Top 10 Patient Safety Concerns for Healthcare Organizations 2017
MISSION STATEMENT

ECRI Institute is an independent nonprofit organization whose mission is to benefit patient care by promoting the highest standards of safety, quality, and cost-effectiveness in healthcare. We accomplish this through our research, publishing, education, and consultation.

Our goal is to be the world’s most trusted, independent, organization providing healthcare information, research, publishing, education and consultation to organizations and individuals in healthcare.
Top 10 Patient Safety Concerns for Healthcare Organizations 2017
Healthcare is striving to become an industry of high-reliability organizations, and part of being a high-reliability industry 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.

Why We Create This List

ECRI Institute creates this annual list of Top 10 patient safety concerns to support healthcare organizations in their efforts to achieve the following:

- Proactively identify potential threats to patient safety
- Improve patient safety by addressing concerns

This report offers perspectives from some of our many experts, as well as links to further guidance on addressing these issues.

How the Concerns Were Identified

In selecting this year’s list, ECRI Institute relied both on data regarding events and concerns and on expert judgment. Since 2009, when our patient safety organization (PSO), ECRI Institute PSO, began collecting patient safety events, we and our partner PSOs have received more than 1.5 million event reports. That means that the 10 patient safety concerns on this list are very real. They are causing harm—often serious harm—to real people.

The process synthesized data from these varied sources:

- Routine review of events in the PSO database
- PSO members’ root-cause analyses and research requests
- A survey of Healthcare Risk Control (HRC) members regarding their top patient safety concerns
- Topics reflected in weekly HRC Alerts
- Voting by a panel of experts from inside and outside ECRI Institute

But this is not an exercise in simple tabulation. 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.

ECRI Institute’s Top 10 Patient Safety Concerns for 2017

1. Information management in EHRs
2. Unrecognized patient deterioration
3. Implementation and use of clinical decision support
4. Test result reporting and follow-up
5. Antimicrobial stewardship
6. Patient identification
7. Opioid administration and monitoring in acute care
8. Behavioral health issues in non-behavioral-health settings
9. Management of new oral anticoagulants
10. Inadequate organization systems or processes to improve safety and quality
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 an organization should address. Rather, it’s intended to serve as a catalyst for discussion about the top patient safety issues faced by the organization.

Determine whether your organization faces similar issues that should be targeted for improvement. Organizations can investigate whether they are experiencing problems with these or related concerns—and whether they 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 Institute resources that provide more in-depth guidance. Some are available without charge; others are benefits of ECRI Institute membership programs or 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.

Consider applications across care settings. Although not all patient safety concerns on this list apply to all healthcare organizations, many are relevant to a range of settings across the continuum of care.
Information Management in EHRs

Healthcare providers have troves of information to manage, and the advent of electronic health records (EHRs) has brought this challenge to the forefront. “But the object is still for people to have the information that they need to make the best clinical decision,” says Lorraine B. Possanza, DPM, JD, MBE, senior patient safety, risk, and quality analyst and health information technology (IT) patient safety liaison, ECRI Institute. Consider the following near miss reported to the Partnership for Health IT Patient Safety, a multi-stakeholder collaborative convened by ECRI Institute:

A newborn’s weight and height were measured at birth and documented in the record. The height carried forward to the pharmacy system, but the weight did not. The pharmacy system displayed an ideal body weight, which the pharmacist used to calculate antibiotic doses for the patient. On receiving the medications, the bedside nurse rechecked the doses, which were more than twice what they should have been given the patient’s actual body weight. The nurse contacted the clinician and the pharmacist and entered the actual weight into the weight field so that the appropriate doses could be calculated.

Health information needs to be clear, accurate, up to date, readily available, and easily accessible, says Possanza. If the information fails to meet any of those criteria, we must consider, “What are the things that can get in the way of that?”

Information management involving EHRs can be subdivided into three main categories, Possanza explains. The first category is interoperability. Systems may have difficulty managing information—because it is not accurately exchanged, is partially exchanged, or is not exchanged in a manner that will result in the same interpretation of that information.

The second category is usability, defined by the Healthcare Information and Management Systems Society as “the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment.” If an organization decides to put patient allergy information in the EHR header, for example, clinicians might assume, sometimes mistakenly, that the header includes all allergies.

The third category is access. For example, many organizations restrict access to parts of the EHR based on role, and clinicians might not realize that they do have access to certain sections. “Do you know the capacity that you have?” Possanza asks.

Approach Health IT Safety Holistically

Healthcare organizations must approach health IT safety holistically. “You can’t just look at this in isolation,” Possanza urges. In approaching this issue, organizations should consider why information must be managed.
Health IT systems function in a highly technical, fast-paced, quickly changing environment involving multiple providers. All of the relevant information must be effectively managed if it is to be available to facilitate patient identification, communication among providers, and ordering of tests and treatments.

One key step is integrating health information management professionals, IT professionals, and clinical engineers into patient safety, quality, and risk management programs. A supportive culture is also necessary. Instead of criticizing or punishing people who have concerns involving health IT safety, healthcare organizations should be “actually encouraging them and investigating what their concerns are,” says Possanza. Such a culture also promotes critical thinking, she adds.

Engaging patients—through patient portals, visit summaries, and tailored and usable discharge instructions—may improve information management. “Focus on making patients partners in their care,” Possanza suggests.

Understand the System’s Capabilities

Users need to understand more than just how to use the EHR system. “Knowing what your system does and what it’s capable of—that’s important,” says Possanza.

Do users know which information is available to them? Do they know which information transfers to other systems? Do they rely on information in the record? Do users know what to expect—for example, do they know whether the most recent lab result appears at the top or bottom of the list? If a list does not include every potential item—such as the list of allergies in the EHR header—does a note indicate that more information is available elsewhere? Do users presume that calculations are correct?

Users also need to recognize what problems can occur. If, for example, the system suggests patient names in a drop-down list once the user starts to type, does the registration representative realize that the drop-down might show both Mary Brown and Mabel Brown but automatically highlight one of the names for selection—and appreciate the potential consequences of selecting the incorrect record?

