Special Report

Top 10 Patient Safety Concerns 2020

EXECUTIVE BRIEF

ECRI

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SPECIAL REPORT

Top 10 Patient Safety Concerns 2020

Executive Brief

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 looming patient safety challenges and offers suggestions and resources for addressing them.

The List for 2020

1. Missed and Delayed Diagnoses
2. Maternal Health across the Continuum
3. Early Recognition of Behavioral Health Needs
4. Responding to and Learning from Device Problems
5. Device Cleaning, Disinfection, and Sterilization
6. Standardizing Safety across the System
7. Patient Matching in the Electronic Health Record
8. Antimicrobial Stewardship
9. Overrides of Automated Dispensing Cabinets
10. Fragmentation across Care Settings

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.

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.

This report offers perspectives from some of our many experts, plus links to further guidance addressing patient safety issues.

How We Identified the Concerns

In selecting this year's list, ECRI relied both on data regarding patient safety events and concerns and on the judgment of interdisciplinary patient safety experts from inside and outside ECRI. Since 2009, when our patient safety organization (PSO), ECRI PSO, began collecting patient safety event data, we and our partner PSOs have received more than 3.2 million event reports. This means that the 10 patient safety concerns on this list are very real. These concerns are harming people—sometimes seriously.

The selection process synthesized data from these varied sources:

- Review of events in the ECRI PSO database
- PSO members' root-cause analyses and research requests
- Topics reflected in weekly *HRC Alerts*
- Voting by experts from inside and outside ECRI

The top 10 concerns are generally ranked according to the number of votes received, with the number-one item receiving the most votes. The list does not necessarily represent the issues that occur most frequently or are most severe. Most organizations already know what their high-frequency, high-severity challenges are. Rather, this list identifies concerns that might be high priorities for other reasons, such as new risks, existing concerns that are changing because of new technology or care delivery models, and persistent issues that need focused attention or pose new opportunities for intervention.

How to Use This List

Use this list as a starting point for conducting patient safety discussions and setting priorities. This list is not meant to dictate which issues organizations should address. Rather, we hope it will serve as a catalyst for discussion about the top patient safety issues your organization faces.

Determine whether your organization faces similar issues that should be targeted for improvement. You can investigate whether these problems are occurring in your organization and whether you have processes and systems in place to address them.

Develop strategies to address concerns. This report offers a few key recommendations for each topic and links to other ECRI resources that provide more in-depth guidance. Some resources are available without charge; others are benefits of ECRI membership programs or are available through our partner 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.

WANT MORE?

This executive brief summarizes ECRI's *Top 10 Patient Safety Concerns 2020*. Members of ECRI PSO, *Healthcare Risk Control* (*HRC*), *Continuing Care Risk Management* (*CCRM*), and *Physician Practice Risk Management* (*PPRM*) can access the full report, which discusses each topic in more detail, by logging in at https://www.ecri.org.

Missed and Delayed Diagnoses

1

ONE

When a diagnosis is missed or delayed, the patient might not get the treatment they need when they need it. When this happens, "we've missed a critical window," says Sarah D. Creswell, MSN, RN, CPHQ, patient safety analyst, ECRI. Symptoms may go unchecked, and the condition may progress. Thus, missed and delayed diagnoses often result in more patient suffering and worse outcomes, sometimes even death, than if the condition had been diagnosed earlier.

Accurate diagnosis requires the clinician to get a complete clinical picture of the patient's relevant circumstances. It takes time to obtain an accurate history and perform a comprehensive physical, and clinician-patient communication is crucial. "So much of diagnosis has to do with paying attention to the patient," says Karen Schoelles, MD, SM, FACP, vice president, Clinical Excellence and Safety, ECRI. Preparing for visits may help patients and clinicians maximize their time together.

The electronic health record (EHR) should be structured so that clinicians and staff can readily understand the story so far: the trajectory of the patient's condition, examinations and tests that have been performed, diagnoses that have been considered, and more. "Think how to virtually create a comprehensive and holistic view, how to put those pieces together," says Schoelles.

