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Moving Mountains Together: PSOs Offer Shared Learning

Executive Summary

At its annual safe table forum, ECRI Institute PSO brought together member organizations and collaborating patient safety organizations (PSOs) to openly discuss patient safety and quality issues for achieving a culture of safety. Topics included patient violence, second victims in serious events, fall prevention, new oral anticoagulants, patient identification, and root-cause analysis (RCA) methods.

Leadership

SHARE, LEARN, PROTECT®

Moving mountains. That's how some healthcare organizations describe the complex journey they are taking to shift to a culture of safety. "Moving Mountains" was also the theme of ECRI Institute PSO's second annual "safe table" forum, bringing together its member organizations and collaborating patient safety organizations (PSOs) at ECRI Institute headquarters in Plymouth Meeting, Pennsylvania, on September 15, 2016. The meeting was designed as a confidential forum for participants to share their experiences in developing a culture of safety.

Opening the meeting, ECRI Institute Executive Vice President and General Counsel Ronni P. Solomon, Esq., reminded the

audience of ECRI Institute PSO's motto, which has guided the PSO since it began operation in 2008. "Share, learn, protect," she said, emphasizing that the meeting was designed as a safe table forum in which participants could openly discuss patient safety and quality issues to move mountains together. "We can share and accelerate learning in the interest of protecting patients."

A safe table forum is conducted under the protections of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). All participants sign confidentiality agreements to attend and to follow rules to share information without identifying any patients, practitioners, or provider organizations. "It's a unique opportunity for us to gather and address topics we would not otherwise discuss," said Barbara G. Rebold, MS, RN, CPHQ, ECRI Institute's director, engagement and improvement. "We can share what has and has not worked."

Culture of Safety

An underlying theme of the meeting was to help participants lay the groundwork to support a culture of safety in their organizations, said Rebold. A culture of safety is partly built on an organization's willingness to learn from failures, using systems thinking for error prevention. "It takes many, many years to transform into one," said Rebold. But by allowing participants to share what they learned from investigating an adverse event or implementing a safety initiative, the meeting offered an opportunity for participating organizations to fast-forward their transformation to a culture of safety. Refer to "ECRI Institute Resources" for information on accessing material from the meeting.

Attendees seized the opportunity for shared learning. Throughout the day, they divided into work groups to discuss various hot topics and to describe lessons they have learned at their

Highlights from ECRI Institute PSO's Safe Table Forum

- Create a safe working environment for staff; patient safety starts with worker safety.
- Debrief after every event to identify opportunities for improvement.
- Establish programs to provide support for healthcare workers involved in patient safety events.
- Adopt multiple strategies to prevent patient identification mistakes; no single solution will eliminate the problem.
- Assess patients for fall risk, and tailor their care plans to the assessment's findings.
- Track events involving new oral anticoagulants to address risks introduced by these medications.
- Continually examine the organization's approach to post-event analysis to identify ways to improve event investigation and response.
- Recognize the importance of examining processes that achieve good outcomes; the lessons learned are just as valuable as understanding why failures occur.

ECRI Institute Resources*

- ECRI Institute PSO Deep Dive: Patient Identification: https://www.ecri.org/components/PSOCore/Pages/DeepDive0816_PatientID_Executive.aspx
- ECRI Institute PSO's February 2015 PSO Navigator on human factors analysis: <https://www.ecri.org/components/PSOCore/Pages/PSONav0216.aspx>
- ECRI Institute PSO September 15, 2016, members' meeting handouts: <https://www.ecri.org/components/PSOCore/Pages/2016PSOMeeting.aspx>
- ECRI Institute PSO Guidance for Patient Safety (GPS) toolkit on oral anticoagulant management: <https://www.ecri.org/components/PSOPlus/Pages/WM.aspx>

* For information on obtaining ECRI Institute resources, contact ECRI Institute PSO at psohelpdesk@ecri.org.

organizations in managing these issues. The topics covered the following:

- ▶ Caring for healthcare staff involved in an adverse event
- ▶ Fall prevention across the care continuum
- ▶ Medication safety with anticoagulants
- ▶ Patient violence
- ▶ Patient identification
- ▶ Root-cause analysis (RCA) of events

Many participants left the one-day meeting ready to pass along the lessons learned to their organizations. “We’re gratified with how willing you were to share your challenges and successes,” said William M. Marella, MBA, MMI, ECRI Institute’s executive director of PSO operations and analytics, at the meeting’s conclusion. This issue of the *PSO Navigator* provides highlights from the meeting and reflects the shared knowledge of ECRI Institute PSO’s collaborating organizations to move mountains together. For a summary, refer to “Highlights from ECRI Institute PSO’s Safe Table Forum.”