Organizations should also have processes for addressing identified problems. For example, a clinician might realize that a patient’s care is being documented in the wrong record. As a user, “what’s my process, where do I go, whom do I tell?” Possanza asks.

Harness the Power of the EHR

Good information management leads to better workflows and safer patient care. And when properly implemented, used, and monitored, EHR systems can also be powerful tools to enhance patient safety.

An EHR system might remind a clinician that months ago, he or she recommended that the patient have a colonoscopy. The system might also indicate whether the patient had the colonoscopy, whether the results are available, and what the results were. This reduces reliance on memory and helps close the loop. “There’s no reason that we can’t harness technology to do that,” says Possanza.
Over the past few decades, improved clinical protocols, training and education for providers, and public awareness campaigns have enabled speedier recognition of and response to stroke and ST-elevation myocardial infarction (STEMI). “People have seen how well the campaigns have worked for stroke and STEMI and how much they’ve improved outcomes,” says Patricia N. Neumann, RN, MS, senior patient safety analyst and consultant, ECRI Institute. What if those same principles could be applied to other conditions that require fast recognition and management? “We could have a big impact on improving outcomes,” Neumann suggests.

If unrecognized, patient deterioration can have catastrophic consequences. Like stroke and STEMI, certain other conditions—including sepsis, some maternal conditions (e.g., hemorrhage, venous thromboembolism, hypertensive crisis), and serious postsurgical complications—“need the same type of prompt recognition and attention in order for the patient to have a good outcome,” says Neumann. The following example from the PSO database illustrates multiple delays in the recognition and management of sepsis:

The patient was in the emergency department (ED) for several hours. During this time, one antibiotic ordered to be given as soon as possible was never given. “Stat” labs were never drawn. No sepsis alert was called on admission. The patient was admitted to the intensive care unit (ICU) with sepsis. On calling the ED to clarify orders, the ICU physician was put on hold for more than five minutes with no response.

A related issue, medication-related respiratory depression, is addressed in patient safety concern #7 on this year’s Top 10 list.

Plan for Appropriate Care and Monitoring

For some conditions, clinicians can proactively assess patients’ risk and plan accordingly. For example, the American College of Surgeons’ Surgical Risk Calculator can be used to predict risk of complications, allowing surgeons to plan for appropriate postoperative care and monitoring. “There needs to be a way to monitor patients’ conditions and make sure they’re receiving the right level of care,” Neumann states.

In some clinical situations, patients at risk for certain conditions are monitored with medical devices. Algorithms have been developed that trigger alerts, such as sepsis alerts or rapid response system alerts, when information in the EHR suggests that a patient’s condition may be deteriorating. These modalities supplement, but do not replace, nurse monitoring.

Build Competencies and Critical Thinking

Different patient conditions manifest deterioration in different ways. For example, stroke signs and symptoms differ from those associated with postsurgical internal bleeding. Therefore, organizations must cultivate staff competencies in rapidly identifying conditions of concern. Ongoing staff education and training can develop these competencies.
Practice in recognizing patient deterioration can support providers’ ability to apply their critical thinking skills to a particular patient’s situation. Simulations or case scenarios can prompt participants to consider the patient’s history and monitoring results, then “think about the scenario and figure out questions to ask based on what they know could be happening with the patient,” says Neumann. In addition, tools such as the Quick Sepsis Related Organ Failure Assessment and the Maternal Early Warning Criteria are intended to aid early recognition.

**Respond Speedily and Effectively**

Once a patient’s deterioration is recognized, the response must be prompt, organized, and effective. Condition-specific protocols should be in place. “There’s a whole sequence of events that you enact for each of these conditions,” Neumann explains. For example, the Surviving Sepsis Campaign’s sepsis guidelines outline two bundles of interventions that should be performed within three and six hours, respectively, of recognizing sepsis. Bundles and clinical protocols have been developed for a variety of maternal, postsurgical, and other time-sensitive conditions as well.

For organizations that already have clinical protocols and bundles in place, a key question is whether they are implemented in a consistent and timely manner. If the organization is struggling, it can analyze its work systems and processes to identify barriers and address them. The idea is to make it easy for providers to adhere to the protocols.

To respond quickly when a patient needs immediate attention or displays general signs of deterioration, organizations can evaluate and optimize the effectiveness of their rapid response systems. These systems may be activated when certain criteria are met or when providers—and even patients or family members, in some organizations—are concerned that the patient’s condition may be deteriorating.

**Raise Public Awareness**

Public awareness can play a vital role in improving outcomes for time-sensitive conditions. To promote sepsis awareness and patient education, the Centers for Disease Control and Prevention (CDC) offers information for patients, and other resources are available from the World Sepsis Day website. Patient information and education for those at risk for particular conditions—including but not limited to maternal and postsurgical conditions—can emphasize what patients should watch for, what they must do if they spot those warning signs, and why it’s important to do those things. Just as public awareness campaigns have taught the public how to recognize stroke and STEMI, healthcare organizations can help educate patients and the general public on other time-sensitive conditions.
Implementation and Use of Clinical Decision Support

Clinical decision support (CDS) encompasses “tools that we use to ensure that the right information is presented at the right time within the workflow,” explains Robert C. Giannini, NHA, CHTS-IM/CP, patient safety analyst and consultant, ECRI Institute. But if implementation or use is suboptimal, opportunities for CDS to aid decision making may be missed. Care could suffer, and patient harm could result. The following example from the PSO database resulted in a delay in treatment:

Antibiotics were ordered for an ED patient, but were not given while he was in the ED. When the patient was transferred to the floor, the ED nurse marked the task “not given” and noted that the antibiotics were sent with the patient. Marking the task “not given” removes it from the medication administration record, so the floor nurse did not even have an “overdue” task to flag that the antibiotics needed to be given. The omission was discovered six hours later. Antibiotics were ordered “stat.”

