to patient safety for radiotherapy. *International Journal of Radiation Oncology, Biology, Physics*. 2008;71(1):S174-7. doi:10.1016/j.ijrobp.2007.06.088

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To provide a deeper understanding of human factors and systems engineering, and what it means to apply its principles to patient safety.
Main Findings: The principles and methods of systems and human factors engineering can be utilized to increase quality of patient care and the efficiency of the health care system. The

Systems Engineering Initiative for Patient Safety Model (SEIPS), Human Factors Paradigm for Patient Safety, and work system analyses can help design safer and more efficient systems.
Strengths/Limitations: N/A
Generalizability to the Medicare Population: Moderate; this article examined the role of human factors and systems engineering in improving patient safety, a topic applicable to improving patient safety for the Medicare population.
Methods: N/A

Rodrick D, Phojanakong P, Timashenka A, Umscheid CA. Adverse events among Medicare hospitalizations in 2021–2023. AHRQ Publication No. 25-0067. Rockville, MD: Agency for Healthcare Research and Quality. September 2025.

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Report
Objective: To analyze adverse events (AEs) among Medicare hospitalizations from 2021 to 2023 and better understand patient safety using the Quality and Safety Review System (QSRS).
Main Findings: The percentage of Medicare patients experiencing at least one AE per hospital stay and the rate of AEs per 1,000 discharges for 2022 and 2023 are lower than in the year prior. The majority of AEs in the sample were caused by pressure injury/ulcers, medication events, and hospital-acquired infections.
Strengths/Limitations: The findings may not represent the entire population of patients hospitalized in the U.S from 2021-2023 as only Medicare beneficiaries with Part A coverage are included in the database. The occurrence of AEs may differ among patients with other insurance types.
Generalizability to the Medicare Population: Strong; the sample was composed entirely of Medicare beneficiaries with Part A coverage, which included approximately 99 percent of all Medicare beneficiaries.
Methods: The QSRS sample represents Medicare beneficiaries ages 18 and older with hospital stays less than 120 days in acute care hospitals from 2021 through 2023.

Sauro KM, Machan M, Whalen-Browne L, Owen V, Wu G, Stelfox HT. Evolving factors in hospital safety: a systematic review and meta-analysis of hospital adverse events. *Journal of Patient Safety*. 2021;17(8):e1285-95. doi:10.1097/PTS.0000000000000889

Subtopic: Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events
Type of Source: Journal Article
Objective: To assess the frequency of hospital adverse events, including change in the frequency over time.
Main Findings: There were 8.6 controllable and noncontrollable hospital adverse events per 100 hospital admissions, translating to approximately 1 adverse event in 12 admissions. Approximately 40 percent of the controllable and noncontrollable adverse events resulted in moderate or significant harm. Among all adverse events, obstetric adverse events affecting the mother were the most common adverse events (7.5 per 100 patient admissions), followed by drug-related adverse events (4.1 per 100 patient admissions). More than half (53 percent) of the adverse events were preventable. The occurrence of controllable and noncontrollable adverse events increased over time.
Strengths/Limitations: One limitation of the study is the heterogeneity in the studies included in the analysis.

Generalizability to the Medicare Population: Moderate; this meta-analysis included studies from 25 different countries and therefore may not be generalizable to the Medicare population.
Methods: This systematic review and meta-analysis included 94 hospital-based studies conducted between 1961 and 2014 from 25 countries.

Seibert HH, Maddox RR, Flynn EA, Williams CK. Effect of barcode technology with electronic medication administration record on medication accuracy rates. *American Journal of Health-System Pharmacy*. 2014;71(3):209-18. doi:10.2146/ajhp130332

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To evaluate the effect of barcode-assisted medication administration (BCMA) with electronic medication administration record (eMAR) technology on the occurrence of medication administration errors.
Main Findings: Implementation of BCMA-eMAR led to significant increases in medication accuracy rates in most units and reduced preventable errors.
Strengths/Limitations: Some medication administration errors cannot be prevented by BCM-eMAR, such as prescribing errors, wrong routes, and intravenous (IV) pump programming.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in this article, findings may be applicable to the Medicare population.
Methods: A pretest-posttest nonequivalent comparison group design was used at two community-based hospitals. Medication administration accuracy rates were observed and recorded before phase 1, approximately six months after phase 2, and 12 months after phase 3.

Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC Health Serv Res*. 2006;6(44). https://doi.org/10.1186/1472-6963-6-44

Subtopic: Measurement of Patient Safety
Type of Source: Journal Article
Objective: To assess health care providers' attitudes about patient safety issues using the Safety Attitudes Questionnaire, report the psychometric properties of the survey, establish benchmarking data, and discuss emerging areas of research.
Main Findings: The Safety Attitudes Questionnaire demonstrated good psychometric properties. Teamwork Climate, Safety Climate, Perceptions of Management, Job Satisfaction, Working Conditions, and Stress Recognition were six factors used to assess provider attitude. Provider attitudes varied substantially both within and among organizations.
Strengths/Limitations: One limitation is that factors could not be assessed across countries, job categories of respondents, or other stratification variables due to the limited scope of the study.
Generalizability to the Medicare Population: Weak; Medicare populations were not explicitly considered in the article, and the sample included providers in the United Kingdom and New Zealand in addition to the U.S.
Methods: Six cross-sectional surveys of health care providers were conducted in 203 clinical areas across three countries. A multilevel factor analysis was conducted at the clinical area level. The total sample size was 10,843.

Shah K, Lo C, Babich M, Tsao NW, Bansback NJ. Bar code medication administration technology: a systematic review of impact on patient safety when used with computerized prescriber order entry and automated dispensing devices. *The Canadian Journal of Hospital Pharmacy*. 2016;69(5):394-402. doi:10.4212/cjhp.v69i5.1594

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To analyze the impact of bar code medication administration (BCMA) technology on patient safety when used with computerized prescriber order entry and automated dispensing devices.
Main Findings: BCMA technology can improve patient safety by reducing medication errors, transcription errors, and non-timing administration errors. Human factors and technical issues prevent complete elimination of errors.
Strengths/Limitations: Additional longitudinal studies are needed to assess the impact on life-threatening errors and associated economic outcomes.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, findings may be applicable to the Medicare population.
Methods: A systematic review of relevant studies from 1992 through 2015 was conducted.

Shen JJ, Cochran CR, Mazurenko O, Moseley CB, Shan G, Mukalian R, Neishi S. Racial and insurance status disparities in Patient Safety Indicators among hospitalized patients. *Ethn Dis*. 2016;26(3):443-52. doi:10.18865/ed.26.3.443

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To analyze how patient race, ethnicity, and insurance status impacted Patient Safety Indicators (PSIs) among hospitalized patients.
Main Findings: Race, ethnicity, and insurance status independently and interactively contributed to disparities in patient safety.
Strengths/Limitations: The report was unable to rule out race-based physiological differences that might be underlying some of the PSI differences by race. Additional race-specific comorbidities for PSIs may be needed.
Generalizability to the Medicare Population: Moderate; Medicare beneficiaries were included in the sample, comprising 54 percent of the analyzed hospital discharges.
Methods: A cross-sectional analysis of the 2009 National Inpatient Sample (NIS) was conducted.

Shreve J, Van Den Bos J, Gray T, Halford M, Rustagi K, Ziemkiewicz E. The economic measurement of medical errors. Milliman. 2010.
https://www.soa.org/globalassets/assets/Files/Research/Projects/research-econ-measurement.pdf

Subtopic: Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Journal Article
Objective: To estimate the direct and indirect costs of medical errors in the U.S.
Main Findings: Controllable and noncontrollable medical errors cost the U.S. $19.5 billion in 2008. Of this total cost, $17 billion (87 percent) represented excess direct medical costs from providing inpatient, outpatient, and prescription drug services to patients impacted by errors. The estimated average direct cost per medical error was $13,000. Controllable and noncontrollable medical errors cost $1.4 billion in indirect costs due to increased mortality rates and $1.1 billion in indirect costs due to lost productivity from short-term disability.
Strengths/Limitations: One limitation of the study is that not all costs associated with medical errors can be identified using medical claims data. For example, pain is not measurable using claims data.

Generalizability to the Medicare Population: Moderate; this national study included claims data for commercially insured and Medicare-eligible retirees and may be generalizable to the Medicare population.
Methods: This study used a claims-based actuarial analysis focused on 2008 data. The study included a national insured population, including commercially insured individuals and Medicare-eligible retirees. Both inpatient and outpatient health care settings were included.

Sittig DF, Ash JS, Singh H. The SAFER guides: empowering organizations to improve the safety and effectiveness of electronic health records. *Am J Manag Care*. 2014;20(5):418-23.

