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A Mountain of Mistakes: Moving from Unspoken Tragedy to Effective Collaboration -FL APPROVED-

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It is said that success sits atop a mountain of mistakes. Healthcare teams boast unprecedented resources and tools for reduction in medication error. Despite staggering technological advances, errors continue. In fact, new opportunities for error have emerged with some of the very tools intended to eliminate systematic errors. Using established psychological principles, human engineering factors are examined and extrapolated to the unique challenges of the contemporary pharmacy setting. Recurring problematic areas in pharmacy practice will be extensively examined within the framework of an effective Continuous Quality Improvement (CQI) Plan and appropriate use of the Root Cause Analysis (RCA) method in identifying, reporting, and evaluating sentinel events. The vitality of intra- and inter-professional communications is emphasized throughout the didactic structure of this presentation.
This course meets the requirement for the Florida Board of Pharmacy Medication Errors credit for pharmacists and pharmacy technicians.

Learning Objectives

After completing this activity, the pharmacist will be able to:

- Identify tools and models for error reduction and patient safety advocacy
- Recognize the most significant contraindications and medication interactions for a variety of patient populations
- Recognize the vitality of workplace culture in the implementation of an effective Continuous Quality Improvement (CQI) plan
- Describe the elements and common players in conducting an effective Root Cause Analysis (RCA)

Identify error prone abbreviations from ISMP's "Do Not Use" list

Accreditation

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Target Audience

The target audience for this activity is pharmacists and pharmacy technicians in hospital, community, and retail pharmacy settings.

Universal Activity Number

Pharmacist	Pharmacy Technician	Nurse
0798-0000-18-113-H05-P	0798-0000-18-113-H05-T	0798-0000-18-113-H05-P

Credit Hours

2.0 Hours

Activity Type

Knowledge-Based

CE Broker Tracking Number

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Introduction

Patient safety is a topic that has generated much attention, both internally within our profession and externally. Many state boards of pharmacy across the nation now require continuing education credits specific to the topic of medication safety. The largest professional advocacy organizations, including the American Society of Health System Pharmacists and the American Pharmacists Association have core language dedicated to the topic of medication safety. Accrediting bodies for pharmacy schools and pharmacy technician programs alike are careful to craft learning objectives that promote safe patient outcomes.[11]

On the surface, such intense focus may seem to be an overtly unwarranted response, given that the overall rate of correctly dispensed prescriptions in America's retail pharmacies is reported to be around 98%. From the perspective of a traditional scale, we make relatively few errors. Placing even a 98% success rate into the environment of a retail pharmacy, however, can be startling. In a pharmacy that fills 250 prescriptions each day, for example, this error rate would equate to approximately 4 errors in any one operating day of the pharmacy. Considered more broadly, over 51.5 million errors occur while processing the nation's 3 billion prescriptions each year.[13]

The true ramification of medical errors remains poorly understood due, in part, to the under-reporting of medical errors. Reporting requirements for medical errors vary drastically from state to state, with no national standard or requirement for the reporting of medical errors. Even the causes of death in the United States are reported via ICD codes (International Classification of Diseases), which do not reflect medical error. Since there is no ICD code for 'medical error,' the patient's death will be reported as heart failure, respiratory suppression, or the like. The complication that this system introduces, unfortunately, steers federal funding dollars away from medical errors and toward other better reported and documented events.[5]

In any discussion of error, the 'human factor' cannot be ignored. Often, well intentioned managers will announce a program designed to 'eliminate errors. Psychologists and human factors engineers, however, have documented repeatedly the futility of eliminating human error entirely. While an admirable goal, it simply is not a realistic one. As humans, we make mistakes and we make them often.[10] Rather than making the erroneous assumption that we can somehow exempt ourselves from this basic human characteristic, this discussion will seek to accept and acknowledge human error as a primary element within which we must practice. This is not to say, however, that we are not going to work diligently to create a system that sets ourselves up for success rather than failure. Perhaps we have metaphorically been 'popped in the face' by stepping on a yard rake that has been left out. It is important that not only we learn from that mistake but that others learn from that mistake as well. Collectively, we learn to store the rake properly in the shed to minimize the chance of being 'popped in the face' again. We share that experience with others so that they, too, may learn from our mistakes.

Sadly, from a historical perspective, we have performed poorly in the communication of our mistakes with one another. As a result, multiple colleagues are learning the same painful lessons at sites across the nation. Regrettably, multiple patients are subjected to the same poor outcomes. In many cases, we even fail to communicate internally within the organization, resulting in multiple failures within our own organization until everyone understands the importance of the rake's proper storage. This chaos has, unfortunately, drawn broad negative attention to the medical community. A quick library search will yield books from best-selling authors with titles like, "Surviving Your Doctors" and "Top Screw Ups that Doctors Make and How to Avoid Them". [4,9,10] Such negative attention erodes patient trust, so it is imperative that we pay attention to the issues and view them critically, not only from our own perspective, but from the lens of our patient as well.

One local news media cover story highlights a case where a child collapsed at school as a result of receiving Lamictal® 150mg tablets instead of the prescribed Lamictal® 25mg tablets at a popular retail pharmacy chain. Another patient is interviewed who erroneously received a thyroid supplement hormone at another pharmacy. Unfortunately, these stories are much too common, popping up on media outlets across the country. And, although state boards of pharmacies take medication errors very seriously, no one truly understands the scope of the problem, as the reporting of medication errors is not required in most states.

Pharmacists sometimes echo the sentiment that production and safety are positioned against one another in many practice environments. And, the reality is that safety mechanisms CAN sometimes be bypassed either locally, corporately, or nationally that sets a haunting stage for disaster. An imbalanced system WILL eventually lead to disaster. [11]

One of my favorite analogies for describing a model for error prevention is called the 'Swiss Cheese Model'.[6] Picture for a moment swiss cheese being sliced in your local deli. Each piece of cheese inevitably will invariably have the characteristic holes in it. These slices of cheese are not unlike our own limitations. Despite the amount of training and expertise a professional has, there will always be 'holes' in that knowledge and 'human factoring'. Each professional, however, carries his or her own slice of swiss cheese that can be stacked on top of other slices. Although each piece of cheese contains holes, it is less likely that two slices of swiss cheese contain holes in the same spot. Therefore, the chance of having a hole between two slices of cheese stacked together is decreased significantly. When a third slice is added, the odds of having three overlapping holes is minimized even further.

Using this analogy, then, it is easy to see the value of multiple layers of protection for patients. Each professional brings a different perspective and different set of 'holes' to the table. Listed below are just some of the examples of 'swiss cheese' that we may employ within our own practice settings:[6]

- Prescriber's knowledge
- Computer Screening

- Pharmacist's knowledge
- Patient risk factors
- Pharmacogenetics
- Drug administration
- Patient education
- Monitoring

This model recognizes the reality that there ARE 'holes' or 'gaps' in each and every slice of cheese. The goal is not to eliminate the holes from the cheese, but to minimize the chance of an error making it to the patient by using as many 'layers of cheese' as possible.

The prescriber is not immune from these gaps, nor are we. In their book, "Top Screw Ups That Doctors Make," medical authors Joe and Teresa Graeden cite a number of routine mistakes that are within the immediate control of the prescriber. One of those errors, the authors claim, is the tendency to haphazardly override computerized medication alerts. One study conducted in 2009 examined over 3 million electronic prescriptions from 2,872 clinicians over three states. This study revealed that approximately 75% of drug allergy warnings were ignored. [4,9] More striking, perhaps, was the observation that 90% of serious drug interactions were ignored! The latter is especially concerning from a risk management standpoint, as most malpractice mistakes arise from drug interactions. Many physicians maintain, however, that the frequency of trivial or clinically insignificant alerts creates 'user fatigue' and a habit of routinely overriding warning messages.

The authors also maintain that physicians routinely fail to report drug problems to the FDA. In fact, one analysis of 37 studies revealed that only 6% of new, rare, or serious adverse reactions were spontaneously reported. Physicians will sometimes avoid reporting to FDA's Med Watch because they often view this patient reported data as either unscientific or anecdotal. Physicians should, however, be encouraged to use this service so that broader data may be pooled and evaluated. While patients may report directly to FDA's Med Watch, physicians are encouraged to become involved in the process as well.[4]

As computerized screening has evolved, the tools for error detection have evolved and changed as well. Upon its introduction, Computerized Provider Order Entry Systems (CPOE) were touted as being an enormous breakthrough with the promise of 'eliminating prescribing errors'. [10] Just as the Titanic was reportedly destined as being an 'unsinkable' ship, the medical community would soon realize that the new tool did not eliminate prescribing errors. In fact, some argue that it created new challenges for which solutions must be sought.