In fact, in a sample of 113 events involving CDS reviewed by ECRI Institute PSO, 5 resulted in patient harm requiring treatment or intervention. In 46% of the events in the sample, the safeguard did not function as expected. Interestingly, in 27% of the events, no CDS was available to address the patient safety concern that was reported, but “staff suggested that clinical decision support should be implemented” to address the problem, Giannini notes, as in the following case:

Shortly after shift change, I went to give the patient his pills [an opioid pain medication]. He told me he was in pain but did not tell me he had just been given the pills. I scanned the medication, and the system allowed me to give it. There was no pop-up screen to alert me that the patient had already taken the pills. The patient was given the additional medication but is fine.

Poorly implemented CDS can also disrupt clinical workflows and frustrate providers, which can contribute to workarounds, ignoring or bypassing of alerts that might be relevant, and other safety concerns. “Just like alarm fatigue, there’s alert fatigue,” says Giannini. As a clinician, “you get so many alerts throughout your workflow that they become white noise.” This can even lead to liability concerns. “If I shut an alert off and something goes wrong, how liable am I for shutting that alert off?” asks Giannini. Many organizations “don’t have good processes in place to understand how clinical decision support impacts workflow,” he states.

Design Systems Judiciously

Healthcare organizations must design CDS systems judiciously. Fortunately, “people are starting to optimize their computer systems,” says Giannini, and resources are available. HealthIT.gov offers a suite of how-to guides.
on CDS implementation and a SAFER (Safety Assurance Factors for EHR Resilience) guide on using computerized provider order entry (CPOE) with CDS. Resources are also available from organizations such as the Healthcare Information and Management Systems Society and ECRI Institute (see “ECRI Institute Resources”).

Oversight of CDS should be assigned to a multidisciplinary team to ensure appropriate planning, testing, implementation, and monitoring. Organizations should also determine the “what, who, how, where, when” for CDS prior to implementation and consider matching CDS workflow with the appropriate provider.

Interruptive CDS alerts can be limited by structuring alerts and assigning them to tiers based on severity. Tiering the action required, Giannini explains, involves deciding whether an alert calls for a forcing function, which requires providers to do something before they can proceed, or a notification, which presents pertinent information but does not require action.

End users must be adequately trained in the proper use of CDS. “When we implement these types of tools, we tend to focus education of the frontline users on the ‘how to’ and not on what their roles and responsibilities are,” says Giannini. CDS functionality should be tested before systems go live, then tested again in the production system before clinical use.

Support Users and Monitor Effectiveness

CDS should be supported and monitored for effectiveness not just for a limited period after implementation but on an ongoing basis. Support structures, such as resources for clinical end users, should be planned as part of the implementation effort.

Organizations should monitor the effectiveness and appropriateness of CDS alerts, evaluate the impact on workflow, review the response from staff to the alerts that fire, and redesign the tool as necessary. CDS functions “not only need to be effective within the workflow of the person, they also need to be appropriate,” Giannini notes. Ongoing monitoring and intervention helps organizations “close that loop in the improvement cycle.”

Part of ongoing monitoring involves analyzing data on how many alerts are generated, to whom the alerts are directed, and how often and how users act on them. Most systems can track and trend what providers are clicking on, according to Giannini. These data can identify functions that are ineffective and can otherwise inform improvement efforts. For alerts that are appropriate, effective, and worthy of a forcing function, department chairs might coach providers who are, for example, entering random keystrokes in order to bypass a forcing function.

Another challenge lies in making sure that the underlying clinical content is up to date—after all, guidelines and best practices can change. “Who’s the expert, and how often do you need to look at that?” Giannini asks. Organizations can assign ownership for specific types of clinical content to specific individuals to ensure that CDS functions continue to support safe and effective evidence-based care.
Test Result Reporting and Follow-Up

Testing is a complex process that involves many healthcare professionals, processes, and technologies. When inadequately managed, this complexity can contribute to fragmentation and gaps in test result reporting and follow-up. “Sometimes as clinicians we become very task oriented—labs ordered, blood drawn and sent; imaging ordered, x-ray completed—and we lose sight of the big picture,” says Kelly C. Graham, RN, patient safety analyst and consultant, ECRI Institute. “Critical thinking and teamwork get lost when you’re focusing just on your assigned task.”

In ECRI Institute’s experience, problems with test result reporting and follow-up frequently contribute to events involving testing by the laboratory, pathology, and blood banking. As Graham notes, ECRI Institute PSO’s Deep Dive: Laboratory Events found that 22% of the events occurred in the postanalytic phase, which involves results reporting, test interpretation and follow-up, and specimen storage.

Difficulties in coordinating care—with other providers or with patients themselves—may complicate an already labyrinthine process. “One thing that really concerns me is patients who are being discharged and still have labs pending,” says Graham, a problem seen in the following example from the PSO database:

A patient who left an ED against medical advice had to be called back to the hospital for further evaluation after the delayed results for a troponin test indicated elevated levels.

Other care coordination issues include lack of information regarding the patient’s primary care provider, difficulty communicating results to providers outside the health system’s network, lack of patient follow-up with the provider, and difficulties reaching the patient directly (e.g., due to outdated contact information).

Ambiguous accountability can also prevent effective follow-up. For example, a result may go to multiple providers, each of whom assumes someone else is following up on the result, when in fact no one is doing so. “We need to make sure it’s taken to the next level and acted upon,” Graham states.

Problems with test result reporting and follow-up can lead to diagnostic errors, such as missed, delayed, or inaccurate diagnoses. For example, failure to follow up on a biopsy result could lead to a patient’s cancer going undiagnosed, possibly for years, with potentially life-threatening consequences. Treatment errors can result as well. For example, if no one notices a test result indicating that a patient’s response to anticoagulant therapy is over therapeutic levels, a bleed or stroke could occur, says Graham.
Analyze the Process

Organizations should analyze their test result reporting and follow-up systems. Some elements should be standardized, such as procedures for reporting critical results, communicating results if ordering providers cannot be reached or do not respond to critical results, communicating results orally, and documenting results. The organization should also identify critical tests, critical results, and critical values that require timely communication and establish time frames for reporting results based on urgency.

