Top 10 Patient Safety Concerns for Healthcare Organizations 2015
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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
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Introduction

NOT JUST A TOP 10 LIST

With this report, ECRI Institute is releasing its top 10 list of patient safety concerns for 2015. This is the second year we have compiled the list, which is partly based on our review of patient safety event reports, research requests, and root-cause analyses submitted to ECRI Institute PSO, one of the first patient safety organizations (PSOs) to be federally certified under the provisions of the Patient Safety and Quality Improvement Act (PSQIA).

PSQIA gives healthcare organizations a unique opportunity to voluntarily share their safety surveillance data in a protected environment so PSOs can aggregate and analyze the data. The law also charges PSOs with the responsibility to share the findings and lessons learned. The release of our top 10 list of patient safety concerns is in keeping with that responsibility.

ECRI Institute’s Top 10 Patient Safety Concerns for Healthcare Organizations is more than just a list; it’s a reminder that, despite the attention given to patient safety over the last 15 years or so, we can do better. Since we began collecting patient safety events in 2009 as a PSO, we have received nearly 500,000 event reports. Each event often describes a systems-related breakdown, or a near failure, in the care process of the patients our members are committed to serving. Some of the events describe serious, preventable patient injuries or deaths.

Behind each event there’s a story about patients and their loved ones who put themselves in the hands of their providers expecting quality care and services. And there’s a separate story about the providers whose lives and careers are torn apart when patients are harmed because faulty systems and processes make problems more likely to occur.

Our patient safety analyst Sheila Rossi, who shares her own encounter with a medication error in this year’s report, reminds us of the stories behind these events and the motivation for our top 10 list. “When we say ‘the patient’ in healthcare, it sometimes becomes impersonal,” Rossi says, urging everyone to put themselves in patients’ shoes and to ask, “How do I prevent this from happening to me?”

Healthcare providers, regardless of what setting they practice in, can start with our top 10 list of patient safety concerns and use it to guide their own discussions about patient safety and improvement initiatives.

We will continue to publish our top 10 list annually because we are committed to patient safety and to helping you to deliver the safest care for all of us, your patients.

Sincerely,

William M. Marella, MBA
Executive Director, Operations and Analytics
ECRI Institute’s Patient Safety, Risk, and Quality Group

ECRI Institute has released its newest list of the top 10 patient safety concerns confronting healthcare organizations. The list serves as a “catalyst for discussion” among healthcare leaders about the top patient safety issues faced by their organizations, says Catherine Pusey, RN, MBA, manager, clinical analysts at ECRI Institute PSO.

ECRI Institute’s Top 10 Patient Safety Concerns for Healthcare Organizations for 2015 is compiled by ECRI Institute PSO, one of the first patient safety organizations (PSOs) to be federally certified. “The list is based on what we see throughout the year among the patient safety event reports, research requests, and root-cause analyses submitted to ECRI Institute PSO,” says Pusey.

Under the Patient Safety and Quality Improvement Act, healthcare organizations can voluntarily submit patient safety reports to PSOs in a protected environment for PSOs to aggregate, analyze, and share findings and lessons learned. ECRI Institute PSO has been collecting patient safety data since 2009 and, by the end of 2014, had received nearly 500,000 event reports.

The list also draws upon ECRI Institute staff expertise, including the knowledge gained investigating incidents, observing and assessing hospital practices, and reviewing health-technology-related problem reports submitted to ECRI Institute’s voluntary medical device problem reporting program. In fact, four of the patient safety concerns identified for the top 10 list also rank among ECRI Institute’s top health technology hazards for 2015. Refer to “ECRI Institute’s Top 10 Lists” for more information on the health technology hazard list, which is compiled by ECRI Institute’s Health Devices Group.

“Most organizations have their own top 10 list. They should review our list of patient safety concerns to identify issues that should be on theirs,” says Pusey. “We’re not saying that every organization must address all 10 topics, but they should determine where there are similarities and variations.”

Using ECRI Institute’s top 10 list proactively to improve quality of care and patient safety is also in keeping with the provisions of the Joint Commission’s recently released patient safety systems chapter for its 2015 accreditation manual. The chapter describes the importance and structure of an integrated approach to patient safety for healthcare organizations.

ECRI Institute’s Top 10 Patient Safety Concerns for 2015

1. Alarm hazards: inadequate alarm configuration policies and practices*
2. Data integrity: incorrect or missing data in EHRs and other health IT systems
3. Managing patient violence
4. Mix-up of IV lines leading to misadministration of drugs and solutions*
5. Care coordination events related to medication reconciliation
6. Failure to conduct independent double checks independently*
7. Opioid-related events
8. Inadequate reprocessing of endoscopes and surgical instruments
9. Inadequate patient handoffs related to patient transport*
10. Medication errors related to pounds and kilograms*

* New to the 2015 list.
Top 10 Patient Safety Concerns for Healthcare Organizations

Half of the items on the top 10 list are new for 2015; the other half are recurring or variations of concerns from 2014 when ECRI Institute first released its top 10 list of patient safety concerns. Refer to “ECRI Institute’s Top 10 Patient Safety Concerns for 2015” for the full list.

Items from the 2014 list that do not appear on this year’s list, such as mislabeled laboratory specimens and patient falls while toileting, still remain a concern, says Pusey. “But other topics have risen to a higher level of attention.”

APPLICABILITY TO MULTIPLE SETTINGS

Many of the topics on ECRI Institute’s list of top 10 patient safety concerns extend to multiple healthcare settings and highlight the relevance of these issues to the continuum of care spanning physician practices and other outpatient medical settings, acute care hospitals, and aging services providers in postacute care environments, nursing homes, and hospice care.

“While some of these hazards are most applicable to acute care, several are also relevant in ambulatory settings, and some—especially those related to medications and care coordination—span the continuum of care,” says William M. Marella, MBA, executive director, operations and analytics for ECRI Institute’s Patient Safety, Risk, and Quality group.

