SPECIAL REPORT

Top 10 Patient Safety Concerns 2021

ECRI

The Most Trusted
Voice in Healthcare

Top 10 Patient Safety Concerns 2021

Introduction

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively.

This annual Top 10 list helps organizations identify imminent patient safety challenges and offers suggestions and resources for addressing them.

The List for 2021

1. **Racial and ethnic disparities in healthcare**
2. **Emergency preparedness and response in aging services**
3. **Pandemic preparedness across the health system**
4. **Supply chain interruptions**
5. **Drug shortages**
6. **Telehealth workflow challenges**
7. **Improvised use of medical devices**
8. **Methotrexate therapy**
9. **Peripheral vascular harm**
10. **Infection risk from aerosol-generating procedures**

COVID-19: Exposing Entrenched Problems in Healthcare

Many of the items on this year's Top 10 list relate to COVID-19. The pandemic threatens patients and staff directly and indirectly and has been a disruptive force in healthcare and in our daily lives. Beyond that, the pandemic has laid bare some of the most entrenched problems in healthcare. By learning lessons from the pandemic, we can improve safety not just for this and future pandemics, but for all patient and resident care.

Why We Create This List

ECRI creates the annual list of Top 10 Patient Safety Concerns to support organizations in their efforts to proactively identify and respond to threats to patient safety.

For each item on our Top 10 list, this report offers recommendations from ECRI experts, plus links to additional in-depth guidance. Tools are available for several items on the list.

How We Identified the Concerns

- We asked experts within ECRI to nominate topics for the Top 10 and provide supporting information.
- Based on presentations by nominators, an interdisciplinary team chose and ranked the final Top 10.
- Subject matter experts developed recommendations and, for some of the Top 10 items, tools.

How to Use This List

Use this list as a starting point for conducting patient safety discussions and setting priorities.

- Collaborate with stakeholders, using the list as a catalyst for improvement.

Determine whether your organization faces similar issues that should be targeted for improvement.

- Are these problems occurring in your organization?
- Do you have processes and systems in place to address them?

Develop strategies to address concerns.

- Check out our key recommendations for each topic.
- Use the sample tools provided with this Top 10.
- Follow the links to other ECRI resources that provide additional in-depth guidance.

Some resources are available without charge; others are benefits of ECRI membership programs or are available through our partner patient safety organizations (PSOs). Contact client services at (610) 825-6000, ext. 5891, or clientservices@ecri.org for information on purchasing resources that are not part of your membership.

Safety across the Continuum

This Top 10 report highlights patient safety concerns across the continuum of care because patient safety strategies increasingly focus on collaborating with other provider organizations, community agencies, patients or residents, and family members. Each patient safety concern on this list may affect more than one setting and involve a wide range of personnel.

More Resources and Tools for ECRI's *Top 10 Patient Safety Concerns 2021*

- Scorecard
- Customizable Risk Map

Racial and Ethnic Disparities in Healthcare

1

ONE

"The experiences of people of color in our health systems reveal that implicit and explicit bias and structural racism are driving health inequities like maternal mortality."

— Joia Crear-Perry, MD, FACOG
Founder and President, National Birth Equity Collaborative

Health disparities are health differences between different groups of people. These health differences may include:

- How many people are screened for diseases
- How many people contract certain diseases
- How severe the diseases are
- How many people have complications related to diseases
- How many people die from diseases
- Whether people can access healthcare

Maternal mortality is **3.3 times as high** among Black mothers as among white mothers.

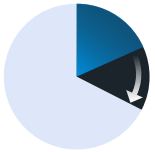
Source: Brookings Institution

Black adults are **50% more likely** to have a stroke than white adults,

Black men are **60% more likely** to die from a stroke than white men,

and Black women are **30% more likely** to die from a stroke than white women.

Sources: OMH; Kochanek et al.



The Hispanic or Latinx population makes up **18.5% of the U.S. population** but **32.5% of COVID-19 deaths** when weighted for population distribution in hard-hit areas.

Source: NCHS

Action Recommendations

Racial disparities in health and healthcare will not disappear overnight and are not solely the responsibility of healthcare organizations, but healthcare organizations can begin taking actionable steps to start improving health equity.

- Incorporate health equity into the organization's strategy.
- Create structures and processes to improve and support health equity.
  - Establish a health equity governance committee.
  - Devote resources to health equity efforts.
- Leverage health information technology resources to identify health disparities within the organization.
- Partner with community organizations (e.g., government agencies, charitable organizations, faith-based organizations, cultural centers, schools) and develop initiatives to improve health equity.
- Assemble an advisory committee of representatives from community groups for guidance with implementation and maintenance of health equity initiatives.
- Undertake specific strategies to address social determinants of health.
- Address institutional racism within the healthcare organization.
  - Examples include making the space welcoming and available to all (e.g., easy navigation, reduced wait times), evaluating which insurance plans are accepted, and implementing strategies to mitigate implicit bias.
- Recruit healthcare workers from underrepresented groups.
- Assess the organization's current cultural competence, identifying both strengths and opportunities for improvement.
- Develop healthcare providers' cultural competence (e.g., through education).
- Periodically reassess cultural competence within the organization, as well as progress toward specific goals.