What We Are Seeing

CULTURE OF SAFETY DRIVES CHANGE

Setting the Stage in Behavioral Health

To set the stage, Monica Cooke, MA, RNC, CPHQ, CPHRM, FASHRM, with Quality Plus Solutions LLS, spoke about a culture of safety within the context of a healthcare organization’s response to aggression and violence, one of the biggest concerns confronting healthcare providers. Although Cooke focused on strategies to improve management of behavioral health patients, many of the themes she introduced were echoed during the breakout sessions as strategies to enhance patient safety and included the following:

- ▶ Engaging leaders to support change
- ▶ Making safety a shared, organization-wide goal
- ▶ Empowering staff with the necessary resources to ensure patient safety
- ▶ Establishing a supportive environment for staff to willingly report events so that the organization can respond to events and analyze and learn from them

These elements are missing in organizations in which the “day-to-day aggression and violence by patients, visitors, and staff” is an ongoing issue, said Cooke. Given that 25% of the population suffers from some type of

behavioral illness, hospitals are treating behavioral health patients every day, she said. “There is no disease as prevalent.”

In many healthcare organizations, “there’s an expectation that abuse is tolerated,” said Cooke. “It’s embedded in the culture.” In fact, one of the breakout sessions addressed an incident involving an acute care patient who attacked and injured two staff members; there had been warning signs because the same patient had become agitated four previous times but was redirected before any harm occurred. Each of the previous incidents went unreported so there was no attempt to address the triggers causing the patient to act up and to prevent another incident from occurring (refer to “Best Practices for Preventing Patient Violence” for suggestions that might have prevented the incident).

Organizations can improve their management of behavioral health patients by applying the principles of a culture of safety and a willingness to improve, said Cooke. Change starts with leadership’s support to examine the organization’s current approaches to behavioral healthcare and to identify opportunities for improvement.

“The findings from the risk assessment will keep you up at night,” said Cooke.

Leaders must be willing to devote resources to address the findings by providing safer treatment environments, supporting staff-competency training in managing behavioral health patients, and ensuring that staff members have access to behavioral health professionals with expertise in managing patients with mental disorders.

Along with a willingness to improve current practices, leaders must create a culture that has zero tolerance for aggression, she said. “The culture [change] needs to start right at the door,” said Cooke. Organizations can set expectations for non-disruptive behavior with notices and signs posted at entrances, stating, “Our goal is safety. Be respectful.”

As part of its zero-tolerance policy, the organization should have a plan in place to manage aggression. “Don’t leave a nurse alone to manage aggression. Have a process to help the nurse manage the situation and to call for help,” said Cooke. Some organizations have established rapid response teams dedicated to managing behavioral health patients before a situation becomes a crisis; staff can activate the team when they don’t feel competent in dealing with the patient’s behavior on their own.

Additionally, staff should feel empowered to activate a chain of command if their concerns about a particular patient or situation are unaddressed. Too many nurses “have concerns about a particular patient, but don’t communicate them, thinking, ‘We just have to deal with it,’” said Cooke. “If you’re in trouble, I want to know.”

An important element of a culture of safety is using the lessons learned from past events to improve patient care and the care environment. Cooke recommended using debriefs after every event so that those involved in the event can reflect upon the experience, discuss what went well, and identify opportunities for improvement. “A debrief is critical for learning,” said Cooke, and can help new staff, as well as those who are fearful of having to confront patient violence, respond proactively to situations before they escalate.

Attendees noted that Cooke’s message to support staff with a safe working environment is also critical for patient safety. “We can’t be serious about patient safety until we’re serious about worker safety,” said one attendee. When workers feel safe and free from distractions of violent encounters, they are able to focus on delivering safe patient care.

Caring for the Caregiver

What happens when staff don’t feel supported? A culture of safety cannot take hold, answered participants at a breakout session on caring for staff involved in patient safety events. “We’re just fooling ourselves if we think we have a culture of safety, but we’re not taking care of our employees,” said one of the session participants.

The session featured the approach taken by one healthcare system to address what is often referred to as the “second victim” phenomenon. A healthcare provider involved in a medical error can become a “victim,” along with the patient injured in the event, feeling traumatized by the event and personally responsible for the patient’s outcome. The person may be haunted by feelings of guilt, incompetence, inadequacy, anxiety, and depression and is unable to turn to anyone for help.

Although some participants at the session were uncomfortable using the term “victim,” everyone agreed that the phenomenon of the second victim is a bigger issue than many in healthcare would like to admit.

In fact, when participants were asked at the start of the session if they’d ever been personally involved in an event that harmed a patient, everyone raised a hand. One participant recalled a mistake she made earlier in her nursing career that nearly harmed a patient. “It was 20 years ago, and I still think about it,” she said. The patient was unharmed and ended up consoling the nurse who was upset and cried after the event. “That’s not the way it should be,” the participant said.

Yet, there is a pervasive attitude that when mistakes happen, caregivers involved in the event are expected to bounce back.

Best Practices for Preventing Patient Violence

- Conduct a comprehensive behavioral health and medical assessment prior to or upon admission.
- Place an alert in the patient chart if he or she has the potential for violence.
- Communicate the patient’s potential for violence at every handoff.
- Provide all staff with de-escalation and nonviolent crisis training; include competency assessment as a component of the training.
- Assemble a behavioral emergency response team whose members include psychiatric unit nursing staff (if available), security, social workers, and supervisors.
- Educate staff on how to activate the behavioral emergency response team.
- Monitor the effectiveness of interventions to prevent patient violence.

