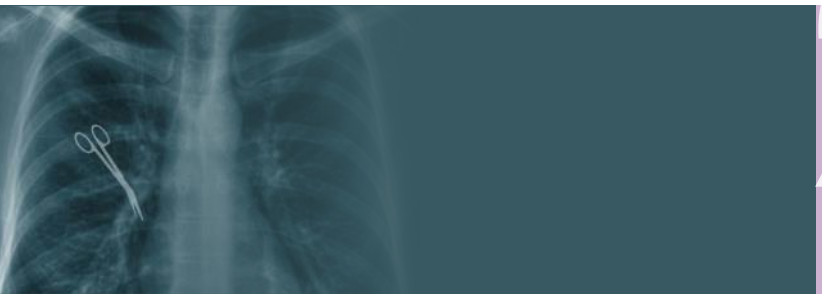
ECRI Institute's TOP 10 Patient Safety Concerns for Healthcare Organizations 2014



ECRI Institute
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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.

ECRI INSTITUTE HEADQUARTERS

ECRI Institute, 5200 Butler Pike
Plymouth Meeting, PA 19462-1298, USA
Tel + 1 (610) 825-6000

Introduction

OUR TOP 10

Ever since Dick Clark featured the American Bandstand Top Ten to unveil the 10 most popular songs for the week, such lists have become ubiquitous. We use them to get ideas in selecting music, movies, books, places to visit, things to do, trends to watch, and more.

We could probably identify the top 10 reasons why top 10 lists are so popular, but suffice it to say that the lists give us a way to focus on a particular issue or choice. When we scan a top 10 list, we compare it to our own experiences. Have I heard that song? Seen that movie? Read that book? Visited that place?

This year, ECRI Institute is publishing its *Top 10 Patient Safety Concerns for Healthcare Organizations* with the same intent: to give healthcare organizations a gauge to check their track record in patient safety. The list originally appeared in our *Healthcare Risk Control* (*HRC*) *System* newsletter, the *Risk Management Reporter*, and is reprinted in this report. The list is partly based on more than 300,000 patient safety events, custom research requests, and root-cause analyses submitted to our federally designated patient safety organization, ECRI Institute PSO, for evaluation and analysis.

Healthcare organizations can use the list to guide their own discussions about patient safety. Look at the list to ask whether any, some, or all of the top 10 areas identified are a concern for your organization. Your organization may decide to use the findings to identify one or more performance improvement initiatives.

No two organizations will have the same response to our top 10 list, and every organization will likely identify their own areas of concern outside of our top 10 list. The list is not meant to dictate areas to address but rather enhance and inform those internal discussions about patient safety.

We intend to publish our top 10 list of patient safety concerns on an annual basis. Use it along with ECRI Institute's other two top 10 lists—our list of health technology hazards and our list of technologies to watch—to stay informed in all areas of patient safety.

Sincerely,

Karen P. Zimmer, M.D., M.P.H., FAAP
Medical Director, ECRI Institute Patient Safety, Risk, and Quality Group, and ECRI Institute PSO

Top 10 Patient Safety Concerns for Healthcare Organizations

Patient safety is a top priority for every healthcare organization, but knowing where to direct patient safety initiatives can be a daunting task. To help guide organizations in deciding where to focus their patient safety efforts, ECRI Institute has developed a list of the top 10 patient safety concerns confronting healthcare organizations.

"We've been collecting events since 2009, and with over 300,000 events, we're at a point where it's important to share where we're seeing recurring themes," says Karen P. Zimmer, M.D., M.P.H., FAAP, medical director of ECRI Institute's patient safety, risk, and quality group and of ECRI Institute PSO, which compiled the list and was one of the first patient safety organizations (PSOs) to be federally certified. The list is largely based on recurring trends identified from the data voluntarily submitted to the PSO for review and analysis. The data includes more than 300,000 event reports, research requests, and root-cause analyses.

ECRI Institute's *Top 10 Patient Safety Concerns for Healthcare Organizations* is intended to enrich, not supplant, internal discussions about how to prioritize projects. "In a time of competing priorities and limited resources in healthcare, this list can help guide internal discussions on where to focus," says Zimmer. Included with this report of the 10 patient safety concerns are recommended risk mitigation strategies for these issues.

The list is one of several initiatives by ECRI Institute PSO to publicly share patient safety feedback based on its ever-growing database of patient safety events, says Catherine Pusey, RN, M.B.A., manager of clinical analysts at ECRI Institute PSO. The initiative underscores the intent of the Patient Safety and Quality Improvement Act of 2005, which laid the groundwork for providers to voluntarily report patient safety events to PSOs in a protected environment for PSOs to aggregate, analyze, and share findings and lessons learned. By collecting data from many providers, PSOs can spot problems and trends that an individual organization, with a limited pool of data, may be unable to detect.

ECRI Institute's list of the top patient safety concerns can be used with other ECRI Institute top 10 lists to guide organizational priorities, Zimmer says. The other two lists are ECRI Institute's annual top 10 health technology hazards and top 10 hospital C-suite watch list. Both reports for 2014 are publicly available; refer to "ECRI Institute's Top 10 Lists" for more information.

