Medication Errors and Patient Safety: Lesson's Learned from Tragedy

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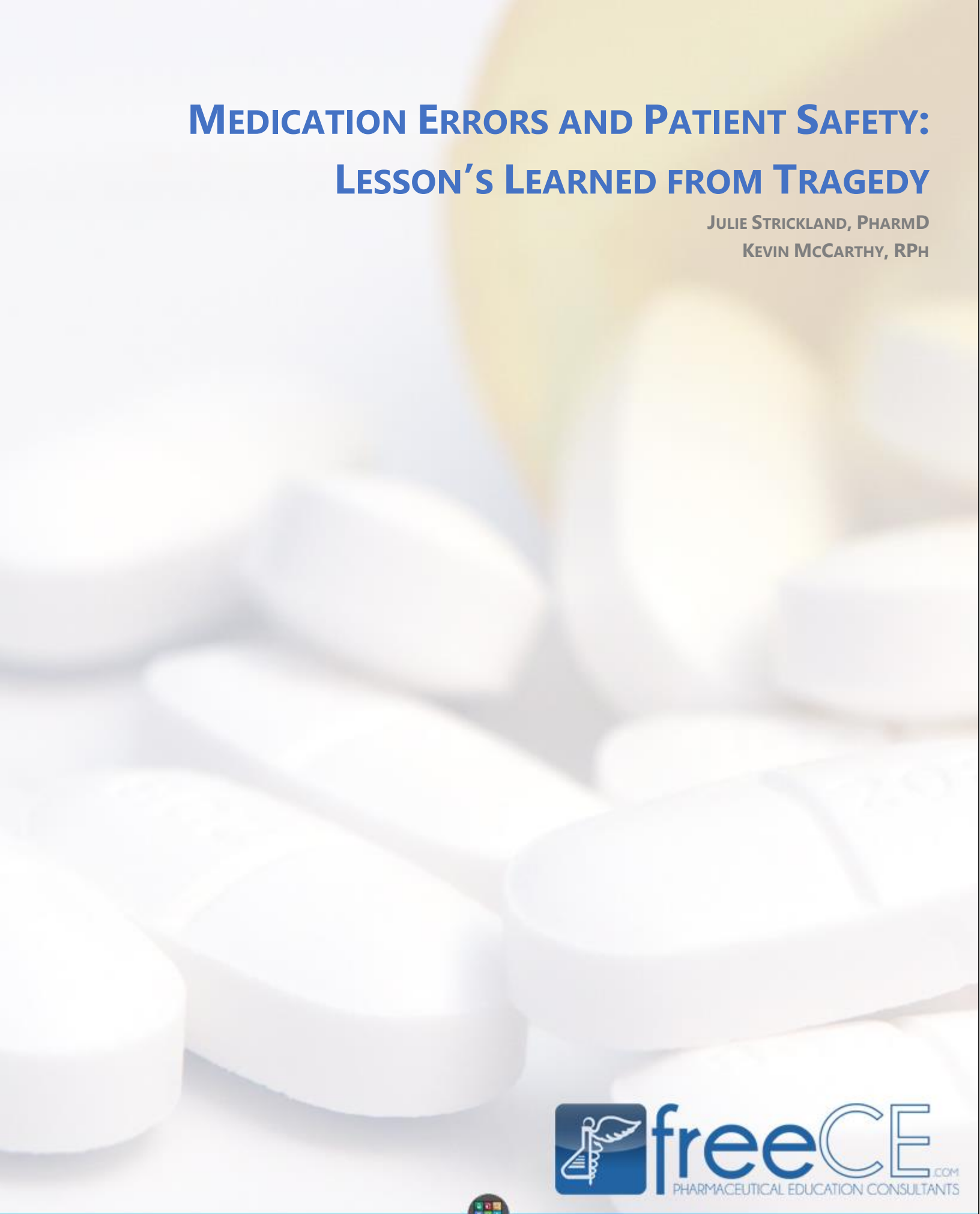

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MEDICATION ERRORS AND PATIENT SAFETY: LESSONS LEARNED FROM TRAGEDY

ACTIVITY DESCRIPTION

To provide pharmacists with an understanding of pharmacy dispensing errors, including causes and prevention. Special emphasis is placed on the State of Ohio vs. Cropp medication error case that resulted in the death of the patient. This monograph meets the Florida Board of Pharmacy criteria for medication errors credit for pharmacists and technicians, as well as credit for medication errors and patient safety in all other states requiring credit in these areas.

