SPECIAL REPORT

Top 10 Patient Safety Concerns 2024

ECRI

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Top 10 Patient Safety Concerns 2024

The healthcare industry is currently at a crossroads. Organizations are adapting clinician workflows to new technologies, steering through changes in care delivery settings, mitigating complex risks like staff burnout and workplace violence, and navigating an uncertain economic and global political climate. Despite these challenges, ensuring patient and workforce safety across the healthcare continuum must remain a top priority for all healthcare organizations.

This annual report from ECRI and the Institute for Safe Medication Practices (ISMP) presents the top 10 patient safety concerns currently confronting the healthcare industry. Drawing on ECRI and ISMP's evidence-based research, data, and expert insights, this report sheds light on issues that leaders should evaluate within their own institutions as potential opportunities to reduce preventable harm. Some of the concerns represent emerging risks, some are well known but still unresolved, but all of them pertain to areas where organizations can make meaningful change. The Top 10 Patient Safety Concerns 2024 is a guide for a systems approach to adopting proactive strategies and solutions to mitigate risks, improve healthcare outcomes, and ultimately, enhance the well-being of patients and the healthcare workforce.

The List for 2024

1. Challenges Transitioning Newly Trained Clinicians from Education into Practice
2. Workarounds with Barcode Medication Administration Systems
3. Barriers to Access Maternal and Perinatal Care
4. Unintended Consequences of Technology Adoption
5. Decline in Physical and Emotional Well-Being of Healthcare Workers
6. Complexity of Preventing Diagnostic Error
7. Providing Equitable Care for People with Physical and Intellectual Disabilities
8. Delay in Care Resulting from Drug, Supply, and Equipment Shortages
9. Misuse of Parenteral Syringes to Administer Oral Liquid Medications
10. Ongoing Challenges with Preventing Patient Falls

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The 2024 Top 10: Vulnerabilities in the Safety and Clinical Operating Systems

To effectively understand where vulnerabilities lie, organizations must examine all elements of the system—people, organizations, tasks and processes, tools and technology, and the physical environment.

Each concern in this year's list represents a failure in at least one of these areas, in fact, many overlap and find causes in multiple areas.

Supporting Total Systems Safety

Total systems safety focuses on creating greater efficiency and resilience in clinical and safety operations. It incorporates principles of human factors, systems design engineering, health equity, and advanced safety science to redesign individual components of systems to be more transparent and aligned, leading to safer and more effective care.

Method for Selecting our List

The top 10 list reflects ECRI and ISMP's broad patient safety and risk management expertise. Our interdisciplinary staff includes experts in medicine, nursing, pharmacy, patient safety, quality, risk management, clinical evidence assessment, health technology, and many other fields. Our patient safety organization (PSO), ECRI and the ISMP PSO, analyzes our patient safety data—a database of nearly six million events— to improve patient care and ISMP is globally recognized as a leader in medication safety.

As part of the topic nomination process, ECRI and ISMP staff proposed important patient and workforce safety concerns to be evaluated. Nominators supported their proposals with information and evidence drawing from scientific literature; trends in event reports, causal analyses, and research requests submitted to ECRI and the ISMP PSO; reports submitted to the ISMP National Medication Errors Reporting Program and the ISMP National Vaccine Errors Reporting Program; medical device alerts, problem reporting, and evaluation; reported medication safety problems; accident investigations; lessons learned from consultation work; and other internal and external data sources. Nominators were also asked to consider whether their concerns impact healthcare disparities, worker safety, and/or patient and family safety.

For the first time this year, ECRI and ISMP also asked our members to nominate topics and share the patient safety issues that concern them most.

A cross-disciplinary team of ECRI and ISMP experts then analyzed the supporting evidence and evaluated each topic using the following criteria:

- **Severity.** How serious would the harm be to patients if this safety issue were to occur?
- **Frequency.** How likely is it for the safety issue to occur?
- **Breadth.** If the safety issue were to occur, how many patients would be affected?
- **Insidiousness.** Is the problem difficult to recognize or challenging to rectify once it occurs?
- **Profile.** Would the safety issue place a lot of pressure on the organization?

Based on these criteria, the interdisciplinary team chose and ranked the top 10 patient safety concerns.

More Tools for ECRI's Top 10 Patient Safety Concerns 2024

- Scorecard
- Customizable Risk Map

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Prioritizing Strategies and Measuring Improvement

To master each concern presented in this year's list, readers can look to our action recommendations, which are framed around the four foundational drivers of safety.

This annual top 10 report propels the implementation of evidence-based recommendations to support the ultimate aim of reducing preventable harm. It shares lessons from ECRI and ISMP's analysis of a wide range of data sources and offers strategies to support continuous improvement in healthcare. This report also illustrates ECRI and ISMP's deep understanding of how systems can contribute to harm—or drive patient safety.

Each item on our top 10 list includes several action recommendations and resources for addressing each concern. No organization can tackle all 10 items and implement all suggested strategies immediately. Organizations must calculate each item's risk score and conduct a gap analysis to evaluate their current practices against our recommendations. To help with this process, organizations can use this year's scorecard.

Healthcare leaders must be intentional about implementing solutions in their own complex, unique organizations. Superficial attempts to improve patient safety will not be enough to make meaningful changes.

Before implementing suggested strategies, leaders must establish systems and processes for measuring and analyzing improvements and be ready to modify or discontinue any strategy based on the results analysis.

Safety concerns can have clinical, cultural, efficiency, and financial impact on an organization. Measuring the results of change should be multimodal—with structural-, process-, and outcomes-related metrics. Sources of data may include event reports; medication-safety data; survey results, including results from culture of safety, employee satisfaction, and patient experience surveys; morbidity and mortality data; length of stay statistics; focus group discussions; and direct observation data. Additionally, organizations should segment data to gain a deeper understanding of inequities that may create disparities in both patient and workforce outcomes.

Ongoing Patient Safety Concerns

Over the years, several patient safety issues have made repeat appearances on ECRI's list of top 10 patient safety concerns. See Ongoing Patient Safety Challenges for a list of perennial patient safety issues.

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Challenges Transitioning Newly Trained Clinicians from Education into Practice

#1 Patient Safety Concern

No one doubts that the typical volume of clinician's hands-on and in-person educational experience was disrupted by the pandemic. Adding this to the growing workforce shortages and demands may result in increased risk of harm to patients as new clinicians transition from education to clinical practice.

Trends in employment rates for new clinicians in 2023 remained positive in comparison to other industries, with 96% of new nurses finding work compared to 53% of new graduates with degrees across disciplines. (AACN "Research") This *appears* promising since staffing shortages in healthcare have been widespread and well documented. However, there is growing concern among physicians and nursing leaders about the difficulty of transitioning new clinicians from education to practice, in the face of several factors exacerbated by the COVID-19 pandemic.