Source: Responding to Patient Violence in the Acute Care Setting. Presented at: Moving Mountains: An ECRI Institute PSO Members’ Meeting; 2016 Sept 15; Plymouth Meeting (PA).

Choosing the Right Words

Listed below are words to stimulate conversation with second victims shaken by a serious event.

- “Are you OK?”
- “I’ll help you work through this.”
- “You are a good nurse working in a very complex environment.”
- “I believe in you.”
- “I’m glad that we work together.”
- “Please call me if you would like to talk about it again.”
- “I can’t imagine what that must have been like for you. Can we talk about it?”
- “I’m here if you want to talk.”

Source: Cox KR, Hirschinger LE, Scott SD. Sharing the load of a nurse “second victim” [online]. Modern Medicine Network 2008 Dec 1 [cited 2016 Oct 14]. <http://www.modernmedicine.com/modern-medicine/news/modernmedicine/modern-medicine-feature-articles/sharing-load-nurse-second-victi>

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“You’re going to get the naysayers who say, ‘I’ve had a lot of events happen to me. I didn’t get any support. I turned out fine,’” said an attendee.

Many attending the session acknowledged that their organizations do not have programs in place to support second victims but that there is a need. One participant remembered asking a surgeon if she was all right after an event. The surgeon responded, “I’ve been working here for 20 years and no one has ever asked me how I am,” and broke down. A few days later, the surgeon phoned the individual to say, “talking to you is what got me through it.”

Representatives from the health system shared tips for providing what they called “emotional first aid” to providers involved in an event. Start by establishing leadership support for the program and defining its structure. One model uses three levels of support, starting with basic emotional support from colleagues. If more support is needed, the next level offers trained peer supporters able to offer help and refer the individual to other available resources. The third level of support can provide the individual with access to professional counseling, such as through an employee assistance program.

Other suggestions for approaching a provider involved in an event include:

- ▶ Provide a timely response. If the provider can’t be reached in person, send a text or e-mail message or call on the phone. “Let them know you’re thinking about them,” the speaker said.
- ▶ Ensure privacy and confidentiality when meeting with the provider; don’t reach out to the person in front of a group of people.
- ▶ Let the provider know the interaction is to offer support and is not an investigation.
- ▶ Make the provider comfortable.
- ▶ Choose the right words to start the conversation. Instead of asking, “What did you do?” pose the question, “Are you OK?” (Refer to “Choosing the Right

Words” for suggestions of words to stimulate conversation with second victims).

Tying the idea of a second victim program with the meeting’s culture of safety theme, the health system’s representatives noted providers who felt supported by their organizations after an adverse event also rated their hospitals as better at ensuring safety in culture of safety surveys compared with staff who did not feel supported after an event. The system added the following questions to its culture of safety surveys to evaluate the impact of its caregiver support program:

- ▶ Within the past year, did a patient safety event cause you to experience anxiety or depression or to wonder if you were able to continue to do your job?
- ▶ Did you receive support from anyone within our healthcare system?

The survey found that the experience of an adverse event lowered staff’s perception of an organization’s overall safety compared with all staff who took the survey; however, staff who received support rated the safety of their organization better in a statistically significant way than those who did not receive support. Indeed, in some of the domains measured by the culture of safety surveys, supported staff rated their organization’s safety higher than or equivalent to the ratings given by staff overall.

“Don’t give up on getting a second victim program rolled out at your organization,” one of the speakers said. “You know it’s right.”

Preventing Identification Mix-Ups

During the break-out session on patient identification errors, participants were outspoken about the adverse effects of a work culture that pushes for productivity to the detriment of patient safety. Mistakes can occur when staff feel pressured to work quickly and, as a result, take shortcuts to verify a patient’s identifiers. “There’s pressure to do workarounds until something bad happens,” said one participant.

Group members shared scenarios in which they had witnessed staff taking

shortcuts to confirm patient identifiers, such as the following:

- ▶ When delivering blood or intravenous medication, nurses were observed scanning only the bags and not the patients.
- ▶ In some neonatal intensive care units, staff did not put identification bands on the babies, but instead attached them to a baby's bassinet or to leads if the band was too big for the baby.
- ▶ Staff members were observed putting labels on patient notebooks and scanning the notebooks instead of the patient.
- ▶ Some staff have been observed giving patients their medication before scanning the medication and patient to confirm that the medicine is intended for that patient.

As a result of productivity pressures and multiple other contributing factors, even one of the most commonly performed procedures in healthcare organizations—confirming a patient's identifiers before any procedure—can have serious consequences for patients and providers when it is performed in error, the work group participants noted. In one case discussed at the break-out session, a healthcare professional involved in a patient identification error that resulted in wrong-patient surgery committed suicide. This situation caused the organization to not only reexamine its patient identification practices, but also to institute a second victim program for its staff.