TARGET AUDIENCE

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

LEARNING OBJECTIVES

After completing this activity, the **pharmacist, pharmacy technician** and **nurse** will be able to:

- Describe the impact of medication errors on the health care system.
- Recognize the leading causes of medication errors.
- Identify strategies to optimize patient safety and reduce medication errors in pharmacy practice.
- Explain how Continuous Quality Improvement and root cause analysis impact medication errors
- Outline the key factors involved in a culture of patient safety in a pharmacy setting

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Universal Activity No.: 0798-0000-14-144-H05-P&T
Credits: 2 contact hours (0.2 CEU)

Release Date: September 30, 2014
Expiration Date: September 30, 2017

ACTIVITY TYPE

Knowledge-Based Home Study Monograph

FINANCIAL SUPPORT BY

Pharmaceutical Education Consultants, Inc.

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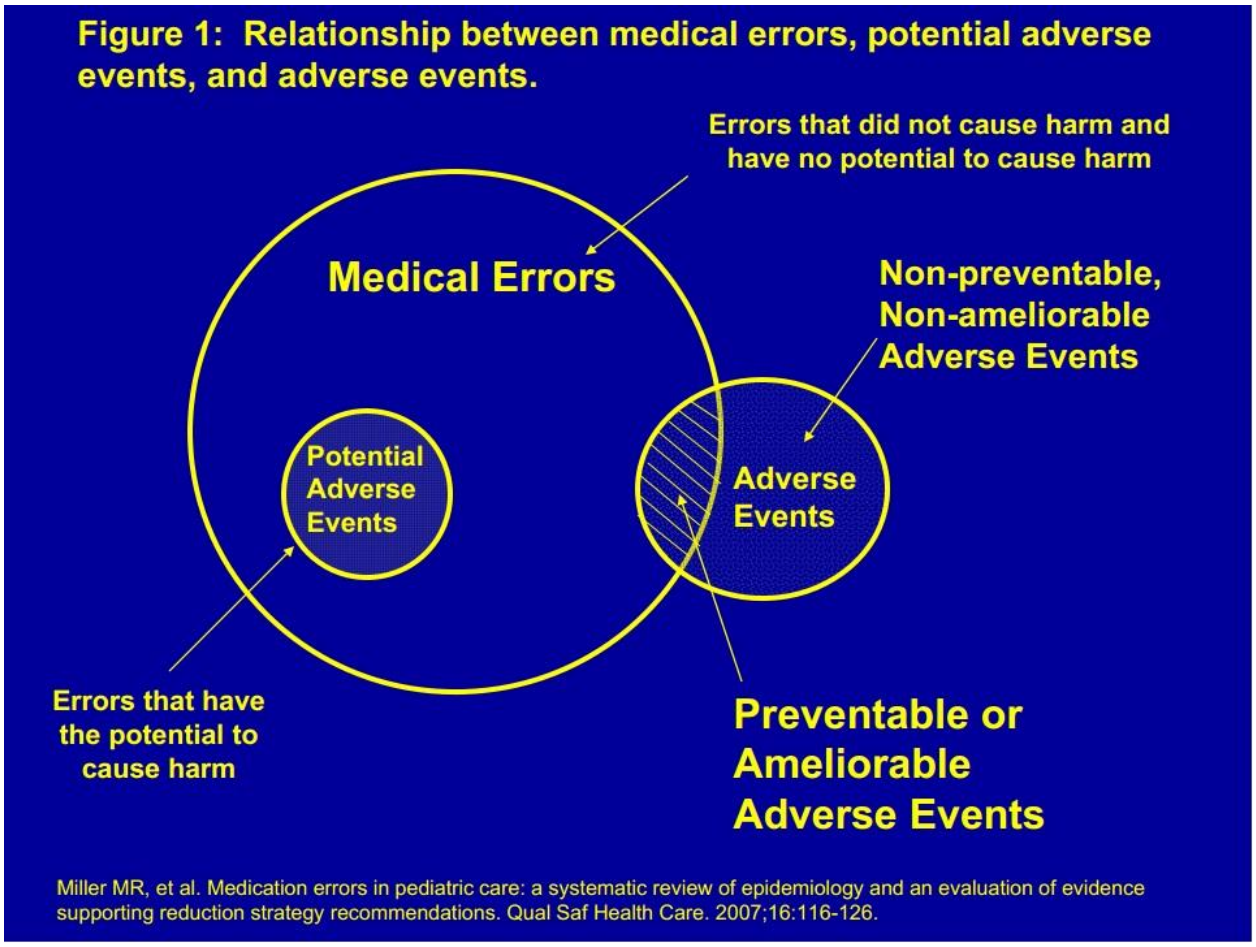
Since medication errors and patient safety are so closely connected, this monograph intends to provide an overview of medication errors including strategies to reduce medication errors and improve patient safety. Throughout this activity there will be details of the Eric Cropp case, one of the most tragic and legally bizarre cases in pharmacy history. This will be included to emphasize the real-life implications of making a medication error and the consequences of a failed system on both those who made the error and the patient that lost her life. The sad truth is that many pharmacists will be able to relate to the Eric Cropp case, as many pharmacists find themselves working understaffed in environments that lack the proper systems and controls to prevent even the most basic medication errors from happening. By identifying and reducing medication errors that occur in pharmacies, pharmacists and technicians will be better prepared to focus on the ultimate goal of optimizing patient safety.