> Thirty percent of nurses with less than two years' experience reported that they do not feel well prepared to practice on their own. (ANF)

Without sufficient preparation, support, and training throughout the transition into practice, new clinicians can experience loss of confidence, burnout, and reduced mindfulness around culture of safety. The coalescence of these factors may lead to a failure to recognize and rescue patients from preventable harm, and/or contribute directly to patient harm events.

Pandemic Disrupted Learning Opportunities

Clinicians who transitioned into practice during the pandemic missed significant learning experiences. Studies show that medical residents experienced decreased procedural education and training in high-risk areas such as surgical specialties, neurology, and anesthesia. (ACGME, Lund et al) Nearly 400,000 new nurses passed their licensing examination during the pandemic—many of whom faced disruptions in their transition to practice (TTP) programs; disruptions included lack of important practice repetition, changes in orientation process, rapidly changing policies and protocols, and increased workloads. (Djukic et al)

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Reduced Mindfulness Around Culture of Safety

Voluntary reporting of safety events is a key component of a healthy culture of safety. According to the Agency for Healthcare Research and Quality's (AHRQ) 2022 Surveys on Patient Safety Culture hospital report, only 33% of clinicians who had worked less than one year in their work setting had voluntarily reported one or more safety events. (AHRQ) This is far below the reporting percentages of more tenured clinicians—50% for clinicians with 6 to 10 years' experience (AHRQ), for example—and may reflect reduced mindfulness around culture of safety among new clinicians. This reporting discrepancy between senior and new clinicians could also be a sign that new clinicians lack a sense of agency around safety event reporting. More research is necessary, however.

> Twenty-eight percent of the time a patient enters an acute care setting, they are likely entering a unit nurses believe is lacking the appropriate staff to provide quality care. (ANF)

Healthcare Workforce Crisis

Unfortunately, this transition from education into practice for new clinicians is compounded by the ongoing, well-documented staffing challenges in healthcare, including:

- **Shortage of trainers and training programs:** Insufficient number of faculty, clinical sites, classroom space, and clinical preceptors resulted in nursing schools turning away tens of thousands of qualified applicants. (AACN "Fact")
- **Experiential knowledge-pool draining:** Approximately 800,000 registered nurses are likely to leave nursing by 2027 (NCSBN) and a shortage of up to 124,000 physicians is predicted by 2034 (AAMC)—making it more difficult for newcomers to work alongside seasoned professionals—while simultaneously increasing new clinicians' workloads.
- **Burnout:** Growing concerns regarding workplace violence combined with complexity of care issues (e.g., behavioral health crisis) is leading to increased staff burnout, even among new healthcare providers. One study showed that 42.5% of new graduate nurses reported they were considering leaving the field of nursing (Ulupinar and Aydogan)—an unsettling sign that the well-documented burnout among healthcare staff is affecting *new* clinicians and not just senior clinicians. Studies show that the physician burnout rate is over 60% with factors including work overload and sleep impairment contributing to medical resident burnout. (Lubell)

> At a time when new clinicians are relatively inexperienced, they are asked to *do more* and work longer, without enough senior clinicians in their network for support, guidance, and mentorship. (ANF)

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Action Recommendations

Preparing new clinicians for TTP is a shared responsibility among leaders in both educational institutions and healthcare organizations. By using a total systems safety approach, leaders can assess and redesign the academic and clinical environment in which clinicians are trained, prepared, onboarded, mentored, and supported. To improve the user experience, newly trained clinicians become involved in system design and in finding solutions—as their perspective and insight are invaluable. It is also important to note that the changes needed reflect deficits at the system level and not on the part of individual clinicians.

Culture, Leadership, and Governance

- Use a total systems safety approach to design a strong safety and clinical operating system that recognizes and mitigates the risks associated with inexperienced clinicians.
- Create collaborative partnerships among academic and healthcare institutions to support increased opportunities for both live hands-on learning and simulation-based learning for interprofessional skill development and practice.
- Support the development of robust TTP programs through intense preceptorships (i.e., a limited time of training overseen by experienced clinicians) that prioritize training opportunities for new clinicians to gain experience and confidence in order to meet practice standards.
- Include diversity, equity, and inclusion (DEI) leaders in the design of new clinician mentorship and training programs; establish diverse preceptors; explore opportunities to support DEI improvement efforts—such as the Accreditation Council for Graduate Medical Education's Equity Matters program.

Patient and Family Engagement

- Help new clinicians develop strong patient engagement skills with tools such as AHRQ's 60 Seconds To Improve Diagnostic Safety—a tool that allows a patient to tell their health story without interruption for one minute, followed by the clinician asking questions to deepen understanding.
- Seek input from patient and family advisory councils on how newly trained clinicians can improve the patient-centered care experience.

Workforce Safety and Wellness

- Use data to drive the design of a safer work environment by measuring the attitudes, perceptions, and beliefs of newly trained clinicians regarding workplace safety; include measurements for environmental hazards and for aggression and violence. Use tools such as AHRQ's Workplace Safety Supplemental Item Set for the Hospital SOPS.
- Adopt wellness programs that help new clinicians develop resiliency and find meaning in their work, for example, the AMA's Joy in Medicine™ Health System Recognition Program or the ANA's Healthy Nurse Healthy Nation Program. Both seek to reduce burnout and support clinician well-being.
- Build a culture of safety that empowers newly trained clinicians to report safety events that impact themselves, their coworkers, and patients, including events highlighting unsafe working conditions, performing tasks outside their competency, or the need for additional training. Monitor the impact of these actions with data from a culture of safety survey

Learning System

- Supplement live hands-on learning with simulation-based education—commonplace in high-risk industries—in order to understand complex issues such as identifying sepsis; recognize how bias can lead to diagnostic errors; and hone professional and personal skills such as leadership, communication, decision-making, situational awareness, managing stress, and coping with fatigue.
- Include patient safety training as a core element of education for all new health professionals at both academic- and healthcare-organization levels. Combine this with regular safety-competency assessments and action plans to advance safety skills and behaviors.
- Leverage clinician-led continuous improvement structures (e.g., shared-governance councils, resident/fellow quality improvement projects) to create opportunities for new and experienced clinicians to collaborate and innovate around important topics, for example, ACGME's Back to Bedside program—designed to empower residents and fellows to develop transformative projects that foster meaning and joy in work.

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ECRI Resources

Hands-On Learning for Health Profession Trainees: Minimize Error-Prone Conditions (ECRI and the ISMP PSO)

A Better Prescription for Preparing Nursing Students for Practice (Medication Safety)

Nursing Students: Supervision and Support Key to Success (ECRI and the ISMP PSO)

Medical Staff Credentialing and Privileging (Health System Risk Management, Ambulatory Care Risk Management)

Students Have a Key Role in a Culture of Safety: Analysis of Student-Associated Medication Incidents (Medication Safety)

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Workarounds with Barcode Medication Administration Systems

#2 Patient Safety Concern

Barcode medication administration (BCMA) systems are important tools for preventing medication errors. However, **scanning or labeling errors may lead staff to develop workarounds, which can compromise patient safety and have serious or even deadly consequences.**

Staff may employ workarounds when a barcode cannot be scanned or is difficult to scan; when the barcode is missing, hidden, or damaged; or when a medication has not yet been added to the system.