The organization's culture should support open discussion of the diagnostic process and learning from diagnosis-related events. Education on cognitive heuristics and the diagnostic process can help illustrate how often all people take these mental shortcuts and emphasize techniques for avoiding common cognitive traps. The ability to discuss cases, brainstorm, and talk through the diagnostic process with providers who have the same or a different area of expertise can further support diagnosis.

Ultimately, accurate diagnosis is a systems issue and everyone's responsibility. Creswell says, "The key is setting aside the safe space to talk about that process."

Diagnostic errors that may have contributed to death have been found in 10% of autopsies.

Source: Shojania et al.

Maternal Health across the Continuum

2

Recent data from the Centers for Disease Control and Prevention shows more than 700 women die each year from childbirth-related complications in the United States and more than half of these deaths are preventable. The U.S. has the highest maternal death rate among the world's developed nations, and it's rising in the U.S., even as it falls throughout most of the rest of the world, explains Carlye Hendershot, MSN, RN, CPPS, CPHRM, senior patient safety analyst and consultant, ECRI.

Addressing alarming maternal health trends means prioritizing mothers' safety across the continuum of care. "What happens before, during, and up to one year after childbirth all play an important role in keeping moms safe and healthy," says Hendershot. In fact, about two-thirds of pregnancy-related deaths occur in the postpartum period, with one-third concentrated in the later postpartum phase (one week to one year after delivery). "Therefore, all healthcare providers for women of childbearing age have an important role to play in ensuring their health and safety," says Hendershot.

Issues that impact maternal health in the U.S. include racial and ethnic disparities; care coordination between ambulatory, specialist, and acute care settings; provider-patient communication and engagement; higher rates of risk factors (such as pregnancy later in life); and access to quality care. Resources from professional organizations, risk assessment tools, obstetric technologies, and knowledge of best care practices can help providers identify risk factors and adjust treatment plans accordingly before complications occur. Hendershot also suggests that healthy, safe mothers emerge from a collaborative partnership between women, their families/support persons, and healthcare and social service providers and agencies.

TWO

> More than 700 women die each year from childbirth-related complications in the United States and about 60% of these deaths are preventable.

Source: Petersen et al.

Early Recognition of Behavioral Health Needs

3

THREE

Healthcare workers face more violence than those in any other industry, "but we probably do the least about it," says Nancy Napolitano, BS, PCHA, patient safety analyst and consultant, ECRI. "Part of this is because people fear what they don't know. When you fear something, you either want to fight it or run from it. We have to understand people and how they work with their emotions."

This fear applies to both patients and clinicians. Patients may be in unfamiliar situations and may be off balance. Clinicians may see a patient with behavioral health issues and automatically raise their guard.

Addressing these issues means recognizing patients' behavioral needs sooner and more efficiently. It also means reframing the conversation with providers. A key to helping providers treat patients with behavioral health needs is recognizing that just because a patient is demonstrating aggressive behavior, such as making violent threats or directing verbally abuse language toward a caregiver, it does not necessarily mean the patient has a mental illness.

"We don't always want to say that violence is due to people who are mentally ill," Napolitano says. "That message has to be loud and clear."

Organizations can improve their recognition of and response to behavioral health needs by providing education, training and retraining, behavioral health assessment for patients, improving rapid response teams' response times by conducting drills, and instituting a culture change that begins with the organization's leadership.

"We have these innate reactive responses to perceived dangerous situations," Napolitano says. "Education and awareness can help stop caregivers' reactive responses, and let them think and act rationally."

Education has to focus on how to destigmatize any aggressive patient. Staff must be trained not to label or judge patients and recognize when patient behavior may be escalating. Listening skills are critical, as is the ability to apologize when necessary. Even learning how to stand with open hands in a nondefensive posture while treating an agitated patient may potentially de-escalate a situation, Napolitano says.