In a municipal court room in Cuyahoga County, Ohio, pharmacist Eric Cropp awaits his fate. The small room is packed. Friends and family of both the pharmacist and the deceased anxiously await the pronouncement from Judge Brian Corrigan. It is Friday August 14th, 2009, a little over three years after a fatal overdose was administered Emily Jerry, a patient at Rainbow Babies Children's Hospital. The judge speaks and the words hit Eric like a boxer's quick punches. He is stunned into a state of disbelief. The bailiff reaches for Eric to get his attention. At that moment, Eric begins his prison term for involuntary manslaughter of Emily Jerry. Both Emily and Eric are victims of a broken system that lead to a fatal medication error.

Frequently Confused Terms

When discussing medication errors, there are three terms that are often confused or used inappropriately. Let's review the following three terms:

- "Medical Errors", which is often used to encompass all adverse health events as a result of human error.
- "Adverse Drug Event" (ADE), which is "an injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy)." [1] Adverse Drug Events may result from medication errors but most do not.
- "Medication Errors", for the purpose of this activity, are defined by the National Coordinating Council for Medication Error Reporting and Prevention as "any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer." [2] Medication errors are a subset of medical errors, as shown in Figure 1, represented by Potential Adverse Events, assuming the error is medication related.[3]



Impact of Medication Errors on the Health Care System

Recent surveys indicate that only about 21% of pharmacists are familiar with the Eric Cropp medication error. Many only vaguely remember something about a pharmacist who prepared a fatal prescription and a child died. Although the incident was well reported in local and national media when it occurred in 2006, interest in this medication error has since been regulated to legal and scholarly articles on the topic of medication errors. Additionally, since 2006, tens of thousands of pharmacists and pharmacy technicians have begun their careers and many have no knowledge of this specific tragedy.

An undercover investigation televised by ABC News in 2007 reported on errors committed at pharmacies in the United States. The report, *Pharmacy Errors: Unreported Epidemic?*, drew attention to a problem faced by many pharmacists today—the dangers associated with the proliferation of dispensing errors. This series of undercover investigations exposed the public to several tragic medication errors resulting in deaths and injuries, and in one segment stated that the retail pharmacies in their study had an alarming 19% error rate. [4] This segment did not include the Eric Cropp case.

The general public is well aware that medical errors exist and, in general, have a genuine fear of mistakes. According to a poll conducted by the National Patient Safety Foundation, 42% of respondents had been affected by a medical error, either personally or through a friend or relative, and 32% indicated that the error had a permanent negative effect on the patient's health. [5]

State boards of Pharmacy are also responding with new regulations with regards to medication errors. Florida, New York, Maryland, and Texas are among states requiring continuing education credits in medication error programs. Florida and Oregon take it to another level with the requirement that all pharmacies have a Continuous Quality Improvement committee to document and resolve medication errors. In their recent decision to add a specific requirement of patient safety continuing education to all Certified Pharmacy technicians (CPhT), the Pharmacy Technician Certification Board (PTCB) acknowledges the importance of medication errors, patient safety, and the critical role that technicians play in the preparation of medications.

The reason why medication errors are such an issue is that we are the most medicated society in history. During the next week, 4 out of 5 US adults will use prescription medicines, over-the-counter drugs, or dietary supplements, and nearly one third of adults take five or more different medications. Of that one third, the majority of them are senior citizens. [6]

While the majority of medication related errors are not serious, some can be deadly.