Participants shared other examples of serious errors and close calls with patient misidentification, including:

- ▶ A patient unnecessarily underwent a mastectomy because the findings from a breast tissue sample were wrongly attributed to her. The patient who had the positive findings did not undergo the mastectomy until later, after the error was discovered.
- ▶ A cardiac catheterization was performed on the wrong patient because the cardiologist's verbal order for the procedure was transcribed in the wrong patient's

record. The cardiologist was assigned to both patients, who were staying in the same room. The assistant who entered the order was unsure which patient in the room was to undergo the procedure and, having made a patient identification mistake a few weeks before, was reluctant to clarify the order. Instead, the assistant made a guess and entered the order for the wrong patient.

- ▶ A medication mix-up occurred for two patients with the same first and last names but different middle initials. One patient was being treated for hepatitis, but the patient's medication was ordered for the other patient.
- ▶ Two female patients with the same name and birth date, but different blood types, were admitted on the same day to deliver their babies. Although there were no adverse events, many near misses occurred because of the patient's similar identifiers. "Even if you're on high alert, mistakes can be made," said one group member.

While acknowledging the challenges in hardwiring best practices for patient identification, many of the work group members said their organizations had implemented strategies that have been successful in reducing patient identification errors. Among the approaches described by attendees are the following:

- ▶ At registration, requiring both the admitting clerk and the patient to initial the patient's wristband to confirm that the correct information is on the band before putting it on the patient.
- ▶ Creating a video that is shown to all incoming staff that demonstrates the right and wrong approaches for confirming patient identification in different scenarios.
- ▶ Flagging the electronic health records (EHRs) of patients with similar names who are admitted to the same unit so staff can ensure that the patients are assigned to rooms as far away from each other as possible to reduce confusion.

- ▶ Adopting a red rule for patient identification, meaning staff are expected to use two patient identifiers every time they have contact with a patient.
- ▶ Implementing a modular online learning system on the organization’s patient identification practices.
- ▶ Using bar-code scanners to double-check the accuracy of the patient information on a labeled specimen container.
- ▶ Deploying bar-code scanners capable of printing labels for specimen containers at the bedside when the specimen is collected.
- ▶ Limiting the number of patient records that can be opened in an EHR system at the same time to one or two.
- ▶ Using a blue wristband to indicate when a patient has a missing identification band or has incomplete or incorrect information in the medical record that needs to be addressed as soon as possible.

ECRI Institute PSO’s Deep Dive on patient identification, which was released at the safe table forum, recommends a multi-pronged approach to prevent patient mix ups.

During the session, Marella summarized the findings and recommendations from the Deep Dive report. Reflecting on the examples of patient mix-ups shared by the work group members and reported in the Deep Dive report, Marella said, “Change in healthcare is not easy, but this is a process we need to change now.” Refer to “ECRI Institute Resources” for information on accessing the Deep Dive report.

Fall Prevention across the Continuum

One of the tenets of a culture of safety is for an organization to communicate its safety priorities to all staff so that patient safety is an organization-wide goal. That was one of the themes that emerged from the discussion among participants in the work group on fall prevention. “We’re trying to get our nurses to understand that it [fall prevention] is not just a nursing issue,” said one participant, noting the challenge of overcoming resistance to

what has been in nurses’ domain. “They won’t let others in. Environmental services [staff] want to get involved, but we’re told, ‘It’s just a nursing issue.’”

Traditionally, nurses conduct a fall risk assessment of their patients “and just assume other people don’t want to be engaged in [the fall prevention] plan. But they need to be involved,” said another participant. For example, without involving housekeeping staff members in fall prevention, they may arrange a patient’s room “to look nice, but actually increase the risk of falls.”

In contrast, another participant described how housekeeping staff were enlisted to be alert for situations that could contribute to infant falls on the labor and delivery unit, which had experienced recurring problems with infant falls. The organization trained environmental services to be aware of risks. “Look for sleepy moms. Are grandma and grandpa holding them? Check in and ask them, ‘Are you OK?’” Before involving environmental services, the unit had four infant falls in two months. In more than 400 days since engaging its housekeeping staff in fall prevention, the unit had no infant falls.

Even staff who may not typically have a role in a patient’s fall prevention plan should be aware of the organization’s overall approach to falls. One participant recounted that an organization used bed alarms as a universal precaution in fall prevention, but some staff were unaware of the measure. Physicians and laboratory personnel would sometimes silence an alarm if they accidentally did something to trigger it. “They’d become irritated that the alarm was going off and turn it off.” The hospital found that falls were occurring after the bed alarms were silenced and determined it needed to educate all staff about the purpose of the bed alarms.

One group member noted that listing patients’ fall prevention plans on a whiteboard in each patient room is a helpful way to communicate the plan to the patient’s care team. “That way, anyone who walks in the room can see the whole plan.” As illustrated in “Table 1. Linking Fall Risk Assessment

to the Care Plan,” each patient’s care plan should be tailored to the findings from the patient’s fall risk assessment.

The work group members discussed the importance of diversifying the membership of an organization’s falls team to include not just nurses but pharmacists, house-keeping and facilities staff, and others. For example, some participants reported success in adding nutritionists to their falls teams. Although bringing nutritionists onto the falls team was difficult because of the time commitment, said one work group member, “it’s really important. Patients are weak [and at risk of falling] if they’re not getting proper nutrition.”

