Bureau of Community Health Systems, Health Facilities Program
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2015 Risk Management Annual Report

"James Reason reminds us, 'Errors are largely unintentional.' It is difficult for management to control what people did not intend to do in the first place." *Robert Wachter*

"There has been a lot of focus on improvement processes and technology in healthcare, but culture is the number one system contributor to safety" (Steve Krieser, Former US Navy Fighter Pilot). Most healthcare leaders desire a culture of safety and reliability but few understand how to realize that goal. Furthermore, the highly complex nature of healthcare delivery, coupled with the many competing leadership priorities, challenges the most well-meaning leader. As an industry, healthcare has had repeated calls to address risks related to adverse events-- and despite gains, medical error continues to be a leading cause of death in the US.

"A safety culture is reliant upon the willingness of its employees to disclose and report errors and near misses and transmit their concerns upward in the organization." (Caroll & Edmondson, 2002). It is through reports of errors and adverse events that an organization learns and engages in process improvements or system redesigns intended to prevent future occurrences. In fact, medical error prevention is unusual-- in that, one of the main sources of understanding comes from its dependence on using the very errors it strives to eliminate as its target of study!

High reliability organizations prize identification of errors and close calls for the lessons that can be extracted from careful analysis of what occurred before these events (DuPree, 2016). Therefore, it is vital that increased reporting of adverse events is an organizational, as well as a state-wide, goal. As reports increase and effective response to understand the cause of those events intensifies, an organization will see the number of serious safety events decline over time.

When leadership commits to zero patient harm and the culture is relentlessly focused on improvement, an organization is positioned to move toward higher reliability and "creation of a high reliability culture is probably the most challenging work that healthcare organization has to do." (Ana Pujols McKee, CMO The Joint Commission).

What are some of the characteristics of an organization committed to high reliability?
Organizations committed to a journey of high reliability are found to be preoccupied with failure. Individuals within such organizations are alert to the smallest signal that a threat to patient safety is present or developing. They operate with a wariness that unexpected results can and do happen. Those within these organizations are proactive and engage in analysis and discussions about how to prevent mishaps, unexpected events or medical errors. Finally, you will find a "collective mindfulness" a milieu where employees are quick to report problems, unsafe conditions and adverse occurrences.

Some years ago I worked at an organization that was on a journey to improve safety and reliability. One leadership strategy that was implemented was to publically acknowledge a patient safety champion. Telling stories about patient safety is an effective tool that serves to unite employees in their commitment to zero harm. Stories also increase transparency and increase trust by cementing the notion that there is little room for blame in the journey toward higher reliability. I will always remember the second champion featured. She was a newly graduated nurse who was working with a preceptor in the neonatal ICU. This nurse was preparing to administer morphine to a neonate. She checked the order, engaged in proceeding through the "5 Rights" of medication administration she had learned in school and everything checked out. The dosage documented on the vial of morphine was the ordered dose—but she felt uneasy. The liquid in the vial was a different shade in color that it had been the day before when she administered it. She approached her preceptor, showed her that the dose on the vial was the same as the ordered dose but she told her preceptor about her uneasiness as she looked at the coloring of the morphine in the vial. The preceptor told her to listen to her gut and call the pharmacy and report why she felt uneasy. The Pharmacy Manager told her not to give the medication while he checked in to her concern. He immediately came to the unit and confiscated 20 vials of the morphine that had been loaded into the automated medication dispensing machine. The morphine was supposed to be 0.2mg and was 20mg! This new nurse's preoccupation with failure and sense of "wariness" likely saved lives!