Just in community pharmacies alone, using an industry agreed upon dispensing error rate of 1.7% which translates into more than 30 million dispensing mistakes a year. [7]

Exact figures are varied and hard to validate due to differences in study or survey design. In 2006, the IOM (Institute of Medicine) report, *Preventing Medication Errors,* estimated that at least 1.5 million patients are harmed each year by medication errors, costing the health care system billions of dollars. [8]

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) states that some of the most common medical errors are related to medication delivery. Furthermore, a poll of 1,500 adults conducted by the National Patient Safety Foundation found that one in three Americans has been affected by serious medical mistakes. Of those, 28% are related to a medication error. [9]

Based on a study by Wolters Kluwer Pharma Solutions, U.S. outpatient pharmacies filled 3.9 billion prescriptions in 2009. Of those, about 325,000 are wrong-drug errors serious enough to cause potential harm to patients, including long-lasting injury or death. Of that amount, it is estimated that 1 in a thousand results in death, which equates to approximately 1 death per day due to a medication error. [10] However, there is a great disparity in the figures regarding

patients deaths, as the IOM reports up to 7,000 deaths per year, or about 19 deaths per day, are attributed to medication errors. [11]

With regards to hospitals, incidence rates of ADEs vary from 2 per 100 admissions to 7 per 100 admissions among the hospitals that have conducted ADE studies. [12]

Several sources agree that more than one million serious medication errors occur every year in U.S. hospitals.[13] Such errors include administration of the wrong drug, drug overdoses, and overlooked drug interactions and allergies. They occur for many reasons, including illegible handwritten prescriptions and decimal point errors.

One source estimates that medication errors result in 3.5 billion dollars in additional hospitalization cost. [14]

ADEs, medication errors and their subsequent injuries lead to increased hospital costs. Depending on facility size, hospital costs annually for all ADEs are estimated to be as much as $5.6 million per hospital.

Patients who experience ADEs have longer, more expensive hospitalizations than patients who do not suffer ADEs. Researchers found that patients who experienced ADEs were hospitalized an average of 1 to 5 days longer than patients who did not suffer ADEs, with additional costs of up to $9,000. [15]

Another study states one ADE adds more than $2,000 on average to the costs of hospitalization. This translates to $2 billion per year nationwide in hospital costs alone. In this study, this

excludes other important costs of medication errors, such as malpractice insurance premiums and losses in worker productivity. [15]

With regards to extended length of hospitalization stay, a study funded by the Federal government's Agency for Healthcare Research and Quality showed that patients with more severe ADEs such as arrhythmia, bone-marrow depression, depression of the central nervous system, seizures, or bleeding had an average length of stay of 20 days, patients suffering from less severe ADEs had an average stay of 13 days, and patients who did not suffer an ADE had an average stay of 5 days. And of course the additional days translates into higher hospital costs.

Error Rates

It is often asked, "What is the national medication error rate"? Organizations like to set standards and goals, and they like to know where they stand compared to other organizations or competitors. However, a national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each hospital or organization is different. The rates that are tracked are a measure of the number of *reports* at a given institution not the actual number of *events* or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting *reported* errors yields limited information about how safe a medication-use process actually is. It is very possible that an institution with a good reporting system, and thus what appears to be a high error "rate," may actually have a safer system.[16]

In a nationwide survey of 1,000 community pharmacists, more than half of the pharmacists reported making a dispensing error in the previous 60 days. [18] The typical retail pharmacist admitted to making an average of 2.5 errors during the previous two-month period, and 8% believed that they made more than six. About one in four pharmacists believed that his or her error rate had increased during the previous year. More than half of the pharmacists reported that they dispensed the wrong dose, and more than 25% reported that they dispensed the wrong drug. [18]

Failure to catch drug interactions and contraindications or warn of potential hazards was much less common, reported by only about 2% of the respondents. [18]

In some studies, workload and/or setting appeared to have an influence - 47% of pharmacists dispensing fewer than 100 prescriptions per day reported making an error, while 60% of those dispensing 100 or more prescriptions per day were aware of a mistake. Among independent pharmacists, about half caught the error themselves, with 38% caught by the patient or family member. Among chain store pharmacists, only 26% caught the error themselves, with 68% being discovered by the patient. [18]

Medication Errors in Hospitals

On Sunday, February 27, 2006, Eric Cropp was the pharmacist in charge of the pharmacy at Rainbow Babies Hospital. In fact, he was the only pharmacist on duty that short – staffed weekend. The previous night, the pharmacy computer was down for routine maintenance, and subsequent attempts to bring the computer back on-line failed until late the next morning around 10am. As a result, the Saturday night pharmacist was not able to prepare

base solutions needed for the next day's prescriptions. From the moment Eric walked into the pharmacy, he was hours behind in his workload, and nurses were already requesting stat medications that were overdue.