> Only 3% to 5% of violent acts are committed by an individual with a serious mental illness.

Source: Mentalhealth.gov

Responding to and Learning from Device Problems

4

FOUR

When an incident occurs involving a medical device, "a lot needs to happen right away to improve the effectiveness of an incident investigation," says Scott R. Lucas, PhD, PE, director, Accident and Forensic Investigation, ECRI. At first, the focus is appropriately on the patient. But if the organization lacks a comprehensive plan for investigating device-related incidents, key steps can be missed. "Develop a plan to investigate a device-related incident now because eventually it will happen," says Lucas. Having a plan ready to go enables the organization to respond in a timely and methodical way. This increases the likelihood that the organization will gather useful information, learn from it, and prevent recurrence.

The initial steps are key but can be easily missed in the aftermath of an incident. ECRI offers a poster listing immediate action steps (see Resources). The organization should also have protocols for investigating incidents involving specific types of devices, equipment, or disposables. Consider issues such as what data logs are kept, which accessories are included, how the equipment would be sequestered and tagged, additional devices or systems with which it interfaces, and what information must be documented and by whom.

Incidents involving medical devices or equipment can occur in any setting where they might be found, including aging services, physician and dental practices, and ambulatory surgery. The devices and domain-specific expertise available in these settings might differ from that of a hospital. However, "the process is the same, the need for a plan is the same," says Lucas. These settings should identify individuals that have the skill set to coordinate investigations and those who can supply domain expertise.

Planning is essential to conducting a thorough investigation. Like having a fire escape plan, "it's about getting ahead of it," says Lucas. Then, when an incident occurs, "You just hit 'go.'"

Patient harm from medical devices occurred in 84 of every 1,000 admissions in one hospital.

Source: Samore et al.

Device Cleaning, Disinfection, and Sterilization

5

FIVE

In spite of several barriers, sterile processing departments (SPDs) are responsible for cleaning, decontamination, inspection, assembly, packaging, storage, and distribution of instruments, equipment, and supplies—tasks that rely on strict adherence to processes that leave no room for error. Some of these barriers include productivity pressures; lack of access to current manufacturer instructions for use and processing technologies; lack of necessary supplies; communication breakdowns between SPD staff and the departments they support; and a lack of universal training and certification requirements.

Incidents involving improperly reprocessed instruments can potentially result in devastating effects on patients, damage to organizational and provider reputations, citations and fines from regulatory bodies, prompt review by accrediting agencies, and lawsuits. However, "patient safety starts in the sterile processing department," says Gail Horvath, MSN, RN, CNOR, CRCST, senior patient safety analyst and consultant, ECRI, and "everyone has a role."

To help mitigate the risk of errors and their consequences, ECRI recommends facilities establish effective workflows that involve SPD and clinical staff input, incorporate quality checks throughout the sterilization process, improve interprofessional relationships, and provide continuing education opportunities for staff. Establishing relationships with instrument manufacturers and accessing resources from organizations such as the Association for the Advancement of Medical Instrumentation, the American Society for Health Care Engineering, and the Association of periOperative Registered Nurses can help fine-tune SPD policies and procedures to ensure timely and safe turnaround times, reduce preventable errors and associated costs, and ensure patient safety and satisfaction.

> Sterile processing failures can lead to surgical site infections, which have a 3% mortality rate and an associated annual cost of $3.3 billion.

Source: CDC

Standardizing Safety across the System

6

SIX

The modern healthcare system stretches beyond hospital walls, across the continuum of care, and across state lines. A system's culture of safety must have the same reach. As the expansion of health systems continues, organizations find themselves facing many settings with differing cultures, processes, and resources. And many healthcare organizations that do not have the infrastructure of a large system are also expanding and grappling with the complexities of providing safe care.

"For the longest time, culture of safety was dedicated to hospitals," says Carol Clark, BSN, RN, MJ, acting director of the ECRI PSO. "Clearly, that never should have been the case. But now the denominators have swung exponentially toward ambulatory, long-term, and other healthcare settings and deserved attention is being paid to the culture of safety in these areas."