Another characteristic often seen in higher reliability organizations is a sensitivity to operations where leaders are not only passionate and committed to patient safety—but they get out and look for safety issues. These leaders pay close attention to those on the front lines—those known to be providing services at the "sharp end" of care. This involvement and engagement with those closest to the patient provides an opportunity to give real-time guidance to the workforce and gain first-hand knowledge about the needs, talents, and skill of their workforce. It fosters trust and a sense of psychological safety in the workforce as they see leadership's commitment to safety. This in turn promotes a "stronger sense of responsibility for patient safety, coupled with a stable and predictable partnership with upper management." (Frankel, et al., 2008). Other advantages of

such rounds include the identification of equipment and technology issues and infrastructure, security or environmental challenges. The Joint Commission Journal on Quality and Patient Safety suggests the use of leadership rounding with questions and conversations such as those illustrated below:

Leadership Rounding Questions and Conversations

- Were you able to care for your patients this week as safety as possible? If not, why not?
- Can you describe how communication between caregivers either enhances or inhibits safe care on the unit?
- Can you describe the unit's ability to work as a team?
- Have there been any "near misses" that almost caused patient harm but didn't?
- Is there anything we could do to prevent the next adverse event?
- What do you think this unit could do on a regular basis to improve safety?
- When you make an error, do you always report it?
- If you prevent/intercept an error, do you always report it?
- If you make or report an error, are you concerned about personal consequences?
- Do you know what happens to the information that you report?
- Have you developed any personal practices that you do to specifically prevent making errors (memory aids, double-checking, forcing functions, etc.?
- Have you discussed patient safety issues with your patients or their families?
- Do patients and families voice any safety concerns?
- What specific information from leadership would make the work you do safer for patients?
- What would make these leadership rounds more effective?

(Joint Commission Journal on Quality and Safety, 2003)

A third characteristic of reliability is a general reluctance to simplify. Health care is complex and humans instinctively deal with complex situations by attempting to simplify how the current situation is interpreted. For example, a lab technician is checking the armband of a patient in an attempt to verify the identity of a patient before drawing blood. Her list says she is drawing blood for Maria Garcia. The name on the identification bracelet is Maria L. Garcia-de Jesus. The lab technician thinks, "I don't know why someone needs all those last names on the ID bracelet. This is definitely the right patient." In this situation the lab technician attempted to simplify by assuming that this was the right patient. Should there be an error she could truthfully say she checked the identification bracelet—and it did say Maria Garcia… Harris County Hospital District

(HCHD) released the following statistics in a recent article entitled, "Improving Patient Care with Positive Patient Identification"

> Number of patients in the HCHD database = 3,428,925
> Number of times when two or more patients share the same last & first name = 249,213
> Number of times when five or more patients share the same last & first name = 76, 345
> Number of times when two or more patients share the same last & first names & date of birth = 69,807
> Number of patients with the name of Maria Garcia = 2,488
> Number of patients named Maria Garcia sharing the same date of birth = 231
>
> Improving Patient Care with Positive Patient Identification, 2016

These organizations as a whole does not support taking shortcuts or skipping safety steps. They support consistency, the use of safety strategies such as using identifiers and checklists and empower employees to ask questions, verbalizing safety concerns and even stopping the line should there be an unresolved safety concern. In these organizations you will find redundancy in operations with efforts to confirm the status or actions to be taken, the implementation of cross checks, and double checks. This mindful approach confirms the understanding that humans are fallible and appreciates the healthy reluctance to rely on competence or professional status alone as a safety measure.