Medication errors occur in about 5% of the patients admitted each year to hospitals, and these errors can be made by medical, nursing, or pharmacy personnel. Since hospital prescriptions are "touched" by more individuals during the preparation, distribution and administration process, it is virtually impossible to compare errors rates in hospitals to those in community pharmacy.

Each hospital experiences a medication error every 22.7 hours and every 19.73 admissions. [19] One reason given for the high number of medication errors in hospitals is the conversion of medications from what the patient was on prior to admission, to equivalent medications stocked by the admitting hospital, and the administration of these different medications by non-pharmacy staff.

Medication errors that seriously adversely affect patient care outcomes occur in 0.25% of all patients admitted to hospitals/year. [19]

Each hospital experiences a medication error that adversely affects patient care outcomes every 19.23 days (or every 401 admissions). [19]

Perhaps one of the most alarming statistics with regards to the hospital setting came from the Institute of Medicine, which stated, "When all types of errors are taken into account, a hospital patient can expect on average to be subjected to more than one medication error each day." [20]

Hospital pharmacists are at a distinct disadvantage when it comes to medication errors. Unlike their peers in community practice, the hospital pharmacist is not afforded the opportunity to know their patients over a period of time, seldom get the chance to counsel their patients on medications, and often are not in close proximity to technicians who are assisting in the preparation of prescription orders. Additionally, once the medication leaves the pharmacy, the pharmacist has no control over other hospital personnel that may introduce errors into the process. Nurses, assistants, and technicians can be involved in the storage, administration and monitoring of medications, and are an additional cause of medication errors.

In the case of Eric Cropp, the above factors played an important part of the deadly sequence of events on that tragic Sunday.

That Sunday morning, a nurse repeatedly requested a stat prescription for two year old Emily Jerry for a chemotherapy agent, etoposide. This was to be Emily Jerry's last chemotherapy treatment for her yolk sac tumor. Ironically, doctors and her parents debated whether or not to have this last treatment, as her most recent MRI showed no signs of the tumor. It was as if it never existed. Although the treatment wasn't scheduled to start until later that afternoon, the nurse insisted that the medication be prepared immediately. Eric instructed a trusted technician to go to the IV compounding area and make the prescription.

Leading Causes of Medication Errors

In a study by the FDA that evaluated reports of ***fatal*** medication errors from 1993 to 1998, the most common error involving medications was related to administration of an improper dose of medicine, accounting for 41% of fatal medication errors. This makes sense as many populations,

especially the elderly and pediatrics, are sensitive to drug dosages. Additionally, patients who intentionally abuse their medications and overdose themselves also fall into this category, as well as terminal hospice patients.

Giving the wrong drug accounted for 16% of the errors. With regards to non-fatal medication errors, the dispensing of the wrong drug may be the most frequent medication error, and thus our concern with lookalike and sound alike drugs.

Giving the wrong route of administration also accounted for 16% of fatal medication errors, and this was mostly due to the IV administration of medication meant to be given IM or SQ.

Almost half of the fatal medication errors occurred in people over the age of 60. [21] Older people may be at greatest risk for medication errors because they often take multiple prescription medications and metabolism abnormalities due to compromised health status.

At Risk Patients

Pediatric and geriatric patients are two groups of patients that are at increased risk of adverse effects due to medication errors. For both groups, this risk is due to altered pharmacokinetic parameters and lack of published information regarding the use of medications in these groups. For pediatric patients, the risk also is due to the need for calculation of doses based on age and weight and the lack of available dosage forms and concentrations for smaller children. Additionally with pediatrics, and in the case of Emily Jerry, lack of body mass makes them more susceptible to an improper medication. With neonatal and some pediatrics, inability to verbally communicate adverse symptoms decreases critical response time. Due to this increased risk of adverse effects, medication errors may do the most harm in these groups.

Unfortunately, according to USP reports, more than one third of medication errors reaching the patient involved a patient aged 65 years or older. Omission errors, improper dose or quantity errors, and unauthorized medication errors were the most common types among seniors. [22]

More than 55% of fatal hospital medication errors involved seniors. Of errors involving seniors, 9.6% of medication errors were classified as *harmful*. The most harmful medication errors to seniors were wrong route, including tube-feeding liquids given intravenously, and wrong administration technique, including administration of undiluted concentrated medications.

To reduce errors, some pharmacists have established double-check systems for calculating doses for these patient groups. A variety of reference books and on-line resources are available to assist with pediatric dosing. Computer alerts can be programmed to remind pharmacists of the recommended weight-based dose for a specific medication. Some computer programs even calculate the dose based on the patient's age and weight. Keeping the age and weight of pediatric patients up-to-date can assure the proper dosing of medications.