CPOE systems clearly brought a new set of clear advantages to the table. These systems, for example, eliminated the potential for the mis-interpretation of many clinician's notoriously questionable handwriting skills. It allowed for easier identification of the prescriber, easing the

complexities that pharmacists are sometimes faced with: determining which of the twelve cardiologist's names on the top of the written prescription best match up with the little 'j-looking' ink squiggle on the signature line. CPOE also brought the data of drug-drug interactions into the equation at the point of prescribing. CPOE also made universal compliance with the Institute of Safe Medication Practice recommendations much more achievable. Improper abbreviations, such as q.i.d., could simply be removed from the menu of options within the CPOE system. [10]

Despite the advantages, CPOE was far from being the 'unsinkable ship' that it was initially touted to be. One study, in fact, identified 22 error increasing aspects of the new system. [10] One of those limitations was the seemingly indiscriminate use of 'forced field' entries. For example, a patient's weight may be a required piece of information before prescribing. A prescriber, who seeks to prescribe a drug in which the patient's weight is of no consideration, may not have immediate access to the patient's weight. To 'force' the system to continue, the physician enters a 'dummy number' into this field, 150 pounds. This allows the prescriber to continue, as a value has been entered into the required field. However, this 'bandage fix' comes at the cost, of course, of compromised data moving forward. Suppose, for example, that this same patient has a need for a medication at a later time that is prescribed using carefully calculated weight-based dosing. This 'dummy number' may be erroneously used, then, to the detriment of the patient if the variance from the actual data is significant.[10]

CPOE also introduced a complication within the dosing realm of pediatrics, as the decimal places were often limited. For medications with finite dosing characteristics, the number of decimal points can be clinically significant. One study even reported a doubling of infant mortality after the introduction of CPOE. We cannot, of course, ascertain that CPOE was the reason for the doubling of infant mortality over this time; yet, the correlation is unsettling nonetheless. Concerns were also raised regarding initial delays in patient care. In short, if the patient's data had not been entered into the system, the prescriber's ability to treat the patient was compromised until this task could be performed. Additionally, some prescribers expressed concern that it altered healthy communication patterns within the healthcare team itself. [10]

Shortly after the introduction of CPOE, decision support systems (DSS) were introduced. These systems were sold as 'add on' features to the basic CPOE systems and offered technology to warn prescribers of things such as: [10]

- Drug-drug interactions
- Dose limits
- Allergies
- Best Practice Guidelines
- "Order sets" (groups of drugs that often work together)

DSS systems introduced the advantage of maintaining current dosage guidelines and warnings based on the latest research, giving the prescriber quick access to evidence-based medical information at the time of prescribing. Industry experts quickly noted, however, that 'alert fatigue' quickly became an issue with the earliest DSS systems. Prescribers were being bombarded with many marginal or seemingly insignificant clinical warnings. As a result, the process of overriding these messages became routine and mundane. In all, an estimated 80 – 96% of alerts were ultimately ignored or overridden by prescribers.[10]

In addition to the questionable practicality of the earliest DSS systems, the accuracy and reliability of the data held within these systems was also drawn into question. A study conducted by Metzger and colleagues made the following assessments: [10]

- DSS detected only 53% of all medications that would have resulted in fatalities
- Drugs prescribed for a wrong diagnosis were caught only 15% of the time
- Drugs inappropriate for a patient of a given age were intercepted only 14.1% of the time

It is no wonder, then, that such systems were initially seen as an annoyance rather than a serious tool to increase patient safety. Since the earlier DSS models, improvements have been made. None of these systems, however, remain infallible. As practitioners, it is imperative that these systems be recognized as a tool, a slice of swiss cheese, in the interest of employing our earlier analogy.[6] As a tool, it requires the experience and focus of the user. It is imperative, then, to ensure that the brain is not 'switched off' as the computer is 'switched on'.

If, as pharmacists, we feel relieved that there is not a best-selling book entitled, "Top Screw Ups That Pharmacists Make," never fear. While we do not have a book title, we have an entire chapter within the Graeden book dedicated exclusively to our own profession! Graeden highlights ten areas in which pharmacists err routinely: [4]

1. Not counseling patients
2. Dispensing the wrong drug
3. Dispensing the wrong dose
4. Ignoring Interactions
5. Not standing up to doctors
6. Trusting all generic drugs
7. Relying on inadequate labels and leaflets
8. Not reporting errors
9. Switching drugs without patient approval

10. Not supervising supporting staff carefully

While not all of these issues will be addressed in detail, this unique perspective provides a very convenient outline to organize our thoughts as we consider medication safety from the lens of a physician 'peeping in' on the profession of pharmacy. First, Graeden observed that pharmacists fail to counsel patients. One 2003 study estimates that the rate of counseling has dropped nearly by half, from 43% to only 27% over the prior 14 years. Another 2009 "secret shopper" study found that patients were offered counseling for new prescriptions only about 25% of the time.[4] Pharmacists frequently report chaotic volume driven environments that make even legally required elements an increasingly challenging task.

Dispensing the wrong drug or dose, however, is most likely what comes to mind as the concept of 'pharmacy error' is introduced. And, in fact, this represents a great extent of the initiatives taken on by the Institute of Safe Medication Practices (ISMP). The creation of the "look alike / sound alike list" was one tool introduced to draw attention to medications that are often mistaken for one another. Medications like Zantac® and Xanax®, for example, have been proven to be problematic when communicated verbally.[4] It is important for medical professionals, then, to familiarize themselves with the medication pairs on this list. The ISMP list is included with this document as an appendix. [(11,15)]

Additionally, ISMP created and periodically updates a list of potential high-alert medications. These are medications that have been observed to have especially high negative patient outcomes when errors occur. The Joint Commission and various regulatory agencies provide direction for handling high-alert medications. As with the previous list, this is a document with which medical professionals should be intimately familiar. This ISMP document is included with this document as an appendix. [(11,15)]

In terms of dosing, it is important that dosing instructions be correlated with the measurement device supplied, preferably in metric units. If, for example, a dosing cup is provided with mL incremental markings, it would be inappropriate to provide instructions to 'give 1 teaspoonful twice each day". Avoid using dosage cups with measurements in fluid drams, as this simply is not a commonly understood means of measurement for most patients.[4]

Just as the observation was made with physicians ignoring potentially dangerous interactions, this was noted as a problem within the profession of pharmacy as well. In a 1996 "secret shopper" investigative report by U.S. News & World Report, shoppers were sent into 245 pharmacies in seven cities, submitting two incompatible prescriptions at the pharmacy counter. At least 33% of the time, the shopper was given both drugs without warning.

While multiple drug interactions exist that require an effective working knowledge by every healthcare team, the American Family Physicians has developed a 'most clinically significant interaction list', in which special diligence must be exercised. This drug list includes: [21]

INTERACTION	***POTENTIAL EFFECT***	***TIME TO EFFECT***	***RECOMMENDATIONS AND COMMENTS***
Warfarin (Coumadin) *plus* ciprofloxacin (Cipro), clarithromycin (Biaxin), erythromycin, metronidazole (Flagyl) or trimethoprim-sulfamethoxazole (Bactrim, Septra)	Increased effect of warfarin	Generally, within 1 week	Select alternative antibiotic.
Warfarin *plus* acetaminophen	Increased bleeding, increased INR	Any time	Use lowest possible acetaminophen dosage and monitor INR.
Warfarin *plus* acetylsalicylic acid (aspirin)	Increased bleeding, increased INR	Any time	Limit aspirin dosage to 100 mg per day and monitor INR.
Warfarin *plus* NSAID	Increased bleeding, increased INR	Any time	Avoid concomitant use if possible; if co-administration is necessary, use a cyclooxygenase-2 inhibitor and monitor INR.
Fluoroquinolone *plus* divalent/trivalent cations or sucralfate (Carafate)	Decreased absorption of fluoroquinolone	Any time	Space administration by 2 to 4 hours.
Carbamazepine (Tegretol) *plus* cimetidine (Tagamet), erythromycin, clarithromycin or fluconazole (Diflucan)	Increased carbamazepine levels	Generally, within 1 week	Monitor carbamazepine levels.
Phenytoin (Dilantin) *plus* cimetidine, erythromycin, clarithromycin or fluconazole	Increased phenytoin levels	Generally, within 1 week	Monitor phenytoin levels.
Phenobarbital *plus* cimetidine, erythromycin,	Increased phenobarbital levels	Generally, within 1 week	Clinical significance has not been established.