Because the topics on ECRI Institute’s list of patient safety concerns are largely based on reports submitted by hospitals, these issues, while important to multiple healthcare settings, may not always rank among the top 10 concerns for nonhospital settings, such as physician practices and aging services providers. For example, appropriate management of alarms is important in long-term care settings such as nursing homes where alarms are used to detect resident wandering and elopement, falls, and other risks, says Victor Lane Rose, NHA, MBA, CPASRM, operations manager of ECRI Institute’s Aging Services Risk Management program within its Patient Safety, Risk, and Quality group. The topic, however, may not rank as aging services providers’ number one concern, he adds, because other issues, such as skin management, appropriate staffing and scheduling, and falls management, are typically among the highest priorities for the aging services sector.
ECRI Institute’s Top 10 Lists

ECRI Institute’s top 10 lists of patient safety concerns and health technology hazards highlight four overlapping issues that deserve the attention of healthcare organizations. Together, they reflect a united effort by ECRI Institute to promote patient safety in healthcare organizations.

ECRI Institute’s Top 10 Health Technology Hazards, released every fall, focuses on technology, whereas ECRI Institute’s Top 10 Patient Safety Concerns for Healthcare Organizations addresses broader patient safety issues. Like the list of patient safety concerns, the top 10 list of health technology hazards reflects ECRI Institute’s healthcare safety expertise. The list is compiled based on the staff’s experience investigating device-related incidents, evaluating medical devices in ECRI Institute’s testing laboratory, and reviewing reports from ECRI Institute’s and other organizations’ databases for medical device problems and patient safety events.

ECRI Institute has published its list of health technology hazards for eight years and its list of patient safety concerns for two years. Both lists are published annually.

Despite the different focuses of the two lists, Catherine Pusey, RN, MBA, manager, clinical analysts at ECRI Institute PSO, is struck that two different teams identified four overlapping areas as priorities for healthcare organizations in 2015. “Separately, we are identifying some of the same issues.” The four overlapping concerns are as follows:

1. Alarm hazards from inadequate alarm configuration policies and practices
2. Data integrity failures from incorrect or missing data in EHRs and other health IT systems
3. IV line mix-ups leading to misadministration of drugs and solutions
4. Inadequate reprocessing of endoscopes and surgical instruments

In fact, these four technology-related topics are the top four items identified in ECRI Institute’s Top 10 Health Technology Hazards for 2015. The overlap of these four priority topics “shows the significance of healthcare technology as it impacts patient safety overall,” says James P. Keller, MS, vice president, health technology evaluation and safety, ECRI Institute. “A big reason why technology shows prominently on the top 10 list of patient safety concerns is the growing complexity of technology and the increased reliance on technology in delivering healthcare,” he says, listing areas such as health IT and alarm hazards.

The 2015 report of health technology hazards also has some broader topics that span multiple technologies. One was insufficient cybersecurity protections for medical devices and systems. “Despite little evidence to date of direct harm to patients, cybersecurity is nevertheless a potential threat that healthcare facilities must begin addressing,” says Rob Schluth, senior project officer at ECRI Institute and the lead project manager for ECRI Institute’s Top 10 Health Technology Hazards for 2015 project. “The vulnerability of medical devices to malware that could affect device functionality or the integrity of patient data is of particular concern.” ECRI Institute predicts that cybersecurity is a patient safety consideration that will require increased attention in the coming years.

Another broad topic on the 2015 top technology hazards list was deficient medical device recall and safety-alert management programs. “We see healthcare organizations with antiquated recall management programs,” says Schluth. “One key concern we have is that the capabilities of some hospitals’ programs may not be keeping pace with the growth over the past decade in the number of recalls and other alerts that are issued.”

ECRI Institute also publishes an annual watch list of the top 10 technology and infrastructure issues that a hospital C-suite should carefully examine. The list draws upon ECRI Institute’s decades of experience evaluating the safety, effectiveness, and cost-effectiveness of health technologies.

“C-suite leaders need a concise way of seeing where new and emerging health technologies fit, if at all, in their health systems,” says Diane Robertson, director, health technology assessment, ECRI Institute.

Topics on the 2015 C-suite list include the following:

- Disinfection robots
- Three-dimensional printers
- Google Glass
- Postdischarge clinics

How the List Was Compiled

To compile its list of patient safety concerns, ECRI Institute PSO reviewed its database of patient safety events, root-cause analyses, and custom research requests submitted throughout the year by healthcare organizations and its partner PSOs, as well as sought guidance from its team of experts.

“Our top 10 list isn’t generated from a complicated algorithm or formula. It’s very much a consensus process that attempts to distill the judgment of ECRI Institute’s patient safety experts, our advisors, and our members,” says Marella. “Topics are nominated based on our analysis of safety events reported to ECRI Institute and our partner PSOs as well as what’s happening in the broader patient safety community.”

The final list reflects the input of ECRI Institute PSO’s team of analysts and other ECRI Institute staff, as well as members of ECRI Institute PSO’s advisory council.

How to Use the List

ECRI Institute recommends that healthcare organizations use its top 10 list of patient safety concerns as a starting point for their patient safety discussions and for setting their patient safety priorities. Use the list to identify whether the organization has experienced patient safety breakdowns in similar areas and whether the concerns should be targeted for improvement. For areas selected for improvement, organizations can create risk mitigation strategies based on the recommendations provided with the top 10 list for each area of concern. Additional ECRI Institute resources, some freely available on ECRI Institute’s website, are highlighted throughout the report.

“Our hope is that healthcare providers use this list to reflect on which of these hazards exist in their care settings and on whether they have systems in place to prevent or minimize harm from those that are relevant in their settings,” says Marella.

Rose recommends that facilities across the healthcare spectrum use the list to “understand the risks that do exist at your organization, to quantify them, and to find out where they’re happening so the organization can identify practices to mitigate the risks.”

Given that patient safety improvements can often require an investment in staff time and the organization’s resources, Pusey recommends that organizations present the list to their senior leaders and members of their governing boards to gain their attention and support.
Topping the list of patient safety concerns is alarm hazards from inadequate alarm configuration policies and practices, a topic which also ranks as ECRI Institute’s top health technology hazard for 2015.