For geriatric patients, decreased renal function can reduce the elimination of medications from the body, leading to drug accumulation in the body. Adjusting medications for renal function can reduce this risk. The pharmacist also can consider the patient's ability to adhere to the recommended therapy. Some geriatric patients may have difficulty remembering to take a medication, leading them to miss doses or take extra doses. If a patient is taking multiple medications, he or she may become confused about the indication or directions. Dosing reminders and pill boxes are available to reduce this problem.

Pharmacist Eric's morning at the pharmacy had gone from bad to worse. Shorthanded, a backlog of prescriptions, and a computer that was down for most of the morning. The only pharmacist on duty, he declined to take any breaks in his haste to catch-up on his work.

He goes into the IV compounding area, looking for the base solutions needed for compounding the chemotherapy prescription for Emily's treatment. Eric finds a 150 ml compounded bag of sodium chloride solution. To his knowledge, he thinks the solution was taken from an empty bag of sodium chloride 0.9%. While checking the bag of solution, he sees vials of sodium chloride 23.4% as well as several empty bags of sodium chloride 0.9%. Both were used in the many prescriptions compounded that morning. Because of the lack of space, everything was mixed together in the compounding area. Around him, Eric sees multiple bins containing syringes, bags and vials. He checks off on the base solutions and brings them to the technician under the chemo hood to add the chemotherapy agent needed for each compounded base. He again checks the bags and sends them off with another technician to be delivered to the oncology nurse.

Strategies to Reduce Prescription Medication Errors and Optimize Patient Safety

All low error pharmacies have a thought out system, or process, to minimize the potential for medication errors and maximize productivity, or work flow. In some pharmacies this system is the result of a trial and error evolutionary process, in others the system is planned before the pharmacy is built. It is essential that the filling process has a recognized and repeated step-by-

step systematic order. All strategies for reduction of medication errors stems from the existence of this fundamental process or system that is in place.

Prescription Review or Triage

While the potential for harm exists with every prescription, the potential is greater for some than others. Thus an important strategy in the minimizing of medication errors is a process described as prescription triage. Prescriptions for medications considered "high alert" or look alike/sound alike medications can be flagged for special attention or counseling in the prescription filling process. Additionally, if the prescription for a pediatric or geriatric patient, further scrutiny may be indicated.

Encourage Prescribers to Include a Diagnosis on Orders and Prescriptions

Even though many medications are used for "off label" purposes, including a diagnosis with a new order or prescription is one more way that a pharmacist can be alerted to a possible medication error. Let's just say that a prescription is interpreted as risperidone 1mg at bedtime for restless legs. Clearly, a transcribing error has occurred and clarification needs to be obtained from the prescriber, since there are no FDA labeled or typical off label uses for risperidone to be used in the treatment of restless legs. Commonly mistaken for risperidone, ropinirole is indicated to treat restless legs. Risperidone is not used for this purpose. Without the diagnosis associated with the order, a pharmacist may not be alerted that the medication was not the intended drug prescribed and the interpretation error could reach the patient.

Employ Effective Patient Communication

In community pharmacy environments, the most important component of patient counseling is effective patient communication. Most medication errors can be prevented, or corrected, before reaching the patient by simply spending a few minutes making sure the patient has a clear understanding of the medication before leaving the pharmacy. The following are components of effective communication:

Patient Education: A crucial step in proper communication is effective patient education. Although often pressed for time by the demands of a busy pharmacy, allowing enough time for patient consultation is a key step in both detecting and preventing medication errors. The consultation doesn't have to be technical and detailed; the information should be specific, clear, and adapted to the patient's level of understanding. It's important to avoid information overload during the patient education process!

Open-ended Questions: Another way to avoid potential medication errors is to ask the patient open-ended questions during counseling-questions that can't be answered by a simple "yes" or "no." Examples include "What did your doctor tell you this medication is for?" "How did your doctor tell you to take this medication?" "What did your doctor tell you to expect from this medication?"

Teach back method: A good way to insure that the patient understands the prescription is the "teach back" method. Ask the patient to repeat back to you the

information that was just shared. One way to approach this may be to say, "Just to make sure that I didn't forget anything important, tell me how you are going to use this medication."