BCMA workarounds may indicate insufficient staff knowledge and training or that the **devices and systems are not configured to support safe clinical workflow.**

BMCA workarounds may also indicate that staff members do not appreciate the safety value of the technology, or that they do not understand that **BCMA workarounds can cause medication errors and compromise patient safety.**

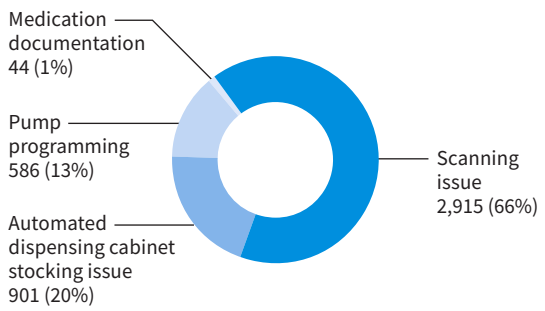
Examples of unsafe BCMA practices include:

- Administering a medication even though the barcode will not scan
- Retroactively charting after a medication is administered (back-charting)
- Scanning barcodes from sources other than the medication itself (i.e., proxy scanning)
- Not understanding a BCMA system alert (e.g., wrong time, medication not on patient profile), yet still administering the medication

Sources: ECRI "Workarounds"; ISMP "Latent"; ISMP "Patient Death"

In an examination of 4,446 technology-related medication safety issues reported to ECRI and the ISMP PSO between January 1, 2019, and December 31, 2019, **66% (2,915) were related to barcode scanning issues, making it the most frequently reported technology issue.**

Figure. Technology-Related Medication Safety Event Types, January 1, 2019–December 31, 2019



Source: ECRI and the ISMP PSO Database

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Action Recommendations

BMCA systems are valuable tools that reduce medication administration errors, but only when used correctly. Staff must be trained on proper use of the system, and procedures must be established to quickly address problems.

Culture, Leadership, and Governance

- Convene a multidisciplinary team to review practices that lead to BCMA workarounds and develop modifications and configurations that address system issues and support safe clinical workflow.
- Have clinical leaders collaborate with human resources partners to implement a just culture approach for addressing staff behaviors related to BCMA workarounds.
- Develop an escalation process for what to do if a barcode will not scan that includes:
  - When and how to report barcode scanning issues
  - Why it is dangerous to use a proxy scan
  - The person responsible for monitoring barcode issues

Patient and Family Engagement

- Explain to patients and families that practitioners will scan each medication prior to administration and encourage them to speak up if this task is not completed.
- If an adverse event occurs as a result of a BCMA system workaround, the error should be communicated to patients and/or their families following organizational disclosure procedures.

Workforce Safety and Wellness

- Utilize clinically informed human-factors-engineering methods to assess challenges with the integration of BCMA technology into clinical workflows.
- Implement a reporting and recognition process to acknowledge staff members that speak up and report near-miss events related to barcode scanning issues.

Learning System

- Set improvement goals that align with national benchmarks and/or safety standards for BCMA processes and share data with leaders and frontline staff.
- Review reported serious safety events involving BCMA to assess for contributing factors related to workarounds or equipment malfunctions.
- Report barcode scanning issues to the product manufacturer, the US Food and Drug Administration, and ISMP/ECRI.

Source: ECRI "Workarounds"

ECRI Resources

Bar-Coded Medication Administration Systems (Health System Risk Management)

A Persistent Hazard: Workarounds Continue to Defeat the Purpose of Bar-Coded Medication Administration Systems (Device Evaluation)

Workarounds Can Negate the Safety Advantages of Bar-Coded Medication Administration Systems (2018 Top 10 Health Technology Hazards)

Disclosure of Unanticipated Outcomes (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

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Barriers to Access Maternal and Perinatal Care

#3 Patient Safety Concern

Limited access to obstetric and reproductive care increases the risk of pregnancy-related deaths, preterm deliveries, low-birthweight babies, infant mortality, adverse outcomes associated with unintended pregnancies, and **disproportionately harms people of color and other vulnerable populations.**

Sources: Brigance et al; Nelson et al

About 2.2 million women of reproductive age in the US live in **maternity care deserts**—representing approximately 1,100 counties with **no hospitals providing obstetric care, no birth centers, no obstetrics-gynecology (OB-GYN) providers, and no certified nurse midwives (CNM).** Another 4.7 million have limited access to care before, during, and after giving birth.

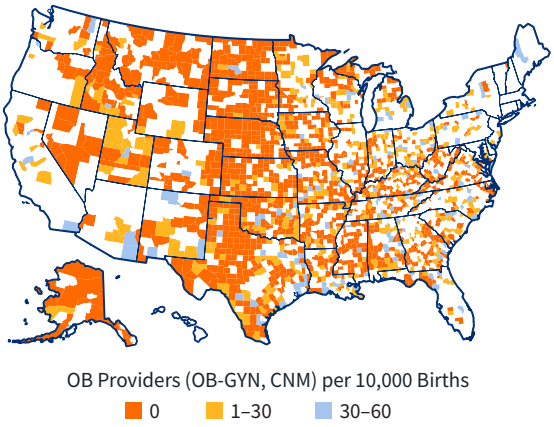
A deficit of 22,000 obstetricians is projected by 2050, and reimbursement for obstetric services—especially covering a full year of care after birth—is not consistent across the country.

Sources: Brigance et al; Rosenberg

Barriers to care contribute to **preventable maternal deaths** and the **increasing US maternal mortality rate**—currently ranked the worst among affluent countries. About 1,200 patients die annually and another 50,000 suffer pregnancy-related complications or severe morbidity.

Sources: Brigance et al; Gunja et al; Hoyert

Figure. Distribution of Obstetric Providers by County (2019)



Source: Brigance et al

In light of the *Roe v. Wade* reversal, providers face legal and ethical challenges and also receive conflicting guidance on managing high-risk patients. These factors impact provider decisions about where—or if—they will continue to practice or even choose an obstetrics career.

Compared to states where abortion is accessible, states that have banned, are planning to ban, or have restricted access to abortion have:

- Fewer maternity care providers
- More maternity care deserts
- Higher maternal mortality rates, especially among women of color
- Greater racial inequities across healthcare systems

Source: Declercq et al

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Action Recommendations

Evolving legal and professional landscapes around reproductive care, together with ongoing challenges for physicians regarding medical-malpractice insurance coverage and the reduction of obstetric services, present patient barriers to adequate, accessible maternal and perinatal care.