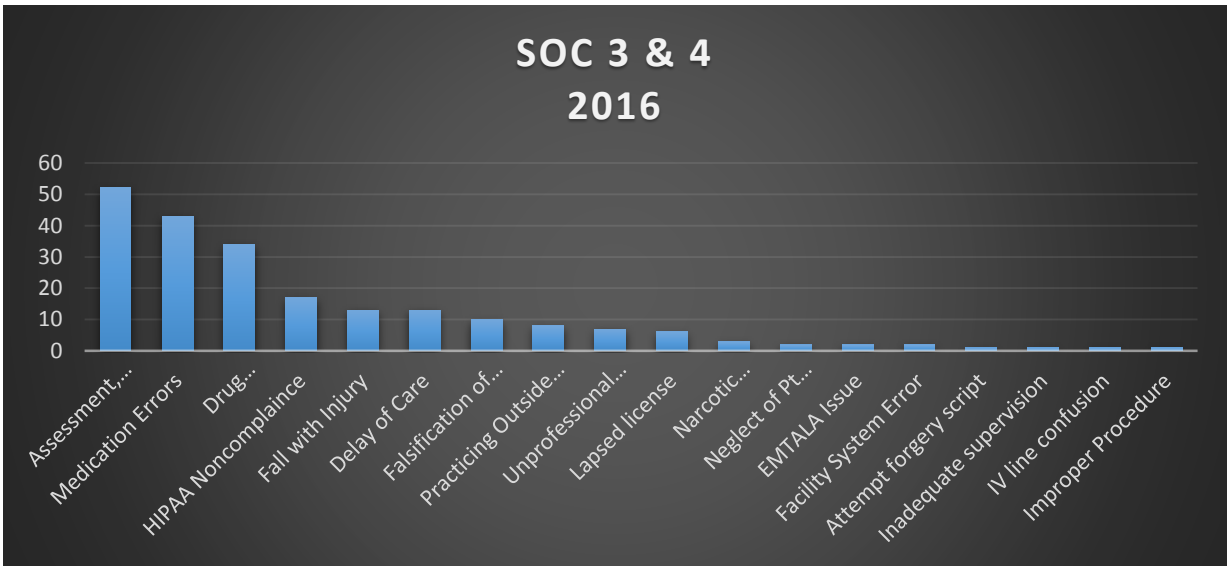
A higher reliability organizations demonstrates a commitment to resilience. They cope well and bounce back after the unexpected. These organization value learning and grow from every opportunity the system presents. The safest organizations do not wait for an error to occur to before responding to it. They are prepared for the unexpected. These organizations prepare for the unexpected by using "near misses" or "close calls" to improve systems and processes that may bring harm on another day. They understand vulnerabilities in their culture that cause hesitancy with speaking up.

Finally, these organizations demonstrate that expertise is valued. Decision making—especially at critical times migrates to the person or group with the most expertise with the challenge at hand, regardless of rank. These organizations not only know the unique skills of their people, they take advantage of those skills. One challenge in many complex organizations striving for higher reliability is the impact of authority gradient. The term "authority gradient" was first heard in aviation circles, because they noted that communication was less effective between pilot and copilot if there was a significant difference in the experience, perceived expertise or authority. (Cosby & Croskerry, 2004). In fact, communication issues related to the authority gradient was one of the root causes of the deadliest aviation accident in history, the Tenerife airport disaster.

Health care has challenges with authority gradient as well and efforts to build teams that can communicate effectively and rely on available expertise in times of crisis is imperative to a safe culture.

Learning From Occurrences in 2015

In 2015, SOC 3's and 4's reported to the Kansas Department of Health & Environment (KDHE) are reported by type in this graph.



As reported to KDHE via Quarterly Reports and Reportable Event Forms

Assessment, Treatment and Diagnosis

This category captures reports of misdiagnosis, inaccurate or incomplete assessment processes, competency issues such as misreading a monitor strip or placing a telemetry monitor on the wrong patient. Events of this type are often a result of human factors, such as our natural limits in cognition. Short term memory errors occur when we forget a step in a process such as forgetting to turn a bed alarm back on. The human memory can only hold 3-5 items at a time and memory is vulnerable to interruptions and time pressures—situations that occur many times during routine patient care.

It is estimated that 3 errors per 100 occur during simple arithmetic, 3 errors per 1000 occur while reading labels, 1 error in 100 is related to forgetting a step in a task, and 25 errors per 100 occur

during high stress. Updating policies and procedures or retraining do not prevent errors due to interruptions, time pressures, or memory lapses.

Mistakes are another cause of human error. Mistakes result from a wrong or incorrect choice and are generally caused by insufficient knowledge, lack of experience or training, inadequate information or the inability to correctly interpret available information, or applying the wrong set of rules or algorithms to a decision. Finally, an individual may choose to take an unacceptable risk, skip safety steps, or violate acceptable practice. Good examples of this is the continued problems in healthcare of poor hand hygiene and patient misidentifications.

Some issues identified in this category include the failure to properly diagnose or stabilize a medical condition. The mother of a 19-year old college student who was diagnosed with a pinched nerve and then died of a rampant infection stated, "They didn't think outside the box. If they hear hoofbeats, they think horses. They don't think about zebras."