Sources: ECRI; IHI

ECRI Resources

Case Studies in Cultural Competence (Health System Risk Management, Aging Services Risk Management)

Culturally and Linguistically Competent Care (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Culturally and Linguistically Competent Care Training Program (Health System Risk Management)

Patients' Racist Requests and Behaviors: A Perspective from the PSO Database (Health System Risk Management)

Refuse Patients' Racist Requests: Rely on Strong Policy, Civil Rights Act, and Legal Standards (Health System Risk Management)

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

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Emergency Preparedness and Response in Aging Services

2

TWO

Emergencies often disrupt routine resident care and facility operations in long-term care. Aging services organizations should take an integrated systems approach to implement emergency response plans that concern all stakeholders: residents, workforce, and visitors. These plans should address:

- All-hazards vulnerability assessment
- Shelter-in-place; evacuation; or modified admission, transfer, or transition protocols
- Communication plans for staff, residents, families, emergency responders, and the public
- Crisis standards of care, including modified visitation
- Staffing and scheduling
- Supplies and equipment
- After Action Reports (AARs) to identify successes and improvement opportunities

2017 Hurricane Irma

Hurricane Irma, 2017: The Centers for Disease Control and Prevention initially reported **123 nursing home deaths**, but once expanded analysis included 30- and 90-day postmortem data, researchers suggest more than **800 deaths** occurred.

Source: Dosa et al.

2019 Hurricane Dorian

Hurricane Dorian, 2019: Florida officials ordered evacuation of **72 nursing homes** and assisted living facilities based on lessons learned from the 2017 hurricane season.

Source: CBS Miami

2021 COVID-19 Pandemic

COVID-19 Pandemic, 2020-2021: Over **570,626 confirmed cases** and over **112,383 deaths** in nursing homes as of February 1, 2021.

Source: CMS

Action Recommendations

Organizations should take an all-hazards and systems approach for responding to emergencies in order to mitigate the impact on staff and residents.

- Comply with the Centers for Medicare and Medicaid Services' emergency preparedness rule requiring annual review and testing of the facility's emergency plan.
- Activate the emergency operations plan, healthcare coalition plan, and incident command system during emergencies.
  - Use clear criteria to evaluate whether to shelter in place or evacuate.
    - Consider the time it will take to evacuate, time of expected event impact, resident acuity, and building structure stability.
  - Activate enhanced safety and security measures (e.g., modified visitation).
- Implement crisis standards of care and operations when appropriate.
  - Monitor surge and transfer or divert residents when surge capacity is exceeded.
  - Use triage protocols.
  - Adhere to strict infection prevention and control precautions (e.g., cohorting, enhanced environmental services).
  - Consider enlisting telehealth services.
- Understand the facility's staffing needs.
  - Collaborate with healthcare coalitions and public health partners to address staffing, disaster volunteers, and temporary credentialing and privileging.
- Routinely evaluate access to supplies, equipment, medication, food, potable water, and fuel. Use conservation strategies and secure alternatives.
- Complete a facility-wide AAR, evaluate findings, and develop a corrective action plan.
- Initiate phased recovery activities to transition to normalized operations.

ECRI Resources

Creating the Plan: Balancing Resources with Capacity (Health System Risk Management)

Essentials: Emergency Preparedness (Health System Risk Management)

Emergency Preparedness: Epidemics, Pandemics, and Outbreak Response (Aging Services Risk Management)

Emergency Preparedness: Planning and Mitigation (Health System Risk Management, Aging Services Risk Management)

Emergency Preparedness: Response and Recovery (Health System Risk Management, Aging Services Risk Management)

Emergency Preparedness Self-Assessment (Health System Risk Management)

COVID-19 Resource Center

Healthcare Recovery Center—COVID-19

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Pandemic Preparedness across the Health System

THREE

3

Over the years, government investigations, congressional reports, and pandemic preparedness reviews have warned that America's healthcare system was woefully unprepared for a fast-moving infectious disease outbreak. COVID-19 has proved these warnings to be true.

Sources: CDC; Levin et al.; OIG; OSHA

Pandemic preparedness involves:

- Surveillance
- Occupational health program
- Triage
- Patient flow and discharge planning
- Surge capacity
- Mortuary management
- Access to care
- Promotion of outpatient care of acute respiratory infections
- Limiting nosocomial spread
- Mass screening
- Infection prevention and control
- Risk communication

COVID-19 pandemic disease progression–with average hospital stays of **27 days**–contributed to extraordinary surge in hospitalized, seriously ill patients.

Source: ASPR-TRACIE "Technical"

Alternative care sites (ACSs), initially earmarked for non-COVID-19 patients, were later modified to accept patients suffering from COVID-19 (e.g., Javits Center). ACSs were overtaxed when **patient conditions worsened beyond the ACS's capabilities**. In addition, patients were not easily readmitted to acute care hospitals overwhelmed by patient surge.

Source: ASPR TRACIE "Alternative"

Staff safety was compromised as the entire healthcare industry was hampered by **inadequate supplies of personal protective equipment (PPE)**.

Source: ASPR-TRACIE "COVID-19"

Action Recommendations

The COVID-19 pandemic revealed that the U.S. healthcare system was unprepared to effectively manage a pandemic. Health systems and federal and state governments can take several steps to better prepare for future pandemics.