clarithromycin or fluconazole			Monitor phenobarbital levels.
Phenytoin *plus* rifampin (Rifadin)	Decreased phenytoin levels	Generally, within 1 week	Clinical significance has not been established. Monitor phenytoin levels.
Phenobarbital *plus* rifampin	Decreased phenobarbital levels	Generally, within 1 week	Monitor phenobarbital levels.
Carbamazepine *plus* rifampin	Decreased carbamazepine levels	Generally, within 1 week	Clinical significance has not been established. Monitor carbamazepine levels.
Lithium *plus* NSAID or diuretic	Increased lithium levels	Any time	Decrease lithium dosage by 50% and monitor lithium levels.
Oral contraceptive pills *plus* rifampin	Decreased effectiveness of oral contraception	Any time	Avoid if possible. If combination therapy is necessary, have the patient take an oral contraceptive pill with a higher estrogen content (>35 micrograms of ethinyl estradiol) or recommend alternative method of contraception.
Oral contraceptive pills *plus* antibiotics	Decreased effectiveness of oral contraception	Any time	Avoid if possible. If combination therapy is necessary, recommend use of alternative contraceptive method during cycle.
Oral contraceptive pills *plus* troglitazone (Rezulin)	Decreased effectiveness of oral contraception	Any time	Have the patient take an oral contraceptive pill with a higher estrogen content or recommend

			alternative method of contraception.
Cisapride (Propulsid) *plus* erythromycin, clarithromycin, fluconazole, itraconazole (Sporanox), ketoconazole (Nizoral), nefazodone (Serzone), indinavir (Crixivan) or ritonavir (Norvir)	Prolongation of QT interval along with arrhythmias secondary to inhibited cisapride metabolism	Generally, within 1 week	Avoid. Consider whether metoclopramide (Reglan) therapy is appropriate for the patient.
Cisapride *plus* class IA or class III antiarrhythmic agents, tricyclic antidepressants or phenothiazine	Prolongation of QT interval along with arrhythmias	Any time	Avoid. Consider whether metoclopramide therapy is appropriate for the patient.
Sildenafil (Viagra) *plus* nitrates	Dramatic hypotension	Soon after taking sildenafil	Absolute contraindication.
Sildenafil *plus* cimetidine, erythromycin, itraconazole or ketoconazole	Increased sildenafil levels	Any time	Initiate sildenafil at a 25-mg dose.
HMG-CoA reductase inhibitor *plus* niacin, gemfibrozil (Lopid), erythromycin or itraconazole	Possible rhabdomyolysis	Any time	Avoid if possible. If combination therapy is necessary, monitor the patient for toxicity.
Lovastatin (Mevacor) *plus* warfarin	Increased effect of warfarin	Any time	Monitor INR.
SSRI *plus* tricyclic antidepressant	Increased tricyclic antidepressant level	Any time	Monitor for anticholinergic excess and consider lower dosage of tricyclic antidepressant.
SSRI *plus* selegiline (Eldepryl) or nonselective monoamine oxidase inhibitor	Hypertensive crisis	Soon after initiation	Avoid.

SSRI *plus* tramadol (Ultram)	Increased potential for seizures; serotonin syndrome	Any time	Monitor the patient for signs and symptoms of serotonin syndrome.
SSRI *plus* St. John's wort	Serotonin syndrome	Any time	Avoid.
SSRI *plus* naratriptan (Amerge), rizatriptan (Mazalt), sumatriptan (Imitrex) or zolmitriptan (Zomig)	Serotonin syndrome	Possibly after initial dose	Avoid if possible. If combination therapy is necessary, monitor the patient for signs and symptoms of serotonin syndrome.

https://www.aafp.org/afp/2000/0315/p1745.html

In another 2003 "secret shopper" study, more than 67% of patients purchased OTC aspirin when they picked up their prescription for warfarin without question. [4] While this may not be entirely surprising, given the chaotic nature of pharmacy environments and the variant ancillary training requirements in the United States, it is concerning nonetheless.

Interestingly, from a physician authors' vantage, the next "screw up" that pharmacists make is reportedly 'failure to stand up to doctors'.[4] There are, of course, frequently many barriers to effective communication between the prescriber and the pharmacist. There are often significant delays before calls are returned, assuming that the pharmacist proceeds past the 'gate keepers' put in place to divert calls not requiring the physician's attention. Admittedly, some prescribers are much more receptive to the idea of receiving input from the pharmacy team than others. Despite these barriers, the authors maintain that it is critical that pharmacists strive to push through the barriers in order to be the best advocate for the patient.

Next, the authors delve into the controversy of generic medications, even including it as one of our 'top mistakes' professionally. Upon first reading this, I was admittedly skeptical. Can switching a patient's generic medication from one manufacturer to another really be one of our top "screw ups" professionally? While I remain unconvinced of the magnitude of this piece, the points made by these authors provide, I believe, an important perspective that warrants consideration. Up to 40% of the drugs Americans take, the authors maintain, are imported. Up to 80% of the active pharmaceutical ingredients are imported, and it is logistically difficult for FDA inspectors to perform site visits outside of the United States. In fact, the Government Accountability Office reports that 64% of foreign plants have NEVER been inspected by the FDA. Inactive ingredients (colors, binders, fillers, etc.) may certainly vary as well as the mechanism of releasing the active ingredient.[4] Given these variables, it may be prudent to not ignore patient

complaints that one generic medication is working better than another one. This is not as far out of the realm of possibility, perhaps, as we once believed. To skeptics, the authors are quick to point out the disproportionately large number of generic medications recalls.

Pharmacists often rely, too, on patient leaflets which are generated with the processing of the prescription to communicate key information to patients. While a helpful tool, leaflets are not without flaw. Dosing instructions can often be vague, leading to less optimal outcomes. Consider, for example, leaflet instructions to 'take before meals. Is this immediately before the meal? 15 minutes before the meal? Hours before the meal? The pharmacist may need to use this tool to expand and clarify instructions and expectations for the patient. Information contained in these leaflets varies significantly from one pharmacy to another, as does the frequency of updates. Shockingly, a 2005 survey concluded that fewer than 10% of all leaflets collected from 384 community pharmacies met quality criteria regarding contraindications, precautions, and how to avoid harm! [4]

The authors also cite an unsettling tendency for pharmacists to avoid reporting errors. This stem, in part, from a lack of regulatory drive. Reporting requirements, after all, are often sparse or non-existent. Most states have no reporting requirements at all. Some, such as the state of North Carolina only require reporting of fatal errors. Fears of litigation are another element often cited as a reason to avoid the reporting or errors. It is important, though, that pharmacists understand the value of reported errors. [(4,5,13)]

The ISMP Medication Errors Reporting Program (MERP) believes in this central message. To combat some of the stigma associated with the reporting of medication errors, ISMP has created a *confidential* national voluntary reporting program that provides expert analysis of the systematic causes of medication errors and disseminates recommendations for error prevention. [(5,13)] Pharmacists are encouraged to make effective use of this resource. In short, what remains unknown within the profession cannot be explored nor improved upon; it can only be feared.

Next, the physician authors ascertain that, as a profession, we fail to train and supervise our ancillary staff appropriately. While this has been a problematic discussion within pharmacy practice for some time, in more recent years, it has been thrust into the public spotlight. National media stories highlighting errors made by pharmacy technicians became common place, as did attention to the training that these individuals receive. One technician, in these national interviews, described a scenario where she felt as if she 'had just been thrown into the lion's den after two hours of training and was going to have to figure things out on her own'. And, in fact, there is no nationally required training standard for pharmacy technicians. Underscoring the urgency, one study of hospital pharmacies found that pharmacists fail to catch one in five technician errors.[4]

The amount and type of training required of pharmacy technicians fluctuates drastically from state to state. In some states, boards of pharmacy do not maintain registration records of

pharmacy technicians at all! Simply put, the boards of pharmacy in those states would have absolutely no idea who the pharmacy technicians are in the state, much less how much training these individuals have received. On the other end of the spectrum, there are states that require the completion of an ASHP accredited pharmacy technician training program. Other states accept a passing score on the PTCE (Pharmacy Technician Certification Exam) for registration and/or certification within the respective state. Some states will only accept a passing score on the PTCE; other states accept the National Health Career Association's ExCPT exam. The range of expectations is wide and arguably irresponsible.