Medication Errors

Although the majority of medication errors are known to be at the prescribing and transcribing points of care—transcribing errors are rapidly decreasing as computerized physician ordering systems are becoming more common. Medication errors are most often reported by nurses and they are in an excellent position for "risk reduction because they often serve as the final point in the checks-and-balances triad" (American Society of Hospital Pharmacists, 1993). Since the reporting of medication errors relies on voluntary reporting, it is estimated that 5% or less of these errors are actually reported (Jones & Treiber, 2010). Medication errors lead to increased mortality, increased length of hospital stays and increased medical expenses. The financial burden associated with medications errors is estimated to be about $77 million annually.

Organizational systems for ordering, dispensing and administering medications should be designed to minimize error. Looking for process issues that may lead to medication errors is important. A few years ago a patient had a bad outcome due to a wrong dose error with a cardiac medication. The nurse continued the loading dose after it should have been discontinued and a maintenance dose started. The variance report attributed the error to the nurse's failure to utilize the "5 Rights" and provided education and counseling to the nurse. Upon further investigation, it was found that the Pharmacy had entered the directions to stop the loading dose and change to a maintenance dose in a comments field in the electronic medication record system. The pharmacist did not know that this field could not be viewed by anyone except those signed in as a pharmacist or physician. Nursing staff could not see this field from their view. Clearly, counseling and education could not fix this error type!

Some of the common causes of medication errors in health facilities include:

- "Ambiguous strength designation on labels or in packaging
- Drug product nomenclature (look-alike or sound-alike names, use of lettered or numbered prefixes and suffixes in drug names;
- Equipment failure or malfunction;
- Illegible handwriting;
- Improper transcription;
- Inaccurate drug calculation;
- Inadequately trained personnel;
- Inappropriate abbreviations used in prescribing;
- Labeling errors;
- Excessive workload;
- Lapses in individual performance;
- Medication unavailability."
- Failure in patient identification;
- Disruptions during critical points in the process; and,
- Insufficient mathematical skills.

(American Society of Hospital Pharmacists, 1993)

Drug Diversion/Substance Use on the Job

Nationwide impaired professionals is an issue—but it is surprising to see that it is the 3rd most common report to KDHE in 2016 behind Assessment, Treatment and Diagnostic Errors and Medication Errors. Some of the clues for concern include:

Narcotic discrepancies, such as incorrect counts, alteration of narcotic containers, increased patient reports of ineffective pain control, discrepancies on records or frequent corrections of records, unusual amount of narcotics wasted, significant variations in the quantity of narcotics ordered for the unit or shift a person may be working, behavioral clues such as increasing isolation from colleagues, friends and family and avoiding social activities, complaints from others about work performance or alcohol or drug use, mood swings, irritability or depression, or suicide threats or attempts, perhaps caused by accidental overdoses or physical symptoms such as obvious intoxication, such as swaying, staggering or slurred speech, odor of alcohol on the breath or

excessive use of breath-fresheners or perfume to disguise the odor of alcohol. Arriving to work late, long lunches or unnecessary breaks, absenteeism and inaccessibility to patients and other staff are also frequently seen.

Healthcare providers can be very good at hiding substance abuse and deterioration in their clinical practice is often one of the last signs. By the time there is a performance issue identified, the problem is often well advanced. Timely identification of issues is a moral responsibility. Facilities should review their policies on the documentation of narcotic administration and wastage and HR policies concerning this topic against best practices to be sure that the policies adequately guide efforts to protect patients, the facility, and the professional as well.

HIPAA Noncompliance

HIPAA compliance issues occupied the fourth most common report made to KDHE in 2016. HIPAA privacy and security rules became effective in April, 2003 and April 2005. The most common HIPAA violations include:

- Disclosing patient information to an impermissible party—This can happen from inattention to where you are discussing patient information, such as elevators, cafeterias or hallways or having conversations at the nursing station that are loud and easily overheard. Many times waiting areas which are close to intake and registration areas lead to a situation where personal information can be easily overheard. Finally, the failure to identify who you are speaking to about a patient can lead to a violation should that person not have permission to have the patient information. Another example is unintentionally faxing patient information to the wrong party because of using an incorrect fax number.
- Incorrectly filing or disposing of patient information. This can result in releasing someone to an unintended party such as a misfiled mammogram result can be released to the wrong party. Not utilizing shredders or secured disposal bins can lead to PHI being available to unintended parties with access to the trash.
- Losing devices or having information on someone's own personal device.
- Getting hacked or not using adequate security measures such as encryption or firewalls
- Employees' dishonesty accessing files. This is the number one reason for HIPAA issues reported to KDHE. Most often employees are looking at files of friends, ex-wives and etc.
- Releasing patient information after the authorization period is expired.