ECRI Institute's Top 10 Patient Safety Concerns for 2014

1. Data integrity failures with health information technology systems*
2. Poor care coordination with patient's next level of care
3. Test results reporting errors
4. Drug shortages
5. Failure to adequately manage behavioral health patients in acute care settings
6. Mislabeled specimens
7. Retained devices and unretrieved fragments*
8. Patient falls while toileting
9. Inadequate monitoring for respiratory depression in patients taking opioids
10. Inadequate reprocessing of endoscopes and surgical instruments*

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* Also included in ECRI Institute's list of the top 10 health technology hazards for 2014. For information on strategies to address these hazards, refer to the publicly available abridged version of the report *Top 10 Health Technology Hazards for 2014*, available online at https://www.ecri.org/2014hazards, and to the full article, published in the November 2013 issue of ECRI Institute's journal *Health Devices*.

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ECRI Institute's Top 10 Lists

ECRI Institute's top 10 list of patient safety concerns for 2014 is one in a series of top 10 lists available from ECRI Institute each year. While each list has a different focus, the three lists reflect a united effort at ECRI Institute to promote patient safety in healthcare organizations.

The newest list, *Top 10 Patient Safety Concerns for Healthcare Organizations*, is derived from ECRI Institute PSO's growing database of patient safety events, research requests, and root-cause analyses submitted to the PSO in a protected legal environment.

ECRI Institute's top 10 list of health technology hazards was the first such list to be issued by ECRI Institute; the first annual list was published in 2007. The list is developed by ECRI Institute's Health Devices Group and is based on various resources: ECRI Institute's and other organizations' databases for medical device problems and patient safety events, a review of medical device recalls and hazards, and ECRI Institute's experience in investigating and consulting on device-related incidents.

"We came up with the top 10 list of health technology hazards to raise awareness about the concerns with medical technology safety," says James P. Keller, M.S., vice president, health technology evaluation and safety, ECRI Institute. The list has gained increasing attention since it was first issued in 2007, and Keller says he has heard from hospital safety committees that use it to review where their organizations stand with each item on the list. "That's exactly what we want," says Keller. "We want hospitals to think about the patient safety concerns we raised, take action to review whether the risks exist in their setting, and make changes to address problems if they are identified."

Among the technology hazards identified for 2014 are the following:

- Medical device alarm hazards
- Infusion pump medication errors
- Computed tomography radiation exposures in pediatric patients

ECRI Institute's top 10 hospital C-suite watch list is not intended as a list of "must-have" technologies. Rather, it is a list of "must think carefully about" technologies and health system issues, says Diane Robertson, director, Health Technology Assessment Information Service, ECRI Institute. "The unbiased evidence that we present about these 10 technologies and infrastructure issues will get healthcare leaders off to a steady start on their often rocky journey of acquiring new technologies or making system-wide changes in 2014 and beyond."

The C-suite list draws upon ECRI Institute's more than 45 years of experience evaluating the safety, effectiveness, and cost-effectiveness of health technologies.

Topics on the 2014 C-suite list include the following:

- Computer-assisted sedation
- Emergency departments for the elderly
- Wearable powered exoskeleton rehabilitation for individuals with paraplegia

An abridged version of ECRI Institute's *Top 10 Health Technology Hazards for 2014* is publicly available at https://www.ecri.org/2014hazards. The *2014 Top 10 Hospital C-Suite Watch List* is freely available at https://www.ecri.org/Forms/Pages/2014-C-Suite-Watch-List.aspx.

How the List Was Compiled

To compile its list of patient safety concerns, ECRI Institute PSO reviewed its database of patient safety events, custom research requests from organizations participating in the PSO, and root-cause analyses submitted to the PSO for review and feedback. After compiling a list of about 20 potential patient safety concerns, the PSO presented it to a larger panel of experts, consisting of ECRI Institute staff and members of its PSO advisory council, to narrow the choices to 10. The list reflects the top choices, in ranked order, selected by the panel.

The final list highlights the risks to patient safety in process and systems issues, says Barbara G. Rebold, RN, M.S., CPHQ, ECRI Institute's director, PSO operations, and director, INsight assessment services. Given ECRI Institute's focus on medical device safety, there is also some overlap with the top 10 health technology hazards in the following three areas:

- Data integrity failures in health information technology (IT) systems
- Retained devices and unretrieved fragments
- Inadequate reprocessing of endoscopes and surgical instruments

"While we see a lot of hazards with medical devices at ECRI Institute, we also see a large amount of errors in processes and systems," says Rebold. The list of patient safety concerns brings another set of patient safety risks that need to be addressed, in addition to the health technology hazards, to the attention of healthcare organizations.

Given the wide range of healthcare organizations reporting to ECRI Institute PSO, the list also reflects a broad spectrum of facilities: large and small; urban, suburban, and rural; and community-based and academic, says Pusey. "The events reported to us are from across the U.S. They give us a deeper understanding that an event we're seeing in one organization, we're also seeing mimicked in others."

How to Use the List

The list is not intended to be comprehensive, and not all of the patient safety concerns listed will be applicable at all healthcare facilities. "We encourage facilities to use the list as a starting point for patient safety discussions and for setting their patient safety priorities," says Zimmer. Healthcare organizations can use ECRI Institute's list of patient safety concerns to identify whether the organization has also experienced failures in these areas. For those areas selected for improvement, organizations should create corrective action plans, ensuring they apply, as needed, across all settings.

Although many of the organizations reporting to ECRI Institute PSO are hospitals, the list of patient safety concerns, such as drug shortages, mislabeled specimens, and care coordination, also applies to nonhospital settings, such as physician practices and long-term care settings, says Rebold. To prevent errors, healthcare organizations must spread what they have been learning about patient safety in the hospital setting and apply the lessons throughout the care continuum, she says.

Given that patient safety improvements can often require an investment in staff time and the organization's resources, Pusey also recommends that organizations present the list to their senior leaders to gain their attention and support. "The list can heighten awareness. Individuals in the risk and quality departments can present the information to their organization's leadership to get the resources they need to mitigate the risks."