Some organizations establish call centers that contact ordering personnel with critical results. Similarly, some EDs have a nurse practitioner check all results and call patients with critical or abnormal results.

Designate Accountability and Close the Loop

To avoid ambiguity, organizations can seek ways to designate accountability for acting on test results. Policies and procedures should address “how to ensure that someone’s responsible for getting the result and following up on next steps,” says Graham. For example, some organizations make ordering physicians explicitly responsible for follow-up, unless the responsibility is delegated to another provider and accepted in advance by the other provider. Policies and procedures should also specify who is accountable in the event that the designated provider is unavailable.

Organizations can also monitor how well they’re doing in “getting the results to the right people and following through with the next steps,” according to Graham. What percentage of reports go unopened after a certain period of time? For what percentage of reports are timely follow-up actions taken?

Direct verbal communication with other providers is still necessary in some situations (e.g., when reporting critical results) and might be prudent in others (e.g., when reporting equivocal results). The Institute of Medicine’s (which has since been renamed the National Academy of Medicine) report on improving diagnosis recommends facilitating collaboration among healthcare professionals involved in treatment and healthcare professionals involved in diagnostic testing, such as laboratory staff, radiologists, and pathologists, both within and across settings. In some circumstances, that means “you need to have a two-way conversation,” Graham states.

Engage Patients

Particularly because they may need to schedule follow-up appointments or seek additional care, patients also play a role in test result communication and follow-up. “Sometimes, we get so focused on our clinical duties, we don’t engage patients in this,” says Graham—but we should.

Providers can teach patients about what tests are being ordered, when the results will be ready, and how they can get the results. Patient engagement and health literacy strategies, such as teach back, user-friendly written materials, patient navigators, and patient portals, can help patients understand what to do and why it is important and support them in seeking necessary care.

ECRI Institute Resources

HRC

- Test Tracking and Follow-Up
- Diagnostic Errors: Monumental Problem or Enormous Opportunity?
- Ask HRC: Must a Physician Review Normal Test Results?

Other Memberships and Sources*

- ECRI Institute PSO Deep Dive: Laboratory Events
- Out-of-Office: Tracking Test Results in the Outpatient Setting
- Test Tracking and Follow-Up Toolkit

* Some ECRI Institute resources are publicly available. To obtain other ECRI Institute reports, contact us by telephone at (610) 825-6000, ext. 5891, or by e-mail at clientservices@ecri.org.
“Since 1928, millions of lives have been saved due to the miracle discovery of penicillin,” says Sharon Bradley, RN, CIC, senior infection prevention analyst, ECRI Institute. But even early on, the discoverer of penicillin, Sir Alexander Fleming, recognized the potential for microbial resistance. Not long after winning the Nobel Prize in 1945, Fleming said, “The thoughtless person playing with penicillin treatment is morally responsible for the death of the man who finally succumbs to infection with the penicillin-resistant organism.”

Fleming’s warning was prophetic. Today, drug choices for treating many bacterial infections are becoming increasingly limited and expensive—and in some cases, nonexistent. According to CDC, resistant organisms cause at least 23,000 deaths and 2 million illnesses in the United States each year. At least 18 drug-resistant organisms are current threats. “We were warned,” Bradley states, “but we’re ignoring the warning.”

A December 2016 CDC blog post by Christian John Lillis, executive director of the Peggy Lillis Foundation, illustrates both the promises and the perils of antibiotics. Lillis notes that antibiotics probably saved his life after he became sick with scarlet fever at the age of six. But he also describes how his mother died of Clostridium difficile infection three decades later:

> My mother’s deadly C. diff infection began with her being prescribed a prophylactic dose of an antibiotic, clindamycin, following a root canal. Within four days, she began to experience diarrhea. Ten days after beginning her course of antibiotics, she was dead.

Inappropriate prescribing is a key factor in promoting resistance and contributing to C. difficile infections. For example, older adults commonly have bacteria in their urine (colonization), but providers sometimes prescribe antibiotics even if the patient has no symptoms of illness. Colonization in the absence of symptoms is not an infection and does not require treatment. CDC has estimated that 30% of antibiotics prescribed in outpatient settings are unnecessary. “If prescribing habits do not change, more people will die from infections for which there is no treatment,” Bradley asserts.

In some cases, patients or family members demand an antibiotic. They may complain to insurance companies or even go elsewhere for care. Many do not understand how resistance occurs or how their taking an unnecessary antibiotic relates to rising rates of antibiotic-resistant infections. “We need to explain the risks and serious side effects of taking unnecessary antibiotics,” says Bradley.

It is true that healthcare organizations are starting to track and talk about how antibiotics are being used. “But progress is slow, and disease-producing organisms continue to develop new resistance patterns at an alarming rate,” Bradley states.
In the future, antimicrobial stewardship may be a requirement rather than an option. The Centers for Medicare and Medicaid Services now requires antimicrobial stewardship programs in nursing homes and has proposed requiring antimicrobial stewardship programs in hospitals and critical access hospitals. A new Joint Commission standard recently took effect, calling for antimicrobial stewardship programs in hospitals, critical access hospitals, and nursing care centers. “The regulators are starting to hold prescribers and healthcare facilities accountable,” says Bradley.

Engage Clinicians and Patients

By engaging clinicians and patients, healthcare organizations can help change attitudes and practices. Bradley suggests holding prescribers accountable for adherence to nationally recognized treatment guidelines. These guidelines help prescribers decide whether antimicrobials are appropriate and, if so, which antibiotic and which dosage to prescribe. A physician advocate, such as an infectious disease physician in a hospital or the medical director in a nursing home, can lead the effort and talk to other physicians as a peer.

In some circumstances, watchful waiting may be appropriate. For example, clinicians may ask patients with certain signs and symptoms who are seen for an ear infection to wait a few days, use symptomatic treatment, and see if they feel better before prescribing antibiotics. Another helpful tool is the antibiogram, a chart that shows antibiotic susceptibility patterns specific to the organization and can be used to guide selection of antimicrobial therapy when it is indicated.