Since ECRI Institute began publishing its list of top health technology hazards in 2007, “alarm hazards have been at or near the top of the list,” says Rob Schluth, senior project officer at ECRI Institute and the lead project manager for the Top 10 Health Technology Hazards for 2015 project. The need to address alarm hazards is particularly important with the Joint Commission’s ongoing National Patient Safety Goal for healthcare organizations to improve the safety of clinical alarm systems.

In recent years, much of the literature related to alarm hazards has focused on alarm fatigue—a condition that can lead to alarms missed by providers who are overwhelmed by, distracted by, or desensitized to the multiple alarms that activate.

In its 2015 list, ECRI Institute encourages healthcare institutions to look beyond alarm fatigue. “In addition to missed alarms that can result from excessive alarm activations, hospitals also have to be concerned about alarms that don’t activate when a patient is in distress,” says Schluth. “In our experience, alarm-related adverse events—whether they result from missed alarms or from unrecognized alarm conditions—often can be traced to alarm systems that were not configured appropriately.”

To meet the Joint Commission’s National Patient Safety Goal on clinical alarm safety, organizations accredited by the group must, as of 2016, establish policies and procedures to manage alarm signals identified by the organization as essential for patient safety. ECRI Institute recommends that organizations examine their alarm configuration policies and procedures to address the full range of factors that can lead to alarm hazards.

“Our accident investigations have found that hospitals have either not had consistent or not had any practices to determine how alarms are set by care area or by patient type,” says James P. Keller, MS, vice president, health technology evaluation and safety, ECRI Institute. For example, “it doesn’t make sense to use the same default alarm settings in pediatric intensive care as in adult intensive care,” he explains, yet ECRI Institute has found that many hospitals do not have a policy to adjust the alarm default settings by care area. Similarly, hospital policies often fail to specify when and who can make adjustments to the default alarm settings, says Keller.

In addition to the recommendations for addressing alarm hazards contained in the Top 10 Health Technology Hazards for 2015, ECRI Institute has compiled its Alarm Safety Handbook and Alarm Safety Workbook to help organizations understand the breadth of alarm hazards, identify alarm safety vulnerabilities, and develop an effective program for managing clinical alarms to improve patient safety. The materials are provided as a membership benefit for certain ECRI Institute programs and are available to others for purchase. See “ECRI Institute Resources” for more information.

ECRI INSTITUTE
RESOURCES

HRC

▷ Clinical Alarms

Other Memberships and Sources*


▷ Alarm Safety Resource Center

▷ Interfacing Monitoring Systems with Ventilators: How Well Do They Communicate Alarms? (Health Devices)

▷ Physiologic Monitoring Systems: Our Judgments on Eight Systems (Health Devices)

▷ Top 10 Health Technology Hazards for 2015

* 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.
Health information technology (IT)–related issues have been a recurring theme on ECRI Institute’s top 10 lists, appearing on the top 10 health technology hazards list for the last six years and on the top 10 list of patient safety concerns since its start in 2014. For the two most recent years, both lists have identified data integrity errors as a result of incorrect or missing data in electronic health records (EHRs) and other health IT systems.

ECRI Institute recognizes that health IT offers numerous potential benefits, such as supporting clinical decision making, enhancing provider communication, providing access to patient data in a secure environment, engaging patients, and reducing medical errors. But the technology can create new safety risks if it is not designed appropriately, implemented carefully, and used thoughtfully.

In fact, in 2014, ECRI Institute convened the Partnership for Health IT Patient Safety, a multi-stakeholder collaborative established to proactively identify and address health IT patient safety risks in a nonpunitive environment.

“With the introduction of any new technology, we need to identify and respond to novel problems it presents as well as old problems that the new technology doesn’t eliminate,” says Marella. Data integrity issues “existed with paper medical records as well, but now as EHRs become more interoperable, incorrect information is more readily available, more easily shared, and harder to eliminate,” he says. “In order to get a return on the investment we’ve made in EHRs and clinical decision support, we now need to tackle the more mundane problem of making sure the data in the EHR is accurate.”

“We’ve seen the rapid growth of health IT systems, particularly in the hospital setting,” says Keller. “Organizations need to have better testing of the systems and checks and balances [after implementation] to make sure failure points for missing data or incorrect data entries are identified and addressed.” As an example, consider the following event reported to ECRI Institute PSO and its partner PSOs involving two separate health IT systems—an EHR system and a dietary management program:

The patient’s peanut allergy was listed in the EHR but the information did not cross over to the dietary department’s system. The patient questioned whether the food allergy information had been received by the dietary department after receiving a food tray that was not identified as free of peanut products.

The near miss highlighted the need for a software fix to ensure that important patient data from the EHR is transferred to the organization’s dietary IT system for patient menu management.

2. Data Integrity: Incorrect or Missing Data in EHRs and Other Health IT Systems
Examples of data integrity failures, as listed in the *Top 10 Health Technology Hazards for 2015* report, include the following:

- Appearance of one patient’s data in another patient’s record
- Missing data or delayed data delivery
- Clock synchronization errors between medical devices and systems
- Default values being used by mistake, or fields being prepopulated with erroneous data
- Inconsistencies in patient information when both paper and electronic records are used
- Outdated information being copied and pasted into a new report

To correct these problems, organizations must identify data integrity failures as they occur in order to apply fixes to prevent similar problems from recurring. To do so, they must empower frontline workers and health IT system users to report all types of health IT-related incidents, including those that do not cause any harm as well as near-miss incidents, and circumstances that precede an actual event and are caught before anything can happen.

Through its problem and event reporting programs, ECRI Institute has found that healthcare staff do not always recognize health IT’s contribution to an event. For example, only after analysis of an incident in which a pharmacist placed a medication order in the wrong patient’s record was it recognized that the error was facilitated by a medication management system that allowed users to have multiple patient records open at the same time. Reporting the event as just a medication error overlooks other contributing factors, such as the health IT system’s configuration to permit multiple patient records to be open on a user’s screen.