In addition to the guidance provided with ECRI Institute's list of patient safety concerns, additional resources are available from other ECRI Institute programs, including some freely available on ECRI Institute's website. Refer to "ECRI Institute Resources" throughout this report.

Data Integrity Failures with Health Information Technology Systems*

With the federal government offering financial incentives for hospitals and physician practices to adopt EHR systems, use of these systems more than tripled from 2009 through 2012. "Health IT systems are very complex," says James P. Keller, M.S., vice president, technology evaluation and safety, ECRI Institute. "They are managing a lot of information, and it's easy to get something wrong" if the systems are not designed and implemented well. While appropriately designed and implemented systems can provide complete, current, and accurate patient care information so that the clinician can make appropriate treatment decisions, the presence of incorrect data can lead to incorrect treatment, potentially leading to patient harm.

For example, the integrity of data in health IT systems can be compromised from any of the following: data entry errors, missing data or delayed data delivery, inappropriate use of default values, copying and pasting older information into a new report, use of both paper and electronic systems for patient care, and patient/data association errors (i.e., patient data from a medical device is mistakenly associated with another patient's record).

Key steps in safeguarding the integrity of electronic patient data include the following:

- Assessing the clinical workflow to understand how the data is, or will be, used by frontline staff
- Testing the system and the associated interfaces, preferably in a simulated setting, to verify that the system is functioning as intended
- Providing sufficient user training and support
- Establishing a mechanism for users to report problems as they are discovered

ECRI Institute Resources

ECRI Institute PSO Deep Dive™: Health Information Technology, published in December 2012

ECRI Institute's *Top 10 Health Technology Hazards for 2014* (available online at https://www.ecri.org/2014hazards)

Electronic Health Records (*HRC System*)

Health Information Technology (ECRI Institute PSO's *PSO Navigator* advisory)

Numerous *Health Devices* articles on health IT and interoperability topic

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*ECRI Institute's top 10 list of patient safety concerns and its top 10 list of health technology hazards have three overlapping areas. Recommendations for preventing these patient safety risks appear in ECRI Institute's report *Top 10 Health Technology Hazards for 2014*. A publicly available abridged version of this report is available online at https://www.ecri.org/2014hazards.

Poor Care Coordination with Patient's Next Level of Care

Care coordination is a "shared responsibility" of all providers involved in a patient's care, says Lorraine Possanza, D.P.M., J.D., M.B.E., patient safety, risk, and quality analyst at ECRI Institute. "It can't just be up to the patients," she says. However, events reported to ECRI Institute PSO reveal gaps in communication about patients' care—between hospital and providers, among providers, and between long-term care settings and hospitals or other providers. For example, in one event, an infant's discharge summary, which contained important follow-up care information, was not provided to the patient's primary care physician:

An infant who died from sudden infant death syndrome had previously been seen in the hospital for a life-threatening event. Because of abnormal findings on the patient's CT [computed tomography] scan, the patient's discharge summary indicated the patient should have an MRI [magnetic resonance imaging] exam. The discharge summary was not sent to the patient's primary physician. The patient did not undergo the MRI study.

While a best practice is for hospitals to send a patient's discharge information to all the patient's providers, staff can be overwhelmed trying to identify those providers. "It's not only the hospital's responsibility," says Possanza, who previously had a podiatry practice and has experience with care coordination challenges. "It's also on me as the patient's provider to communicate with the patient's other providers," she says, recalling that in addition to communicating with patients' providers as needed, she used to "touch base" with her patients' other providers at least once a year "so they know I've been involved in the patient's care."

Electronic health records (EHRs) can facilitate communication about a patient's care among providers, but organizations must establish procedures that address accessing, reviewing, and acting on the findings in those records. For example, what happens if a provider who is viewing a patient's record discovers that results of tests ordered by another provider have not been acted upon? EHRs could become a barrier "if physicians are second-guessing one another," says Possanza. Organizations might find it helpful to develop a policy specifying procedures for a provider who finds an abnormal laboratory or pathology result with no indication that the abnormal result was acted upon.

One "simple and basic" strategy to improve care coordination between hospitals and ambulatory settings, such as physician practices, is for practices to provide current contact information, such as phone and fax numbers, on their websites, says Possanza, adding, "Identify the providers in your practice. If the hospital needs to contact you, the information is right there."

With increasing pressure to shorten hospital stays, many patients are discharged to postacute care settings to continue their rehabilitation, such as poststroke care or rehabilitation following joint replacement surgery. "The postacute care provider is becoming

a critical piece in care coordination," says Linda C. Wallace, B.S.N., M.S.N., CPHRM, director of aging services risk management at ECRI Institute. But communication breakdowns can occur between hospitals and that next level of care. "We're seeing more opportunities for missed information transfer, errors in information, errors in orders" when patients are transferred to the postacute care setting, she says.

In one event reported to ECRI Institute PSO, communication breakdowns between a hospital and a postacute care facility about a patient's condition may have contributed to the patient's decline, requiring that the patient be readmitted to the hospital:

An elderly patient was treated for a fractured femur following a fall and discharged to a rehabilitation facility for postacute care. Ten days later, the patient returned to the hospital with a diagnosis of sepsis and C. [Clostridium] difficile *infections. The patient died the next day.*

Among the strategies Wallace has seen put in place to improve care coordination between hospitals and postacute care providers are the following:

- Permitting preadmission nurses from the post-acute care setting to evaluate the patient before discharge and prepare the postacute provider for the patient's needs
- Engaging hospital representatives to visit the postacute care provider's organization to ensure an understanding of the services available in that setting and to minimize the risk of transferring patients whose condition cannot be managed at that postacute care facility
- Developing closer affiliations between the hospital and the postacute care provider either through an accountable care organization (ACO) or other means

In smaller communities, where there may be only one or two hospitals, some of the long-term care providers are intentionally installing EHR systems that are compatible with the hospitals' systems "so the flow of information is seamless," says Wallace.