Patients, family members, and the general public need a better understanding of antimicrobial stewardship and the reasons behind it. CDC offers information and tools for patients, healthcare settings, and the general public.

Implement the Core Elements

CDC has outlined core elements for antibiotic stewardship for hospitals and nursing homes. Recently, CDC identified core elements for outpatient settings as well. Bradley suggests using the checklists included in each set of core elements to identify gaps.

Across all three settings, one of the core elements is tracking and reporting of antibiotic use and giving feedback to prescribers. Healthcare organizations can “start tracking how antibiotics are used, identify barriers to optimal practice, and hold prescribers accountable for compliance with nationally recognized treatment guidelines,” Bradley suggests. By understanding how antibiotics are used in their organizations, they can begin to find ways to improve.

ECRI Institute Resources

HRC

- High-Profile Healthcare-Associated Infections
- Overview of Infection Prevention and Control

Other Memberships and Sources*

- Clostridium difficile Infections

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

The release of ECRI Institute PSO’s Deep Dive: Patient Identification, based on events submitted to the PSO database, focused the spotlight on a process essential for safe patient care. A basic tenet of safe care is to deliver the correct intervention to the correct patient, says William M. Marella, MBA, MMI, executive director, PSO operations and analytics, ECRI Institute. Yet, the 7,613 events analyzed for the Deep Dive represent examples when safe care didn’t occur or almost didn’t occur because of patient identification mistakes. The events spanned a 32-month period at 181 healthcare organizations.

“The report brought national attention to an issue that most healthcare providers recognize as a significant problem,” says Marella.

Although the majority of the events were caught before they caused patient harm, about 9% resulted in patient injury, including two deaths. Consider the following example:

A newborn needed follow-up care as a result of a patient identification mistake. The infant received another infant’s breastmilk. The mother who produced the breastmilk was infected with the hepatitis B virus, so the infant had to be treated with hepatitis B immune globulin.

Although healthcare organizations support the use of at least two patient-specific patient identifiers to make sure each patient gets the correct medicine and treatment, the Deep Dive analysis found that “it’s often not done or it’s not done as intended,” says Marella. The report recommends “high-leverage strategies” to support correct patient identification throughout the care process.

Gain Leadership Support

Preventing patient mix-ups starts with the organization’s senior leaders giving their full support for initiatives to ensure correct patient identification. Recounting the experience of one organization that experienced a fatal patient identification error, Marella says the organization’s leaders took ownership of the issue, asked staff to identify the barriers that prevented them from following safe identification practices, made attention to patient identification practices a top priority, and empowered staff to speak up when they observed unsafe behavior, such as failing to ask a patient to provide two patient identifiers with each encounter.

Leaders must send the message that nearly every staff member plays a role in ensuring correct patient identification, says Marella, emphasizing involvement of both clinical and nonclinical staff. About 13% of the mistakes identified in the Deep Dive report occurred during the registration process, and these errors can have a downstream effect on patient care. “Everyone is aware of the importance of capturing accurate patient information for billing purposes, but patient intake staff don’t always recognize the effect [such mistakes] can
Standardize

Standardization is “an elegant solution” that can improve patient identification without always requiring staff to alter their work processes, says Marella. For example, presenting critical information for patient identification (e.g., patient date of birth, age, gender) in a consistent manner and format in electronic displays can reduce the likelihood that a staff person will select the wrong patient record. About 15% of events from the Deep Dive analysis were associated with health IT. Other visual cues, such as font size and display of patient photographs, can also help reduce patient record mix-ups. Many of these principles are outlined in the National Institute of Standards and Technology’s (NIST) 2015 recommendations for standardized approaches for electronic displays to improve clinicians’ ability to differentiate patients’ records.

“The NIST standards are an example of a standardization strategy that doesn’t burden clinicians but instead reduces the cognitive complexity of what they are doing,” says Marella. “The standards reduce the chances that clinicians will pull up a wrong record and do something incorrect without noticing.”

Standardizing patient identification band designs and labels may also reduce identification mistakes.

Enlist Technology

Technology also plays a role in improving patient identification—as long as it is used as intended. Bar-code systems, for example, allow the user to scan bar codes with important information about a patient’s identifiers, and are an important adjunct to patient identity verification. The technology can alert a caregiver to a potential medication administration mistake if a scanned medication and patient identification band don’t match. “Technology has the potential to eliminate variation in human performance,” says Marella, by detecting mistakes that people miss for a variety of reasons, such as distractions and fatigue.

Nevertheless, organizations must have a well-defined approach to implement the technology. Technology may be used inappropriately if it is poorly designed, staff do not know how to use it correctly or optimally, or staff perceive it as interfering with their workload. Some of the events from the Deep Dive analysis showed that staff took shortcuts with bar-code scanning, circumventing the safety features that help identify patient mix-ups.

Acknowledging that there’s “no single magic bullet” that can eliminate all patient identification errors, Marella emphasizes that organizations can increase the likelihood of preventing patient mix-ups with “redundant processes” for patient identification. “Individual strategies will fail at times. The idea is to have enough [strategies] so that one or more will avert the most significant events.”

ECRI Institute Resources

HRC
- Patient Identification
- Self-Assessment: Patient Identification

Other Memberships and Sources*
- ECRI Institute PSO Deep Dive: Patient Identification
- ECRI Institute PSO Deep Dive on Patient Identification (webinar)
- INsight Patient Identification Assessments
- Health IT Safe Practices: Toolkit for the Safe Use of Health IT for Patient Identification

*Some ECRI Institute resources are publicly available. To obtain other ECRI Institute reports, contact us by telephone at (610) 825-6000, ext. 5891, or by e-mail at clientservices@ecri.org.
In analyzing events for its upcoming Deep Dive on opioid safety, ECRI Institute PSO noted problems of concern with opioid administration and monitoring of patients on opioids. “We’re seeing the same issues with administration that you see with other medications,” says Gail Horvath, MSN, RN, CNOR, CRCST, patient safety analyst and consultant, ECRI Institute. However, “unlike with some of these other medications, opioids can have catastrophic consequences.” The following example from the PSO database illustrates one adverse event involving opioid administration:

During a shift-to-shift handoff, the patient was observed to be very drowsy and was slurring her words. She was unable to lift her arms. The medication administration record was reviewed; the patient had been given an opioid, a benzodiazepine, and a muscle relaxant all within an hour of one another. The patient’s vital signs were stable. The rapid response team was called for further assessment, and a reversal agent was administered. The effects of the medications were reversed, after which the patient was alert and oriented and able to move all extremities equally. The physician ordered a brain computed tomography scan and periodic neurologic assessments.