- Evaluate the impact of a pandemic on logistics, such as personnel shortages; surge in patient numbers; increased supply demands, security risks, behavioral health needs, and media demands; infrastructure needs and vulnerabilities; and inadequate communication processes.
- Conduct ongoing surveillance of changing needs.
  - Examples include staffing resources, cleaning products, ventilators and ventilator supplies, antibiotics, antiviral medications, isolation capabilities, and cold storage for the deceased.
- Plan for patient surges by evaluating command and management processes, creating surge capacity thresholds, enhancing staff protections, enhancing communication, and improving patient tracking (see California Hospital Association Surge Plan and Checklist).
- Identify supply chains.
  - Examples include entering into agreements with local, regional, national, and international suppliers before a pandemic occurs so that contingency plans can be quickly activated with minimal supply disruption.
  - To ensure continuation of care at all levels, a centralized approach to mitigate local or regional shortages of supplies, equipment, drugs, and personnel is recommended.
- Monitor expiration dates of PPE supplies such as N95 masks, gloves, and gowns, and refresh supplies as needed to maintain a stockpile par level.
- Develop comprehensive infrastructure planning.
  - Examples include maintaining isolation capabilities as well as access to water and electricity.
- Regularly conduct full scale drills and tabletop exercises to test the pandemic response plan.

ECRI Resources

Surge Plan Checklist (Health System Risk Management)

Essentials: Emergency Preparedness (Health System Risk Management)

Emergency Preparedness: Planning and Mitigation (Health System Risk Management, Aging Services Risk Management)

Emergency Preparedness: Response and Recovery (Health System Risk Management, Aging Services Risk Management)

Emergency Preparedness Self-Assessment (Health System Risk Management)

Overview of Infection Prevention and Control (PSO Plus, Health System Risk Management, Aging Services Risk Management)

COVID-19 Resource Center

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Supply Chain Interruptions

4

FOUR

The COVID-19 pandemic severely strained healthcare supply chains, creating widespread shortages of key medical equipment and supplies, including ventilators, testing equipment, and personal protective equipment (PPE) such as masks, gloves, and gowns. Shutdowns in countries that manufacture and produce raw materials, coupled with limits on exports, resulted in severe and extended delays for much-needed supplies.

To address these shortages, healthcare organizations have turned to nontraditional approaches, including:

- Off-label use of existing devices
- Expansion of device indications for use
- Use of nonmedical-grade equipment

Alternate manufacturers and suppliers are often new and insufficiently vetted.

When ordered from these alternate manufacturers, products were often **expired, damaged, below standard**, or different from the product ordered—and **some products did not arrive at all**.

Sources: OIG; ECRI "Navigating"

ECRI testing found that:

60% to 70% of imported non-NIOSH-certified respirator alternatives **failed to reach 95% filtration efficiency**.

Source: ECRI "Imported N95 Masks"

52% of gowns with unstated levels of protection **failed to meet even the lowest protection standards**.

Source: ECRI "Isolation Gowns"

Action Recommendations

Tackling supply chain interruptions during emergencies and health crises requires planning, preparation, flexibility, and cooperation with outside collaborators.

- Source medical supplies from multiple suppliers that are not all concentrated within a single region. Consider tracking country of origin data for both products and raw materials; entering into dual-source agreements; and establishing connections with international brokers.
- Reassess inventory models (e.g., supply chain methodologies, amount of inventory on hand) to determine if they are still effective.
- When vetting nontraditional suppliers, follow the recommendations in Self-Assessment: Vetting Nontraditional Suppliers. Additionally, track both nontraditional domestic suppliers and nontraditional international suppliers (see ECRI Resources).
- Establish and maintain relationships with collaborators such as government agencies, group purchasing organizations (GPOs), manufacturers, distributors, and other healthcare providers.
- Identify functional equivalents to medical supplies (e.g., by consulting ECRI's proprietary database [see ECRI Resources]), and seek GPO and distributor solutions that identify all available alternatives.
- Determine which devices are appropriate to reuse when feasible, and follow all proper disinfection protocols.
- Follow ECRI's recommendations for addressing shortages of devices such as facemasks, isolation gowns, gloves, and eye protection, as well as for conserving existing PPE supplies, evaluating imported N95-style masks, and using homemade facemasks (see ECRI Resources).

Source: ECRI "Navigating"

ECRI Resources

Vetting Nontraditional Suppliers Self-Assessment (Health System Risk Management)

Outbreak Preparedness and Response: The Essentials

Healthcare Recovery Center: COVID-19

COVID-19 Technology Management Resources

ECRI/Association for Health Care Resource & Materials Management (AHRMM) Collaboration to Track Nontraditional Suppliers:

- Domestic Suppliers
- International Suppliers

PriceGuide: Functional Equivalents [ECRI proprietary database]

ECRI Exclusive Reports

- Strategies for Addressing Expected or Known Facemask Shortages
- Strategies to Combat Inadequate Supplies of Isolation Gowns
- Strategies for Addressing Expected Glove Shortages
- Strategies for Addressing Expected or Known Eye Protection Shortages
- Strategies to Conserve Existing Supplies of Personal Protective Equipment
- Strategies for the Use of Homemade Facemasks
- Use of Imported N95-Style Masks, without NIOSH Certification or Independent Lab Validation, May Put Healthcare Workers and Patients at Risk during the COVID-19 Pandemic

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

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Navigating non-traditional suppliers in untraditional times. 2020 AHVAP Virtual Conference & Supplier Showcase. 2020 Oct 27.