As providers build more arrangements to ensure care coordination, Possanza reminds them, "You can't forget the patient. The patient is overwhelmed by their disease process and by navigating the system. Whether a discharge planner in a hospital, a nurse manager in a physicians' office, or a care coordinator within an ACO, someone needs to help that person, especially an elderly patient, to remind them to make appointments, to take medications, and to help them know what to ask and expect at their next healthcare visit." Ensuring patients understand their conditions and self-care responsibilities is another critical component, as it may improve their adherence and their engagement in their care and care coordination.

ECRI Institute Resources

Discharge Planning (*HRC System*)

Health Literacy (*HRC System*)

Subacute Care in Long-Term Care Settings (*HRC System*)

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Test Results Reporting Errors

Breakdowns in test results reporting can occur for a variety of reasons, such as the following: the ordering provider never gets the results; there is a delay in getting the results to the provider; or results with important findings are reported to the ordering provider who is unavailable and there is no backup process for reporting the results to someone else who can act on them. These breakdowns can contribute to the "bigger issues of delays in patient care, as well as delays in diagnosing an acute condition," says Christine M. Callahan, RN, M.B.A., physician practice management consultant for ECRI Institute.

Delays or failures to report test results to ordering providers were among the top types of errors in the laboratory testing process found in ECRI Institute PSO's Deep Dive™ analysis of laboratory testing. Test results reporting errors represented 10% of all 2,420 events reviewed for the analysis and included examples like the following:

- A baby's treatment with antibiotics was delayed because the test results confirming an infection were not reported promptly to the ordering clinician.
- Prompt management of a patient with *C. difficile* infection was hindered because of a delay in reporting test results confirming the infection.
- A patient's seizure due to a low sodium level could have been avoided if blood chemistry results had been provided on a timely basis.

Callahan observes that breakdowns in test results reporting, particularly in physician practices, typically have one of three causes or a combination of them: (1) technology limitations, such as an inadequate interface between an EHR system and a laboratory system that provides the results electronically; (2) provider-to-provider communication gaps, such as those that occur when no backup plan is in place to designate a provider to review test results for another provider who is unavailable or on vacation; and (3) staffing and training failures, such as requiring a staff member to periodically check an EHR system for test results but not informing the person of what to expect in terms of the volume of test results typically reported to the practice.

As more healthcare organizations adopt EHR systems, Callahan warns against being lulled into thinking the systems are a panacea and can prevent test reporting failures. "It's another tool," she says. "It won't improve test results reporting if it's not used correctly."

Whether test results are reported on paper, electronically, or a combination of both, organizations must have policies and procedures to guide reporting of the results and must provide staff with education and training about the policies, says Debra Ann Maleski, M.B.A., senior associate with ECRI Institute's Applied Solutions Group (ASG),

which provides customized consulting. Questions to address in the policy include the following:

- Who gets the results?
- What is the process for reporting abnormal findings?
- Is there a designated backup provider to review the results if the ordering provider is unavailable or does not review the results within a specified time frame?
- What is the expected time frame for providers to review results?
- How are the findings communicated to the patient?
- What is the policy for making certain that information gets to the patient if that person is unavailable?

Additionally, organizations must audit staff compliance with the policies, Maleski advises. "You may have a great policy, but if it's not enacted or followed, the organization needs to be aware and implement corrective action."

ASG Director Robert P. Maliff, M.B.A., notes that vendors are developing software that has the ability to integrate laboratory and radiology IT systems with other systems, such as providers' handheld devices, to deliver results to those devices. "There's a lot of interest in these systems," which are primarily being considered to notify providers and others about alarms, but they also have the capability to notify providers of test results. "Organizations are discovering the capabilities of alarm integration systems, but they're trying to figure out how to use them. How do you close the loop [when information is delivered to providers]? How long do they have to acknowledge the information?" he asks.

Ultimately, healthcare organizations should turn to technology to improve processes rather than replicate them, says Maliff. Both he and Maleski have seen EHR systems used by healthcare providers that cannot incorporate test results data within specific fields in the record. Instead, the provider must scan the record to find the results—a limitation that also existed with paper records and can contribute to delays in patient care. Organizations must ensure that interfaces between their EHR and laboratory systems enable test results data to automatically populate fields in the electronic medical record in a standardized format, they recommend.

ECRI Institute Resources

Communication (*HRC System*)

ECRI Institute PSO Deep Dive: Laboratory Testing, published March 2014

Laboratory Testing (ECRI Institute PSO's *PSO Navigator* advisory)

Test Tracking and Follow-Up (*HRC System*)

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Drug Shortages

The potential patient care implications of drug shortages came to the attention of ECRI Institute PSO when a hospital contacted the PSO about a severe shortage of emergency drugs. The hospital was unable to replenish its supply of injectable unit-dose medications stored on its crash carts for patient resuscitation and wanted to know whether its remaining supply of expired drugs could be used instead.