A merger may mark the first time an ambulatory or other facility comes under the umbrella of a larger organization. Such facilities often must build their resources from scratch and they may lack the framework and infrastructure of larger organizations. But standardized culture of safety principles must be emphasized, implemented, and supported in smaller sites just as they are in the larger parent organizations.

"No healthcare entity can do their work and fulfill their mission without having a culture of safety," Clark says. "Building it from scratch requires education and practice so that it may be truly embraced."

Achieving this goal requires standardizing policies, processes, procedures, and education. With this approach in place, a culture of safety across the system can be established, regardless of how far across the continuum of care, or across the country, a facility is located from its parent organization.

"No matter what your resources are—whether you're a smaller critical-access facility or a large academic institution—everyone should be held to the same standard, regardless of the circumstances," says Clark.

90 mergers and acquisitions were announced by healthcare organizations in 2018.

Source: Kaufman, Hall & Assoc., LLC.

Patient Matching in the EHR

SEVEN

Patient matching is grounded in strong patient identification practices. “It is important to think of matching as part of a multipronged approach,” says Lorraine Possanza, DPM, JD, MBE, FACFOAM, FAPWCA, program director, *Partnership for Health IT Patient Safety*, ECRI. This approach, she explains, includes catching (capturing patient identifiers), matching (correlating information for the correct match), and displaying (how users see that information).

When matching is not successful, says Robert Giannini, NHA, CHTS-IM/CP, patient safety analyst and consultant, ECRI, duplicate and overlay records are created. “Overlay happens when one patient’s information is documented in another patient’s record. It can create errors that impact everything from medication administration to lab testing,” he says, “These errors cause significant downstream safety effects.”

Therefore, strong matching practices should be applied in EHR systems, prescription drug monitoring programs (PDMPs), health information exchanges (HIEs), and other digital health technologies, to allow for the flow of correct patient information across the continuum of care. Within one organization, a duplicate chart or overlay error is contained, says Possanza. But if the record or records in question are part of an HIE, “the potential for compounding the error is exponential” as the misinformation spreads throughout the exchange. Needed care may be hindered, and errors are more difficult to correct the longer they go undetected.

Consistent implementation of active identification practices at appropriate points throughout the patient encounter can act as a fail-safe to ensure that the correct medications or tests have been ordered for the correct patient; that they have been ordered through the correct record; and that the correct information is associated with the correct patient, regardless of setting. Whether staff are accessing a single record or a pharmacy order, performing a search of the PDMP, or accessing information from an HIE, these patient matching fail-safes are key to patient safety.

> In the ECRI PSO Patient Identification Deep Dive, both of the two deaths identified in the sample related to EHR documentation failures.

Source: ECRI PSO

Antimicrobial Stewardship

8

EIGHT

Despite the increased focus on the importance of antimicrobial stewardship in healthcare, and increased recognition among healthcare workers and patients alike, antibiotics are still being prescribed unnecessarily, when no longer needed, in the wrong dose, and with the wrong indication—any of which can increase antimicrobial resistance. Many of these antibiotics are being prescribed in care settings such as long-term care organizations, urgent care centers, and dentist offices.

As antimicrobial resistance increases, treatment options become limited for affected patients, placing the public at large at risk. "These bugs are smarter than we are. They adapt," says James Davis, MSN, RN, CCRN-K, HEM, CIC, FAPIC, senior infection prevention and patient safety analyst/consultant, ECRI. "We need antibiotics to work when we need them. We are getting these extremely resistant, extremely contagious pathogens, and we need to be able to treat the infected patients, not only for the benefit of the patients, but for the benefit of those around them."