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Drug Shortages

5

FIVE

Drug shortages can affect both patients and healthcare practitioners, and recent emergencies have brought the problem into focus. During the COVID-19 pandemic, for example, supply chain disruptions and an increasing number of critically ill patients led to shortages in almost every drug class used for mechanical ventilation. Additional crises have also led to drug supply shortages—for example, in September 2017, a shortage of IV saline bags occurred after Hurricane Maria damaged a key saline manufacturing plant in Puerto Rico.

Sources: ECRI and the ISMP PSO; Rosenthal; Sacks

Drug shortages can result in:

- Changed, delayed, or canceled medical procedures
- Limited treatment options
- Missed or delayed therapies
- Increased costs
- Increased stress on healthcare workers
- Compromised patient safety (e.g., through increased medication errors)

A review of 88 events related to drug shortages found that such events are widespread.

Ninety percent of the reported events **reached the patient**.

Twenty-nine percent of the reported events were associated with **temporary, mild, or moderate patient harm**.

Sixty-seven percent of reported event types were **missed or delayed doses**.

Source: ECRI and the ISMP PSO

Action Recommendations

Preparation, standardization, communication, and monitoring are essential for safely managing drug shortages and reducing adverse events.

- Use a team approach for tackling drug shortages–including providers, pharmacists, and other stakeholders; recognize that pharmacists alone cannot address shortage issues.
- Monitor drug shortages with resources from the American Society of Health-System Pharmacists (see Current Drug Shortages) and the U.S. Food and Drug Administration (FDA) (see FDA Drug Shortages) as well as information from wholesalers, manufacturers, and other healthcare organizations.
- Formalize a drug-shortage communication and management plan that includes prioritization of and response to shortages of critical pharmaceuticals. The plan should include:
  - An evaluation of the amount of product on hand, using recommendations from groups such as ASHP (see Small-Volume Parenteral Solutions Shortages).
  - Potential sources of supply and identification of alternatives
  - Purchase history and usage estimates
  - An evaluation of the effects (e.g., safety impact) on the distribution, prescribing, and administrative processes, as well as any financial impact
  - Implementation plan
  - A method to quickly communicate to frontline staff how to limit or extend products in short supply
- Communicate drug shortage information to practitioners through electronic communication tools (e.g., team intranet site), focus group meetings, and discussions during pharmacy rounds.

Sources: ECRI and the ISMP PSO; ISMP

ECRI Resources

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

Medication Safety (Health System Risk Management, Aging Services Risk Management)

Technology for Medication Safety (Health System Risk Management)

Emergency Preparedness: Response and Recovery (Health System Risk Management, Aging Services Risk Management)

Communicating Medication Orders (Health System Risk Management, Aging Services Risk Management)

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Telehealth Workflow Challenges

6

SIX

"Telehealth has been in its adolescence for decades, but the COVID-19 crisis accelerated its maturation within a matter of weeks."

— The Agency for Healthcare Research and Quality (AHRQ)

The percentage of hospitals using telehealth increased from 35% in 2010 to 75% in 2017.

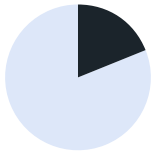
Source: American Hospital Association

ECRI and the ISMP PSO reviewed a sample of 42 telehealth-related events and found several evolving themes, including:

- Poor WIFI accessibility in the healthcare setting
- Inadequate or inappropriate monitoring
- Inadequate availability of monitors and rooms with monitoring capability
- Inadequate language services
- Health Insurance Portability and Accountability Act (HIPAA) privacy concerns

Source: ECRI and the ISMP PSO

19% of events included concerns regarding **escalation of care**.



Source: ECRI and the ISMP PSO

Example HIPAA privacy event: Patient could see the video feed of the other operating room, including the patient.

Source: ECRI and the ISMP PSO

Example escalation-of-care event: Patient was told to schedule an in-person visit during COVID-19 even though protocols stated they should have been seen virtually and prescribed an oral antibiotic.

Source: ECRI and the ISMP PSO

By 2030, more than half of healthcare services provided will be virtual.

Source: American Telemedicine Association

Action Recommendations

Telehealth is adding value-based care and ensuring greater access to meet patient demand. The challenge providers now face is continued expansion of services within in a safe environment.

- Plan a strong foundation that is adaptable and fluid.
- Connect organizational goals to appropriate patient populations.
- Provide a professional workspace that promotes professional communication practices.
- Work with financial analysts to develop a sustainable reimbursement model.
- Ensure that issues related to privacy, informed consent, and HIPAA are addressed.
- Provide interactive telemedicine training to help providers become skilled at providing care through telehealth.
- Implement quality review and peer review processes related to telehealth.
- Develop policies and procedures that incorporate regulations from government bodies and state and federal agencies.
- Implement standard-of-care policies based on service line, visit type, and scheduling templates.
- Integrate telehealth documentation into the electronic health record.
- Implement cybersecurity controls.
- Analyze patient preferences, patient resources, health disparities, and access gaps.
- Assess patient medical, cultural, and language needs.
- Consider creating the role of telehealth coordinator to support staff and patients.
- Perform postvisit patient education and referrals.