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To define how the Safety Assurance Factors for EHR Resilience (SAFER) guides could be used to self-assess safety and effectiveness of electronic health record (EHR) implementation, identify specific areas of vulnerability, and create solutions and culture change to mitigate risks.
Main Findings: SAFER guides empower organizations to address EHR-related safety issues and foster meaningful conversations about optimizing EHR functionality.
Strengths/Limitations: N/A
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, this topic is relevant to the Medicare population.
Methods: N/A

Slawomirski L, Klazinga N. The economics of patient safety: from analysis to action. OECD Health Working Papers No. 145. August 12, 2022. https://dx.doi.org/10.1787/761f2da8-en

Subtopic: Key Highlights; Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Report
Objective: To estimate the direct and indirect costs of patient harm.
Main Findings: The direct cost of all controllable and noncontrollable harm is $878 billion per year across Organisation for Economic Co-operation and Development (OECD) countries. The direct cost of avoidable harm was $606 billion per year (nearly 9 percent of total health expenditure) across OECD countries. The social cost of harm is estimated to be $1-2 trillion per year. Eliminating patient harm could boost global economic growth by nearly 1 percent per year, potentially translating to $118 trillion between 2000 and 2020.
Strengths/Limitations: One strength of the study is its use of multiple approaches to estimate the indirect cost of patient harm.
Generalizability to the Medicare Population: Moderate; this study estimated the direct and indirect costs of patient harm in OECD countries and may be generalizable to the Medicare population.
Methods: This study reviewed international literature on patient harm. Indirect costs were estimated using human capital and willingness-to-pay approaches. Health care settings included in the analysis were acute/inpatient care, primary and ambulatory care, and long-term care. The study focused on infections, medication errors, venous thromboembolism, diagnostic error, falls, and pressure injuries.

Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, Koroukian SM. Adherence to surgical care improvement project measures and the association with postoperative infections. *JAMA*. 2010;303(24):2479-2485. doi:10.1001/jama.2010.841

Subtopic: Value-Based Care Efforts to Promote Patient Safety
Type of Source: Journal Article
Objective: To examine the relationship between the Surgical Care Improvement Project (SCIP) infection-prevention process of care measures and postoperative infection rates.
Main Findings: Adherence measured using a global all-or-none composite infection prevention score was associated with a lower probability of developing a post-operative infection while adherence reported on individual SCIP measures was not.
Strengths/Limitations: The rates of adherence to quality measures in the study may not be reflective of the rest of the country.
Generalizability to the Medicare Population: Strong; nearly half (46 percent) of the study participants were Medicare patients.
Methods: A retrospective cohort study was conducted using Premier Inc's Perspective Database for discharges between July 1, 2006, and March 31, 2008 from 398 hospitals across the U.S.

Subbe C, Hughes DA, Lewis S, Holmes EA, Kalkman C, So R, et al. Value of improving patient safety: health economic considerations for rapid response systems–a rapid review of the literature and expert round table. *BMJ Open*. 2023;13:e065819. http://dx.doi.org/10.1136/bmjopen-2022-065819

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To explore the impact of safer care on health economic considerations for clinicians, providers, and policymakers.
Main Findings: Care needs beyond the hospital, income of patients, and sickness of health care staff exposed to serious adverse events should be included when analyzing heath economic impact, but literature and existing studies are limited.
Strengths/Limitations: The existing literature related to the topic is limited.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, findings may be applicable to the Medicare population.
Methods: A literature review and expert round table was conducted.

Tanner C, Gans D, White J, Nath R, Pohl J. Electronic health records and patient safety: co-occurrence of early EHR implementation with patient safety practices in primary care settings. *Appl Clin Inform*. 2015;6(1):136-47. doi:10.4338/ACI-2014-11-RA-0099

Subtopic: Mitigation Factors for Patient Safety Errors
Type of Source: Journal Article
Objective: To analyze early adopters of electronic health records (EHRs) in primary care to understand how early adopters promote patient safety.
Main Findings: EHR-based practices consistently outperformed paper-based practices across all domains of patient safety.
Strengths/Limitations: The scope of this article may be limited as the study only considered early adopters of EHR.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, findings may be applicable to the Medicare population.
Methods: The Physician Practice Patient Safety Assessment (PPPSA) was used to compare primary care practices with fully implemented EHRs to those utilizing paper records.

Tedesco D, Moghavem N, Weng Y, Fantini MP, Hernandez-Boussard T. Improvement in patient safety may precede policy changes: trends in patient safety indicators in the United States, 2000-2013. *J Patient Saf*. 2021;17(4):e327-e334. doi:10.1097/PTS.0000000000000615

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To examine the relationship between improvement in patient safety and policy changes in the U.S. between 2000 to 2013.
Main Findings: Patient safety in U.S. hospitals has improved significantly since 2000, though improvements in safety indicators often precede policy changes.
Strengths/Limitations: One limitation is that the study does not establish causality between policy changes and safety improvement.
Generalizability to the Medicare Population: Strong; many of the Patient Safety Indicators (PSIs) studied in the article are directly linked to Medicare payment policies, and CMS payment reforms were analyzed.
Methods: A retrospective longitudinal analysis was conducted using a national inpatient sample from the Agency for Healthcare Research and Quality (AHRQ). PSI trends were analyzed along with policy changes.

Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ*. 2000;320(7237):741-4.

Subtopic: Background on Patient Safety
Type of Source: Journal Article
Objective: To determine the incidence and types of preventable adverse events in older adult patients.
Main Findings: Preventable adverse events were more common among older adult patients. Preventable adverse drug events, events related to medical procedures, and falls were particularly common in older adult patients and should be targets for intervention to prevent errors.
Strengths/Limitations: One limitation is that the study did not directly measure and adjust for variables that may have influenced the rate of preventable adverse events in older adult patients.
Generalizability to the Medicare Population: Strong; payment methods, including Medicare, for hospitalized patients were used to analyze differences in preventable adverse events.
Methods: A review of a random sample of medical records was conducted by nurses and physicians to detect adverse events.

Topaz M, Peltonen LM, Zhang Z. Beyond human ears: navigating the uncharted risks of AI scribes in clinical practice. *NPJ Digit Med*. 2025;8(1):569. doi:10.1038/s41746-025-01895-6

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To define the potential risks artificial intelligence (AI) scribes pose in clinical practice.
Main Findings: AI scribes have the potential to significantly reduce clinician burnout, however implementing AI scribes without comprehensive validation can lead to risks in patient safety and clinical integrity. Regulations and vigorous validation are needed to responsibly and effectively implement AI scribes.
Strengths/Limitations: One limitation is that no datasets were analyzed for the article.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, findings may be applicable to the Medicare population.
Methods: Existing literature on AI scribes was reviewed and analyzed.

Van Den Bos J, Rustagi K, Gray T, Halford M, Ziemkiewicz E, Shreve J. The $17.1 billion problem: the annual cost of measurable medical errors. *Health Aff (Millwood)*. 2011;30(4):596-603. doi:10.1377/hlthaff.2011.0084

Subtopic: Key Highlights; Background on Patient Safety; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Journal Article
Objective: To estimate the frequency and direct cost of controllable medical errors in the U.S.
Main Findings: The annual cost of controllable medical errors that harmed patients was $17.1 billion in 2008. Ten types of controllable errors accounted for more than two-thirds of the total cost of errors. Pressure ulcers were the most common errors, costing nearly $3.3 billion, and postoperative infections were the second most common errors, costing over $3.3 billion.
Strengths/Limitations: One limitation is that the study relied on claims data to identify medical injuries. However, claims data cannot be used to identify certain medical errors, such as wrong diagnoses or errors of omission.
Generalizability to the Medicare Population: Moderate; the sample included commercially insured and retiree patients and findings may be applicable to the Medicare population.
Methods: The authors used an actuarial approach to assess the frequency and costs of medical errors in the U.S. Medical errors were identified using medical claims data from 2000 to 2008. The nationwide sample included commercially insured and retiree patients in inpatient and outpatient settings.

Wiegmann DA, Wood LJ, Cohen TN, Shappell SA. Understanding the "Swiss Cheese Model" and its application to patient safety. *J Patient Saf*. 2022;18(2):119-123. doi:10.1097/PTS.0000000000000810

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To describe the theory behind James Reason's Swiss cheese model.
Main Findings: The Swiss cheese model can be used to understand human error and why patient safety errors occur. The model indicates that harmful events typically result from a combination of failures throughout a system. The model separates failures into those that happen during patient care and those that exist within the system itself, such as organizational or supervisory issues that go unnoticed. These weaknesses in a system can change and interact in complex ways. When the weaknesses align, patient harm can occur. The article emphasizes that improving patient safety requires going beyond addressing immediate errors by also identifying and addressing deeper system-level issues that create conditions for those errors.
Strengths/Limitations: One strength of the article is the background information provided to explain and clarify the underlying theory behind the Swiss cheese model.
Generalizability to the Medicare Population: Moderate; the Swiss cheese model can be applied to many different populations to understand why patient safety errors occur.
Methods: This narrative review provided an overview of the theory behind the Swiss cheese model, the Theory of Active and Latent Failures.

Wong A, Otles E, Donnelly JP, et al. External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. *JAMA Intern Med*. 2021;181(8):1065-1070. doi:10.1001/jamainternmed.2021.2626

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To externally validate the Epic Sepsis Model (ESM) and evaluate its potential clinical value.