The question "got us thinking about this issue" and the possibility for errors when drugs are unavailable or substitute drugs are provided, says Patricia Neumann, RN, M.S., patient safety analyst/consultant for ECRI Institute PSO. "In the intervening months, the topic remained on our radar and showed, if anything, an escalating level of interest from healthcare providers." An event reported to ECRI Institute PSO highlighted the need for policies to be in place to guide pharmacists, nurses, and physicians on the steps to take when a drug is unavailable:

A patient in intensive care had a critical phosphate level. The physician ordered an intravenous sodium phosphate for the patient. The pharmacist could not fill the order because the drug was unavailable and did not tell the patient's nurse or the ordering physician about the shortage. The patient had a seizure due to abnormally low phosphate levels in the blood.

Neumann advises healthcare organizations to develop a proactive plan for managing drug shortages. The plan should assign accountability to a task force to monitor impending shortages, she says. Two good resources for identifying potential drug shortages are the following: (1) the U.S. Food and Drug Administration's (FDA) website on drug shortages, which provides a list of national shortages for which there are no substitutes, and (2) the American Society of Health-System Pharmacists' (ASHP) drug shortage website, which also provides information on regional drug shortages.*

In addition to tracking shortages that can affect the organization's supplies, the action plan should address the following areas:

- Documenting drug shortages and approving alternatives to drugs that are unavailable or in short supply
- Monitoring adverse drug events to determine whether any may have been caused by shortages
- Keeping the quality improvement and pharmacy and therapeutics committees informed of any shortages
- Providing an annual report on shortages and their effect on the organization to its leaders

* FDA's website on drug shortages is at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm. ASHP's website is at http://www.ashp.org/shortages.

Information about drugs in short supply or substitute drugs must be communicated to clinical staff. All ordering providers must know what drugs are in short supply, when they will return to regular distribution, what alternative or substitute medications exist, the alternative drug's application, existing preparations, contraindications, error potential, and additional guidelines to ensure patient safety.

To keep clinical staff informed about any shortages and the organization's planned response, it should consider posting updates on an intranet site available to clinical staff at all times, suggests Neumann. Additionally, it should ensure that a pharmacist is available to clinical staff to answer any questions. More than likely, various components of the organization's health IT system—EHR systems, electronic drug ordering, and electronic medication administration records—must be kept up to date as drug availabilities change. Although time-consuming, system updates are needed to prevent medication errors, says Neumann.

Drug shortages will remain an ongoing concern, she predicts. To control costs, manufacturers keep their drug inventories low, focusing on making and supplying their products as orders are submitted. Hospitals also keep a just-in-time approach to inventory so that unused products are not left on their shelves. "It's not to their advantage to stockpile," says Neumann. As a result, "the whole chain of drugs can be emptied out quickly when a shortage happens," she says, adding that "organizations always need to plan ahead."

ECRI Institute Resources

Coming Up Short: Coping with Medication Shortages (*PSO Monthly Brief*, publicly available at http://www.ecri.org)

Planning, Communication Key in Coping with Shortages (*HRC System*)

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Failure to Adequately Manage Behavioral Health Patients in Acute Care Settings

When patients with behavioral health needs are treated in an acute or emergency care setting, their mental health needs must still be addressed along with the clinical condition leading to the emergency visit or hospitalization. Several events reported to ECRI Institute PSO highlight the challenges for staff in acute care settings in managing the behavioral health needs of patients, particularly those who exhibit psychiatric illness or emotional agitation in addition to their acute clinical needs. Many of these reports describe incidents of patient violence, some of which cause harm to the patient, staff, or others, as in the following report of an event in an acute inpatient unit:

The patient resisted treatment and became violent, hitting and kicking the bedside RN [registered nurse]. The patient spit in my direction and began kicking and hitting with force. The patient [landed] blows to my chest, shoulders, abdomen, and thorax. Several other team members rushed into the room to restrain the patient, who was still combative.

From the reports submitted to ECRI Institute PSO, "we know that in an acute care setting, doctors, nurses, security officers, and ancillary staff have difficulty safely managing patients who become violent or threaten to become violent," says Ruth Ison, M.Div., STM, patient safety analyst/consultant at ECRI Institute PSO. Many of the reports suggest that caregivers and staff "may not recognize the warning signs of imminent violence while the patient is being clinically evaluated."

Warning signs of potential patient violence can include shouting, demanding behavior, physical restlessness and tension, and excessive fear or paranoia manifesting as cursing, insulting, or resisting the provider. Signs of substance intoxication may forewarn the potential for a violent situation. According to the research literature, these warning signs signal the need for an urgent response to the patient's emotional state and psychological needs to keep the situation safe. Healthcare providers who are not trained in behavioral health "may not recognize that's what these behavioral signals mean, and they may not have sufficient training on how to respond," says Ison. "Healthcare providers, while possibly anxious about the patient's behavior, usually continue with the patient's medical care or assessment. These are very dedicated people. Their objective is to provide care, and when the patient is resisting, they're being challenged to accomplish their mission."

The reports of patient violence to the PSO suggest that "we need more attentiveness to behavioral health issues in healthcare overall," says Ison. Historically, there has been a gap between acute and behavioral healthcare. "We have to bridge those knowledge gaps and really increase healthcare staff's understanding of behavioral health symptoms that can appear anywhere throughout the care spectrum."

ECRI Institute PSO's research into managing patient violence started with a project to evaluate reports of patient suicides or attempts during a patient's hospital stay or after discharge. "There were some reports of patient suicide in the database," says Ison, "but what we kept finding was even more incidents of patient violence."

"By raising the issue of patient violence and by talking about it, we're making it clear that this is a patient safety concern," says Ison. The project has also resonated with PSO member organizations. "We're certainly getting feedback that this is a concern in our member hospitals, and we'll keep working in this area of patient safety and behavioral health," she notes.