Workforce training is required for all "covered entities" and covered entities must have and apply appropriate sanctions against workforce members who violate the privacy policies and procedures. In case of disclosures, individuals have a right to an accounting of any disclosure of their protected health information. Noncompliance can trigger civil monetary penalties of up to $100 for each

HIPAA violation (up to $25,000 per person). Criminal violations such as large scale violations, cases involving identity theft or the selling of patient information are investigated and prosecuted by the US Department of Justice. Individuals convicted of criminal violations can be fined up to $250,000 and receive up to ten years in prison. You can obtain more information about HIPAA at http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

Fall with Injury

Falls reported to KDHE are only those falls where injury to the patient occurred and the standard of care was not met. Most often these falls occur when the internal policy for fall prevention was not followed, the caregiver failed to turn a bed alarm on or the caregiver was found to have neglected their patient assignment in some manner. Patients of any age and physical ability can fall in health facilities. Every year in the US hundreds of thousands of patient fall in hospitals and it is estimated that 30-50% of these falls result in injury. The Joint Commission identified the following factors as contributors to falls that result in injury:

- Inadequate assessment;
- Communication failures;
- Lack of adherence to protocols and safety practices;
- Inadequate staff orientation or supervision, staffing levels or skill mix;
- Deficiencies in the physical environment; and,
- Lack of leadership.

In their September, 2015 Sentinel Event Alert, The Joint Commission identified the following best practices that should be used to prevent falls resulting in injury:

1. Raise awareness to the need for fall prevention efforts;
2. Establish an interdisciplinary falls injury prevention team or evaluate the team already in place;
3. Use a standardized, validated tool to identify risk factors for falls;
4. Develop an individualized plan of care based on identified risks;
5. Implement interventions;
6. Implement a standardized hand-off communication process;
7. Provide one-to-one education of each patient at the bedside;
8. Conduct post-fall huddles to discuss what happened, how it happened and why;
9. Report, aggregate, and analyze contributing factors on an ongoing basis as a QI effort; and,
10. Provide for continued patient reassessment.

Delay of Care

Delays in care and treatment is a significant problem in healthcare and in 2002 The Joint Commission issued a Sentinel Event Alert on the topic because reports to The Joint Commission verified that this was a significant patient safety concern. Despite this alert, delays continue to be a significant concern and from 2004-2015 a total of 1,052 delays have been reported to TJC that were severe enough to have caused death or permanent loss of function. Causes of delays break down as follows:

Root Causes of Delays in Treatment Reported to TJC (causing death or permanent loss of function)	
Communication Issues	25
Assessment Related	22
Human Factors	19
Leadership	16
Information Management	5
Continuum of Care	5
Care Planning	3
Physical Environment	3
Medication Use	1.3
Health Information Technology related	0.7

Of those who reported delays of treatment to TJC in 2002, the Sentinel Event Alert said that the strategies to improve timeliness of care and treatment focused on redesign of the following:

- Orientation and training processes (80%);
- Transfer procedures (27%);
- Staffing plans (25%);
- On-call specialist contract procedures (22%);
- Triage procedures (16%); and,
- Physical space (11%).

Other strategies that have proven effective in eliminating critical delays include the implementation of improved communication procedures, the revision or redesign of specialist on-call procedures, more complete and effective patient assessment procedures, and better communication of lab or radiology results. Communication processes are especially critical to eliminating critical delays. Organizations should implement processes to improve the timeliness, completeness, and accuracy of staff-to-staff communication. Implementing face-to-face change of shift debriefings and improving communication during handoffs prior to the patient leaving the patient care unit for testing is vital, as well. Finally, organizations must take steps to eliminate

verbal orders except in emergency situations. When verbal or telephone orders are used, a "read back" verification process will help eliminate communication errors.