Another participant’s hospital engaged two of its dietitians to develop a two-question tool to screen patients for nutrition-related risks. The tool has helped in reducing both falls and pressure ulcers, the hospital found.

Participants agreed that an organization’s fall prevention efforts must also involve patients and their family members, but they cautioned against healthcare staff becoming over-reliant on them. “You need to engage the family,” said one attendee, “but you do not abdicate responsibility.”

Improving Safety of New Oral Anticoagulants

One of the break-out sessions examined patient safety events occurring with new prescription alternatives to warfarin for anticoagulation and prompted participants to underscore one of the foundations of a culture of safety—encouraging staff to report safety events without fear of punishment or retribution so that organizations can examine the events to understand why they occur and make changes to prevent future events.

“We need to encourage our organizations to report events with the newer anticoagulants so we can get the word out there” about their safety profile, said one participant. During the session, participants discussed some of the patient safety events occurring with the new anticoagulants and shared examples of safety practices to prevent the events.

Since 2010, the U.S. Food and Drug Administration has approved four anticoagulant oral medications. Marketing materials have touted the drugs’ benefits, such as less need to monitor patients taking the oral anticoagulants compared with warfarin,

Table 1. Linking Fall Risk Assessment to the Care Plan

Risk Factor	Intervention
Impaired gait	Gait belts and training Assistive devices
Decreased balance and strength	Balance and strength training Walking programs
Cognitive impairment	Delirium and dementia screening Delirium prevention and management Diversion boxes Supervision (consider sitter)
Altered elimination	Toileting schedule Purposeful rounding
High-risk medications	Medication review (proactive and after a fall)
Depression	Depression screening and treatment
Orthostatic changes	Patient evaluation for orthostatic hypotension before allowing to walk to the bathroom Application of the Centers for Disease Control and Prevention’s STEADI (stopping elderly accidents, deaths & injuries) materials Rolling walker with seat

Source: Falls Prevention across the Continuum. Presented at: Moving Mountains: An ECRI Institute PSO Members’ Meeting; 2016 Sept 15; Plymouth Meeting (PA).

which requires regular monitoring of a patient’s blood clotting function. Nevertheless, patients taking the newer anticoagulants should still be monitored to check their renal and liver functions, said Stephanie Uses, PharmD, JD, ECRI Institute’s patient safety analyst/consultant, who described patient safety events reported to ECRI Institute PSO with the new anticoagulants (refer to “Table 2. Benefits and Cautions with New Oral Anticoagulants” for more information about the medications’ risks and benefits).

Using search terms associated with the newer anticoagulants, such as their trade and generic names, a query of ECRI Institute PSO’s event report database identified 1,226 events associated with the new oral anticoagulants since 2010. Of the 494 events for which a harm score was provided, almost 34% resulted in patient harm, ranging from temporary injuries to death. Uses said that bleeding events, partly due to failure to adequately monitor a patient on the new medications, were among the most common types of events that reached patients.

In one event, for example, an elderly patient suffered intracranial bleeding while taking one of the drugs at home. Despite laboratory test results that indicated impaired kidney function, the patient had been prescribed a dose that was “borderline” for her age and condition, said Uses. Another elderly patient experienced gastrointestinal bleeding after being prescribed one of the new anticoagulants at

a dose that was too high for her. “She had too much, but how do you know [without monitoring]?” asked Uses.

Sharing a “best practice” adopted at her organization, one of the participants said pharmacists monitor the laboratory values of patients on anticoagulants on a daily basis and follow protocols to change a patient’s dose, if necessary, based on the laboratory results.

“It’s concerning when there’s no clinical monitoring of the drug’s efficacy,” said another participant. Others agreed that “a cavalier” attitude has developed around monitoring a patient taking an oral anticoagulant because “it’s just a pill, and [people wrongly assume] no monitoring is needed.”

Following bleeding events in frequency were events involving patients who were inappropriately prescribed two different anticoagulants, which Uses referred to as “duplication of therapy.” Some ordering systems may have alerts that trigger when two or more blood thinning agents are ordered for a patient, but the prescribers “may get used to the alerts and ignore them.” In one near-miss event, the patient’s orthopedic surgeon ordered an oral anticoagulant for the patient and the attending physician ordered an anticoagulant injection. The patient’s nurse recognized the duplication of therapy and alerted the attending physician, who discontinued the oral anticoagulant.