ECRI Institute Resources

Patient Suicide: Assessment and Prevention (*HRC System*)

Patient Violence (*HRC System*)

Psychiatric Treatment (*HRC System*)

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Mislabeled Specimens

Specimen mislabeling is the leading type of event in the laboratory testing process identified in ECRI Institute PSO's 2013 Deep Dive analysis on laboratory testing. Mislabeled specimens (e.g., a specimen with a label from a different patient, two contradictory labels, or a label that does not correspond with the order) represented 31% of all 2,420 events reviewed for the analysis.

"One of the chief causes of mislabeled specimens is the collector is distracted by workload or other patient needs," says Elizabeth Drozd, M.S., MT(ASCP)SBB, patient safety analyst at ECRI Institute. Because of the distractions, the collector can make an error, for example, in forgetting to label a sample or putting the wrong label on the sample, as in the following event reported to ECRI Institute PSO describing how a collector grabbed the wrong patient label from a printer and applied it to a specimen:

The collector pulled the labels off the printer and brought them into the patient's room to draw the blood. After the blood was drawn, the tubes were labeled and sent to the lab. The nurse manager noticed the patient's labels were still on the printer. The lab was immediately notified that the blood tubes were mislabeled. The blood tubes were discarded, and the collector redrew the blood and labeled the tubes correctly.

As in the sample event, many specimen labeling mistakes are caught before the lab analyzes the specimen and reports the results to the provider who ordered the test. Although catching these mislabeled specimens before testing is done prevents potentially harmful errors from occurring, there is still some harm to the patient when a sample must be re-collected, particularly when blood is redrawn. Specimen re-collection can also contribute to delays in obtaining important diagnostic information for patient care.

To prevent labeling mistakes, organizations have adopted a practice of using two patient identifiers (e.g., patient name, date of birth, unique identification number) to correctly identify the patient before a specimen is obtained and to label the specimen container immediately after it is collected in the patient's presence.

Automated technology, such as electronic bar-coding systems, can help ensure positive verification of a patient's identification. The specimen collector uses a handheld device at the patient's bedside to scan a patient's wristband with unique bar-coded patient identifiers. Some scanners can generate specimen labels with the bar codes specific to the patient when the patient's identification is confirmed.

Whether or not technology is in place to help with specimen labeling, hospitals "must still depend on the human element" to prevent specimen labeling errors, says Drozd. Organizations must reinforce the importance of using two patient identifiers with every patient encounter, she says. For instance, if a mislabeled blood specimen leads to a

blood typing error, a patient could die from a transfusion of the wrong blood type, says Drozd, a medical technologist and former phlebotomist.

"You can be lulled into a false sense of security if you think you know the patient," Drozd says. "Organizations must reinforce in their staff training and education that for every patient encounter, whether you know the patient or not, you must properly use two patient identifiers." In some organizations, the specimen collector always engages the patient, if that individual is alert, by following a script to tell the patient that the collector is checking the patient's name and birth date and confirming them on the patient's identification bracelet.

Once these practices become part of the organization's culture and approach to patient safety, using two patient identifiers becomes the expected behavior, says Drozd. "Anyone who deviates from the practice should be counseled and coached by their peers."

ECRI Institute Resources

ECRI Institute PSO Deep Dive: Laboratory Testing, published March 2014

Lessons from the 2013 Health Devices Achievement Award: How Halton Healthcare Services Used Bedside Bar Coding to Improve Specimen Identification (*Health Devices*)

Tackling the Most Common Laboratory Errors: Specimen Labeling Mistakes (ECRI Institute PSO's *PSO Navigator* advisory)

Where Do Most Lab Errors Occur? Not the Lab (*PSO Monthly Brief*, publicly available at http://www.ecri.org)

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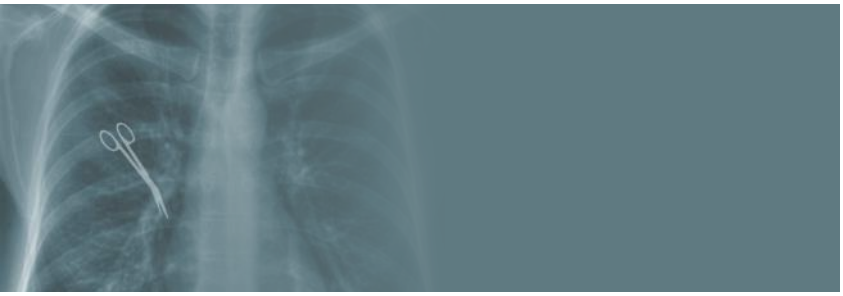

Retained Devices and Unretrieved Fragments*

Although attention has been given to the risk of unintentionally leaving a surgical item in a patient after surgery, childbirth, or an interventional diagnostic procedure, reports to ECRI Institute PSO and other event reporting programs, as well as investigations by ECRI Institute's Accident and Forensic Investigation Group, indicate that these events continue to occur, even though they can largely be prevented.

Retained items can involve an entire device, such as a surgical sponge of towel, unknowingly left behind, or a portion of a device that breaks away and remains inside the patient. Risks to the patient include prolonged or additional surgery when a retained item is discovered and removal is deemed appropriate or future complications if the retained item leads to infection or causes damage to surrounding tissue.

Initiatives to prevent retained items include adhering to accepted surgical count procedures, using x-ray imaging to examine patients for retained items, and visually inspecting devices for interventional procedures before and after use. "After an interventional procedure, you really need to inspect a device tip, for example, to see if there is any damage that might suggest something was left behind," says Keller.