The next several issues are related to human factors or human behavior. Falsification of documentation, practicing outside one's defined scope and unprofessional behavior entail a person making a bad or unwise decision while on duty. Human factors experts categorize human error in 4 different ways:

1. Knowledge-based errors are those errors due to a lack of knowledge or experience when confronted with a specific process or experience. This may occur when a health care employee is working in an unfamiliar area or a pediatric patient is being housed on an adult unit due to overflow.

2. Rule-based errors are errors involving the misinterpretation or misuse of data or applying the wrong rule to the situation. This is a misapplication of a good rule or proper application of a bad or contraindicated rule. This may occur if a mathematical formula for dosage is used for pounds when it was meant to be used for kilograms.

3. Skill based errors are due to inattention and memory lapses. James Reason calls these slips, lapses and fumbles. They are essentially actions that deviate from the intention. It is a higher level failure of mental processes that were involved in planning, formulating intentions, judging, and problem-solving. They are often automatic actions taken with routine tasks and generally in familiar surroundings. This is the person who drives away from the gas station with the gas cap off or the nurse who hangs a piggyback on the right patient, at the right time but does not turn the piggyback to drip.

4. Unlike errors, violations are deviations from safe operating practices, procedures, standards or rules. It may involve noncompliance, cutting corners or skipping steps in a process. Violations are intentional and are caused not by applying the wrong rule, a mental lapse or lack of knowledge—but for some type of personal reason or in response to an organizational cultural issue. Violations do not respond to more education, better procedure and protocols or increased attention. James Reason discusses violations in his article, "Understanding adverse events: human factors" and helps us understand that there are three basic types of violations:
    - "Routine violations, which entail cutting corners, such as skipping hand hygiene;
    - Optimizing violations, which entail actions taken for "kicks" or to alleviate boredom; and,

- Necessary or situational violations that seem to offer the only path to getting the job done, and where the rules or procedures are seen as inappropriate for the present situation." (Reason, 1995). An example frequently seen of a situational violations is skipping patient identification or surgical time-out processes due to production pressures.

One challenge in addressing violations in organizations is acknowledging the balance between a "no blame", just culture and accountability.

> "Our failure to create real accountability for patient safety partly represents a fundamental misunderstanding regarding both how other, safer industries carry out their safety activity and the nature of errors. The pilot who neglects to use a checklist before takeoff would not be allowed to fly. In most meatpacking plants, workers are monitored by remote video and are held accountable for performance. In these industries, once a reasonable safety rule is implemented and vetted (since some rules create unanticipated consequences or work-arounds and need to be reworked after initial implementation), failure to adhere leaves the world of "no blame" and enters the domain of accountability" (Wachter & Pronovost, 2009).

The use of James Reasons' "Performance Management Decision Guide" (available as Appendix A) is helpful as one attempts to sort out how to proceed when human factors are part of the patient safety equation.

Lapse of Licenses

While licensed professionals are ultimately responsible for timely renewal of their licenses, a licensed professional working with a lapsed license is a significant event which places the health facility at risk. Facilities should have process in place to identify the licensure status for individuals providing care in their organization. When a licensed professional is practicing with a lapsed license there should be a SOC discussed for that individual and the facility itself—as this is almost always also a facility system issue. If individuals are held accountable for having a current license and facilities have adequate process in place concerning licensure status—this event should be reduced to zero.

Summary

Often the "hierarchical and fragmented healthcare systems in the US rely on outmoded systems and poor work design set the workforce up to fail—regardless of how hard they try (Kuhn & Youngberg, 2002). It is not a matter of trying harder, working harder—but of working smarter by understanding the vulnerabilities within your system that could lead to harm. This understanding starts with a culture of safety, embracing the characteristic of a higher reliability organization, assuring accountability and fixing those systems that lead to error. "The challenges have never been greater, the work force never smaller, the technology more complicated, the patients' demands never higher but, despite all of these tensions, healthcare professionals and those who assist them in managing the risks associated with their responsibilities must continue to remember that, every day, patients and their families entrust their lives to us" Kuhn & Youngberg, 2002).

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