Source: ECRI

ECRI Resources

Telehealth (Health System Risk Management, Ambulatory Care Risk Management)

Telemedicine: The Future Is Here, When It Works (ECRI and the ISMP PSO)

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

The HIPAA Privacy Rule (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

The HIPAA Security Rule (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Photography, Filming, and Other Recording of Patients (Health System Risk Management, Aging Services Risk Management)

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

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SEVEN

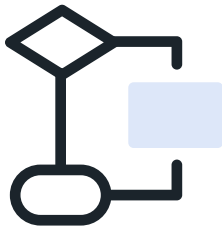
Improvised Use of Medical Devices

7

For various reasons, providers may choose to modify or repurpose a medical device, workflow, or system. However well-intended, such improvisation may lead to serious safety and regulatory compliance issues. Consider, for example, the following event submitted to ECRI and the ISMP PSO:

A COVID-19 positive patient was placed in a room with the ventilator outside the room to conserve personal protective equipment (PPE). While the nurse was connecting intravenous tubing through a hole in the wall, the heater plug on the ventilator circuit became disconnected. It took several seconds to reconnect the plug, potentially exposing staff to contagions.

Improvisation also occurs during nonemergent circumstances.



A study from 2017 surveyed whether anesthetists would proceed with surgery based on varying degrees of available equipment or hospital support. Despite consensus among the clinicians in 6 of the 11 surgical scenarios presented to them, results indicated considerable variation in risk assessment concerning the lack of essential equipment defined by regulatory minimum standards when deciding to proceed under suboptimal circumstances.

Source: Greig et al.

Action Recommendations

In addition to having inspection and preventive maintenance programs, healthcare organizations should implement a risk management approach that documents equipment limitations, failures, user errors, and improvisations that may affect patient care. Such data can better inform equipment decisions and thus alleviate the need to improvise.

- Form a multidisciplinary medical device management team that solicits input from end users to perform medical device planning, acquisition, evaluation, and replacement.
  - Analyze device impact on heating, ventilation, and air conditioning (HVAC) systems and other facility structures through an infection control risk assessment (ICRA).
  - Consider device interoperability and staff training requirements during device purchase decisions and management.
- Perform regular quality assurance checks to monitor device safety.
  - Routinely conduct failure mode and effects analyses and ICRAs, particularly prior to device implementation or modifications.
  - Analyze equipment failures; human factors; and device hazards, risks, and deficiencies.
  - Solicit user feedback on usability, limitations, and the potential for improvisation.
- Involve the facility's medical device reporting manager in quality improvement.
  - Ensure staff participate in the medical device reporting program.
  - Consider requiring staff to report events involving improvisation, regardless of patient harm.
- Design and test plans for temporary or permanent containment environments that may require, necessitate, or lead to improvisation during emergencies.

ECRI Resources

Technology Acquisition and Management (Health System Risk Management)

Failure Mode and Effects Analysis (Health System Risk Management, Aging Services Risk Management)

Getting the Most out of Root-Cause Analyses (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Medical Device Adverse Event Recognition and Investigation (Health System Risk Management)

Healthcare Device Adverse Event Recognition and Investigation (Aging Services Risk Management)

Medical Devices and Information Systems (Ambulatory Care Risk Management)

COVID-19 Resource Center

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

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Greig PR, Higham HE, Darbyshire JL, Vincent C. Go/no-go decision in anaesthesia: wide variation in risk tolerance amongst anaesthetists. Br J Anaesth. 2017 May 1;118(5):740-6. https://bjanaesthesia.org/article/S0007-0912(17)31334-X/fulltext PubMed: https://pubmed.ncbi.nlm.nih.gov/28510736/ doi: 10.1093/bja/aew444

Methotrexate Therapy

EIGHT

8

Methotrexate is a folic acid antagonist that was originally approved to treat various cancers and is now used to treat some autoimmune diseases (e.g., severe rheumatoid arthritis, psoriasis, lupus). When used for immunomodulation to treat such disorders, the drug is administered once a week.

Few medications are dosed weekly; thus, inadvertent daily dosing of oral methotrexate occurs all too frequently in all stages of the medication use process—from prescribing to self-administration. Serious methotrexate overdoses have led to vomiting, mouth sores, stomatitis, serious skin lesions, liver failure, renal failure, severe myelosuppression, gastrointestinal bleeding, life-threatening pulmonary symptoms, and, in some cases, death.

Source: ISMP "Call"

In combined data reported to ECRI and the Institute for Safe Medication Practices (ISMP), the most common error types were dosing and dosing frequency.

Table. Breakdown of Methotrexate Adverse Events by Type

Type of Error	Number of Events N=100	Percentage of total events
Wrong dose	41	41%
Wrong frequency	31	31%
Wrong drug	21	21%
Improper reconciliation	7	
Transitions of care	5	
Other	7	7%

Source: ECRI and the ISMP PSO; ISMP "Methotrexate"

Action Recommendations

Proper prescribing of methotrexate hinges on effective communication of instructions to patients, accurate documentation of dose and frequency, and accurate reflection of this information in computerized provider order entry (CPOE) systems.