ECRI Institute Resources

- The Case of the Missing Sponge: Practice Variation Is Culprit (*HRC System*)
- Count Early and Often to Prevent Retained Surgical Items in Labor and Delivery (ECRI Institute PSO's *PSO Navigator* advisory)
- ECRI Institute's *Top 10 Health Technology Hazards for 2014* (available online at https://www.ecri.org/2014hazards)
- Radio-Frequency Surgical Sponge Detection (*Health Devices* evaluation)
- Retained Foreign Objects: It's Not the Robot's Fault (ECRI Institute PSO's *Patient Safety E-lerts*, publicly available at http://www.ecri.org)
- Retained Guidewires: On the Rise? (ECRI Institute PSO's *Patient Safety E-lerts*, publicly available at http://www.ecri.org)
- Unintentionally Retained Surgical Items (*HRC System*)

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Patient Falls while Toileting

Patient falls are among the top patient safety events reported to ECRI Institute PSO, representing about one-quarter of all events in the PSO's event report database. One particularly problematic area in patient falls is those that occur while patients are toileting, as in the following report submitted to ECRI Institute PSO of a patient at risk of falling who was not assisted while toileting:

A postpartum patient sustained a fracture after getting out of bed to use the bathroom. The patient was unassisted.

Although hospitals have implemented regularly scheduled rounding of patients in their rooms with an emphasis on falls prevention, "the typical rounding schedules don't always work for people in terms of their need for toileting," says geriatrician Karen Schoelles, M.D., SM, FACP, director, ECRI Institute's Evidence-based Practice Center. During rounding, nurses may ask if the patient needs to use the bathroom. Schoelles suggests modifying the question to be more specific. "Rephrase the question by asking, 'Do you want to go now or the next time I come in?'" says Schoelles, who was an ECRI Institute coauthor of a falls prevention toolkit available from the Agency for Healthcare Research and Quality (AHRQ).*

Another strategy to improve the effectiveness of rounding is to cluster patients at high risk of falling in rooms closest to the nurses' station. Those high-risk patients can be on a rounding schedule of 15-minute intervals, while the remainder of the patients on the floor are visited by a nurse every hour, Schoelles recommends.

One of the challenges in preventing falls while the patient is toileting is "balancing the person's need for privacy and dignity with the need to be sure they are safe," says Schoelles. "Whatever can be done to preserve the dignity of the person while someone is assisting them in the bathroom is important." For example, some hospital garments provide more coverage to ensure some privacy. Nevertheless, healthcare staff must remain with the patient at risk of falling during the voiding process, despite the patients' frequent requests for privacy. Leaving the patient unattended could compromise the individual's safety.

An organization's falls prevention program should incorporate nightly toileting rounds. "It's a mistake to reduce staff who assist with toileting" during the evening and night shifts, says Schoelles. "Maybe the organization doesn't need staff to administer medications, but they do need staff who can help with toileting."

AHRQ's toolkit Preventing Falls in Hospitals: A Toolkit for Improving Quality of Care is available online at http://www.ahrq.gov/professionals/systems/long-term-care/resources/injuries/fallpxtoolkit/ index.html.

Other strategies to prevent patient falls while toileting include the following:

- Limit, when possible, attachments to the patient, such as intravenous poles, which can be tripping hazards.
- Provide assistive devices in the patient's room and bathroom, such as bedside commodes, raised toilet seats, toilet and commode armrests, and grab bars.
- Conduct comprehensive falls risk assessments of all patients, including those in the emergency department.

Although these strategies apply to all patients, Schoelles advises that when managing elderly patients in particular, staff must be aware of older patients' "many physiological reasons for needing to void frequently," says Schoelles. "Especially with older patients who are confused, it can be easy for staff to dismiss their concerns," she says.

ECRI Institute Resources

Falls
(*HRC System*)

Falls Happen: Here's How to Lessen the Risk (*PSO Monthly Brief*, publicly available at http://www.ecri.org)

Falls Prevention (ECRI Institute PSO's *PSO Navigator* advisory)

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Inadequate Monitoring for Respiratory Depression in Patients Taking Opioids

For more than a decade, Joint Commission accreditation standards have underscored patients' rights to have their pain assessed and managed. Healthcare providers have responded with an intensified focus on pain management, using pain medications such as opioids. Increased use of opioids also raises the possibility of adverse events. Opioids are considered a high-alert medication. These drugs have a heightened risk of causing significant patient harm if used in error. The most serious adverse effect of opioids is respiratory depression, which is often preceded by sedation. Several event reports submitted to ECRI Institute PSO suggest that patients receiving opioids are not being adequately assessed and monitored for respiratory depression.

"One of the problems is that sedation is not adequately understood," says Stephanie Uses, Pharm.D., M.J., J.D., patient safety analyst at ECRI Institute PSO. Sedation is the most important indicator of respiratory depression, she says. Patients who show signs of sedation (e.g., frequently drowsy, drift off to sleep during conversation) may need a reversal agent (naloxone) to prevent them from progressing to respiratory depression.

Facilities should educate staff to assess patients for risk of respiratory depression, be aware of the risk of oversedation, recognize signs of opioid toxicity, and know what to do when such events occur, says Uses. Awareness starts with knowing who is at higher risk of opioid-induced respiratory depression. These high-risk patients include very young or elderly patients, patients with sleep apnea, and patients who are morbidly obese. Staff must also be aware of other possible scenarios that can increase the risk of respiratory depression, such as inappropriate dosing for the patient's weight and insufficient time intervals between doses.