“It’s scary that the error was not detected until the nurse was ready to administer one of the drugs,” said Uses. Even when the

Table 2. Benefits and Cautions with New Oral Anticoagulants

Benefits	Cautions
Routine coagulation tests are not required	Education of clinical staff necessary
No food interactions	New dosing protocols to follow
Fewer drug interactions	Limitations of coagulation monitoring
Quick onset of action	Renal and liver function monitoring needed
	Specific reversal agent commercially available for only one of the new oral anticoagulants
	Higher costs for patients compared with warfarin therapy

Source: New Oral Anticoagulants: Scrutinizing the Risks, Monitoring for Safety. Presented at: Moving Mountains: An ECRI Institute PSO Members’ Meeting; 2016 Sept 15; Plymouth Meeting (PA).

patient's medication profile appears on a medication administration record, it can be difficult to identify duplicates if the medications are not listed close to each other, said one participant. Given that the trade name for one of the new oral anticoagulants begins with the letter "X" for Xarelto®, if medications are listed alphabetically, Xarelto may not be listed near other anticoagulants, such as Coumadin® and Lovenox®. Refer to "ECRI Institute Resources" for information about ECRI Institute PSO's GPS Toolkit on oral anticoagulant management.

Other events illustrate the risk of prescribing new anticoagulants without checking for drug-drug interactions that can increase bleeding risks. For example, a patient with HIV who was being treated with a medication that can increase the effect of an oral anticoagulant experienced intracranial bleeding after being started on the anticoagulant while in the emergency department. Uses emphasized the need to educate providers about the risk of drug-drug interactions with the new anticoagulants, despite marketing claims that the new anticoagulants have fewer drug-drug interactions than other anticoagulants, such as warfarin.

Equally important, said Uses, is the need to educate providers about the different dosing protocols for the four new oral anticoagulants. The 4 medications have 16 possible different dosing regimens, based on the indication, she said. By comparison, there are fewer choices in selecting a starting dose for warfarin.

One participant indicated that her organization has developed electronic order sets for the new oral anticoagulants to reduce the risk of wrong-dose orders. Although the participants agreed that standard order sets can reduce the risk of adverse events with the new anticoagulants, one group member commented on the unexpected consequences of converting to a new EHR system, which had not optimized the order sets for the new anticoagulants. "We're taking a step backward," she said.

Uses also noted that each of the new oral anticoagulants has a different protocol for reversing the drug's effect on bleeding in

emergency situations. In one event reported to ECRI Institute PSO, the patient was not treated with the correct reversal regimen for the particular anticoagulant.

Because patients may be taking any one of the four anticoagulants, which are not interchangeable, healthcare facilities must stock all four drugs in their formulary, ensure that reversal agents for each of the drugs are available, and educate staff about the reversal regimens. "Make sure everyone knows how to reverse [the effects of each anticoagulant] and where to find the agents and that enough of each agent is available," Uses cautioned. The reversal plan should also be routinely reviewed and revised as needed, she said, emphasizing, "Everything is so new."

Organizational Learning in a Safety-Oriented Culture

Two other break-out sessions highlighted a basic principle of a safety-oriented culture: organizational learning. Organizations with a culture of safety use analytical methods, such as an RCA, after patient safety events and near misses to identify the latent issues in systems that create conditions for people to make mistakes. Two organizations discussed their work with ECRI Institute PSO to improve their approach to event analysis. Their message underscored the need to extend organizational learning to RCAs by continually examining the organization's approach to event analysis and identifying ways to improve it.

Root-cause analysis. In one case, a health system submitted its completed RCAs to its PSO for analysis. The PSO partnered with ECRI Institute PSO to review the RCAs and accompanying documents and to provide feedback using an RCA review methodology developed by ECRI Institute PSO.

The analysis found that among the organization's best practices in its approach to RCAs were the following:

- ▶ Distributing to the facilities within the system a preliminary summary of a serious safety event immediately after it occurred to make others aware of potential risks and hazards that may

Education Teaser*

An initial action to improve your organization's safety culture is to:

- Assess the current culture of the organization.
- Create policies to require adherence to existing safety standards.
- Evaluate existing policies to identify characteristics of a culture of safety.
- None of the above.

The most important information that can be gained from assessing a safety culture are the perceptions, attitudes, and opinions of:

- Leaders
- Managers
- Staff
- All of the above.
- b and c only.

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exist. The summary, presented in an SBAR (situation-background-assessment-recommendation) format, is prepared by a quality coordinator at the facility where the event occurred.

- ▶ Using event and causal factor analysis to dissect the event and map the steps leading up to the incident.
- ▶ Visually depicting the breaks in safety practices with the so-called Swiss cheese model, developed by James Reason, for illustrating systemic failures.
- ▶ Developing action plans that go beyond educating staff and address the issues involved.
- ▶ Sharing the findings from the RCA with the system's leaders and its facilities to extend the lessons learned beyond the facility where the event occurred.

The RCA review by the two PSOs also identified ways for the organization to improve its RCA process, including the following:

- ▶ Extending its SBAR event notification to all safety events, not just those involving serious harm.
- ▶ Digging deeper during event investigation interviews to understand the event's contributing factors. As one participant explained, "Keep asking, 'Why?'"
- ▶ Being aware that there can be more than one root cause for an adverse event or near miss.
- ▶ Designing action plans for widespread application so they help fix similar problems beyond the unit where the event occurred.

One other change to the organization's RCA process came from a recent report from the National Patient Safety Foundation on improving RCAs, titled [RCA²: Improving Root Cause Analyses and Actions to Prevent Harm](#). The report, which ECRI Institute has endorsed, discouraged including staff members directly involved in an event on the RCA team because their presence on the team can make it difficult for team members to ask tough questions and have frank

discussions. Those individuals should be interviewed, however, as part of the event investigation.