Be Aware of and Avoid Common Medication Error Causes

SALA Drugs

Sound-alike/Look-alike (SALA) drugs have always presented special challenges in pharmacy. Surveys of pharmacist requesting their most troublesome SALA drug pairs often reflect medications specific to their practice setting. Often we think of these drugs when trying to decipher a written prescription order. However, the challenges associated with phone-in prescription orders are equally difficult, as English is a second language for many health care professionals and their support staff. Repeating the prescription order is essential whenever there is any doubt as to the medication being prescribed, as well as getting the initials of the person issuing the order. Additionally, if the phoned-in order is being reduced to writing on a prescription, pharmacists must be aware of their own handwriting as well. It has been the comment of many technicians that the pharmacist's handwriting is as bad as the physicians. Even the increasing use of electronic transmission of prescriptions (e-scripts) has not negated the problem of SALA medications. Many physicians operate software that utilizes alphabetical drop down list of medications, and inadvertent selection of the wrong drug or dose is easily done.

Although the FDA is working to prevent and eliminate look-alike/sound-alike medication names, medication errors still occur due to look-alike/sound-alike names. The ISMP has

developed an extensive list of confused drug names. This list contains more than 300 medication pairs that have been involved in medication errors published in the *ISMP Medication Safety Alert!* The entire list is available at www.ismp.org . A similar list is maintained by the National Association of Chain Drug Stores on its Web site, www.nacds.org. This list is a more modest list of medications encountered in ambulatory pharmacy settings.

For health care facilities, the Joint Commission also has developed a list of look-alike/sound-alike medication names. This list is available at www.jointcommission.org. From this list, the Joint Commission requires each accredited organization to identify a list of lookalike/ sound-alike medications in order to meet the safety requirements of the National Patient Safety Goals within the organization.

Abbreviations and Symbols

The use of abbreviations, symbols, and dose designations is common in writing prescriptions. Although the use of this shorthand may prove time-saving for the writer, it has been criticized as a significant cause of confusion or misinterpretation. Such abbreviations may include abbreviated medication names, such as MTX (methotrexate), MS for Morphine Sulfate or Magnesium Sulfate. In community pharmacy settings, T3 in is often meant to mean Tylenol # 3, but in hospital settings could mean liothyronine. The ISMP recommends writing the complete drug name to avoid confusion. For the complete list of abbreviations to be avoided, click on this link, http://ismp.org/Tools/errorproneabbreviations.pdf

The Joint Commission also requires accredited health care facilities to develop and publish a list of approved abbreviations, in conjunction with a list of "do not use" abbreviations, acronyms, and symbols.

Along with avoiding abbreviations, the pharmacist should avoid confusing dose designations. When writing whole numbers or medication strengths or dosages, avoid adding a decimal point with a trailing zero. For example, write "55 mg," rather than "55.0 mg." If the decimal point is not noticed, the administered dose could be 10-fold higher than intended.

ISMP also has created a listing of abbreviations that should not be used, the intended meaning, the misinterpretation, and the ISMP's suggested correction.

One of the most common dosing abbreviations that should be avoided is QD (once a day). Which although many of us use for once daily, it can be confused with QID, or for times daily. ISMP suggest writing "once daily" instead of QD.

Due to confusion caused by abbreviations, ISMP developed this list of abbreviations that should be avoided. This list basically includes most common dosing abbreviations except BID and TID.

Note that AD, AS, AU and eye abbreviations are also on the do not use list, which should help reduce the ophthalmic and otic product mix-ups.

The complete list as well as other valuable tools is located on the ISMP web site, click here to see the entire listing. http://ismp.org/Tools/errorproneabbreviations.pdf

Drug Name Abbreviations

ISMP's Error Prone Abbreviations list also contains drug name abbreviations that should not be used. Some of the more common abbreviations include HCL, intended as "hydrochloride" but could be mistaken for "potassium chloride" as the "H" is sometimes misinterpreted as "K". ISMP recommends using complete drug name unless expressed as a salt of a drug.

The use of MgSO4 and MSO4 have been especially troublesome, especially in hospital settings. Patients have died from injections of morphine sulfate and magnesium sulfate, which are both common meds in hectic emergency room settings.