To combat antimicrobial resistance, Davis recommends that hospitals, long-term care settings, and outpatient settings evaluate their antimicrobial stewardship programs to ensure that they align with current guidelines and recommendations, and verify that staff are following best practices. In addition, because so many antibiotics are being prescribed outside the acute care setting, Davis recommends that care settings work together to ensure that best practices are being implemented across the continuum of care.

"When we have the oldest of the old or the sickest of the sick, and they have a resistant pathogen, and we do not have any antibiotics to give them because we are out of options, that is not a good place to be," says Davis.

In 2014, antibiotics were prescribed for antibiotic-inappropriate respiratory problems for 45.7% of patients who visited urgent care centers.

Source: Palms et al.

Overrides of Automated Dispensing Cabinets

9

NINE

Automated dispensing cabinets (ADCs) allow practitioners quick, controlled access to medications, and over time, their widespread adoption has greatly improved medication safety. However, when overrides are used to remove medications from the ADC before pharmacist review and approval, it can lead to dangerous—even deadly—consequences for patients.

"The issue with ADC overrides is that you have access to more medication than is specifically ordered," says Stephanie Uses, PharmD, MJ, JD, patient safety analyst/consultant, ECRI. "It is easy to choose the wrong medication or the wrong dose of the medication and administer it to the patient."

Overrides are a safeguard designed for emergency situations, when certain medications may be needed immediately and there is no time to seek the approval of a pharmacist. "However, not every medication needs to be 'on override,'" says Uses.

An interdisciplinary medication safety committee should review medications to determine if ADC override access is warranted, based on clinically urgent needs that outweigh the risk of medication errors. In addition, organizations should determine which patient populations are likely to be treated in the area where the ADC is located, and then ask whether the medications stored in the ADC are appropriate to treat that population.

"You want to have the least amount of medications available through override in the ADC as possible," says Uses. "Ask, 'Does this medication need to be in this machine?' Look at the patients you are treating in that area, and ask whether that medication would be needed to treat these patients."

Other risk mitigation strategies include incorporating a system for retrospective pharmacist review of overrides; requiring a medication order before removing any ADC medication, including overrides; and implementing technology-based safeguards.

In one analysis of adverse event reports involving the use of overrides, 77% involved ADCs.

Source: Grissinger

Fragmentation across Care Settings

10

TEN

As healthcare delivery grows more complex, with multiple provider settings for care delivery, care fragmentation is a top patient safety concern for 2020 because it can impede communication among a patient's providers and interfere with care coordination.

Breakdowns in care from a fragmented healthcare system can lead to readmissions, missed diagnoses, medication errors, delayed treatment, duplicative testing and procedures, and general patient and provider dissatisfaction.

"The more complexity in the system, the greater the chance for error," says Patricia Stahura, MSN, RN, senior analyst and consultant, ECRI.

Consider as an example the recent emergence of urgent care centers and retail pharmacy care clinics. "There is an opportunity to get faster care, but it may cause more fragmentation if there is no process to communicate findings to the patient's primary care physician," says Jean Harpel, MSN, RN, GCNS, CPASRM, operations manager, Aging Services, ECRI.

Fragmentation can occur from one provider setting to another, as well as within a healthcare facility from one unit or department to another.

Healthcare organizations must collaborate with each other and decide how to transfer information about patients they share. In particular, technology, such as health information technology, can help providers share information about their patients. Organizations must devise strategies to "close the loop" and ensure that providers are aware of and address actionable patient information, such as test results. Engaging patients in their own care is also important to ensure that important information about their care is not overlooked.

Patients with several chronic conditions may visit up to 16 physicians in a year.

Source: Pham et al.