Main Findings: The ESM has poor discrimination and calibration in predicting the onset of sepsis, raising concerns about sepsis management on a national level.
Strengths/Limitations: Though the cohort included in the study was large and diverse, the study included a single center which could limit generalizability.
Generalizability to the Medicare Population: Moderate; the study population overlapped with Medicare beneficiaries in terms of age and comorbidities.
Methods: This retrospective cohort study was conducted at the University of Michigan.

World Health Organization. Global patient safety report 2024. Geneva: World Health Organization; 2024. https://www.who.int/publications/i/item/9789240095458

Subtopic: Key Highlights; Background on Patient Safety; Appendix C. Global, National, Regional, and State Prevalence Rates of Adverse Events; Appendix D. Direct and Indirect Costs of Patient Safety Errors
Type of Source: Report
Objective: To report on the current state of patient safety globally, including the burden of harm, economic burden of unsafe care, and strategic objectives to improve patient safety.
Main Findings: More than 1 in 10 patients experience controllable and noncontrollable harm across medical settings. Half of patient harm is preventable. Approximately 1 in 20 patients experience preventable medication-related harm globally. Preventable harm is more prevalent in specialized care settings, such as intensive care units, emergency departments, and surgical units, compared with general hospital and primary care settings. Over 3 million people die each year from unsafe care. While some studies place the direct costs of patient harm in acute care at 2 percent of total health expenditures, other studies place the aggregate burden of hospital harm between 6 to 12 percent of total health expenditures. Indirect costs of patient harm exceed direct costs. The global societal indirect cost of patient harm is $1.17 trillion per year. Indirect costs are largely driven by lost productivity, costing $1.9 billion.
Strengths/Limitations: One strength of the report is its comprehensive coverage of patient safety across different geographies, demographics, and health care settings.
Generalizability to the Medicare Population: Weak; this report focused on patient safety globally and may not be generalizable to the Medicare population.
Methods: A patient safety survey was completed by 108 Member States between 2022 to 2023, covering approximately 84 percent of the global population. The report includes a synthesis of the evidence in published literature, including systematic reviews and meta-analyses.

Yuan CT, Dy SM, Lai AY, Oberlander T, Hannum SM, Lasser EC, et al. Challenges and strategies for patient safety in primary care: a qualitative study. *American Journal of Medical Quality*. 2022;37(5):379-87. doi:10.1097/JMQ.0000000000000054

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To explore challenges and strategies for patient safety in primary care in Patient-Centered Medical Homes (PCMHs).
Main Findings: The most critical patient safety issues in primary care are communication failures, electronic health record (EHR) interoperability, medication adherence and reconciliation, and follow-through on screenings and diagnostic tests. Patients and clinicians generally agree on safety issues, but patients highlight trust and communication as most important.
Strengths/Limitations: One strength of the study is its comprehensive qualitative data collection. One limitation is that the study was only conducted across four states and therefore may have limited generalizability to other states.

Generalizability to the Medicare Population: Moderate; the study addressed patient safety challenges and strategies in primary care settings that are relevant to Medicare beneficiaries.
Methods: A multi-method qualitative study was conducted consisting of interviews, focus groups, and observations in Pennsylvania, Maryland, North Carolina, and Colorado. Data were collected across four safety domains: missed, delayed, or incorrect diagnoses; delays in treatment or preventive services; medication safety issues; and communication and coordination of care.

Zamani Z, Joy T, Abbey M. Exploring environmental design attributes impacting staff perceptions of safety in a complex hospital system: implications for healthcare design. *Journal of Hospital Management and Health Policy*. 2023;7. doi:10.21037/jhmhp-23-93

Subtopic: Causes of Patient Safety Errors
Type of Source: Journal Article
Objective: To investigate the relationship between the quality of the physical environment and staff perceptions of safety within a complex health care system.
Main Findings: Physical environment factors such as private rooms, sound-absorbing materials, and acoustical privacy are important for perceptions of safety. Positive distractions, spatial planning, team visibility, and ergonomic furniture can promote the development of health care spaces that meet regulatory standards and prioritize staff and patients' safety.
Strengths/Limitations: One strength of the study is its mixed methods approach and diverse participant pool.
Generalizability to the Medicare Population: Moderate; although the Medicare population was not explicitly considered in the article, findings may be applicable to the Medicare population.
Methods: A mixed-methods study consisting of an online survey with closed and open-ended questions was administered to a sample of 1,145 clinical and non-clinical staff. A regression analysis was conducted to understand how specific physical environment qualities correlate to safety perceptions.

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