The three prescribed drugs were all central nervous system depressants. Although each may have been appropriate if administered at a different time from the others, administering such medications so close together can result in respiratory depression.

Unrecognized respiratory depression can be fatal. Patients who do survive can suffer anoxic brain injury, possibly requiring care for the rest of their lives. Notably, respiratory depression can occur in the absence of a medication error. A patient can become oversedated even if the opioid is appropriately prescribed and administered, underscoring the importance of patient monitoring.

But in the event that a medication error involving an opioid does occur, appropriate monitoring may be the last chance to prevent a terrible outcome. “When we combine a medication error with a failure to monitor, we’re setting up the perfect storm,” says Horvath.

Although regulators’ and accreditors’ emphasis on pain management has been tempered, patient satisfaction scores—not to mention patients’ need for effective pain management—remain a concern. However, “we can’t medicate to a patient satisfaction score,” Horvath cautions. “If in an attempt to do good we’re causing harm, we’re not meeting our ethical responsibility to our patient.”
Evaluate Protocols and Seek Best Practices

At a basic level, ensuring safe opioid administration involves doing “the same things you do with any other medication” to ensure safe administration, Horvath states. The organization may wish to evaluate and address work system and process factors that may contribute to opioid administration errors, such as organizational culture, communication and documentation of pertinent information (e.g., allergies, medication administration), staffing, workload, and distractions. The ECRI Institute resources listed here offer further guidance and resources.

Because opioids are capable of causing severe patient harm, additional measures are indicated. Organizations can evaluate whether protocols for opioid administration are in place—and whether they are followed and whether they are effective. Best practices can be implemented for processes such as patient identification, medication purchasing (e.g., to avoid look-alike packaging), labeling, dispensing (e.g., appropriate setup and stocking of automated dispensing cabinets), use of bar-code medication administration systems, independent double checks, and use of smart pumps.

Assess and Monitor Patients Appropriately

Safe opioid use calls for careful evaluation of the patient both before and after administration. Before administration, the patient is assessed for factors including level of pain, opioid tolerance, respiratory function, vital signs, and level of consciousness. “We should be assessing the patient thoroughly before administering opioids,” Horvath suggests. “Make sure clinical staff are really trained on how to do it.”

After administration, the patient is monitored for pain, level of sedation, both the rate and the quality of respirations, and vital signs. Several opioid-induced sedation scales exist to aid staff in monitoring patients.

Technology can supplement, but not replace, diligent nurse monitoring. ECRI Institute recommends that healthcare organizations implement measures to continuously monitor the adequacy of ventilation for two groups of patients:

- Patients receiving parenteral and neuraxial opioids in medical-surgical and general care areas
- Patients receiving opioids in hospitals and ambulatory surgery or endoscopy facilities during procedural sedation and while in postanesthesia care units

These patients can be monitored either with capnography—that is, the measurement of end-tidal carbon dioxide—or by assessing minute ventilation. Organizations will need to determine which patients will be monitored and for how long. However, ECRI Institute does not recommend purchasing pulse oximeters, which monitor adequacy of oxygenation, for this application. “By the time the oxygen saturation drops, the patient’s in trouble,” says Horvath.

ECRI Institute Resources

HRC
- Patient-Controlled Analgesia
- Infusion Pumps
- Pain Management

Other Memberships and Sources*
- Pain Relief: How to Keep Opioid Administration Safe
- Opioids and Oversedation: Still a Common Problem
- Patient Risk Factors for Opioid-Induced Respiratory Depression
- Preventing Opioid-Induced Respiratory Depression (webinar)
- Implementing Monitoring for Opioid-Induced Respiratory Depression in Medical-Surgical and Other General Care Units
- 2017 Top 10 Health Technology Hazards

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Today, “violence in our society has become commonplace,” and healthcare organizations are not immune, says Nancy Napolitano, patient safety analyst and consultant, ECRI Institute. The problem of violence in healthcare settings is multipronged, but one crucial element is patients’ unaddressed behavioral health needs.

Some patients in hospitals’ medical units have behavioral health disorders; others may have adverse reactions to medical treatment (such as delirium) or experience an adverse effect of a medication. Particularly in the absence of screening and assessment, healthcare organizations do not always recognize when a patient has behavioral health needs—and the patient’s needs may therefore go unmet. “We’re very reactive, and that’s part of the problem,” according to Napolitano.

Some unmet behavioral health needs can cause hostile or aggressive behavior. The behaviors can be frightening or frustrating for staff, especially if they do not have the necessary training or support to handle such behaviors. Patients and staff can be injured, sometimes seriously. “Hospitals have a difficult challenge keeping staff and patients safe while maintaining patient rights,” Napolitano states.

When a patient’s behavior becomes a concern, “usually, the first line of defense is to call security, which can escalate an already heightened situation,” says Napolitano. Consider the following example from ECRI Institute’s PSO database:

A nurse was attempting to redirect a patient, for the fifth time, who kept walking in and out of his room half-dressed. The patient suddenly became violent and physically attacked two staff members. A security alert was sounded, and three security staff responded. The patient was immediately tackled to the ground, contained, and restrained. The patient had scratches and an abrasion. The two staff members suffered more serious injuries.

Many hospitals seek to hire moonlighting or former police officers or people who have served in the military as security officers. However, “the skills that they have are usually very aggressive and life-or-death in nature,” Napolitano explains, and they are not always well trained in how to work with patients in hospitals versus people on the streets. With some hospitals now allowing security staff to carry weapons, a situation can quickly escalate to a lethal level.