“When reporting an adverse event or near miss, staff should consider whether some function or feature of a health IT system could have contributed to the problem,” says Schluth.

Some event reporting programs give reporters the ability to identify the report as a health IT-related issue. For example, the Agency for Healthcare Research and Quality’s most recent version of the Common Formats (version 1.2) includes an event report for health IT events and unsafe conditions. The Common Formats are used by PSOs and their participating providers for event reporting and allow data aggregation in a systematic manner.
Every day, U.S. hospitals deal with violent patient incidents and threatening behaviors that affect the safety and well-being of staff, patients, and visitors. According to current literature on the topic, violence is occurring in all care settings, even in oncology and maternity units, and not just in the emergency department (ED).

Clinical staff in acute care units typically lack training in behavioral health and may dismiss or poorly handle behavioral cues that signal imminent violence, says Ruth Ison, MDiv, STM, patient safety analyst/consultant at ECRI Institute PSO. Ison notes that reports submitted to ECRI Institute PSO and its partner PSOs show that doctors, nurses, ancillary staff, and even security officers working in emergency and acute care settings are greatly challenged in managing patients who become violent or threaten violence. In 2014, failure to adequately manage threatening or violent behavior of patients in acute care settings was among ECRI Institute’s top 10 patient safety concerns.

The range and impact of patient violence across the hospital is not limited to incidents that make the headlines. Clinical staff may feel abandoned and left without the resources to do their jobs safely, given the frequency with which they must manage violent behavior in patients—at least 15 incidents a day, according to one PSO member hospital.

The first thing that hospital leadership must do is acknowledge that violence is occurring within the facility’s walls, says Judy Gushue, RN, BS, MJ, CEN, CPHQ, patient safety analyst, ECRI Institute PSO. When healthcare workers perceive assaults and threats as a workplace hazard that must be tolerated, they underreport—resulting in lack of awareness and inaction by hospital leadership. “Lack of psychiatric services and interventions puts pressure on nurses and other frontline staff to be trained in violence de-escalation techniques,” she points out.

Ison believes that training staff in de-escalation strategies is a smart investment that can improve patient and worker safety on many levels, reducing coercion and empowering staff to engage, rather than avoid, patients with agitation or threatening behavior while promoting safe conditions. The effort may prove to be more cost-effective than use of untrained “sitters,” who have been mentioned in PSO event reports as the targets of attacks by patients, Ison says. The sitter’s presence or behavior may be perceived by the patient as provocative, as the sitter is placed in the position of preventing the patient from engaging in certain unsafe behaviors, she notes. Untrained sitters may not be sensitive to the patient’s clinical situation, may not fully understand the recommended safety precautions, or may argue with the patient. Other sitter behaviors (e.g., texting, chatting, playing games on a smartphone) might result in sitter inattention or even provoke a violent response from the patient.
Gushue adds that in addition to requiring reporting and providing staff training in de-escalation strategies and skills, the hospital should have a facility-wide safety plan that considers all levels of risk, from the single acute episode of threatening behavior to an active shooter situation anywhere in the facility or on campus. “Know the risks posed by your patient population—local police statistics may help identify areas of risk or peak periods when risk may be greater.” The program should address physical security and response (e.g., use of hidden alarms, cameras, electronic staff locator services, increased strategic security presence, limiting sites of entrance and egress at night), implementing and monitoring compliance with policies and procedures for inspecting belongings of visitors and patients for weapons, reconfiguring ED waiting areas, invoking emergency legal processes for commitment or treatment (when appropriate), and establishing a trained rapid response team to assess potential violent behavior and intervene when summoned.

Ison agrees: the acute symptoms that demonstrate a patient’s behavioral or medical inability to cooperate with care interventions should not be misinterpreted by healthcare workers as unwillingness; however, “aggressive or agitated behavior signals a high-risk, high-acuity situation that needs immediate clinical attention comparable to a stroke, cardiac, or respiratory event.” Ison has identified the following patient factors from ECRI Institute PSO event reports involving violent patient behavior: acute substance abuse or addiction, acute withdrawal, drug-seeking behavior, psychosis, postsurgical status, and various medical and mental health comorbidities (e.g., neurologic disorders, infections, delirium, adverse prescription drug reactions, developmental disabilities) combined with behavioral health symptoms (e.g., paranoia, motor agitation, emotional volatility) and social dislocation.

Clinical management strategies can include standing orders and medication order sets that can be activated immediately by the staff on duty, as well as security measures. And while acutely agitated or threatening, violent patients should never be handed off, as these are emergency situations. Subsequent handoff communication of the patient’s medical status should include identification of acute socioemotional or behavioral health issues that are adversely affecting the patient, Ison says. These might be addressed by social workers or behavioral health staff.

Diminishing the risks involved with patient violence starts with accepting its reality across healthcare settings, Gushue says. The expertise of leadership, management, and clinical staff at all levels is needed to develop a comprehensive response that meets these vulnerable patients’ medical needs and keeps all healthcare staff safe in the process.
4. Mix-Up of IV Lines Leading to Misadministration of Drugs and Solutions

Intravenous (IV) line mix-ups can lead to medication errors, resulting in wrong-drug, wrong-rate, wrong-dose, or wrong-site infusions, some with serious consequences. Patients, particularly those in critical care settings, can have multiple IV infusions, increasing the risk of connecting the line to the wrong infusion pump, wrong fluid container, or wrong administration route.

Patients may have other interfering factors, such as leads and cables for physiologic monitors, increasing the risk of mistakes with IV line mix-ups, says Keller. Sometimes described as “spaghetti syndrome” or the tangle of tubes, catheters, and cables that engulf patients, the multiple lines “make it harder to track the source of an IV line as it leads from the patient’s insertion site to the original source,” he says.