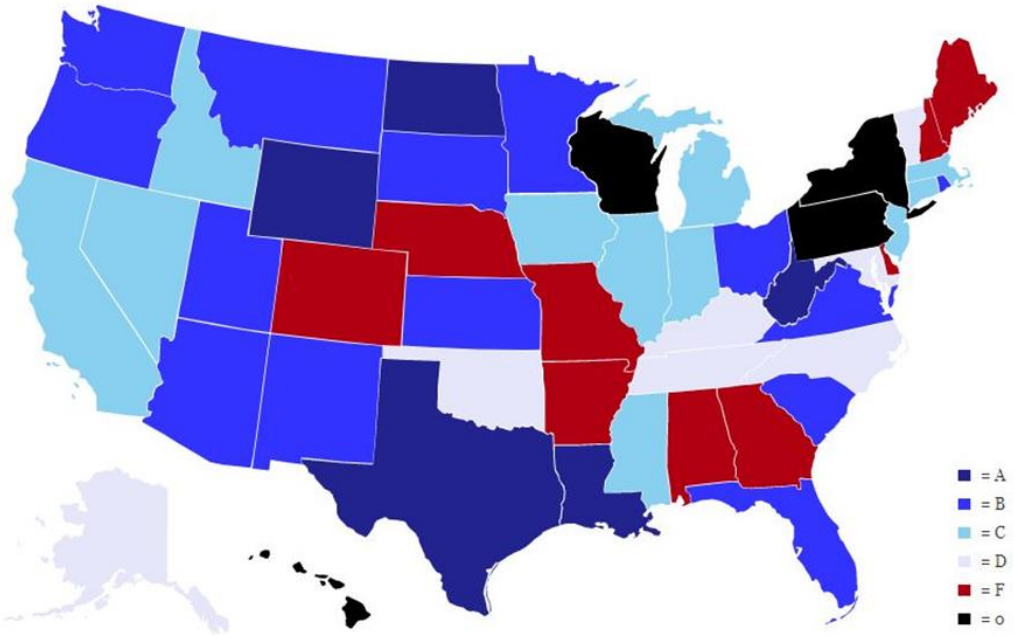
This excessive variation in state standards creates a problem on several levels, including reciprocation from state to state. If, for example, an individual has been a practicing certified pharmacy technician in the state of New York and moves to South Carolina, that individual may be ineligible for certification in South Carolina without first attending an ASHP accredited program, despite the previous qualifications or experience carried over from the state of New York.

In 2006, tragedy struck at a hospital in Ohio, a state that did not register pharmacy technicians at the time. Two-year-old patient, Emily Jerry, was scheduled to receive her final dose of chemotherapy on February 24, 2006. It was to be a day of celebration for her family, as previous scans had shown no traces of the cancer that had previously afflicted her small body. The upbeat atmosphere of triumph, however, ended abruptly in tragedy shortly after Emily's infusion began. Emily suffered massive brain damage after a pharmacy technician filled a plastic bag with a concentrated sodium chloride solution of 23.4% of which she had compounded herself in lieu of the standard 0.9% normal saline. In the analysis of the incident, the technician did not appear to understand the fundamental differences between the two concentrations. [19]

But the pharmacist should have checked this medication before it left the pharmacy, right? Well, as it turns out, he did. But, as many who have worked in a chaotic pharmacy environment may relate, many items were jumbled together on the table awaiting the pharmacist's approval. The empty vials of saline were thought to have been associated with another prescription preparation on the table. In addition, the computer system in the pharmacy had been down for an extended period and the floor was calling anxiously for the 'STAT' infusion that would ultimately prove to be fatal. Many pharmacists can empathize with the conditions faced by the pharmacy staff on this fateful day. No amount of empathy, however, changes the outcome of a jailed pharmacist whose license was permanently revoked. It does not change the outcome of a family dynamic that was forever changed by the loss of a child. It does not change the fact that our medication safety system failed this two-year-old child.

From this tragedy, arose a momentous push for the appropriate training of pharmacy technicians. Emily's father, Mr. Chris Jerry, created the Emily Jerry Foundation (http://www.emilyjerryfoundation.org). Part of this organization's initiative was to bring attention to the variance in pharmacy technician training requirements in the United States.

The Emily Jerry Foundation went as far as 'grading' each state based upon requirements in place for pharmacy technician education in each state. The most current version of this map may be viewed on the Emily Jerry Foundation's website. As of the printing of this document, the map reveals this summary: [19]



This is a fluid map, as more states seek to modify requirements for pharmacy technician education and training. If your state scores poorly in this area, this should serve as a 'wake up call' for serious intra-professional communications with the respective boards of pharmacy. This glaring piece simply can no longer be ignored in an effective and rounded discussion of medication safety initiatives.

In addition to pediatric patients, geriatric patients are at an increased risk for poor outcomes subsequent to medication errors. Senior citizens take 1/3 of all prescriptions dispensed, with 52% taking more than five medications. This grossly increases the risk of unintended outcomes. One study suggested that patients taking seven or more medications have an 82% chance of experiencing an adverse drug interaction! [4] Consider for just a moment the number of patients in your own practice taking multiple medications. The opportunity for intervention is enormous!

Many prescribers are inadequately trained in evaluating the special needs of senior citizens. In one study designed to assess physician knowledge about prescribing to elderly patients, 71% scored poorly. Especially concerning, 75% of these physicians reported feeling confident in their abilities to prescribe drugs to older patients! There are currently approximately 7,000 geriatricians, compared to over 80,000 pediatricians in the United States. [4] As observed by John

Rowe, MD, IOM committee chairman in a testimony to the U.S. Senate, "*"We are woefully unprepared. The U.S. Healthcare System is in denial about the impending demands. Little has been done to prepare the health care workforce for the aging of our nation and the current supply and organization of the health care workforce will simply be inadequate to meet the needs of the older adults of the future."* [4]

The 'Beers List' was created as a resource for prescribing within the senior population. Drugs appearing on the 'Beers List' should be avoided in elderly patients or given extreme consideration. A copy of the 'Beers List' is included with this document as an appendix.

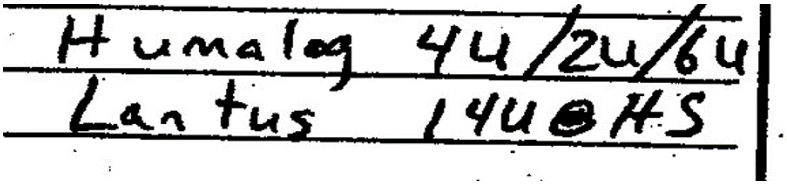
Healthcare professionals should familiarize themselves with this resource. Effective procedures for the retrieval of outdated and recalled medications is another component to an effective patient safety program. A process must be established to regularly review the pharmacy drug inventory to remove expired medications. Written procedures should be established to facilitate a timely removal. It is imperative that ALL areas in the facility where these items may be stocked are considered. Sometimes, an item is removed from the primary storage site, while ancillary storage sites are not considered.

The Institute of Safe Medication Practices (ISMP) and FDA conducted a national campaign to eliminate the use of error-prone abbreviations in all forms of medical communications. Many abbreviations historically used within the practice of medicine were found to be a source of confusion and error. For example, 'qid' (or, four times a day), was sometimes confused with 'qd' (or, daily). Trailing zeroes were often mistaken. For example, '5.0' may be read as '50'. Likewise, the use of a decimal without the leading zero was easily confused, where '.5' was mistakenly read as '5'. [14] These are simple and immediate measures that can be incorporated into daily practice. Unfortunately, some of the 'easiest' tools to implement often prove to be tough habits to break. It is important, however, that medical professionals make concerted efforts to implement these ISMP recommendations. A great start is to ensure that all improper abbreviations are removed from standardized ordering forms and databases. Key areas to consider include: [14]

- Written orders
- Internal communications
- Telephone/verbal prescriptions
- Computer-generated labels
- Labels for drug storage bins
- Medication administration records
- Preprinted protocols

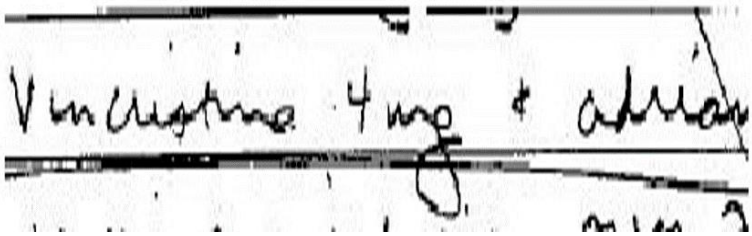
- Pharmacy and prescriber computer order entry screens

Consider this example illustrated by the ISMP team: [14]



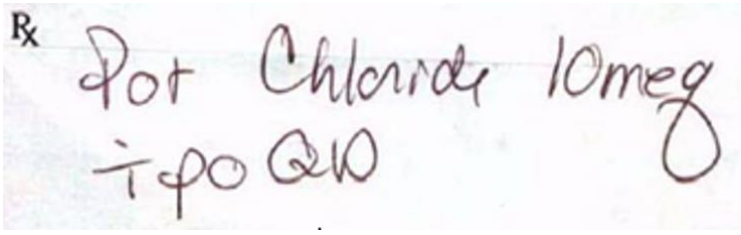
In this case, an intended dose of 4 units in the patient's history was misinterpreted as 44 units. As ISMP recommendations state, "U" should be written out as "unit" rather than abbreviated, which was formerly the standard of practice.