Culture, Leadership, and Governance

- Prioritize preventable maternal harm as a quality improvement goal, aligning with US maternal health initiatives.
- Seek board support to advocate for public policies that:
  - Extend insurance coverage to 12 months postpartum and promote family planning services.
  - Reimburse community partnerships with midwife and doula care and maternal home visiting programs.
  - Develop obstetric workforces to support care in maternity care deserts.

Patient and Family Engagement

- Empower pregnant and postpartum patients to speak up and raise concerns if they suspect warning signs of serious pregnancy-related complications.
- Provide adequate time during the obstetric discharge process for discussions about maternal support resources, including scheduling a postpartum visit.
- Employ health-literacy universal precautions and encourage culturally and linguistically appropriate care.

Workforce Safety and Wellness

- Implement a great-catch reporting program to recognize staff members who speak up and identify potential harm to pregnant and postpartum patients, prevent harm from occurring, and whose actions lead to a strong and impactful system change.
- Develop plans to provide both physical and psychological safety for staff (e.g., peer support programs) when providing perinatal care during stressful or traumatic instances.

Learning System

- Utilize simulation, scenarios, and feedback to train healthcare teams on how to respond to obstetric and neonatal emergencies and common postpartum complications.
- Develop improvement plans following a maternal or perinatal safety event and consult with OB-GYN experts to implement and monitor compliance with evidence-based clinical bundles (e.g., Obstetric Hemorrhage Patient Safety Bundle).

Sources: ACOG; AHRQ; AIM; Askew; CMS; The White House

ECRI Resources

Best Practices for Fetal Monitoring Credentialing of Clinical Staff with Obstetrics Privileges (Clinical Evidence Assessment)

Program Improves Infant and Maternal Outcomes in Communities with High Infant Mortality (ECRI and the ISMP PSO)

Resource Collection: Obstetrics (Health System Risk Management)

Resource Collection: Maternal and Perinatal Health and Safety (Ambulatory Care Risk Management)

Obstetrics and Neonatal Safety (Health System Risk Management, Ambulatory Care Risk Management)

Taking Action: Effective Provider-Patient Communication (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Maternal Health Risks after Delivery (Health System Risk Management, Ambulatory Care Risk Management)

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Unintended Consequences of Technology Adoption

#4 Patient Safety Concern

As healthcare technologies such as electronic health records (EHRs) have been adopted over recent decades, their widespread implementation without full appreciation of **their potential impact has been associated with serious risks, including patient injury or death.**

Providers have also experienced negative impacts, including **diminished work-life balance** and **increased burnout.** One study found that **physicians in ambulatory care settings spend more than five hours using the EHR for every eight hours of scheduled patient time.**

Source: Melnick et al

Now, a new wave of emerging technologies such as artificial intelligence (AI), machine learning, and digitally mediated diagnostics and treatment are becoming routinely used in healthcare, sparking concerns that similar safety issues will arise.

Although AI has been successfully used in healthcare for applications such as medical imaging, its quality depends on the data used to train the clinical AI application. **Unreliable AI functionality may result in misdiagnoses or inappropriate care decisions.**

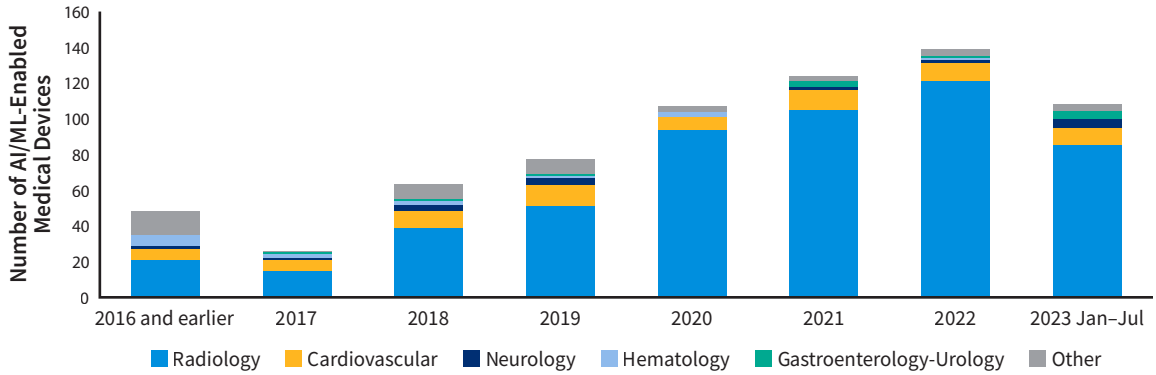
Beyond risks linked to changing existing workflows, challenges surrounding AI applications in healthcare include **difficulty in obtaining high-quality data; bias; scaling and integration; lack of transparency; privacy issues; and uncertainty over liability.** These challenges can reduce AI's effectiveness and compromise patient safety.

Source: US GAO and NAM

Likewise, **bias within AI data can affect accuracy and effectiveness.** AI applications are inherently biased toward patient populations that resemble the population used in training the algorithm, which may not be representative of all patient populations.

Sources: Mittermaier et al; Seyyed-Kalantari et al

Figure. FDA: Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices, Grouped by Panel (Lead)



Source: FDA

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Action Recommendations

The untested nature of emergent technologies can hinder the ability to fully assess their effectiveness or understand and mitigate their risks. Organizations must establish processes for evaluating, implementing, and maintaining these technologies to prevent unintended consequences and to address emerging issues.

Culture, Leadership, and Governance

- Establish a multidisciplinary committee to evaluate new technologies and determine risks. Include representatives from leadership, clinical services, human factors engineering, clinical engineering, patient safety, and risk management.
- Establish policies on the implementation of technology that incorporates AI. Include predeployment and ongoing validation, testing protocols, how to perform risk assessments, how to investigate and address issues that may occur, and how to maintain the technology throughout its life cycle.

Patient and Family Engagement

- Be prepared to address questions and concerns from patients and families regarding the potential risks associated with AI technology, including those related to privacy, accuracy, and potential bias.
- Engage patient and family advisory councils in order to understand the patient's perspective on the impact of digital solutions on health literacy and shared decision-making.

Workforce Safety and Wellness

- Be aware of issues (e.g., staffing shortages, burnout, cognitive overload) that can contribute to overreliance on or misuse of AI and other emerging technologies.
- Use clinically informed human-factors-engineering methods to perform assessments of clinical workflows to determine potential impact of new technologies, including changes to the EHR.

Learning System

- Properly train staff on equipment that uses AI and emphasize the importance of reporting unusual results. Staff should trust their own clinical judgment, seek second opinions, and report such instances as they would other anomalies that should be investigated and addressed.
- Validate AI applications on your organization's historical data and look for inequitable or inadequate performance or inherent biases before implementation. Monitor for these factors over time.