As it was incorporating the recommended changes to its RCA process, the organization also decided to adopt the report's suggestion of not including staff members directly involved in the event on the RCA team. Involving those individuals can "get too personal," said one participant.

As an alternative, the organization chooses someone with similar job responsibilities and knowledge as the individual directly involved in the event to be an RCA team member. The individual may even be someone from a different facility within the health system. Although there was some reluctance at first to excluding those affected by the event from the RCA team, the organization has embraced the revised approach. "The emotion is taken out," said a participant from the organization. Also, when the team includes individuals from other facilities in the health system, "they are even able to identify things in their own facilities to work on" for greater organizational learning from the event.

Even though involved staff do not participate in the RCA, they are kept apprised of its progress and resulting plans. In fact, the system developed templates for system-wide sharing of lessons learned, including an executive summary that includes a description of the event, immediate and remedial actions, root causes, contributing factors, and actions to prevent recurrence. The system's leaders, including quality, patient safety, and clinical leaders in each of the system's hospitals, are then responsible for sharing this information with appropriate staff and discussing the lessons learned.

Participants from the organization described its Level I and Level II action plans that are developed to address root causes; actions should "look past reeducating because reeducating isn't going to fix issues," they said. Level I actions are the "high-level" processes, such as ensuring appropriate scheduling to avoid wrong-site surgeries, while Level II actions flow from the Level I plan to describe the details of how it will be

accomplished. For both types of actions, the health system stressed the importance of assigning responsibility for following up at regular intervals to ensure that incomplete tasks are acted on.

Human Factors Analysis and Classification System. In another collaborative effort, ECRI Institute PSO and a partner PSO evaluated five RCAs for surgical events occurring at facilities affiliated with the partner PSO. The project used the human factors analysis and classification system (HFACS) “as another lens to look at the RCAs and give feedback,” said a representative from the partner PSO.

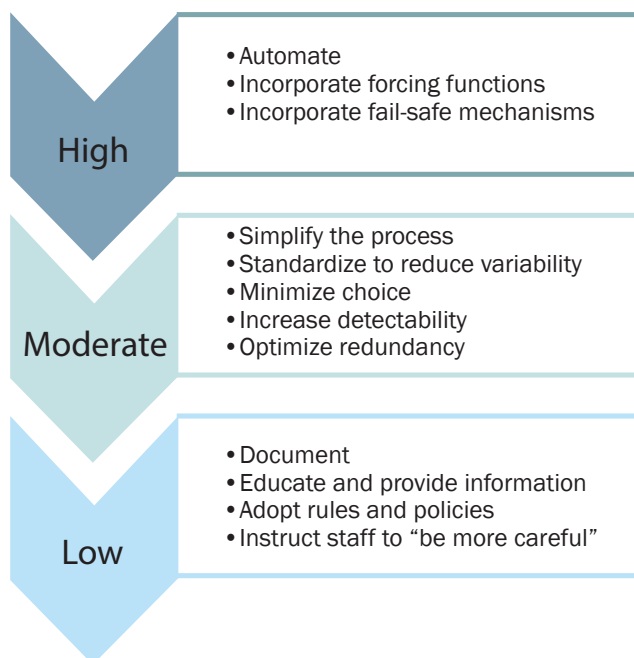
HFACS was discussed at ECRI Institute PSO’s first safe table forum in 2015 (for more information, refer to the [February 2016 PSO Navigator](#)). The process systematically examines the underlying causes of events by looking at four tiers of error causation and applying nanocodes that describe the specific behaviors and system situations that lead to the errors. Depending on the classification system, there are more than 150 nanocodes

to apply, such as a procedure performed out of order and noise interference.

Using only the facts available from the RCA investigation, the analysts from the two PSOs applied nanocodes to identify causes for each of the five surgical events. HFACS “forces you to think about the systems issues,” said the representative from the partner PSO.

Tallying all the nanocodes for the five events, the evaluation found that communication and judgment errors were most commonly associated with the events. Even so, the action plans from the RCAs focused on measures, such as education and training and policies, that were less likely to correct these deficiencies. “These are weak strategies,” the PSO’s representative said. The HFACS approach showed the need to dig deeper with the corrective actions, identifying measures to improve systems issues, such as work flow and communication, she said. Refer to “Figure 1. Hierarchy of Error-Reduction Strategies” to see the three tiers of corrective actions.

Figure 1. Hierarchy of Error-Reduction Strategies



Source: Human Factors Analysis and Classification System (HFACS) Approach to Root Cause Analysis (RCA): Evaluation of Five Surgical Events. Presented at: Moving Mountains: An ECRI Institute PSO Members’ Meeting; 2016 Sept 15; Plymouth Meeting (PA).

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Another participant said that her organization has used HFACS to supplement the RCA investigations from more than 50 sentinel events. “The difference is phenomenal,” she agreed. “With RCAs, it’s easy to focus [action plans] on policy and education. HFACS forces you to look beyond that and think about systems solutions.”