- Verify prescription dosage strength (e.g., mg per tablet, number of tablets per dose) when updating (or obtaining) a patient's medication history, during handoffs, when refilling prescriptions, and during patient education.
- Program CPOE systems to default to weekly rather than daily dosage regimens.
- Require a hard stop verification and mandatory entry of an appropriate oncologic indication to override weekly dosage in order to select a daily schedule.
- Give discharged patients oral and written instructions that specify the weekly dosing schedule and emphasize the danger of taking extra doses.
- Have patients discharged on methotrexate or filling prescriptions for methotrexate repeat back instructions to validate their understanding of the weekly dosing schedule and toxicities if taken more frequently than prescribed (see ISMP's high alert consumer guide Oral Methotrexate).
- Prescribe only the number of tablets (or other dosage forms) needed for weekly dosing, not to exceed a 4-week (30-day) supply when prescribing for nononcologic use.
- Verify that all medication lists and discharge instructions indicate the correct dosage regimen before giving them to the patient.

Source: ISMP "Call"

ECRI and ISMP Resources

Consumer Guide: Oral Methotrexate (Health System Risk Management)

Be Wary during Changes in Care when Managing Patients with Methotrexate (ECRI and the ISMP PSO)

Call to Action: Longstanding Strategies to Prevent Accidental Daily Methotrexate Dosing Must Be Implemented (ISMP)

Oral Methotrexate (ISMP High-Alert Medication Consumer Guide) (ISMP)

Medication Safety Self-Assessment® for High-Alert Medications (ISMP)

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

References

ECRI and the ISMP PSO. Methotrexate related event report data reported from January 2015-May 2018. ECRI and the ISMP Patient Safety Organization Database. Component of ECRI and the ISMP Patient Safety Organization, Plymouth Meeting, Pennsylvania.

Institute for Safe Medication Practices (ISMP)

Call to action: longstanding strategies to prevent accidental daily methotrexate dosing must be implemented. 2018 Aug 9 [cited 2020 Oct 22]. https://www.ismp.org/resources/call-action-longstanding-strategies-prevent-accidental-daily-methotrexate-dosing-must-be

Methotrexate event data reported to ISMP from 1999-present. Institute for Safe Medication Practices Database. Institute for Safe Medication Practices, Horsham, Pennsylvania.

Peripheral Vascular Harm

9

NINE

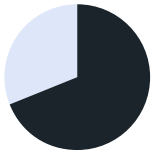
Peripheral intravenous catheters (PIVCs) are the most widely used invasive devices among inpatients. Severe cases of PIVC infection require intensive care or long-term care. They can lead to extended lengths of stay and antibiotic treatments—and even death.

Noninfection forms of harm include:

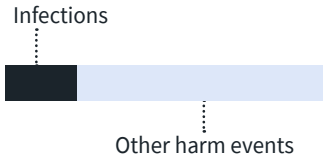
- Phlebitis
- Infiltration
- Burns
- Leaks
- Redness
- Erythema
- Swelling
- Drainage problems
- Ecchymosis

Source: ECRI and the ISMP PSO

Up to **69% of PIVCs** are removed due to failure or infection before completion of scheduled intravenous therapy.



Source: Blanco-Mavillard et al.



An ECRI and the ISMP PSO analysis of 27,320 reports of PIVC events found **6,119 reported infections** and **21,201 noninfection all-harm events**.

Source: ECRI and the ISMP PSO

72 hours—The point beyond which patients are at greatest risk for PIVC-related bacterial infection.

Source: Pennsylvania Patient Safety Authority

Example of patient safety event: A patient was stuck seven or eight times before the IV was properly inserted.

Action Recommendations

The challenge of an effective PIVC harm prevention program is to reduce the rate of PICV infections as much as possible given a specific patient population. Sustained progress will require continued effort. A multidisciplinary effort should involve leadership, those who allocate resources, infection control personnel, vascular access teams, those who insert and remove IVs, and patients themselves. Reporting these events to a patient safety organization is essential.

- Provide continued education and assessment regarding proper intravenous catheter use.
- Audit process measures and promote reporting of events and near misses.
- Set a target of PIVC placement with as few attempts as possible, with a goal of no more than two attempts.
- Consider the use of sterile techniques and sterile components.
- Research and acquire proven technology to assist with proper catheter securement.
- Ensure a process for proper catheter selection.
- Avoid anatomical complication zones such as antecubital areas and joints and ensure policy recommends forearm placement.
- Implement appropriate use of ultrasound technology.
- Utilize visualization technology appropriately.

Sources: ECRI; O'Grady et al.

ECRI Resources

High-Profile Healthcare-Associated Infections (Health System Risk Management)

Invasive Lines (Health System Risk Management)

Overview of Infection Prevention and Control (Health System Risk Management)

Sharps Injury Prevention Programs (Health System Risk Management)

Top 10 Patient Safety Concerns for 2019: Infections from Peripherally Inserted IV Lines (Health System Risk Management)

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

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Blanco-Mavillard I, Rodríguez-Calero MÁ, de Pedro-Gómez J, Parra-García G, Fernández-Fernández I, Castro-Sánchez E. Incidence of peripheral intravenous catheter failure among inpatients: variability between microbiological data and clinical signs and symptoms. Antimicrob Resist Infect Control. 2019 Jul 22;8:124. https://pubmed.ncbi.nlm.nih.gov/31367345/ doi: 10.1186/s13756-019-0581-8

ECRI. Invasive lines. Health System Risk Management. 2014 Apr 10. https://www.ecri.org/components/HRC/Pages/CritCare7.aspx?tab=1