Clinicians, pharmacists, and nursing staff caring for patients taking opioids should also be aware of any other sedating drugs that the patient is taking, says Uses. Sometimes these drugs, such as muscle relaxants and antianxiety medications, are used in combination with opioids, resulting in a potentially dangerous mix of drugs that increases the patient's risk of respiratory depression, as in the following event reported to ECRI Institute PSO:

A male patient in his 60s received a combination of opioids, a benzodiazepine [a central nervous system (CNS) depressant], and an antihistamine [another CNS depressant] during a 12-hour shift. The patient's respiratory rate dropped to five to six breaths per minute. He required two doses of naloxone to counter the effects of the drugs.

Uses recommends that nurses administering opioids to patients use a four-point scale, called the Pasero Opioid-Induced Sedation Scale, to assess the patient's condition and determine whether intervention is needed if the patient is frequently drowsy or

groggy. "Along with a pain scale to see if a patient's pain is controlled, you also want to look at sedation," she explains.

Patient care staff cannot rely on technology alone to detect oversedation. Although patients who are administered opioids may be monitored with pulse oximetry, a technique to noninvasively monitor oxygen saturation, oxygen saturation only changes after respiration has become difficult. Capnography, or end-tidal carbon dioxide monitoring, is used as a reliable monitor of respiratory rate in anesthetized patients, but the technology has not been widely deployed outside the operating room.

Assessment is particularly important during the first 24 hours after a patient is given opioids. "More patients are taking opioids, and some are patients who have never received opioids before," says Uses. These patients are referred to as "opioid naïve." During the first 24-hour period following opioid administration, caregivers must assess the patient's tolerance for the drug as it reaches its peak effect, particularly if the patient has never taken opioids before. "The first 24 hours puts the patient, especially the opioid-naïve patient, at greatest risk for oversedation," says Uses.

If, during the 24-hour period, the patient is transferred from one setting to another—say, from the emergency department to a care unit—information about any opioids given must be communicated during the handoff so caregivers at the next level of care can monitor for any sedating effects, says Uses. "The information should be given in the report. How much was given? When was it given?" Additionally, communicating information about any pain medications given reduces the risk that the patient will be given additional pain medications upon arriving on the floor, says Uses.

ECRI Institute Resources

Feeling No Pain: Balance Pain Relief with Safety When Prescribing Opioids (*PSO Monthly Brief*, publicly available at http://www.ecri.org)

Pain Medication and PRN Orders (*HRC System*)

Pain Relief: How to Keep Opioid Administration Safe (ECRI Institute PSO's *PSO Navigator* advisory)

Patient-Controlled Analgesia (*HRC System*)

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Inadequate Reprocessing of Endoscopes and Surgical Instruments*

Because instrument reprocessing is "very process-oriented, healthcare organizations need to have good procedures in place to be sure all steps for cleaning and disinfecting are happening," says Keller. "If any step in the process is missing, problems can happen" with the transmission of infectious agents and the spread of diseases, such as hepatitis C, HIV, and tuberculosis, from contaminated instruments and devices.

Every day, healthcare facilities reprocess thousands of reusable surgical instruments and devices to be used for subsequent procedures. "If there is pressure to meet procedure volume, we can see steps skipped to hasten the turnaround," says Keller. One area in particular is adequately rinsing the instrument and allowing it to dry.

ECRI Institute has analyzed reports of reprocessing failures with flexible endoscopes, as well as reports of inadequate reprocessing of other instruments and devices, such as arthroscopy shoulder cannulas and surgical instrument trays.

In addition to consistent adherence to a multistep procedure, effective reprocessing requires that appropriate reprocessing protocols be developed, documented, and followed for all relevant instrument models in a facility's inventory. Staff need to be trained in these protocols, and they need adequate space, equipment, and instructional materials, as well as sufficient time, to perform the procedure correctly. Additionally, organizations must ensure adequate communication between departments that need the reprocessed devices reprocessed and the sterile processing department.

ECRI Institute Resources

Clear Channels: Ensuring Effective Endoscope Reprocessing (*Health Devices* Guidance Article)

ECRI Institute's *Top 10 Health Technology Hazards for 2014* (available online at https://www.ecri.org/2014hazards)

Inadequately Reprocessed Instruments: If It's Dirty, How Can It Be Clean? (*PSO Monthly Brief*, publicly available at http://www.ecri.org)

Reprocessing in Central Service (*HRC System*)

Reprocessing of Flexible Endoscopes (*HRC System*)

Sterile Processing Department's Role in Patient Safety (ECRI Institute PSO's *PSO Navigator* advisory)

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▷ UNITED STATES
5200 Butler Pike,
Plymouth Meeting, PA
19462-1298, USA
Telephone +1 (610) 825-6000
Fax +1 (610) 834-1275

▷ EUROPE
Suite 104, 29 Broadwater Road
Welwyn Garden City,
Hertfordshire, AL7 3BQ, UK
Telephone +44 (1707) 871 511
Fax +44 (1707) 393 138

▷ ASIA PACIFIC
11-3-10, Jalan 3/109F,
Danau Business Centre,
Taman Danau Desa,
58100 Kuala Lumpur, Malaysia
Telephone +60 3 7988 1919
Fax +60 3 7988 1170

▷ MIDDLE EAST
Office No. 1101, 11th Floor,
Al Shafar Tower 1, TECOM
P.O. Box 128740
Dubai, United Arab Emirates
Telephone +971 4 3638335
Fax +971 4 3637364