Source: US GAO and NAM

ECRI Resources

Artificial Intelligence Applications for Diagnostic Imaging May Misrepresent Certain Patient Populations (2021 Top 10 Health Technology Hazards)

State of Artificial Intelligence: Viewpoints from ECRI Clinical and Technical Experts (Device Evaluation [webcast])

Technology Acquisition and Management (Health System Risk Management)

Artificial Intelligence Software for Improving Outpatient Scheduling and Patient Chart Management (Clinical Evidence Assessment)

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Complexity of Preventing Diagnostic Error

#6 Patient Safety Concern

Frequent diagnostic errors and delayed diagnoses are costly and contribute to lost opportunities for the delivery of timely, necessary treatment for patients—risking patient harm.

Source: PCAST

Women and minorities have been found to have a **20% to 30% increased risk of diagnostic error** in studies indicating an association with gender, race, or ethnicity.

Source: Newman-Toker et al "Diagnostic"

Population and other risk factors that may lead to possible diagnostic inequity include race; ethnicity; where a patient lives; income level; insurance status; age; disabilities; literacy; language; sex (biologic/assignment); gender (identity); and sexual orientation.

Source: McDonald

Frequent diagnostic errors are costly to both patients and healthcare systems.

Source: AHRQ "Making"

The first step for improving diagnostic safety is **measuring the harm** itself.

Sources: ECRI "Performance"; AHRQ "Measure Dx"; Singh et al "Operational"

About half of serious harm caused by diagnostic error is related to 15 diseases. Improving **diagnosis of the top five** (stroke, sepsis, pneumonia, venous thromboembolism, and lung cancer) represents an opportunity to significantly reduce harm.

Source: Newman-Toker et al "Burden"

Factors That Contribute to Diagnostic Errors

System-level factors
- Communication breakdown
- Staffing shortages
- Time pressures

Cognitive biases
- Mental shortcuts/heuristics
- Confirmation bias
- Anchoring bias
- Availability bias
- Framing effect
- Bandwagon effect

Incomplete or inaccurate patient information
- Gaps in information sharing between providers

Limited time with patients
- Incomplete history
- Incomplete physical examination

Patient factors
- Language or other barriers
- Inability to adhere to treatment plan

Sources: Betsy Lehman Center; ECRI "Safety"

Since approximately 40% of patient encounters in primary care offices involve some kind of medical test, effective test result management **offers a significant opportunity to reduce error and patient harm.**

Source: AHRQ "Diagnostic"

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Action Recommendations

The diagnostic process is a complex, collaborative process that involves clinical reasoning and information gathering. Beyond the clinician's own skill, system factors—latent and active—may inhibit diagnostic excellence. A comprehensive approach must range from the individual clinician to organizational strategies.

Culture, Leadership, and Governance

- Utilize mechanisms (workflow management tools, interventions, electronic and verbal notifications, checklists, alerts, and dashboards) to ensure that all actionable patient data and information are delivered and communicated appropriately.
- Prioritize health information technology infrastructure that creates interoperability of patient data and diagnostic results.
- Align improvement goals with published benchmarks; provide feedback on diagnostic performance to clinicians and organizational leaders.
- Assess the extent to which the organization supports the diagnostic process and communication around diagnoses.

Patient and Family Engagement

- Close the communication loop among patients, family, caregivers, and provider(s) throughout care visits and beyond.
- Develop shared decision-making tools for patients and families to foster diagnosis and treatment discussions.
- Implement communication, apology, and resolution processes for unanticipated outcomes related to diagnostic error.

Workforce Safety and Wellness

- Develop staff training resources to enhance awareness of cognitive bias and empathetic listening.
- Provide peer support to team members that are involved in diagnostic-error events that resulted in patient harm.

Learning System

- Use evidence-based tools to measure diagnostic errors, including:
  - Quality and safety event data
  - Patient experience, claims, and complaint data
  - Electronic health record (EHR)-based data
  - Solicited reports from clinicians and staff
  - Clinical surveillance
- Provide evidence-based resources, such as those from the Society to Improve Diagnosis in Medicine, to support organizational learning.
- Analyze social determinants of health data and develop strategies to identify and reduce disparities in the diagnostic process.
- Strengthen the causal analysis process to identify improvement opportunities for latent and active system failures of the diagnostic process; share lessons learned throughout the organization.

Sources: AHRQ Toolkit; ECRI "Performance"; *Partnership*; National Academies; Newman-Toker et al "Diagnostic"; PA-PSA; Singh et al "Developing"; SIDM

ECRI Resources

Implementation Approaches for Closing the Loop (*Partnership for Health IT Patient Safety*)

Diagnostic Errors: Why Do They Matter, and What Can You Do? (Health System Risk Management)

Cognitive Biases and Diagnostic Error (Top 10 Patient Safety Concerns for 2022)

Safety Break—Provider Cognitive Bias: Impact on Diagnosis (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Missed and Delayed Diagnoses (Top 10 Patient Safety Concerns for 2020)

Ask ECRI: Primary Care Provider Liability for Test Result Tracking (Health System Risk Management)

Performance Improvement Project Basics (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Sample Form: Diagnostic Test Tracking and Follow-Up (Health System Risk Management, Ambulatory Care Risk Management)

Fighting Healthcare Disparities: Utilizing Shared Decision-Making (ECRI and the ISMP PSO Deep Dive)

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Providing Equitable Care for People with Physical and Intellectual Disabilities

#7 Patient Safety Concern

More than **27% of US adults have a disability**, but only **41% of physicians feel "very confident" regarding their ability to provide equitable care** to these patients.

Sources: Valdez and Swenor; Iezzoni et al

People with disabilities, including difficulties related to mobility, cognition, hearing, vision, independent living, and self-care, are more likely to experience **higher rates of adverse health conditions, including COVID-19; mental health concerns; and abuse, violence, and neglect.**

Sources: Bishop-Fitzpatrick et al; CDC "Disability and health healthy living"; CDC "Disability and health overview"; Gleason et al; Mitra et al

People with disabilities are also at greater risk for health disparities related to **diagnostic overshadowing,** i.e., an incorrect attribution of symptoms to a major diagnosis, such as a disability, rather than to a potential coexisting condition.