ECRI and the ISMP PSO. All-harm peripheral intravenous vascular catheter (PIVC) PSO events: 1/1/2019-12/31/2019. Patient Safety Brief. https://www.ecri.org/components/PSOCore/Pages/E-lert030421.aspx

O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, Lipsett PA, Masur H, Mermel LA, Pearson ML, Raad II, Randolph AG, Rupp ME, Saint S; Healthcare Infection Control Practices Advisory Committee (HICPAC) (Appendix 1). Summary of recommendations: guidelines for the prevention of intravascular catheter-related infections. Clin Infect Dis. 2011 May;52(9):1087-99. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3106269/ doi: 10.1093/cid/cir138

Pennsylvania Patient Safety Authority. Peripheral vascular catheter–related Infection: dwelling on dwell time. 2014 Mar 11 [cited 2020 Oct 30]. http://patientsafety.pa.gov/ADVISORIES/Pages/201403_30.aspx

Infection Risk from Aerosol-Generating Procedures

10

TEN

Aerosol-generating procedures have always posed risks to healthcare workers, but COVID-19 has amplified these risks. COVID-19 spreads to humans via exposure to respiratory droplets. Comparisons with two similar viruses, SARS and MERS, suggest that aerosolization of particles—and thus potential infection of clinicians during aerosol-generating procedures—is possible. The exposure risk of performing aerosol-generating procedures on suspected COVID-19 patients is very high.

Sources: CDC "Scientific"; Harding et al.; OSHA Healthcare; OSHA Dentistry

Droplets are larger than 5 µm, while aerosol particles are no larger than 5 µm. Aerosol particles rapidly evaporate, leaving behind nuclei that **can remain airborne for hours**.

Sources: CDC "Scientific"; Fennelly

Airborne transmission can occur if aerosols generated during a procedure (e.g., via laser plumes, splashes, or sprays of blood or body fluid) contain viral or bacterial load.

Clinicians may be exposed to significant COVID-19 viral loads from a patient's upper aerodigestive tract, nasopharyngeal glands, and salivary glands.

Sources: Mick and Murphy; Tran et al.

Action Recommendations

Infection control leaders across the continuum of care should assess practitioners' safety during aerosol-generating procedures and work to develop, implement, and enforce appropriate precautions. (See the resource page Resources by Specialty: Managing Aerosol-Generating Procedures and COVID-19 for more information.)

- Identify the healthcare workers at highest risk and implement safe work practices. Consider the risks of aerosol-generating procedures across a range of specialties.
- Minimize factors related to increased transmission risk during the procedure, such as length of exposure and proximity to the patient's airway and/or the aerosol.
- Implement a hierarchy of controls to decrease risk of transmission related to aerosol-generating procedures.
  - Elimination: Postpone nonemergency aerosol-generating procedures.
  - Substitution: Use hand-driven devices instead of higher-powered drills, lasers, or other tools.
  - Engineering controls: Ensure proper ventilation, use negative-pressure air systems, ensure there are at least 12 air changes per hour, and install partitions if single rooms for patients are not available. In oral procedures, use extra suction and inline filters.
  - Administrative controls: Schedule aerosol-generating procedures for the end of the day, test patients for COVID-19 before their procedures, restrict personnel and visitors in the room, and train staff on risk reduction and personal protective equipment (PPE) use. Monitor emerging guidance and literature for best practices, such as preprocedure mouth and nasal rinsing.
  - PPE: Wear PPE appropriate to the aerosol-generating procedure, including eye protection, gowns, gloves, masks, and respirators.

Sources: CDC "Hierarchy"; Howard

ECRI Resources

Resources by Specialty: Managing Aerosol-Generating Procedures and COVID-19 (Health System Risk Management)

COVID-19 Resource Center

COVID-19 Recovery Center

Indoor Air Quality (Health System Risk Management)

Laser Use and Safety (Health System Risk Management)

Overview of Infection Prevention and Control (Health System Risk Management) (Ambulatory Care Risk Management) (Aging Services Risk Management)

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org

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Centers for Disease Control and Prevention (CDC)

Hierarchy of controls. 2015 Jan 13 [cited 2021 Feb 2]. https://www.cdc.gov/niosh/topics/hierarchy/default.html.

Scientific brief: SARS-CoV-2 and potential airborne transmission. 2020 Oct 5 [cited 2021 Feb 2]. https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html

Fennelly KP. Particle sizes of infectious aerosols: implications for infection control. Lancet. 2020 Sep 1;8(9)914-24. https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30323-4/fulltext

Harding H, Broom A, Broom J. Aerosol-generating procedures and infective risk to healthcare workers from SARS-CoV-2: the limits of the evidence. J Hosp Infect. 2020 Aug;105(4):717-25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7263217/

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Mick P, Murphy R. Aerosol-generating otolaryngology procedures and the need for enhanced PPE during the COVID-19 pandemic: a literature review. J Otolaryngol Head Neck Surg. 2020 May 13;49:29. https://www.ncbi.nlm.nih.gov/research/coronavirus/publication/32393346

Occupational Safety and Health Administration (OSHA)

OSHA. Healthcare workers and employers. [cited 2020 Dec 5]. https://www.osha.gov/coronavirus/control-prevention/healthcare-workers

OSHA. Dentistry workers and employers. [cited 2020 Dec 5]. https://www.osha.gov/coronavirus/control-prevention/dentistry

Recurrent Patient Safety Challenges

Lessons from ECRI's Past Top 10 Lists

Over the years, several patient safety issues have made repeat appearances on ECRI's list of Top 10 Patient Safety Concerns. The following perennial patient safety issues do not appear on this year's Top 10 list; nonetheless, they deserve sustained attention in many organizations.