In the next example, the potential consequences of failure to use a 'leading zero' are highlighted. [14]



This order was erroneously interpreted as 'vincristine 4mg' instead of 'vincristine 0.4mg'. This is an error that could have been avoided had the prescriber made use of the ISMP recommendations.

In another case, a potassium chloride prescription was mis-translated as "Take one tablet by mouth four times a day," rather than the intended dosage of one tablet daily. [14]



Yet another tool introduced by ISMP is 2008 is the use of 'tall man lettering'. ISMP maintains a list of drug name pairs and trios with recommended, bolded tall man (uppercase) letters to help draw attention to the dissimilarities in look-alike drug names. For example, bu**PROP**rion is differentiated with bus**PIR**one. Likewise, **DOBUT**amine is distinguished from **DOP**amine. A complete listing of tall man lettering recommendations are attached to this document as an appendix. [16]

Aside from ISMP efforts, error prevention strategists have long recognized key elements of error prevention including: [11]

- Simplifying / Standardizing
- Reducing Reliance on Memory
- Using constraints and forcing functions
- Improving Information Access
- Making Errors Visible
- Reducing Handoffs
- Automating Wisely
- Mitigating the Unwanted Side Effects of Change
- Improving Communication
- Providing Adequate Training

As Apple's Steve Jobs observed, "Simple can be harder than complex: You have to work hard to get your thinking clean to make it simple. But, it's worth it in the end, when you get there, you can move mountains." Standardization of procedures can add another important element of continuity. If an alternate worker must be introduced to the system unexpectedly, the goal is to have the new worker enter seamlessly, resuming the standardized process. This minimizes our reliance on memory as to how the process works on Mondays as opposed to Tuesdays … and at a site on the west side of town versus a site on the east. By reducing the number of hand-offs from one person to another, mistakes are minimized as there is continuity and a clear understanding of what has happened between point A and point B.

Constraints and forcing functions can also be an effective tool, but not without risk. Most will recognize these functions from completing forms online for various reasons. The fields all require a response, perhaps, before you are permitted to place an online order. This, in theory, prevents the omission of the shipping information or payment details. It is important to remember, however, that when new constraints or forcing functions are added, new possibilities for error inherently emerge. Earlier in the discussion, we mentioned the example of the physician who entered a 'dummy value' for the patient's weight so that he could move past this field to order the patient's medication. As these constraints are added, it is imperative that potential problems be given careful forethought. Or, as these specialists have observed, 'mitigate the unwanted side effects of change' and 'automate wisely'.

Historically, the tendency has been for pharmacy errors to be 'swept under the rug' and handled discretely. It was an embarrassing secret to the store or chain in which the error occurred and seemingly understood as a topic not to be discussed. This prevailing culture must dissipate, however, if we are committed to learning from both our own mistakes and the mistakes of others. Maintaining visibility of errors made, even if in an anonymous fashion, is an important piece in analyzing trends and developing processes to circumvent poor outcomes.

In looking at the process of thought itself, psychologists identify three different types of thought processing. The first type of thought processing, called skill-based processing (or automatic processing), refers to routine tasks that require minimal focus, with only occasional 'checks' to verify that the task is progressing normally. [11] When waking this morning, for example, you probably gave little thought to the routine of getting ready for work. You unlikely read the instructions on the back of the toothpaste package to determine how to proceed with your morning routine. It is a pattern that you have performed many times, so it does not require great planning or thought to carry out the routine. Nonetheless, mistakes sometimes happen. Have you ever caught yourself in the mirror just before rushing out to realize that you failed to comb your hair during the routine process? Forgotten to shave? To the horror of co-workers, neglected to apply deodorant? If you are human, it is likely that you have.

The second type of thought processing is known as 'rule-based processing' (or 'intuitive processing'). This type of processing occurs when there is a conscious awareness of an issue. [11] The solution is matched with a past solution. Often, this is an effective translation. In training, for example, a technician may be told that 'STAT' orders are sent to the floor via the tube delivery system. Upon seeing the word 'STAT' on an oral tablet that she has not previously seen, she correctly ascertains that the medication should be sent via the hospital's tube delivery system. On another occasion, however, a prescription for a fragile protein drug is marked as a 'STAT' order. Having never seen this drug before, but seeing the word 'STAT', the technician matches this to previous orders and erroneously sends a fragile protein drug through the jarring tube delivery system. A mistake is made because a past solution is applied to a new situation or exception. [11]

The third type of thought processing is known as 'knowledge-based processing' or 'analytical processing'. This also occurs when there is an awareness of an issue. In this case, however, the individual is unable to match the issue with a past solution. This requires, then, focus and attention. Knowledge-based processing may, indeed, lead to a high risk of failure if there is not much time or allowance for trial and error. Although the risk of error is very high with this level of thought processing, it is encountered less frequently. As a result, it is a low contributor to the overall number of actual errors in most pharmacy systems. [11]

In reality, all three levels of thought processing may occur at once. We are continually making decisions, whether consciously or not. Human error may occur in either the planning, storage, or execution phases of a process. Slips & lapses occur in the storage or execution phases

(within skill-based processing), whereas mistakes occur in in the planning stage (within the rule-based or knowledge-based processing realms). [11]

Slips and lapses may occur simply as the result of an attention failure. Remember the day that you forgot to wear deodorant? Yes, that was a slip and lapse error. In the pharmacy, this may be the omission of an auxiliary label. It could also be the subconscious perception failure of a 'look-alike / sound-alike' drug. Slips and lapses are often caused by attentions failures, such as preoccupation with another task, stress, or other distractions in the environment. Ultimately, the human mind will "fill in the blanks," so that the mental checks appear to confirm that the action is being carried out correctly. Because we expect meaning to be there, it's easier for us to miss when parts (or all) of it are absent. This reality competes with the expectations that exist in our minds. [11]

According to psychologist Tom Stafford of the University of Sheffield (UK), *"When you're writing, you're trying to convey meaning. It's a very high-level task. As with all high-level tasks, your brain generalizes simple, component parts (like turning letters into words and words into sentences) so it can focus on more complex tasks (like combining sentences into complex ideas). We don't catch every detail, we're not like computers or NSA databases. By the time you proof read your own work, your brain already knows the destination."* This phenomenon underscores the value of a 'second pair of eyes' on any given task. To illustrate the power of the mind in ignoring detail in order to focus on understanding, consider this passage:

> *"I cdnuolt blveiee that I cluod aulaclty uesdnatnrd what I was rdanieg. The phaonmneal pweor of the hmuan mnid, aoccdrnig to a rscheearch at Cmabrigde Uinervtisy, it dseno't mtaetr in what oerdr the ltteres in a word are, the olny iproamtnt tihng is that the frsit and last ltteer be in the rghit pclae. The rset can be a taotl mses and you can still raed it whotuit a pboerlm. This is bcuseae the huamn mnid deos not raed ervey lteter by istlef, but the word as a wlohe. Azanmig huh? Yaeh and I awlyas tghuhot slpeling was ipmorantt!"* [20]

Slips and lapses can result in anything from minor inconveniences to absolute tragedy. Consider, for example, a parent who has a well-developed routine of driving the same route to work each morning. One morning, however, the parent is tasked with an important exception to this developed routine: he/she is to drop the baby off at the daycare center. Being in 'auto pilot mode' following the usual routine, the parent neglects to make the stop at the daycare center, leaving the baby in the back seat of the car. As neglectful as this may sound, it is not a unique occurrence. There have been, in fact, over 400 incidents of death or brain damage from similar incidents since the 1990's alone.[3] It is important to note that such incidents are rarely the result of intentional abuse. Most parents, are in fact, devastated upon realizing what tragedy has unfolded. Why does the death of a child seem to make that lapse so much more blameworthy? It is after all, the same error that humans make routinely, albeit with drastically

different consequences. Humans have a tendency to assign blame for an error in a manner that is roughly proportional to the severity of the outcome, a phenomenon that psychologists refer to as 'symmetry bias'. [11]

A 'rule-based mistake' is one where the problem is assessed incorrectly and incorrectly "matched" to a previous problem OR a poorly written or misunderstood process is followed. [11] We mentioned earlier the technician's assumption of placing the fragile protein medication into the hospital's tubing system. That was a 'rule-based mistake'. Another example might be the poor practice of using IV syringes for oral doses. Because the potential exists for someone to attach a needle to an IV syringe and inject the oral product, this practice should always be avoided.

A 'knowledge -based mistake' is one that occurs during focused problem solving. No experience with the problem combined with the absence of a rule to apply means that there is a high likelihood that the devised plan will be incorrect. [11] Often, 'knowledge-based mistakes' may be countered or minimized by effectively consulting another colleague. Health care professionals should not be hesitant to reach out to other professionals when these gaps in knowledge arise. The more slices of swiss cheese introduced, the better!