Source: Hallyburton

Despite the passage of the Americans with Disabilities Act (ADA) more than 30 years ago, barriers to accessible care still exist, including:

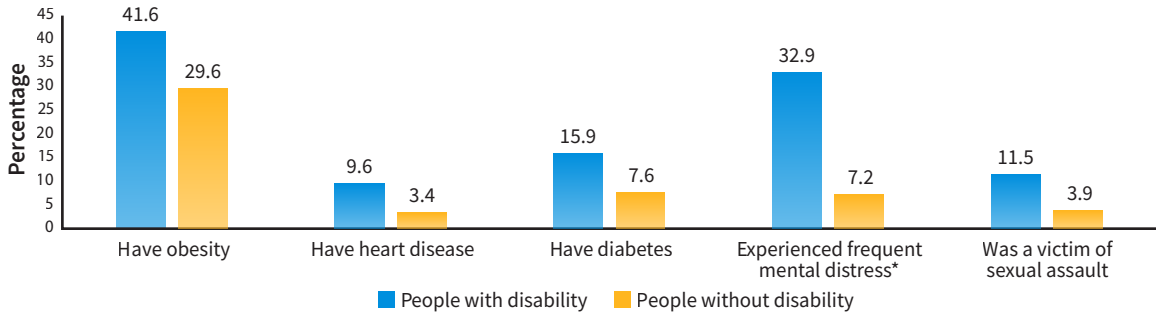
- Attitudinal (e.g., stereotyping, discrimination)
- Communication (e.g., no American Sign Language interpreters)
- Physical (e.g., mammography equipment that requires patients to stand)
- Policy (e.g., denying reasonable accommodations)
- Programmatic (e.g., insufficient time scheduled for examinations or procedures)
- Transportation (e.g., lack of public transportation)

Source: CDC "Common"

As a result of these barriers, **one in four adults with disabilities between ages 18 and 44 do not have a dedicated healthcare provider** and **one in five between ages 45 and 64 has not had a routine check-up** within the past year.

Source: CDC "Disability impacts"

Figure. Percentage of US Adults with Disabilities Reporting Selected Health Conditions Compared to People without Disabilities



*Defined as 14 or more self-reported mentally unhealthy days in the past 30 days

Sources: CDC "Disability and health healthy living"; CDC "Disability impacts"; Cree et al

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Action Recommendations

Healthcare organizations must ensure that adequate infrastructure and system processes are in place so clinicians can provide equitable care for patients with all types of disabilities.

Culture, Leadership, and Governance

- Provide full and equitable access to services for people with disabilities as required by ADA and state and local regulations. Ensure compliance with all requirements related to service animals, parking, and mobility and communication devices.
- Create an organizational goal to promote disability-competent healthcare values.

Patient and Family Engagement

- Assess and document the patient's health literacy and capacity to provide informed consent. Provide sufficient time for the patient to understand information and ask questions. If the patient is incapable of providing consent, follow appropriate legal and ethical procedures.
- Partner with the patient and family on a shared care plan, which will assist in coordinating care across the healthcare continuum.
- Discuss any necessary accommodations with the patient prior to their visit, if possible. Ensure this information is prominently featured in the EHR.
- Include an individual with a disability on the patient and family advisory council.

Workforce Safety and Wellness

- Ensure that staff communicate the presence of service animals at each handoff. If a staff member is allergic, designate another staff member to provide care; do not deny care to the patient.
- Train staff in the safe use of all equipment (e.g., patient lifts, exam tables and scales for patients with mobility difficulties, communication aids).

Learning System

- Analyze safety events that impact patients with intellectual and physical disabilities in order to understand contributing factors, including diagnostic overshadowing and other instances of diagnostic error.
- Provide feedback and education to clinicians to improve competency and reduce unconscious bias when caring for patients with disabilities.

Sources: ADA; AHRQ "Develop"; AHRQ "Health"; IDD; RIC

ECRI Resources

Americans with Disabilities Act: An Overview (Health System Risk Management, Aging Services Risk Management)

ADA: Physical Facilities (Health System Risk Management, Aging Services Risk Management)

Taking Action: Strategies to Advance Health Equity (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Taking Action: Strategies to Promote Equitable Healthcare for Autistic Patients (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Person-Centered Care (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Health Literacy (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Informed Consent (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

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Delay in Care Resulting from Drug, Supply, and Equipment Shortages

#8 Patient Safety Concern

Drug, supply, and equipment shortages disrupt the ability to meet patient needs across the care continuum, often causing **delayed treatment and services, worse patient outcomes, and increased health system costs.**

Source: Hughes

Growing shortages of raw materials, overcentralization of production, and sole- or limited-source vendor decisions may also make **shortages more widespread and unpredictable,** especially as natural disasters, geopolitical issues, and worldwide illnesses cause further disruptions.

Sources: ECRI; HIDA

The healthcare supply chain continues to struggle to recover from unprecedented shortages during the COVID-19 pandemic as **93% of healthcare provider executives report they are still experiencing product shortages.**

Source: HIDA

In mid-2023, the US healthcare system experienced **shortages for 309 drugs—the highest number since 2014.** Many of these drugs (e.g., central nervous system agents, antimicrobials, fluids/electrolytes, chemotherapy drugs, hormones) are medically necessary for critically or chronically ill patients.

Source: ASHP

A survey of nearly 200 healthcare professionals reported **drug, supply, and equipment shortages affecting several clinical departments:** surgery/anesthesia (74%), emergency care (64%), pain management (52%), cardiology (45%), hematology/oncology (44%), infectious disease (39%), and obstetrics/gynecology (37%)—some with serious adverse effects.

Source: ISMP

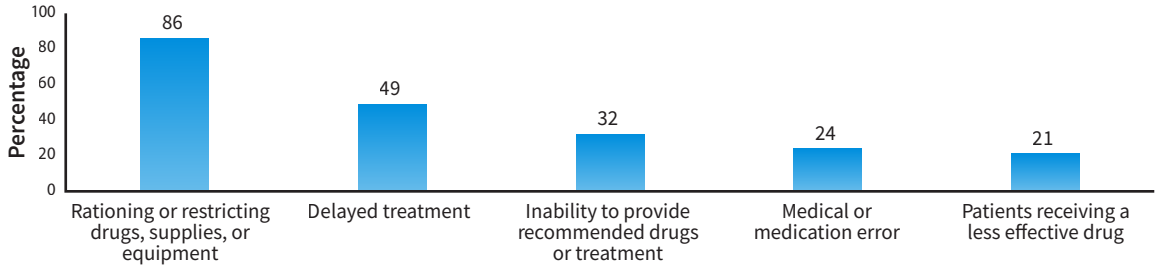
Additionally, 24% of respondents reported being aware of at least one shortage-related error within the last six months. Due to a lidocaine multidose vial shortage, for example, a single-dose lidocaine vial was procured but inadvertently utilized as a multidose vial.

Source: ISMP

To combat shortages, organizations often use secondary or tertiary substitutes, which may require new workflows or training, increasing the likelihood of errors.

Source: Kacik

Figure. Impacts of Drug, Supply, and Equipment Shortages on Patient Care



Source: ISMP

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Action Recommendations

Drug, supply, and equipment shortages remain persistent and can impact the ability to treat patients and protect staff, emphasizing the importance of prioritizing and improving inventory management and supply chain decision-making.

Culture, Leadership, and Governance

- Take routine inventory of all critical supplies and perform periodic risk assessments to identify and prioritize vulnerable items.
- Leaders should ask for increased transparency from manufacturers, group purchasing organizations, or other suppliers regarding source information and alternative acquisition plans.
- Consider shifting offshore suppliers to onshore, nearshore, or friendly-shore manufacturers to lower the risk of geopolitical and other global-based disruptions. Compare costs/benefits among sole-source and multisource agreements.