Although the following items have appeared in several past Top 10 lists, the list begins with the most frequently mentioned. The linked ECRI resources offer guidance on these challenges. Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at clientservices@ecri.org. Memberships often contain additional resources on these topics; the following are a selection of key resources.

Medication Safety

ECRI's Medication Safety Membership

Deep Dive: Medication Safety (ECRI and the ISMP PSO)

Deep Dive: Opioid Use in Acute Care (ECRI and the ISMP PSO)

Medication Safety (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

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

Medication Safety Training Program (Health System Risk Management, Aging Services Risk Management)

Medication Administration (Ambulatory Care Risk Management)

Diagnostic Stewardship and Test Result Management

Diagnostic Errors: Monumental Problem or Enormous Opportunity? (Health System Risk Management)

Deep Dive: Laboratory Events (ECRI and the ISMP PSO)

Closing the Loop (Partnership for Health IT Patient Safety)

Test Tracking and Follow-Up (Health System Risk Management, Ambulatory Care Risk Management)

Test Tracking and Follow-Up Toolkit (Ambulatory Care Risk Management)

Self-Assessment: Waived Laboratory Practices (Health System Risk Management, Ambulatory Care Risk Management)

Behavioral Health

Deep Dive: Meeting Patients' Behavioral Health Needs in Acute Care (ECRI and the ISMP PSO)

Suicide Risk Assessment and Prevention in the Acute Care General Hospital Setting (Health System Risk Management)

Mental Health in Aging Services (Health System Risk Management, Aging Services Risk Management)

Suicide Prevention in Aging Services (Aging Services Risk Management)

Self-Assessment: Behavioral Health: Patient Safety (Health System Risk Management)

Health Information Technology and Patient Safety

Health IT Safe Practices (Partnership for Health IT Patient Safety)

Health IT Safety Program (Partnership for Health IT Patient Safety)

Deep Dive: Health Information Technology (ECRI and the ISMP PSO)

Electronic Health Records: Functionality (Health System Risk Management, Ambulatory Care Risk Management)

Electronic Health Records: Operational Issues (Health System Risk Management, Ambulatory Care Risk Management)

Documentation: A Primer on Charting in the Medical Record (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Self-Assessment: Establishing a Health Information Technology Safety Program (Health System Risk Management)

EHR Vendor Checklist (Health System Risk Management, Ambulatory Care Risk Management)

Detecting Changes in Patient Condition

Communication (Health System Risk Management, Aging Services Risk Management)

Documentation: A Primer on Charting in the Medical Record (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

An Overview of Nursing Liability (Health System Risk Management)

Clinical Alarms (Health System Risk Management)

Beat the Buzzer: The Alarm Safety Game Show! (Health System Risk Management)

Triage Toolkit (Ambulatory Care Risk Management)

Culture of Safety and the Infrastructure for Safety

Culture of Safety: An Overview (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Measuring Safety Culture (Health System Risk Management)

Patient Safety and Quality Improvement Act (Health System Risk Management, Aging Services Risk Management)

Patient Safety, Risk, and Quality (Health System Risk Management)

System Safety Analysis (Health System Risk Management)

The Role of the Patient Safety Officer (Health System Risk Management)

Culture of Safety 101 Training Program (Ambulatory Care Risk Management)

Device Cleaning, Disinfection, and Sterilization

ECRI's Infection Prevention and Control Services

Reprocessing of Reusable Medical Devices (Health System Risk Management)

Reprocessing of Flexible Endoscopes (Health System Risk Management)

Overview of Infection Prevention and Control (Health System Risk Management, Aging Services Risk Management)

Infection Prevention and Control (Ambulatory Care Risk Management)

Self-Assessment: Instrument Sterilization and Disinfection Practices (Health System Risk Management)

Care Fragmentation and Poor Care Coordination

Deep Dive: Care Coordination (ECRI and the ISMP PSO)

Inpatient Care Coordination (Health System Risk Management)

Discharge Planning (Health System Risk Management)

Transitions of Care (Aging Services Risk Management)

Subacute Care (Aging Services Risk Management)

Care Coordination and Transitions (Ambulatory Care Risk Management)

Guidance for Patient Safety (GPS) Toolkit: Handoff Communication (ECRI and the ISMP PSO)

Antimicrobial Stewardship

Physician Leader Huddle: Antimicrobial Stewardship: What You Can do Now (ECRI and the ISMP PSO)

Overview of Infection Prevention and Control (Health System Risk Management, Aging Services Risk Management)

Infection Prevention and Control (Ambulatory Care Risk Management)

Patient Identification

Deep Dive: Patient Identification (ECRI and the ISMP PSO)

Patient Identification: Implementation Guide and Toolkit (Partnership for Health IT Patient Safety)

Patient Identification (Health System Risk Management)

Resident Identification (Aging Services Risk Management)

Medical Records (Ambulatory Care Risk Management)

Self-Assessment: Patient Identification (Health System Risk Management)

Self-Assessment: Resident Identification (Aging Services Risk Management)