Resources*

1. Missed and Delayed Diagnoses

- Diagnostic Errors: Monumental Problem or Enormous Opportunity?
- Diagnostic Errors: Why Do They Matter, and What Can You Do? (infographic)
- *Partnership for Health IT Patient Safety:* Closing the Loop
- Test Tracking and Follow-Up
- Test Tracking and Follow-Up Toolkit
- ECRI PSO *Deep Dive™: Laboratory Events*
- ECRI Guidelines Trust
- ECRI PSO *Deep Dive™: Safe Ambulatory Care*

2. Maternal Health across the Continuum

- Perinatal Safety: Attention to Care Bundles to Prevent Adverse Events
- Obstetrics and Neonatal Safety
- Obstetrics (self-assessment)
- Safety First for Staff: Obstetric Emergencies (staff handout)
- Culturally and Linguistically Competent Care
- Ask *HRC:* Emerging Obstetric Technologies
- Vaginal Birth after Cesarean
- Obstetrical Liability

3. Early Recognition of Behavioral Health Needs

- Behavioral Health: Patient Safety (self-assessment)
- Patient Violence
- Ready, Set, Go: Patient Violence (leadership tool)
- Essentials: Behavioral Health
- Patient Violence (podcast)
- Ask *HRC:* Encouraging Reporting of Violent Patient Incidents

4. Responding to and Learning from Device Problems

- Device Incident Response Poster
- Medical Device Adverse Event Recognition and Investigation
- Risk Management Tips for Device-Related Events
- Investigating Device-Related Skin "Burns"
- Incident Investigation in Aging Services
- Medical Device Reporting
- Medical Device Tort Liability
- Medical Devices: Unique Compliance Issues
- *Partnership for Health IT Patient Safety:* Health IT Safety Program

5. Device Cleaning, Disinfection, and Sterilization

- *Top 10 Patient Safety Concerns for 2018:* Device Cleaning, Disinfection, and Sterilization
- *Top 10 Health Technology Hazards for 2018:* Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk
- Sterile Processing Department's Role in Patient Safety
- Instrument Sterilization and Disinfection Practices (self-assessment)
- Reprocessing of Reusable Medical Devices
- Endoscope Reprocessing (podcast)
- Reprocessing of Flexible Endoscopes
- Endoscope Reprocessing: The Importance of Being Proactive
- If It's Not Clean, It's Not Sterile: Reprocessing Contaminated Instruments
- Overview of Infection Prevention and Control

Resources (cont.)

6. Standardizing Safety across the System

- *Top 10 Patient Safety Concerns for 2019:* Standardizing Safety Efforts across Large Health Systems
- Culture of Safety: An Overview
- Managing a Multifacility Risk Management Program

7. Patient Matching in the EHR

- Essentials: Health Information Technology
- Health IT Safe Practices: Toolkit for the Safe Use of Health IT in Patient Identification
- Recommendations and Implementation Strategies: Safe Use of Health IT for Patient Identification
- ECRI PSO *Deep Dive™: Patient Identification*—Background/Methods/Results
- Patient Identification
- Patient Identification (self-assessment)
- *Top 10 Patient Safety Concerns for 2017*: Patient Identification
- Safety First: Patient Identification (staff handout)
- Leadership Tool for a Learning Organization: Patient Identification

8. Antimicrobial Stewardship

- Antibiotic Stewardship: Solutions to Turn the Tide Against the Threat of Antibiotic Resistant Bacteria (webinar)
- Antibiotic Stewardship: Engaging Physician Compliance
- Overview of Infection Prevention and Control
- Medication Safety
- High-Profile Healthcare-Associated Infections

9. Overrides of Automated Dispensing Cabinets

- Driven by Data: Don't Leave ADC Override Safety Outside the Drawer (webinar)
- Know Your ADCs: Poor Configuration Risks Medication Errors
- Medication Distribution Approaches and Technologies
- Medication Safety
- ECRI PSO *Deep Dive™: Opioid Use in Acute Care*

10. Fragmentation across Care Settings

- Essentials: Care Coordination
- ECRI PSO *Deep Dive™: Care Coordination*
- Communication
- Discharge Planning
- Medication Reconciliation
- Test Tracking and Follow-Up
- *Partnership for Health IT Patient Safety:* Health IT Safe Practices for Closing the Loop