Violations are another source of error in the pharmacy. Violations occur when a good rule, standard, or safe operating procedure is bypassed. Error specialists categorize violations into three distinct types. The first of these categories is 'optimizing violations,' which I hope are not a broad concern to us professionally. 'Optimizing violations' occur when a rule is willfully violated because it is fun or exciting to do so. This is the mentality that drives an individual to exceed the posted speed limit when driving an exotic sports car, for example. [11]

More commonly, violations within the pharmacy are classified as either 'necessary violations' or 'routine violations'. 'Necessary violations' occur when the rule is violated because it is impossible or inadvisable to follow the rule at the time. For example, assume that a hospital policy requires that a certain medication be verified by two pharmacists prior to dispensing. While this may be an effective policy during most circumstances, there may be rare instances where only one pharmacist is on duty. In that situation, the pharmacist is forced to violate the rule in order to dispense the prescription in a timely manner. [11]

'Routine violations' occur when a rule is violated because it is deemed to be clumsy or unnecessary. This is frequently due to a lack of understanding of the purpose and/or importance of the rule. As managers, then, it is imperative that new rules be 'sold' to employees at every level. No diligent healthcare worker would intentionally bypass steps that he/she believes to be fundamental to patient safety. If, however, the rule is not effectively connected to the end goal, the rule may be seen as intrusive and 'red tape' indiscriminately added to the process. Experts encourage managers to remain positive and to stay focused on rewarding those who follow the process appropriately. [11]

Sleep deprivation can be another distinct source of medication error. While few studies exist specifically examining pharmacy error and sleep deprivation, quite a few studies exist that examine medical interns. Medical internships are one of the more 'traditional' experiences in which medical students are 'put to the test' by being assigned a list of rigorous expectations with limited opportunities for rest. Sadly for patients under the care of these interns, sleep deprived interns made nearly twice as many errors as those who had adequate rest. In addition, interns working for longer than 20 consecutive hours were found to have a 61% increased odds of suffering a needle-stick or scalpel injury on the morning after working all night. Startlingly, working a schedule of 24 hours every four to five nights (with three hour naps) impaired a residents' driving performance to the same degree as a blood alcohol level of 0.04 – 0.05%. [10] For reference, commercial drivers with a blood alcohol level of 0.04% can be charged with driving under the influence (DUI) in all 50 states. It is imperative that managers carefully consider the risks associated with this phenomenon before allowing a sleep deprived worker to work an additional shift, despite the perceived operational needs.

Night shift workers were also observed to be more prone to error. The body's circadian rhythms are out of phase, resulting in poorer sleeping patterns. Studies have revealed a broad and substantial loss of sleep efficiency in daytime sleepers. Depending upon the worker's routine, the shifts often begin many hours after awakening, at a time when the worker is more fatigued.[10] On the other hand, sleep inertia is also cited as being problematic. Sleep inertia refers to an impaired alertness and performance immediately after awakening. For example, if a worker is abruptly woken from sleep to respond to an emergency telephone call, the worker's critical thinking skills may be significantly impaired. This, of course, gradually dissipates over time, but it may have effects lasting up to two hours. Some studies suggest that the propensity to err in the first few minutes after awakening may exceed even that which is induced by 24 hours of total sleep deprivation.[10]

Pharmacy managers, then, are wise to take efforts to reduce workplace fatigue in the pharmacy. Educate staff about sleep hygiene, the use of caffeine, and the effects of fatigue on patient safety. This may be a matter of discussion at scheduled staff meetings or it may take a more pro-active approach. Managers may wish to evaluate shift length, overtime, and rotating shifts. Developing a policy on second jobs to reduce workplace fatigue may even be in order. It is important to consider what role workplace fatigue could play when reviewing and evaluating all medication errors. [8]

Pharmacists are 'programmed' to 'sweat the small stuff', and this is, perhaps, good programming from a medical safety standpoint. The "small stuff" is often the BIGGEST thing in patient safety! It is the thousands of actions and routines that precede, accompany, and follow the bigger "miraculous" feats in medicine that often make the difference.[10] It lends itself well to the stereotypical perfectionist nature of the pharmacist, which can be both an enormous professional advantage and programmed personal detriment. It is important, then, for pharmacists to recognize the value of the 'small stuff' but to also accept the fact that errors

can, and often do, occur. Our goal is to build additional 'layers of swiss cheese' so that the fewest possible number of errors reach the patient. When those errors do occur, it is important that the PROCESS be evaluated and not become a catalyst for self-blame. We can be our own worst critic. It is important that we do not allow our own criticism to become the very anchor that prevents constructive systematic progress.

Unchecked, this misguided idea of self-blame or intra-professional blame may easily become the cultural norm for the organization. It forms our overall workplace culture. It can become a culture that places emphasis on assigning blame for problems rather than seeking solutions for improvement. These cultures, sadly, promote little interest in a broad, high-level investigation of strategies for reducing systemic medical errors. Instead, it becomes a 'blame and train' culture. [5]

The premise, and inherent flaw, of a 'blame and train' culture is this: Those who do not exhibit perfect human performance need further education to attain perfection, with the option of bypassing training in favor of termination in severe incidents. The assertion, whether or not explicitly stated, is that the threat of this type of discipline will encourage those who have not yet erred to continue exhibiting perfect human performance.[11] While it seems absurd to see the rationale clearly stated, it is nonetheless a traditional rationale that holds fast in many organizations to this day.

Another phenomenon exists that tends to be quite prominent in medicine. This is a problematic source of systematic error that stems from a spoken or unspoken 'hierarchy of healthcare' mentality. It was not too many years ago that the thought was that the physician was the 'captain of the ship' and that those practicing under his direction should follow orders without question. I hope that you can immediately see how many 'layers of swiss cheese' we are removing from the system by blindly adopting this simple remnant from earlier healthcare traditions. [10]

Not only does this mentality foster a reluctance to report errors made by an attending physician, it builds fear within the system regarding contacting the attending physician due to perceived or actual repercussions for doing so. Everyone makes mistakes. It is imperative that our system does not discourage mistakes from being discussed on all levels. The "*what*" was discovered should always be viewed as being more relevant than "*who*" made the discovery. [10] Does our system demonstrate that it can be dangerous for a junior person to 'trump' a senior practitioner? Are we unknowingly equating "messing up" in the management of power relationships with the value of patient safety?

Are we completely comfortable in saying, "Please tell me if I'm making a mistake"? This, indeed, is a vital piece. Do any of us really want to work within a life critical setting that intimidates or discourages others from pointing out our mistakes or questioning our rationale? Re-training of the "captain's orders" mentality is an absolute 'must' for any system that seeks to move forward in reducing errors by making complete use of each 'slice of swiss cheese' in

the stack. Healthcare journalist Suzanne Gordon eloquently conveyed this observation in the following assertion:

> "*People who have been socialized to believe that they are "subordinates" dealing with a "superior" will be reluctant to cross status boundaries and will fear reprisals if they do. They will be unlikely to tell "superiors" that there is a problem or that the "superior" is about to make a very bad mistake if they have been socialized to defer to those status hierarchies. That is why, when input is offered, someone with team intelligence will acknowledge it, consider it, and thank the person for his or her efforts."* [10]

It is important, then, to recognize that the potential for error exists throughout the entire healthcare system. Most noted among cases involving litigation included: [1]

- undisclosed harmful side effects

- inadequate follow through with regulatory authority after products have been approved

- human error

- inadequate patient education

One way that managers may quickly assess workplace culture is via the use of a patient safety culture survey. Sample surveys were developed by the Agency for Healthcare Research and Quality and may be accessed online at www.ahrq.gov. These surveys allow an organization to get a sense of how employees feel about the safety culture and their work environment. Surveys are available for various settings including hospitals, nursing homes, and even office-based settings. It is recommended to conduct these surveys every other year to continually evaluate this important collaborative measurement of workplace culture. Many of the measures addressed in the surveys are associated with communication and teamwork, so even distribution of the survey itself arguably positively reinforces the presence of a top-down emphasis on patient safety. [5]

Continuous Quality Improvement, or CQI, is a tool that has been implemented with success. In fact, many state boards of pharmacy are contemplating or are already requiring community pharmacies to have a Continuous Quality Improvement (CQI) program in place. CQI is defined as "a systematic, organized approach for continually improving processes to deliver quality services and products." Another source defines CQI as being "a structured, organizational strategy for involving personnel in planning and executing continuous flow of improvements to provide quality healthcare that meets or exceeds expectations." [(2,13)] While CQI plans differ somewhat between states and even institutions, effective CQI programs share some central elements. Those shared elements include: [11]