In the following event reported to ECRI Institute PSO and its partner PSOs, an older patient received too much heparin because the IV lines for heparin and saline were misconnected:

The ED patient was suspected of having a heart attack and was started on a high-risk protocol for IV heparin. After the patient was transferred to the unit, the nurse noticed that the heparin bag was almost empty. The nurse checked the pump and saw that it was running at the faster rate intended for the saline solution. The tubing lines were mixed up, and the heparin ran for four hours at the faster rate, resulting in the patient receiving seven times as many units of heparin as intended. The patient was treated for a heparin overdose and transferred to the critical care unit.

Although the risk of IV line mix-ups is pronounced in the critical care setting, the risk also exists in other acute care settings, as the above event illustrates, and in nonhospital settings, such as a nursing home, where residents may require, for example, both an IV antibiotic and pain medication. Although patients in these settings may have fewer lines, mistakes can still occur, particularly if the provider does not have the same advanced training as a critical care nurse to ensure safety, says Keller.
Among ECRI Institute’s recommendations to prevent IV infusion-line confusion are the following:

- Trace all lines back to their origin before making connections. Doing so verifies that the correct lines will be joined. Lines should be rechecked upon the patient’s arrival in a new setting or service and at shift changes as part of the handoff process.

- Develop a policy of positioning different lines on different sides of the patient. Consistently putting lines in the same place might make it easier for clinicians to correctly identify them and connect them appropriately.

- Label each infusion line with the name of the drug or solution being infused.

- Do not force connections. If a connection is difficult to make—that is, if it requires a lot of effort—chances are it should not be made.

Separately, misconnections can also occur when tubing from one delivery system is misconnected to a system intended for a different purpose (e.g., an enteral feeding pump being connected to an IV line). New connector standards are being developed to reduce this risk; however, the standards will not prevent all line misconnections. Once the new design standards for connectors are fully in place, IV lines will continue to use the same type of connector, making it possible to still have IV infusion mix-ups.

ECRI Institute recommends using posters to remind staff about strategies to prevent tubing misconnections. For example, tips for clinical staff are summarized in a poster developed by ECRI Institute summarizing its TRACER™ program to prevent tubing misconnections. Information for obtaining the poster from ECRI Institute, as well as other resources, is provided in “ECRI Institute Resources.”
At every care transition, such as admissions, transfers, and discharges, “the patient’s medications should be reconciled to ensure the patient is on the correct medications for the next phase of care,” says Mary Beth Mitchell, MSN, RN, CPHQ, CCM, SSBB, patient safety analyst and consultant at ECRI Institute PSO. Inadequate medication reconciliation puts patients at risk for medication errors, inadequate follow-up care, and hospital readmissions.

On admission, medication reconciliation is challenging to conduct effectively unless the patient or family members have kept accurate records of the patient’s medications, says Mitchell. To ensure the list’s accuracy, she recommends verifying the patient’s medication list with another source, such as the patient’s primary care physician and/or pharmacy. The backup approach is not fail-safe, however, if the patient goes to multiple pharmacies or is seen by multiple specialists, “all of whom may order prescriptions for the patient,” she says. Providers should also ask about any over-the-counter and herbal medications that the patient may be taking, as well as any transdermal patches that are in place.

A facility might also refer to the patient’s last medical record from a previous stay to identify the patient’s list of medications at discharge. “But that may not be a good source for information if it’s been a long time since the patient’s last hospitalization or if the patient has had medication changes by their primary care physician and/or specialists,” says Mitchell. The patient’s medications may have changed if the previous hospitalization was not recent, as in the following event reported to ECRI Institute PSO and its partner PSOs:

The patient was admitted through the ED. The patient brought a list of current medications. The list was compared to the patient’s medication list from a previous stay. Two other medications, an antipsychotic drug and a diabetes medicine, from the previous stay were not on the patient’s medication list and were ordered. No one went over the patient’s current medication list with the patient. During the patient’s stay, the patient’s wife reported the patient was having hallucinations and seemed continually drowsy when that wasn’t the patient’s norm. It was determined that the patient had not taken the two additional medications for a year, so they were discontinued.

When a patient is admitted for care, providers may decide to discontinue some or all of the patient’s medications taken before the admission in order to address the patient’s acute needs. They may also introduce new medications to treat the acute condition. As the patient’s condition improves or changes and when the patient is transferred to another level of care, clinicians must continue to evaluate the patient’s medication needs, deciding whether to discontinue the medications for the acute condition, introduce any new drugs, or resume any of the medications that the patient took before admission.

“By the time the patient is ready for discharge, they should not be receiving new medications that they did not receive while in the hospital,” says Mitchell. “The point of conducting medication reconciliation every step along the way of the hospitalization is that by the time the patient is ready for discharge, they should be on the right medications and the healthcare providers should know that the patient can tolerate the medications when taken together.”
While EHRs can improve communication among providers about patients’ medications, Mitchell warns to use the technology cautiously. For example, at discharge, don’t simply print the patient’s list of medications without assigning someone to go through the list to look for errors, such as dosing errors and duplicate orders for similar drugs with different names, she recommends. In addition, some EHRs allow only one person to reconcile the medications, which means that that physician must be sure of all of the medications and recommended doses from the specialist physicians.

If the patient is being discharged to another healthcare setting, medication reconciliation can only be achieved by effectively managing the patient’s discharge from the hospital and the admission to the other facility, such as a nursing home or subacute care facility, says Rose. “Both pieces need to be managed . . . for medication reconciliation to work well,” he says.

If the discharge and admission process from one facility to another is poorly managed, patient care can suffer. “Medications that were discontinued at the hospital may not be restarted when the person comes back to an aging services provider or returns home,” says Rose. The aging services provider must then coordinate with the hospital and physician who was overseeing the patient’s care or the patient’s primary care physician to identify the patient’s medications. “It’s not an easy process and can lead to delays in resuming the patient’s care,” Rose says.

Typically, aging services providers conduct chart checks within 24 hours of a resident’s return to the facility after a hospital discharge to review the resident’s medications, to see if anything was stopped or added, and to determine if there’s a reason for the change, says Rose. If the resident is new to the facility, the organization will verify that information with the individual’s primary care physician.