Assess Patients and Identify Needs

Comprehensively assessing all patients can help providers proactively determine patients’ behavioral health needs. “You can’t just assess what their medical needs are, you need to really assess what their mental needs are, too,” says Napolitano. “You need to know about the whole patient [whom] you’re dealing with.”
Some organizations have a means of identifying patients who have a history of violence. Having some kind of indicator in the chart may be helpful, whereas publicly visible indicators, such as color-coded dots on patient room doors, may anger patients or family members and perpetuate stigma. The idea is to find “some way of identifying the patient without labeling the patient, some way that doesn’t make people avoid the patient or talk about them in the hallway,” Napolitano suggests. Risk for violence can also be discussed during handoffs.

**Develop Skills for All Staff**

All staff should be trained to work with patients who have behavioral health needs and should participate in frequent mock drills. Training should address how to recognize early signs or cues of behavioral health needs, use nonoffensive techniques, and de-escalate a situation. Training and frequent drills are crucial because “de-escalating someone is not your normal reaction,” says Napolitano. When confronted with aggression, people typically go into fight-or-flight mode, but de-escalation requires a calm, measured response. “It’s a learned behavior,” Napolitano adds.

Staff also need to listen and respond empathically. “Sometimes, the patient needs to be heard,” Napolitano states, even if staff do not agree with what the patient is saying. It is possible, for example, that the patient does not understand the proposed treatment or wants to consider alternatives.

Processes for hiring and training security officers should also be refined. Napolitano suggests discussing safety requirements and the role of the security officer during recruitment and in job descriptions. Security officers must also be trained in how to work with patients in a healthcare setting.

**Consider Behavioral Emergency Response Teams**

Some hospitals have created behavioral emergency response teams that staff members can call when a patient’s behavior becomes agitated or threatening. Team members may include psychiatrists, psychiatric nurses, social workers, psychiatric technicians, and security personnel.

Working collaboratively with the patient’s nurse, these teams provide timely consultation and intervention. This early assessment and response is critical in reducing behavioral challenges in the care of the whole patient. “It is so important to be proactive versus reactive to behavioral health needs,” says Napolitano.

**ECRI Institute Resources**

**HRC**

- Patient Violence
- Suicide Risk Assessment and Prevention in the Acute Care General Hospital Setting
- Mental Health in Aging Services

**Other Memberships and Sources***

- Assessing and Managing the Behavioral Health Needs of the Medical Patient (webinar)
- Managing Behavioral Health Needs of Adult Medical Inpatients
- Behavioral Rapid Response Teams for Acute Care Medical Units

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Since 2010, the U.S. Food and Drug Administration (FDA) has approved four new oral anticoagulant medications that their manufacturers promote as needing less patient monitoring than warfarin, an anticoagulant therapy requiring regular checks of a patient’s blood clotting function.

The new agents appeal to patients because they do not need monthly monitoring at anticoagulation clinics. “People see the commercials [for the new oral anticoagulants] and are asking for them,” says Stephanie Uses, PharmD, MJ, JD, patient safety analyst and consultant, ECRI Institute. With their increased use, “ECRI Institute PSO is starting to see more event reports involving the drugs,” she says. “We need more awareness of the proper use of the agents; it’s not ‘one size fits all’ and you’re done.”

For example, the four agents have 16 possible dosing regimens, based on the indication. Choices are fewer in selecting a starting dose for warfarin. Additionally, with the new agents some patient monitoring is still needed to evaluate the drug dose, particularly if a patient’s renal function changes.

A query of ECRI Institute PSO’s event report database identified 1,226 events associated with the new oral anticoagulants between 2010 and mid-2016. Of the 494 events for which a harm score was provided, almost 34% resulted in patient harm, ranging from temporary injuries to death. Bleeding events were among the most common types of events that reached patients, says Uses. Many events are associated with prescribers’ unfamiliarity with the new drugs, resulting in failure to monitor patients, dosing mistakes, and duplication of anticoagulant therapy. Consider the following example:

* A prescriber ordered an anticoagulant as part of a standard order set to prevent deep vein thrombosis, without recognizing that the patient was already taking one of the new oral anticoagulants for atrial fibrillation. Both the prescriber and the pharmacy overrode duplication warnings from the ordering system. Both medications were administered for two days before the duplication was discovered.

In another event, duplication of therapy was overlooked by several individuals involved in the patient’s care:

* The orthopedist ordered an oral anticoagulant from a postoperative orthopedic order set for a patient. The next day, the attending physician ordered an injectable anticoagulant from the prophylaxis order set for deep vein thrombosis. The pharmacist processing the order did not notice that the patient was already taking an oral anticoagulant. The nurse taking care of the patient did not catch the duplication of therapy and gave the patient the injection. After the patient received the injection, the clinical pharmacist discovered the error and orders were obtained to discontinue the injectable anticoagulant.
Use Clinical Decision Support

To minimize the risk of duplicating a patient’s anticoagulation therapy, Uses recommends that organizations use clinical decision support in the CPOE system to alert healthcare practitioners to the duplication of therapy. Organizations should ensure that the clinical decision support that is bundled with the ordering system has been upgraded to detect duplication of therapy with the new anticoagulants and to alert practitioners. Additionally, organizations should review use of the alerts to determine whether practitioners are addressing or ignoring them, as in the case reported to ECRI Institute PSO. Providers may need education about the new oral anticoagulants and the importance of not doubling up on different agents, says Uses.

Adopt Order Sets

Because the oral anticoagulants have multiple dosing protocols, Uses recommends that organizations institute standardized order sets with doses specified for the different medications based on indication. The order sets ensure that the ordering practitioner selects the correct dose based on the medication, indication, and patient parameters, such as renal function, says Uses. Additionally, a pharmacist should review the order to check that the dose matches the indication and is appropriate for the patient’s condition and that the patient has no contraindications.

Because patients may be taking any of the currently available anticoagulation therapies, healthcare organizations must ensure that all of the agents are in their formularies. “You can’t interchange the drugs,” she explains.