- A well-defined CQI plan with clear links to the organization's strategic plan

- An established quality control council comprised of organizational leadership
- An inherent focus on the patient
- Established work teams to promote employee process improvement
- Established and maintained educational and training programs
- A structured process for identifying problems and solutions
- Securement of adequate resources for process redesign
- A supportive atmosphere of employee ideas for change
- An acknowledgement of the front-line staff as being the most knowledgeable about the work or problem to be solved
- A clear integration with The Joint Commission national patient safety goals (NPSGs)

While multiple accepted strategies exist for the implementation of a CQI program, one popular model is known by the acronym FOCUS-PDCA: [11]

F find the process to improve

O organize the interdisciplinary team

C clarify the baseline problem

U understand variation in the current process

S select the process for change

P plan the change

D do (implement) the change

C check the results of the change

A act to spread or sustain the change

As author Benjamin Wiker observed, "*Sometimes a clearly defined error is the only way to discover the truth*." The importance of error reporting and critical analysis of the error, then, is fundamental to the process. Root Cause Analysis is one technique used to systematically evaluate an error. Root Cause Analysis is formally defined as 'a systematic process to identify the causal factors that contributed to the occurrence of a sentinel event'. (The Joint Commission defines a sentinel event as an unexpected occurrence involving death or serious physical or psychological injury or risk thereof.) Root Cause Analysis is a design that focuses on

systems and processes, not individual performance. It points out significant underlying and fundamental systemic conditions that increase the risk of adverse events. The overall goal is to design *systems* to prevent or attenuate errors through proactive risk assessment. [13]

Deciding which personnel to include in a Root Cause Analysis team is one of the first, but most critical steps, to the project's success. It is important, for example, that the organization's leadership (or owner) be included in the team. Having an empowered individual who is at liberty to make systematic changes may be fundamental to the project's outcome. It is also important to include an individual knowledgeable about the actual event. This individual will be able to provide great insight into the environment in which the error occurred. In addition, a colleague familiar with the pharmacy's processes should be included. This will be important in determining if policies were bypassed or if, perhaps, no appropriate policies or procedures were in place. [13]

In working within the Root Cause Analysis Team, it is important that effective team intelligence techniques be employed. This begins by an effective introduction of all team member to one another. Sadly, it is not unusual for teams to be formed without each member knowing other team member names and/or specialized functions in within the team. Beyond base introductions, key elements of team intelligence include: [10]

- Sharing of common goals and information
- Listening, acknowledging, and respecting one another's concerns
- Viewing other team members as resources, not competitors or obstacles
- Cross-managing of one another to prevent, manage, and contain error
- Engaging in team learning and teaching opportunities
- Recognizing and dealing with obstacles and barriers to teamwork
- Placing the team mission (patient safety) over considerations of status or false authority
- Publicly acknowledging the roles and contributions of other teammates

The Root Cause Analysis team will seek to answer many questions, but key among those include: [13]

1. What happened?
2. What normally happens?
3. What do policies/procedures require? (helps determine the reliability of processes and how often staff cut corners to get the work done)

4. Why did it happen?
5. How was the organization managing the risk before the event?

To effectively address these questions, the team will review all documentation carefully. This raw data may include written prescriptions, computer data entry pieces, compounding logs, and counseling logs among other relevant documentation. The team will attempt to assess the physical environment and review the labeling and packaging process. The team will interview pharmacy staff involved in the incident in order to gain understanding of the event from different perspectives. Creating a flow chart outlining key occurrences may be useful in visually depicting areas of transition that are, perhaps, weak within the system. [13]

An effective Root Cause Analysis will determine if the finding/proximate factors identified are 'root causes' or 'contributing factors'. It will indicate whether or not action is needed for each 'root cause' and 'contributing factor'. In addition, an effective Root Cause Analysis seeks to: [13]

- Identify necessary system and process changes
- Focus on systems and processes rather than individual performance
- Continuously ask "why did this (or that) happen" until **all** root causes have been identified
- Engage organizational leadership in problem solving and quality and safety improvement
- Include participation by individuals most closely involved in the processes and systems under review
- Be internally consistent—does not contradict itself or leave obvious questions unanswered
- Include consideration of relevant literature, identifying successful strategies in similar situations
- Include a method to measure the effectiveness of implemented strategies over time

To illustrate how these pieces are placed into action, consider this occurrence in an Illinois hospital: In this case, a male infant, born four months premature, remained in the hospital's care for the next six weeks. The patient died suddenly after coming out of a heart operation without any clear complications from the operation itself. Upon investigating the incident, the team made the following determinations:[7]

(1) A pharmacy technician unwittingly entered information into a computer program when processing an electronic IV order for the infant, resulting in a massive sodium chloride overdose in the bag's solution.

(2) The infant received 60 times the amount of sodium chloride prescribed by a physician.

(3) The automated alerts in the IV compounding machine responsible for identifying such problems were not activated at the time when the customized bag was prepared for the infant.

(4) The outermost label on the IV bag did not accurately reflect the compound's actual contents

(5) When a blood test on the infant showed an abnormally high level of sodium, a lab technician mistook the reading for an inaccuracy.

There was an initial critical error made when the pharmacy technician entered incorrect information when processing the electronic IV order for the infant. This would have been the 'root cause', but it quickly becomes obvious that other verifications built into the system had been bypassed. These subsequent failures would be deemed 'contributing factors'. It is unfortunate to see how many factors could have initiated concern before the patient was dosed, but failed to do so. Beyond the pharmacist's check, the automated alerts built into the IV compounding machine had been deactivated. The team would certainly want to look into the reasons for that deactivation. Was this an intentional action to bypass safety measures or were there specific reasons that this feature was not being used? We see, too, that another opportunity for concern was missed when a lab technician dismissed the infant's abnormally high level of sodium as an anomaly. This, too, is a piece that the Root Cause Analysis team will want to explore as an opportunity for future improvement of the systematic checks.

In looking at cases such as the one in this Illinois hospital, it is important that healthcare professionals do not quickly dismiss the events as not being possible within their own practice setting. Experts refer to such assertions as hindsight bias, or the tendency for those evaluating an error to overestimate what they would have known, or should have known, at the time of the error.[11] Critically evaluating the policies and daily procedures at one's own facility is an absolutely critical process in moving patient safety initiatives forward.

Some hospitals, especially larger academic hospital settings, have introduced the role of the Medication Safety Officer (MSO). The MSO's responsibilities extend into every virtually corner of healthcare. Primarily, a MSO is a clinical practitioner designated by an organization to serve as the authoritative expert in safe medication use. While roles of the MSO vary from facility to facility, each MSO should be intimately familiar with the standards of care for Joint Commission, ASHP Accreditation Standards, APhA Positional Statements, and various State

Board of Pharmacy Interpretations. Some of the key words used by one facility regarding the position of the Medication Safety Officer included:[11]

- *Educator*
- *Preceptor*
- *Mentor*
- *Detective*
- *Compliance Officer*
- *Risk Manager*
- *Engineer*
- *Accountant*
- *Statistician*
- *Computer Analyst*
- *Counselor*

Facilities have dedicated personnel specifically to the initiative of medication safety, in part, because they understand the enormous costs associated with systematic error. While much of the data is obscure and difficult to analyze due to varying reporting requirements, there is one estimate for hospital pharmacies of the extra costs of inpatient care for a preventable ADE incurred while in the hospital. That figure was estimated at $5,857 in 1993! (Bates et al., 1997) Even using this antiquated and likely under-valued estimate, this yields an annual cost of $2.3 billion in 1993 dollars or $3.5 billion in 2006 dollars.[11]

Undoubtedly, patient safety is a trade-off. Management is asked to make daily decisions that hold the potential to topple the scales for patient safety in one direction or another. Among countless other things, managers find patient safety to be a delicate trade-off between:[10]

- Time
- Staffing levels
- Money
- Training
- Amount/Quality of supervision
- Hiring decisions

- Labor Relations
- Promotion Decisions
- Quality of technology
- Management style
- Macroeconomic policies

Even the country's political environment impacts patient safety initiatives! Sometimes, these are directly and more overtly impacted by policies and decisions made by those in power, which serve to topple the scale either toward or away from patient safety ideals. Other pieces introduced politically have more indirect impacts. Among other pieces, these more indirect political pieces may include:[10]

- Adjustment of reimbursement limits
- Limitation of working hours
- Ability of patients to obtain insurance coverage / medical care
- Defined limitations on professional functions

And, while political impacts are usually well intended, they can sometimes unknowingly tilt the scales in an unintended direction. As we seek to punish the person who made the mistake rather than to critically evaluate the system, for example, the system may be allowed to continue unchecked for the incident to happen again under another professional's tenure.[10] As author E.A. Bucchianeri so eloquently noted, "*Errors do not cease to be errors simply because they're ratified into law*."