There are many ways to manage medication reconciliation. Some publicly available resources for medication reconciliation recommend pharmacist-led interventions, but there are other approaches as well. A good mechanism to ensure that the medication reconciliation process works well is to proactively evaluate the process using a failure mode and effects analysis (FMEA) to identify gaps in that process. Consider involving the pharmacists, case managers, nursing, and other FMEA team members in identifying solutions to close the gaps, says Mitchell. “Pharmacists don’t necessarily need to lead the interventions, but they need to be involved with the multidisciplinary team in closing the gap,” she says.

Rose, who also recommends that aging services providers conduct a similar proactive analysis of their medication reconciliation processes, encourages hospitals and aging services providers to engage each other in the medication reconciliation assessment. “Find out where the risks exist and have intelligent conversations with your care partners in the community to put practices in place to mitigate them,” he says. Refer to “ECRI Institute Resources” for additional information.
In blood banking, having two practitioners perform an independent double check of the blood group before transfusion is a long-standing requirement. “Nobody in the universe would think of doing a blood transfusion without doing an independent double check first because you could kill the patient pretty quickly,” states Elizabeth Drozd, MS, MT(ASCP) SBB, CPPS, patient safety analyst, ECRI Institute PSO. “But for high-alert medications, we’ve seen a lot of controversy about doing independent double checks and have seen a lot of failures in that process.”

The following two events reported to ECRI Institute PSO and its partner PSOs illustrate how failures in independent double checks can affect patients:

*Patient was receiving a heparin drip, which required a double check per policy. The dosing nomogram and rate were double-checked appropriately, but there was no double check when the nurse changed the rate on the infusion pump. The drip rate was changed to 18 mL/hr instead of 15 mL/hr, resulting in an elevated partial thromboplastin time with bleeding from the IV site.*

*An independent double check was not completed when a patient-controlled analgesia (PCA) pump was set, resulting in a 10-fold opioid overdose. Naloxone was administered, and the patient was transferred to the intensive care unit (ICU).*

When double checks are used, one major issue is the failure to conduct them in a way that is truly independent. As the second provider, “I want to check your work totally independently of what you’re telling me,” says Drozd. “I want to look at everything,” such as patient identity, indication and appropriateness, drug or blood type, dose, programmed infusion rate, and route.

To achieve truly independent double checks, the organization needs staff buy-in. “They have to understand why independent double checks are done independently,” Drozd emphasizes. Importantly, the process must be free of the potential for confirmation bias. For example, if the first provider asks the second provider, “I got 5,000 units of heparin. What do you get?” the second provider is already biased toward a specific dose and drug. A provider may overly rely on the second provider’s check, possibly skipping steps, if he or she expects that simply doing a double check will catch any errors or believes that the second provider “doesn’t make mistakes.”
In addition, the organization must be judicious when deciding which processes require an independent double check. A common mistake is to “add a double check as a solution to everything,” says Drozd, potentially leading to double check fatigue. Instead, “use independent double checks with a lot of caution and only for processes that could harm the patient very, very quickly.”

Systems issues should also be investigated. For example, if policies and procedures require an independent double check in a particular situation but a second provider is often unavailable, staff may use workarounds or even skip the double check.

How can organizations investigate whether they are performing independent double checks in a way that is truly independent? “The only way, really, is to begin to audit and observe the actual process,” says Drozd. “You have to be out there in the patient care areas and observe,” using a checklist of what to look for. This approach is labor-intensive, but “it’s also your opportunity to link with the individuals to explain the importance of doing it properly.”

Although there are many potential barriers to truly independent double checks, the Institute for Safe Medication Practices (ISMP) calculates that they can detect up to 95% of errors. “When done properly, they do detect a significant amount of errors,” says Drozd.
7. Opioid-Related Events

“The use and the prescribing of opioids has significantly increased in recent years,” says Stephanie Uses, PharmD, MJ, JD, patient safety analyst, ECRI Institute PSO, and “that’s one of the reasons opioid safety has become more of an issue.” According to the U.S. Department of Health and Human Services’ National Action Plan for Adverse Drug Event Prevention, the number of prescription opioids dispensed doubled between 1999 and 2010, and by the end of that period, the number of related deaths exceeded the number of overdose deaths involving heroin and cocaine combined. The number of ED visits related to opioid misuse and abuse totaled more than 420,000 in 2011—double the number of visits in 2004.

Problems related to opioid overdose, such as over-sedation and respiratory depression, are a major patient safety concern, but they are not the only ones. Other issues include gastrointestinal adverse events (e.g., nausea, vomiting, constipation), hyperalgesia, pruritus, and immunologic or hormonal dysfunction.

Among events in ECRI Institute’s PSO database, the problem is “not specific to any one opioid,” says Uses. However, those commonly involved in events are hydromorphone, oxycodeone, opioids used in PCA, and fentanyl patches.

Two issues are especially concerning. First, “some of the more common errors with hydromorphone are due to its potency,” says Uses. Hydromorphone is about seven times as potent as morphine, but physicians sometimes prescribe the same amount of hydromorphone as they would morphine, leading to overdose, as in the following event reported to ECRI Institute PSO and its partner PSOs:

Patient presents to ED with abdominal pain. The patient’s pain is poorly relieved with morphine 4 mg; attending physician changes pain orders to hydromorphone 4 mg intravenously every 4 hours as needed. The patient’s nurse administers a dose of hydromorphone. Shortly after the dose is given, the nurse notices decreased responsiveness, the patient becomes apneic, and code blue is called. Two doses of naloxone are given. Patient becomes responsive and is transferred to the intensive care unit for monitoring.