Patient and Family Engagement

- Notify patients immediately if their recurring medications, supplies, or equipment are in short supply or if procedures may be delayed.
- Use a shared decision-making approach when evaluating alternative treatments. Reassess informed consent requirements, if applicable.

Workforce Safety and Wellness

- Confirm that quality, effective personal protective equipment is deemed critical and maintain sufficient supplies.
- Utilize a tiered safety-huddle process to escalate important alerts for medication and supply shortages, hazards, and recalls to all appropriate clinical and operational team members.

Learning System

- Monitor drug shortages using data from ASHP, the US Food and Drug Administration, wholesalers, manufacturers, and other healthcare organizations.
- Gather and analyze supply chain data to identify historically challenging supplies, seek acceptable substitutes, and diversify supplier/vendor relationships to ensure all supply needs are met.
- Track and analyze data from patient safety/adverse events believed to stem from drug, supply, and equipment shortages. Use this data to inform supply chain management and decision-making.

Sources: ECRI; ISMP; Kaufman et al; Park et al

ECRI Resources

"But We Don't Have Any": When Medication Shortages Hinder Patient Care (ECRI and the ISMP PSO)

Supply Chain Shortfalls Pose Risks to Patient Care (Device Evaluation)

Vetting Nontraditional Suppliers (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Lessons of COVID-19: Three Actions for a More Resilient Supply Chain (ECRI [white paper])

PriceGuide: Functional Equivalents (ECRI proprietary database)

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Misuse of Parenteral Syringes to Administer Oral Liquid Medications

#9 Patient Safety Concern

Using parenteral syringes (i.e., syringes with Luer connectors that can be attached to needleless intravenous [IV] systems) in order to administer oral/enteral liquid medications, presents a risk of wrong-route misadministration if the syringe is mistakenly attached to and its contents injected into an IV line.

The unintended administration of oral liquid medications via the IV route can result in serious consequences, including infection, embolus with oral suspensions, and even patient death.

The risk of misadministration can be reduced or eliminated through consistent use of oral or enteral syringes for preparation and administration of small-volume oral/enteral liquids. These syringes have specially engineered hubs that cannot be easily or securely connected to standard IV lines.

However, **nurses and other providers may be unaware of the differences among oral, enteral, and parenteral syringes** and the risks associated with using a parenteral syringe to prepare and administer oral liquid medications.

ISMP continues to receive reports describing patients who were inadvertently given an oral liquid medication intravenously. For example:

- A nurse withdrew a 2.5 mg dose of oral oxyCODONE liquid from a unit dose cup into a parenteral syringe, as no oral or enteral syringes were available. The nurse inadvertently attached the syringe to an IV access port and injected it.
- Fatalities have occurred when the contents of liquid-filled capsules (e.g., niMODipine) were drawn into a parenteral syringe for administration via an enteral tube, then inadvertently administered intravenously.

Source: ISMP "Oral"; ISMP "Speaking"

Note: Syringe tips. Syringes 1 and 2 are ENFit (enteral) syringes equipped with tips that prevent them from attaching to an IV (Luer) connector; syringe 3 is an oral syringe that is difficult to attach to an IV connector; and syringes 4 and 5 are Luer (parenteral) syringes made to attach to IV connectors. Photo courtesy of GEDSA, www.stayconnected.org.

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Action Recommendations

The use of oral/enteral syringes is an effective risk-reduction strategy. Organizations must maintain availability of oral and/or enteral syringes and educate staff on the importance of using them when preparing and administering oral liquid medications.

Culture, Leadership, and Governance

- Invest in a technology-enabled process to ensure an adequate supply of oral and/or enteral syringes in all patient care areas where oral/enteral medications may be prepared and administered.
- Leaders should make it an organizational goal to convert to ENFit enteral devices as soon as practical. (ENFit syringes are designed for oral or enteral administration and are not compatible with Luer connectors.)
- Engage nursing leaders to emphasize to all nurses that parenteral syringes should never be used to prepare oral liquid medications and to explain the rationale behind using oral and/or enteral devices as a forcing function to prevent wrong-route misconnections.

Patient and Family Engagement

- Educate patients and families regarding established organizational policies on prevention of wrong-route medication errors.
- For hospital patients discharged with a feeding tube that includes an enteral-only connector, educate families and caregivers on the importance of access to compatible enteral syringes.

Workforce Safety and Wellness

- Implement a peer support program to provide emotional support for team members involved in serious medication safety events.

Learning System

- For all serious safety events involving parenteral syringes used for oral or enteral medications, conduct a root cause analysis that reviews both active and latent contributing system factors.
- Create an internal review and response process for any concerns or reported events within your organization regarding improper use of parenteral syringes for administering oral liquid medications; gather feedback from staff.

Sources: ISMP "Oral"; ISMP "Preventing"

ECRI Resources

Avoiding Inadvertent IV Injection of Oral Liquids (Medication Safety)

ISMP Targeted Medication Safety Best Practices for Hospitals (ISMP)

Implementing the ENFit Initiative for Preventing Enteral Tubing Misconnections (Device Evaluation)

Oral Syringes: A Crucial and Economical Risk-Reduction Strategy That Has Not Been Fully Utilized (ISMP)

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Ongoing Challenges with Preventing Patient Falls

#10 Patient Safety Concern

Patient falls **continue to be the number one sentinel event reported to Joint Commission**—resulting in serious harm and death—despite the focused attention given to their frequency and severity.

Source: Joint Commission "Sentinel Event Data"

Unintended fall-related deaths were highest for non-Hispanic Whites and lowest for non-Hispanic Blacks for those between ages 75 and 84.

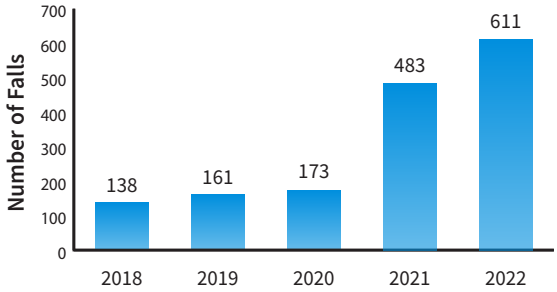
Source: Garnett et al

Seniors (over age 65) experienced harm from falls almost twice as often as younger adults, while sensory-impaired adults had a 15.9% higher rate of injury compared to patients without sensory impairment.

Source: AHRQ

According to Joint Commission, of 611 sentinel events classified as patient falls in 2022—a 27% increase since 2021—**70% resulted in severe harm and 5% resulted in death.** Leading injuries included head injury or bleeding and hip or leg fracture.