Several participants asked for input from the others on learning to use the HFACS approach. To reach consensus in applying the nanocodes, “it’s much easier to work as

a team,” said the representative from the partner PSO. “You won’t get there as easily on your own.” Another participant noted that some organizations have done extensive education and training while others have found that getting started with HFACS is a relatively straightforward process.

As a follow-up to the HFACS project, the partner PSO plans to conduct a safe table for its facilities to identify effective, system-based best practices to address a wrong-site event covered by the evaluation.

Lessons Learned

LEARNING FROM SUCCESS

Although much of the safe table forum focused on what can go wrong in healthcare delivery and what can be done to improve, speaker Ellen S. Deutsch, MD, MS, FACS, FAAP, CPPS, medical director at ECRI Institute, concluded the day’s meeting by reminding participants that a culture of safety also includes learning from what goes right.

“There’s a constant drumbeat of things that go wrong even though we put energy into making healthcare better and safer,” said Deutsch. Instead of always directing efforts at what she called “whack-a-hazard,” healthcare organizations “can also debrief about what is successful.” Deutsch emphasized that the overwhelming majority of healthcare interactions are successfully completed and much can be learned from those accomplishments. In the evolving science of safety, this approach is referred to as “Safety-II.”

Safety-II looks at the many situations in healthcare with good outcomes and tries to understand how that happens. “Was it just luck or did the team do the right things?” asked Deutsch. “There’s value in understanding that.”

Safety-II also examines resilience, which is the ability of the healthcare system to adjust to varying conditions and still achieve a good outcome. Remarking on the resilience and adaptability of humans operating within

the healthcare system, Deutsch said, “I don’t think humans are the problem. They are the solutions. People are an essential and awesome resource. We need to appreciate and nurture them.”

By contrast, Safety-I is defined by failures and examines why they occur, Deutsch explained (refer to “Figure 2. Safety-I and Safety-II Attributes” for a comparison of the two approaches).

An organization with a culture of safety combines both approaches. For example, when a care unit is confronted with an increase in patient falls, it examines the practices on the unit and other data to understand why the falls are occurring. But it should also examine the practices on another unit that has a low patient fall rate to understand what that unit is doing right to prevent patient falls. Deutsch also recommended scheduling regular meetings, similar to morbidity and mortality conferences, to “talk about what went well and to look through healthcare delivery through a Safety-II lens” or what she called a “success mode and effects analysis” as opposed to a failure mode and effects analysis.

Deutsch, who oversees a simulation program at Children’s Hospital of Philadelphia in addition to her work at ECRI Institute, recommended using simulation as a non-threatening way to examine processes and to understand what works best and what

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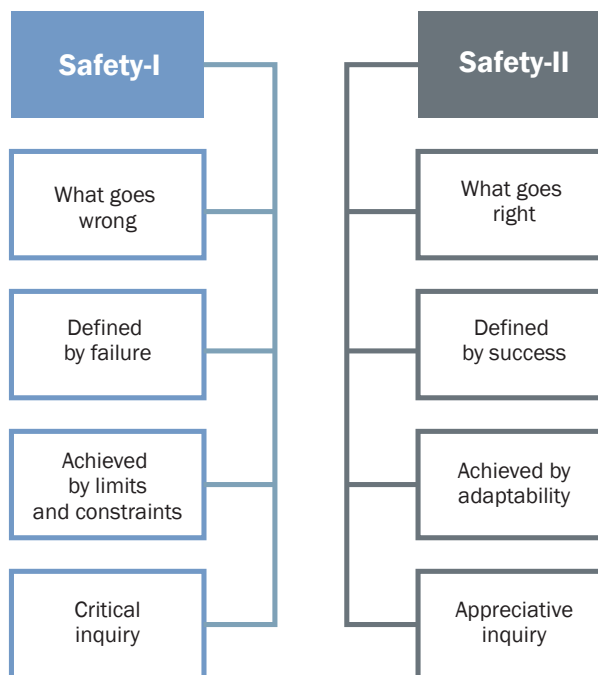
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MISSION STATEMENT

ECRI Institute PSO's mission is to achieve the highest levels of safety, quality, and cost-effectiveness of healthcare by collecting and analyzing patient safety information and sharing lessons learned and best practices.



Figure 2. Safety-I and Safety-II Attributes



Source: Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: a white paper [online]. 2015 [cited 2016 Oct 14]. <http://resilienthealthcare.net/>

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can be improved. For example, simulation can be applied to the following situations:

- ▶ To practice a response to a regularly encountered emergency, such as cardiac resuscitation
- ▶ To learn to work as a team
- ▶ To trial a complicated procedure to determine the best approach
- ▶ To learn to respond to an infrequently encountered situation, such as management of a patient infected with the Ebola virus

- ▶ To recreate an event to understand what happened

Returning to the day's theme of moving mountains to develop a culture of safety, Deutsch's final remarks add a crucial component to that task. While a safety culture recognizes that "to err is human," the same culture also knows that "to better is human," concluded Deutsch.