Second, prescribers sometimes fail to distinguish patients who are opioid-tolerant (those who have been taking an opioid of at least a certain threshold dosage for at least a week) from those who are opioid-naïve (those who have not). For example, opioid-naïve patients should not be prescribed fentanyl patches, and these patients should receive only very low doses of sustained-release oxycodone, if the drug is used at all. They should not receive continuous infusion when PCA therapy is initiated; rather, bolus-only therapy should be used.
Opioid-related events are not restricted to the hospital. For example, oxycodone and fentanyl patches may be used in long-term and ambulatory care settings and at home. In addition, family members or friends may inappropriately take the patient’s medications to self-treat their pain, or the drugs may be otherwise misused or abused by the patient or others. ISMP has also reported on incidents, including deaths, in children and older adults with cognitive impairment who have stuck fentanyl patches on their bodies or ingested them. “Fentanyl is so potent,” says Uses, “a young child will stop breathing right away” after ingesting or applying a fentanyl patch.

Although many strategies should be employed to promote safety throughout the medication-use process, Uses highlights a few key interventions to prevent and mitigate the kinds of events ECRI Institute PSO is seeing.

Prescribers should be educated about opioid safety and the events that can result. One central issue is appropriate prescribing. “Does the patient really require an opioid?” says Uses. “Sometimes that’s not the first choice that we need to go to.” Order sets—with different drug forms and dosages for opioid-naïve and opioid-tolerant patients, for example—may help guide clinicians as well.

In hospitals, staff should be trained to monitor for sedation. “A lot of times, people don’t monitor for sedation and don’t recognize sedation as a problem until the patient is already experiencing respiratory depression,” Uses cautions. The Pasero Opioid Sedation Scale is one tool that staff can use to monitor for opioid-induced sedation.

At home and in other nonhospital settings, patients and caregivers must know how to appropriately store and dispose of opioids. These drugs should not be kept in easy view and reach of others, and disposal options include take-back days, locked drop boxes, and appropriate disposal at home.

To investigate opioid-related events they are experiencing, healthcare organizations can not only look at their adverse event database but also use trigger tools—for example, by running daily reports to identify when naloxone, a reversal agent, is dispensed. Faster notification allows for easier investigation of events, and “you can track and trend and see what your problems are,” Uses notes.
Reprocessing of endoscopes and surgical instruments, a top 10 patient safety concern and health technology hazard for 2014, returns to both top 10 lists for 2015. In fact, reprocessing has been raised as a top 10 health technology hazard for six years in a row.

“We continue to see reprocessing issues in our accident investigations” and in media reports, says Schluth. Additionally, as ECRI Institute was preparing Top 10 Health Technology Hazards for 2015, the Ebola virus had become front-page news, further “highlighting the critical importance of the reprocessing function,” says Schluth.

The potential harm to patients from the transmission of infectious agents remaining on reusable devices can be severe. More than half of the “immediate threat to life” findings from Joint Commission surveys conducted in 2013 were directly related to improper equipment reprocessing, Schluth notes.

Healthcare facilities reprocess thousands of reusable surgical instruments and devices every day for subsequent use. Not only are the devices difficult to clean, but “multiple steps are required to get it right,” says Keller. Each step must be properly performed from start to finish. For example, if the devices are not thoroughly cleaned, organisms may remain on the devices, unaffected by disinfection or sterilization. Similarly, if the devices are not thoroughly dried in the final reprocessing step, “they are a breeding ground for organisms to grow postprocessing,” says Keller.
Further complicating the reprocessing function are the multiple types of devices, each with their own cleaning and disinfection or sterilization instructions, says Keller. If automated reprocessing systems are used for endoscope disinfection, each device model will likely require unique model-specific channel adapters to properly flush each channel of the device, he adds.

Any time a change is introduced to reprocessing, such as a new disinfectant, cleaning agent, or channel cleaning brushes, the impact of the change needs to be evaluated for any ripple effect on the quality of the process. For example, after being asked to investigate an infection outbreak in an endoscopy clinic, ECRI Institute discovered that the clinic had switched to a new cleaning solution that required a longer soak time for instruments than required with the previously used cleaning solution. The clinic’s reprocessing procedures were no longer effective, because the clinic had not adjusted the instrument soak time required with the new solution.

In addition to the recommendations for ensuring adequate device reprocessing listed in Top 10 Health Technology Hazards for 2015, other guidance from ECRI Institute is listed in “ECRI Institute Resources.”
Top 10 Patient Safety Concerns for Healthcare Organizations

9. Inadequate Patient Handoffs Related to Patient Transport

“Transporting a patient within the hospital to another clinical setting or between units within the facility presents risk of harm to the patient and, depending on the needs of the patient, can be an unsettling experience for nurses charged with caring for the patient, and for the transporter,” says Kelly Graham, BS, RN, patient safety analyst at ECRI Institute PSO.

Safe transport involves identifying and providing appropriate resources and requirements for each patient during transport and includes proper handoff communication to and from appropriately trained transporters. Patients may be transported to the wrong department, the wrong patient may be transported, or patients may be left unmonitored at the receiving site. A standardized process for patient transport and handoff communication can reduce risk during transport and at the sending and receiving ends of the process, Graham says.

Risks of transport vary with patient acuity. “Ideally, the level of care provided during transport pairs with the care the patient receives in the unit,” Graham adds. Critically ill patients, for example, are exposed to periods of potential instability during transport. Maintaining oxygenation during transport and activating a code when a patient’s condition rapidly deteriorates during transport are but a few examples of potential risk.

To enhance safety, critically ill patients are typically transported by teams of qualified critical care providers with defined roles for monitoring and ensuring ventilator support. The transport process and related communication is guided by formal policy reflecting guidelines from the Society of Critical Care Medicine and the American College of Critical Care Medicine for transporting critically ill patients. But because danger is inherent in the transport process of all patients, facility transport policy and procedures should guide handoff communication for the safe transport of the non-ICU patient.

The Joint Commission requires that each patient handoff communication include a standardized and interactive approach for the safe transfer of a patient from one care area to another. Handoffs are an integral part of safe transport, and without careful attention to handoff communication and transport safety at each point in the transport process, errors can occur, Graham says.