Figure. Annual Number of Sentinel Events: Patient Falls



Source: Joint Commission "Sentinel Event Data"

Patient falls were reported while ambulating (40%), from bed (23%), and while toileting (10%).

Source: Joint Commission "Sentinel Event Data"

Sentinel event falls occurred in these settings:

- Hospitals: 45%
- Critical access hospitals: 43%
- Ambulatory care: 22%
- Home care: 20%
- Behavioral health: 18%

Source: Joint Commission "Sentinel Event Data"

ECRI and the ISMP PSO reviewed 83 events, revealing contributing factors related to falls with injury:

- Communication: 20.66%
- Staff performance: 20.19%
- Management/supervisory/workforce: 17.84%
- Equipment/device/supply healthcare IT factors: 10.33%

Source: ECRI and the ISMP PSO

Fall prevention is a 2023 National Patient Safety Goal for hospitals and long-term care facilities because 700,000 to one million hospitalized patients and about 800,000 nursing home residents fall each year.

Source: PSNet

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Action Recommendations

While patient falls may not be eliminated within healthcare settings, adherence to protocols and interdisciplinary approaches to caring for at-risk patients can significantly decrease the frequency and severity of falls and injuries.

Culture, Leadership, and Governance

- Designate an executive sponsor to be accountable for fall prevention efforts including appropriate staffing plans, adoption of fall prevention technology (i.e., alarms and video-based patient monitoring), and safe patient-handling and movement programs.
- Use a just culture approach while reviewing fall-related safety events to evaluate staff's actions and choices that result in patient falls.
- Evaluate culture of safety survey results to identify opportunities to improve communication and teamwork related to patient falls.

Patient and Family Engagement

- Design a plan to engage patients and families—including those who do not speak English as their primary language—to become active partners in developing fall prevention strategies.
- Conduct purposeful rounding to assess a patient's personal needs, including toileting and the desire to be out of bed and mobilized if medically indicated.
- Tailor interventions to patients with differing fall risks based on current fall prevention research.

Workforce Safety and Wellness

- Implement initial and ongoing fall prevention training for staff, including how to speak up and report risks that may lead to falls.
- Use the tiered safety-huddle process to escalate and address staffing, safety, and environmental concerns that may place patients at higher risk of falling.

Learning System

- Create an interdisciplinary falls management team to design and implement a program including prevention practices, data monitoring, fall risk assessments, and continuous improvement activities.

Sources: AHRQ; ECRI and the ISMP PSO; Joint Commission "Sentinel Event Alert"; OSHA

ECRI Resources

Essentials: Falls (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Falls Prevention Training Program (Health System Risk Management, Aging Services Risk Management)

Fall Risk Assessment Methods (ECRI and the ISMP PSO)

Preventing Fall-Related Injuries (Health System Risk Management, Aging Services Risk Management)

Proactive Falls Prevention for Independent Living (Aging Services Risk Management)

Self-Assessment: Falls (Health System Risk Management, Aging Services Risk Management)

Video-Based Patient Monitoring for Preventing Falls (Clinical Evidence Assessment)

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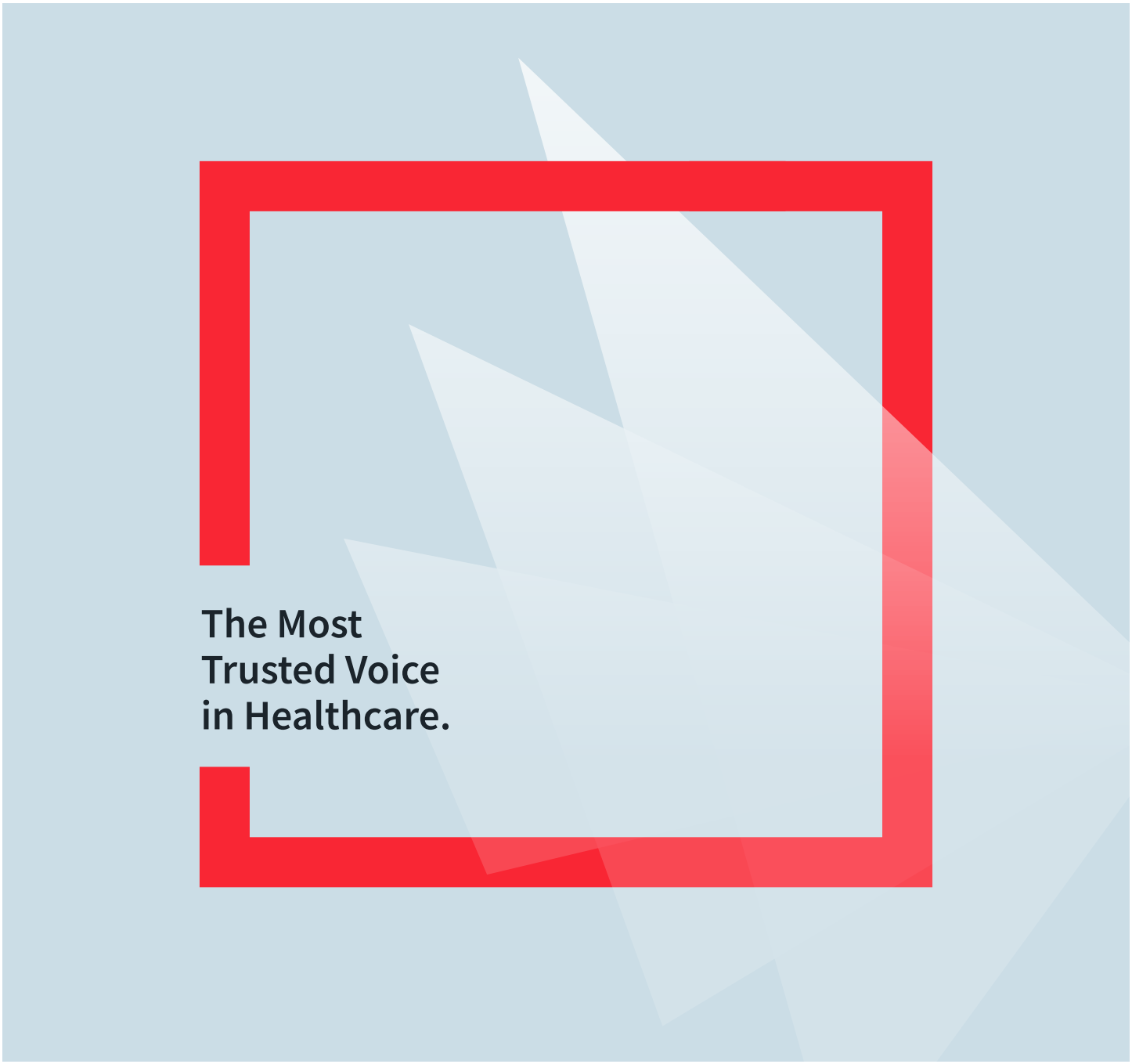

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