Plan Reversal Strategies

Just as the new oral anticoagulants have multiple dosing protocols, multiple strategies are also available to reverse the drugs’ effect on bleeding in emergency situations. One of the four drugs has an FDA-approved reversal agent, and other reversal strategies are available for the remaining three drugs. Healthcare organizations should have reversal strategies on hand, make sure their clinicians know how to use them, and ensure that sufficient supplies of reversal agents are readily available and accessible, says Uses. The reversal plans should be developed by a multidisciplinary team consisting of pharmacists, nurses, and physicians from the emergency and neurology departments. “Make sure everyone is on board with the plan,” says Uses.

Monitor Events

Uses reminds organizations to “collect and analyze events that are occurring [with anticoagulants] and look to see what else can be put in place” to prevent future events. In time, the number of events associated with oral anticoagulants could decline as practitioners become more familiar with the drugs. Some of the increased reporting could be occurring “because these are new agents, and we see increased awareness to report,” says Uses.

ECRI Institute Resources

HRC
- High-Alert Medications
- Medication Safety

Other Memberships and Sources*
- One Is Enough: Don’t Double Up on Oral Anticoagulants
- Oral Anticoagulant Management
- Oral Anticoagulants Old and New: Scrutinizing the Risks, Monitoring for Safety (webinar)

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Inadequate Organization Systems or Processes to Improve Safety and Quality

Numerous studies show a link between error prevention and a good safety culture that places a premium on patient safety as reflected in the values and attitudes of an organization’s staff. Nevertheless, healthcare organizations have been slow to adopt all the necessary features of a high-reliability organization that is vigilantly focused on learning from errors and identifying problems proactively.

These concerns are reflected in event reports submitted to ECRI Institute PSO, findings from culture-of-safety surveys of healthcare organizations, and in reviews of organizations’ root-cause analyses (RCAs) of serious events. For example, some event report narratives reflect staff concerns about attitudes and behaviors that can undermine patient safety, as in the following:

*I hope that more staff feel compelled to report these types of issues, [which] get swept under the rug by our management far too often.*

*Patients were put at risk by a fatigued doctor, and no one stopped this.*

Year-to-year findings from culture-of-safety surveys conducted by ECRI Institute, as well as those compiled in a national database, find that “a nonpunitive response to error is one of the lowest scoring dimensions,” says Elizabeth Drozd, MS, MT(ASCP), CPPS, patient safety analyst and consultant, ECRI Institute. If staff are afraid that they’ll be punished for making errors or reporting errors of others, they won’t report any errors, robbing organizations of a chance to learn about the system breakdowns that can cause people to make mistakes, she says.

Additionally, when ECRI Institute PSO is asked to provide feedback about organizations’ RCAs, “we’ll hear staff say, ‘That’s been a problem for a long time here.’ That begs the question, why wasn’t anything done sooner?” asks Drozd.

**Be Proactive**

Acknowledging that RCAs are vital to dissecting events and identifying strategies to prevent future events, Drozd also recommends that organizations “be proactive rather than waiting until a patient is harmed.” For healthcare organizations accredited by Joint Commission, a proactive approach to safety is an element of its accreditation standards. In addition to requiring that healthcare organizations conduct an RCA of a sentinel event, Joint Commission requires that healthcare organizations conduct a proactive risk assessment of a high-risk process every 18 months.

Even for facilities that are not accredited by Joint Commission, a proactive approach to safety is essential to examine processes, identify what can go wrong, and make the process less vulnerable to error before mistakes can occur, says Drozd. If possible, she recommends conducting more than one proactive risk assessment every 18 months. “A
lot of organizations think that because the Joint Commission only requires one every one-and-a-half years, ‘that’s all we’re going to do,’” she says. While that may be all that a small hospital, with limited resources, can accomplish, larger hospitals should do more, says Drozd. “When the organization is bringing in new technology or changing a process, that’s an opportunity for a proactive risk assessment to see what could go wrong.”

Look beyond Educational Fixes

Whether an organization is conducting an RCA or a proactive assessment, the preventive strategies identified from the analysis “should go beyond the weaker strategies of educating everyone, designing a policy, or sending a memo,” says Drozd. While these interventions are important, ECRI Institute often observes organizations adopt only these approaches in response to error, without exploring higher-level error reduction strategies, such as standardization and automation, that target system solutions and help individuals safely perform tasks.

Not all the higher-level strategies need to be expensive solutions, says Drozd. “I’ve seen creative, inexpensive solutions to prevent errors, such as using color-coded bins to identify where supplies are kept to give people visual cues to prevent them from selecting the wrong item.”

Adopt a Just Culture

Essential to a learning organization is supporting a “just culture” where people feel free to report mistakes without fear of retribution so that the organization can take steps to prevent similar problems. The emphasis is on learning rather than blaming, says Drozd, adding, “It’s not totally nonpunitive. If you do something to intentionally harm a patient, you may need to be referred to the right agency, which might be, for example, the local police.”

Rather than focusing only on nonpunitive approaches, organizations should foster a just culture, Drozd recommends, by taking the following actions:

- Get senior leadership involved so they back the program
- Obtain good training in how to implement a just culture, and fully communicate the concept to frontline staff to gain their support
- Follow a framework to balance individual accountability with organizational responsibility to design and improve systems to ensure the delivery of safe care
- Embed the just culture theory in the organization’s policies, including human resource policies
- Encourage reporting of events and near misses

Finally, Drozd reminds all organizations to “have a good and actionable quality and patient safety plan with high-level approval.” The plan, which should be reviewed and updated annually, establishes the organization’s goals for safety, defines roles for patient safety and quality departments within the organization, and outlines the organization’s response when events occur. “It’s a blueprint,” says Drozd. “The plan says this is what we’ll do in the next year, and here’s how we’ll do it.”

ECRI Institute Resources

HRC
- Culture of Safety
- Failure Mode and Effects Analysis
- Getting the Most out of Root-Cause Analyses

Other Memberships and Sources*
- INsight Safety Culture Assessments
- The Results from Our Surveys of Safety Culture Are In: Now What?

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