Notably, of 2,390 patient-transport-related reports submitted to the Pennsylvania Patient Safety Authority from May 2004 through September 2008, 41% involved communication issues, according to an article in the March 2009 Pennsylvania Patient Safety Advisory. ECRI Institute PSO and its partner PSOs have received reports involving ineffective handoffs in the patient transport process that have contributed to patient harm in a variety of care settings. The following report provides an example of inadequate handoff communication during transport of an infant within a hospital:

Immediately after undergoing a surgical procedure, the infant was transported to the neonatal intensive care unit (NICU) in an open crib. Staff in the unit had not been informed that the infant’s
body temperature dropped in the operating room (OR), or that the infant was transported directly from the OR to the unit, and that the infant had not been monitored in a recovery unit. A nurse preparing the infant for the NICU stay expressed concern about the infant’s pale coloring and slowed respiration. The baby was given vigorous spinal stimulation in an effort to restore breathing and return body temperature to normal, and required intubation when breathing did not fully respond to the spinal stimulation.

Graham recommends that facilities’ event and near-miss reporting systems capture transport-related incidents and near misses that occur “off unit” and during transport. Such reports can identify gaps in policies, procedures, or training; the need for improved communication processes and oversight for follow-up and monitoring of handoff protocols; and other problems that may require reassessment of transport policies and procedures.

Graham suggests that transport policies and procedures be based on consideration of numerous issues, the following among them:

► Identifying units are most often involved in transport and safety hazards particular to the units
► Developing criteria for determining the level of transport team needed (depending on patient assessment and the level of care required)
► Ensuring availability of equipment, assigning responsibility for maintenance of therapies during transport, and troubleshooting equipment during transport
► Determining training, experience, and competency required of transport personnel in light of expected levels of intervention that may be required during transport
► Developing and implementing tools and checklists to support handoff communication among the care team, transport personnel, and staff at the receiving site

Policies and procedures might incorporate use of a transport form, often referred to as a “Ticket to Ride” form, that helps convey essential information from the sending unit, provides a checklist to be addressed by transport staff and by the receiving unit, and incorporates a situation-background-assessment-recommendation (SBAR) format to enhance communication at each end of the process. ECRI Institute has also developed handoff communication strategies that address transport. For additional information, see “ECRI Institute Resources.”
10. Medication Errors Related to Pounds and Kilograms

The patient safety events presented in this report are not just statistics, as the issue of pound-kilogram mix-ups illustrates. “We definitely see these events in the PSO data,” says Sheila Rossi, MHA, patient safety analyst/consultant, ECRI Institute PSO. But she gained a first-hand understanding of the issue through her own personal experience.

On a visit to a local ED, Rossi’s two-year-old son was weighed in the triage room. Later, the physician determined that he needed two oral medications, to be given by Rossi and her husband. “Having previously given him two similar medications at home, we had some idea of the dosing based on his age and weight,” Rossi says. When the nurse brought in two big syringes, Rossi and her husband said, “Wow, that looks like a lot of medication,” and questioned the amount. “Almost in unison, the nurse and the doctor said, ‘It’s weight-based dosing.’” Still trusting their instinct that something wasn’t right, Rossi and her husband gave their son a portion of each dose, disposing of the excess in a napkin, after the providers left the room.

The next morning, the physician called and apologized, informing Rossi that there had been a mix-up in the weight-based calculation. Their son had been weighed in pounds, but his 30-pound weight had been entered into the EHR as 30 kilograms (equivalent to about 66 pounds). The oral syringes had each contained roughly twice the amount of medication he should have received; fortunately, neither was a high-alert medication. But, says Rossi, “My concern wasn’t so much for my child; my concern was for the next child that comes along and what system fixes they were going to make so that this would not occur again.”

Mix-ups between pounds and kilograms are not limited to EDs and hospitals; they can happen “anyplace that has a scale,” says Rossi. And although the problem poses “a huge potential for error with adults,” children and older adults may be even more sensitive to medication dosing errors. Similarly, overdoses involving high-alert medications pose a particular patient safety concern. Consider the following event reported to ECRI Institute PSO and its partner PSOs, which involved an older adult:

Weight was entered in the EHR incorrectly. The employee used pounds for kilograms. A low-molecular-weight heparin was dosed for more than double the patient’s weight. The pharmacy discovered the error, and the order was discontinued. The anticoagulation status of the patient was monitored.
One of the most effective strategies to reduce the risk of such errors is to “get rid of scales that measure in pounds,” says Rossi. There are many barriers to employing this strategy. For example, it requires substantial capital, and parents often want to know their child’s weight in pounds. Alternatives may include adjusting electronic scales so that they display only in kilograms and giving parents weight conversion charts. “If you can get rid of that mix-up at the very first step in the process, pounds are never introduced into the equation,” says Rossi.

Other high-impact strategies include the following:

- Ensuring ready availability of pediatric scales (e.g., to reduce reliance on parental estimates, which are likely to be in pounds)
- Recording and displaying weight only in kilograms in the EHR
- Integrating digital scales with the EHR to eliminate or reduce the need for data entry
- Using clinical decision support functions that compare entered weight with expected weight (e.g., based on growth charts)
- Purchasing infusion pumps with dose error reduction features
- Not storing in clinical areas any high-alert drugs or other medications that have the potential to cause patient harm if weight-based doses are miscalculated

To investigate this issue, organizations may start by reviewing their event-reporting systems. But that may yield limited information because “it assumes that people are actually reporting these events as weight-based errors,” Rossi notes. Chart audits and observation can help the organization explore further. “How are patients being weighed, what scales are used, how is the weight entered into the EHR, where are the chances for error?” says Rossi.

Rossi’s encounter offers some motivation and perspective for all patient safety events. “When we say ‘the patient’ in healthcare, it sometimes becomes impersonal, and we see the patient as someone else, a body or object to which care is delivered and in some cases bad events or outcomes occur. We have all been or will become ‘patients’ at some point in our lives,” says Rossi. “How are we going to improve patient safety for ourselves? How do we put ourselves in the patient’s shoes and say, ‘How do I prevent this from happening to me?’”