***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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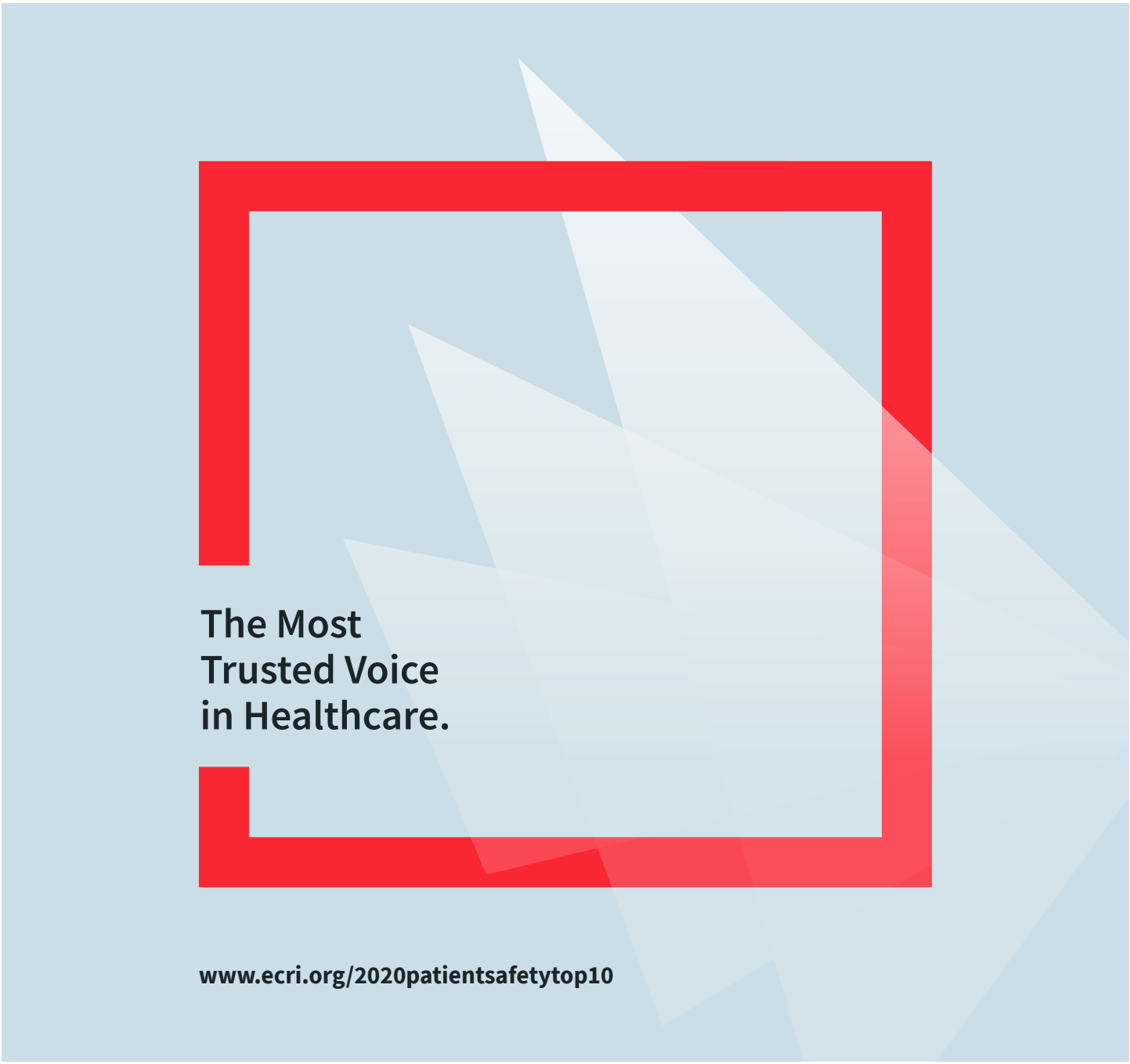

About ECRI

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit ecri.org and follow @ECRI_Org.

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