There is also an unspoken paradox to medical error. This paradox lies in the fact that facilities can't charge patients more money for not harming them, but ironically, facilities can sometimes make more money from treating the harm that they have caused. The financial incentive, arguably, is not toward patient safety initiatives at all. It was this very pattern of thought that drove the United States' decision to deny reimbursement to hospitals for certain avoidable errors. These were deemed "never events" and become the financial responsibility of the institution to treat.[10]

Sadly, there are other financial conflicts of interest that serve to tip the scales away from patient safety initiatives. Physicians, for example, are community hospital revenue generators who bring business with them. Hospitals may be reluctant to question a physician's methods or outcomes in fear that the physician will take his patient population to a competing hospital.[10] Again, patient safety is inherently a trade-off. And, at times, the stakes may be high. It is important to remember that the stakes of a problematic system may far exceed all others.

Dr. Ross Koppel, in his book, *First Do Less Harm*, argues, "*Patient safety is something we strive to ensure but cannot achieve by doing any one thing, or even by improving many things. Patient safety requires fixing everything that we can think of and many more things that we do not yet know about. Patient safety efforts themselves can endanger patients' safety through conflicting or confusing initiatives or onerous reporting requirements."* [10] In short, success is said to be found atop a mountain of mistakes. And, as a profession, we have made many mistakes. Only when we critically evaluate our collective failures, perhaps, will our greatest successes be found.

An imbalanced system will eventually lead to a catastrophic event. We must ask difficult questions of ourselves. Are the original processes inadequate … or are they being bypassed in the interest of production? Can we assess our influence adequately?[11] Are we seeing an accurate representation when we peer into the mirror? And, perhaps, most importantly, *How does **our own** image appear from the patient's lens?*

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A Mountain of Mistakes: Moving from Unspoken Tragedy to Effective Collaboration -FL APPROVED-

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1a. PHARMACISTS ONLY: Does this lesson meet the learning objectives? (Circle choice).

- Identify tools and models for error reduction and patient safety advocacy YES NO
- Recognize the most significant contraindications and medication interactions for a variety of patient populations YES NO
- Recognize the vitality of workplace culture in the implementation of an effective Continuous Quality Improvement (CQI) plan YES NO

1b. TECHNICIANS ONLY: Does this lesson meet the learning objectives? (Circle choice).

- Identify tools and models for error reduction and patient safety advocacy YES NO
- Recognize the most significant contraindications and medication interactions for a variety of patient populations YES NO
- Recognize the vitality of workplace culture in the implementation of an effective Continuous Quality Improvement (CQI) plan YES NO

2. Was the program independent & non-commercial? YES NO

	Low Relevance						Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like MOST about this lesson? _____

_____

5. What did you like LEAST about this lesson? _____

_____

6. How would you improve this lesson? _____

_____

PLEASE MARK THE CORRECT ANSWER(S)

1) Advantages of Computer Provider Order Entry (CPOS) systems include:

A) Elimination of handwriting misinterpretations
B) Elimination of prescribing errors
C) Ability to avoid use of inappropriate prescribing abbreviations
D) Both 'A' and 'C' are correct
E) Both 'B' and 'C' are correct

2) Decision Support Systems (DSS):

A) Eliminate the element of human error in clinical decisions
B) Warn prescribers about drug-drug interactions that have been pre-programmed
C) Are current, with reliability rating of 100%
D) Both 'A' and 'B' are correct
E) Both 'A' and 'C' are correct

3) Given an ISMP approved measuring device for liquid medication dosing, a patient would be best instructed to take:

A) 1 tablespoonful
B) 15 ml
C) 0.5 fluid drams
D) 3 teaspoonfuls

4) Which of the following sigs contain an "error-prone abbreviation" as denoted by ISMP?

A) Take 1 tablet qod
B) Instill 1 drop OU bid
C) Alprazolam .25mg, Take 1 tablet qid prn
D) None of the above are correct
E) All of the above are correct

5) A "Root Cause Analysis":

A) Would be an appropriate step following a sentinel event
B) Focuses on the behavior of the individual that made an error
C) Is conducted by one individual, typically a person in leadership of the organization
D) Both 'A' and 'B' are correct
E) All of the above are correct

6) When analyzing a sentinel event, a pharmacist assisting with the analysis remarks, "I would have never authorized that had I been in that situation with an offline computer." This is a potential example of"

A) Hindsight bias
B) Root-Cause Analysis
C) FMEA
D) Continuous Quality Improvement

7) Errors made in the pharmacy are most appropriately reported by the pharmacy to:

A) FDA's MedWatch
B) ISMP's MERP
C) FDA's CQI
D) AARP

8) In regard to the requirements of becoming a pharmacy technician:

A) Some states do not require registration of pharmacy technicians in any manner
B) Some states recognize ASHP accredited educational programs in combination with a passing score on the PTCE exam to be an acceptable means of certification
C) Some states recognize a passing score on the EXCPT exam to be an acceptable means of certification

D) All of the above are correct
E) None of the above are correct

9) The Emily Jerry Foundation is an organization that actively seeks to:

A) Decrease pharmacy technician requirements in the interest of meeting market demand
B) Increase pharmacy technician requirements in the interest of patient safety
C) Promote compliance of USP 800 for safer working environments for employees
D) Protect the reporting of medication errors from view of the general public
E) Promote competency in prescribing standards for geriatric patients

10) Which of the following drugs should, generally, be avoided in geriatric patients?

A) Amitriptyline
B) Dipyridamole
C) Diphenhydramine
D) All of the above are correct
E) None of the above are correct

11) Which of the following medications are included on ISMP's list of "high alert medications"?

A) Insulin U-500
B) Magnesium sulfate injection
C) Concentrated potassium chloride for injection
D) All of the above are correct
E) None of the above are correct

12) The use of "Tall Man" lettering was introduced in 2008 in an effort to:

A) Identify drugs with the highest incidence of toxicity
B) Identify DEA schedule II controlled substance medications
C) Help draw attention to dissimilarities in look-alike drug names
D) Eliminate the problem of sound-alike drug names

13) A hospital policy requires that two pharmacists check a prescription for a certain medication. The overnight pharmacist, working alone, receives an urgent order for the medication. He bypasses the policy because he is the only pharmacist in the hospital at the time. This is an example of:

A) An optimizing violation
B) A necessary violation
C) A routine violation
D) A knowledge-based mistake
E) Human fallibility

14) A new pharmacy technician has been instructed that all STAT medication orders are transferred through the hospital's automated tube system. She is asked to deliver a STAT dose of a protein that is fragile and should be handled with extreme care. Unaware of this fact, she assumes that this is simply another STAT order to be transmitted through the automated tube system like the other drugs. This is an example of:

A) An optimizing violation
B) A skill-based processing error
C) Symmetry bias
D) A rule-based processing error
E) A necessary violation
F)

15) A pharmacist makes a mistake in the pharmacy and the mistake, thankfully, is intercepted at the nursing station prior to being administered to the patient. The pharmacists is given a verbal warning by his supervisor. Months later, another pharmacist makes the same mistake. This time, however, the dose is administered and results in the death of a patient and subsequent litigation. The hospital promptly ends in its employment relationship with the pharmacist who made this error. This is an example of:

A) Symmetry bias
B) An optimizing violation
C) A necessary violation
D) A routine violation
E) FMEA

16) A systematic process to identify the casual factors that contributed to the occurrence of a death or serious injury is known as a(n):

A) Sentinel event
B) Root-Cause Analysis
C) MSO
D) Survey of Patient Safety Culture

17) In regard to the reporting of errors by pharmacies:

A) Federal law requires that pharmacy errors be reported within 30 days of occurrence
B) Reporting of pharmacy errors is completely voluntary in some states
C) Reporting of errors is not advised, given concerns of litigation
D) Individual pharmacy error rates may be retrieved on the FDA's website

18) Challenges of evaluating data regarding medication errors is complicated by:

A) The lack of complete reporting
B) The absence of an ICD code for medical error
C) Varying mechanisms of collecting and communicating information from one facility to the next
D) All of the above are correct
E) None of the above are correct

19) "A systematic, organized approach for continually improving processes to deliver quality services and products" is known as a(n):

A) Contingency Based Initiative Model
B) Administration Quality Mandate Model
C) Continuous Quality Improvement Model
D) Central Quality Control Model

20) A patient taking a maintenance dosage of carbamazepine is prescribed erythromycin for a sinus infection. Which statement is most accurate?

A) These medications interact and should never be prescribed together
B) The patient's erythromycin levels should be carefully monitored
C) The patient's carbamazepine levels should be carefully monitored
D) There is no drug-drug interaction in this case