ISMP recommends they should NEVER be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

Tall Man Letters

One of the newest resources on the ISMP web site is a table showing drug names using tall man lettering. http://ismp.org/Tools/tallmanletters.pdf

The look-alike drug names that are shown on the table have been modified using tall man (mixed case) letters to help draw attention to the dissimilarities in their names. Several studies have shown that highlighting sections of drug names using tall man letters can help distinguish similar drug names, making them less prone to mix-ups. The ISMP, FDA, The Joint Commission, and other safety-conscious organizations have promoted the use of tall man letters as one

means of reducing confusion between similar drug names. These drugs are FDA-approved established drug names with recommended tall man letters, which were first identified during the FDA Name Differentiation Project.[25]

One of the difficulties with the use of tall man letters includes inconsistent application in health settings and lack of standardization regarding which letters to present in uppercase. ISMP uses the CD3 rule. The methodology suggests working from the left of the word first by capitalizing all the characters to the right once two or more dissimilar letters are encountered, and then, working from the right of the word back, returning two or more letters common to both words to lowercase letters. When the rule cannot be applied because there are no common letters on the right side of the word, the methodology suggests capitalizing the central part of the word only. ISMP suggests that the tall man lettering scheme be followed when presenting these drug names to healthcare providers to promote consistency. It should be noted, at this time, scientific studies do not support the use of tall man letters when presenting drug names to patients.

High Alert Medications

High-alert medications are medicines that bear a heightened risk of causing significant patient harm if used incorrectly. These medications may or may not be associated with an increased incidence of medication errors, but all of them are associated with significant consequences if an error occurred. Some of the classes of medications in this group include narcotics, anticoagulants, hypoglycemic, antiarrythmics. A complete list is available on the ISMP web site, http://ismp.org/Tools/highalertmedications.pdf

This list is created using data from the USP and ISMP database on medication errors, input from practitioners on medications that were most frequently considered high-alert drugs by individuals and organizations, and input from the ISMP clinical staff, advisory board, and safety experts. The complete list is divided into classes of medications and specific medications associated with significant consequences if an error occurred. Of particular concern are medications with multiple formulations.

The availability of this list allows pharmacies and health care organizations to develop strategies to prevent errors with these medications. Pharmacists may consider limiting access to these medications within the pharmacy and offering training on safeguards to prevent errors to personnel who would have access to them. When processing orders, the pharmacist should pay attention to automated alerts in the computer related to these medications. The development of standardized orders for these medications also can reduce the risk of errors. When storing the product, the use of auxiliary labels on the original package also can serve as an alert to pharmacy staff as to the high-alert nature of the medication.

The pharmacy technician had prepared Emily's etoposide with three vials of 23% sodium chloride, instead of 0.9% normal saline. It is unlikely she knew that hypertonic sodium chloride was a high alert medication. When the technician was told that Emily was in grave danger because her IV contained 23% sodium chloride, she seemed confused, because to her it was saline solution. Within minutes after the administration of the lethal solution, Emily cried out to her mother, "Mommy, my head hurts". Emily went completely limp and the

nurses began to resuscitate her. Within seconds, there were doctors and nurses everywhere. Emmy was rushed to the intensive care unit as the team was urgently attempting to find out what could possibly be going so very wrong. By the time the doctors determined she was suffering from an overdose of sodium chloride, she was on life support. The next morning, the day of her second birthday, found Emily brain dead and on life support. Emily was essentially dead due to the massive brain damage she had incurred.[24]

Unceasingly Work to Improve Processes and Prevent Errors

Employees representing all job roles in a pharmacy should be involved in patient safety and the prevention of medication errors. In the case of Eric Cropp, why were there so many factors that contributed to the medication error? What processes failed and what could be done to prevent those failures from occurring again? It's easy to look back at his case and think "I would have done it differently, even if I were being rushed." But in reality, many find themselves in similar work environments. The challenge is to contemplate what you really should do differently and unceasingly work to meet standards of excellence in all environments.

Continuous Quality Improvement (CQI) and Root Cause Analysis

Many pharmacists and technicians reading this monograph are licensed in Florida. One of the requirements of an approved medication errors presentation is the inclusion of the topics Continuous Quality Improvement and Root Cause Analysis, as stated in Sec. 64B16-27.300 of the Florida Standards of Practice for pharmacists. [23]

However, everyone, regardless of which state you are licensed in, can benefit from inclusion of this topic, which not only has applications in pharmacy but also in nearly every businesses and industry.

As a reminder, Florida law requires that every pharmacy shall establish a Continuous Quality Improvement (CQI) Program which shall be described in the pharmacy's policy and procedure manual. Even if you are not working in a Florida pharmacy, consider creating your own pharmacy CQI program.

Some of the key components of this program must contain a committee made up of pharmacy staff members, and the committee conducts a review of Quality Related Events (medication errors) at least every three months.

High reliability organizations and industries, such as manufacturing and the airline industry have employed the principles of CQI and Root Cause Analysis (RCA) for decades. Applying these principles to pharmacy allows us to consistently and systematically gather information and proceed in a logical and methodical manner to determine the cause of an error, analyze how the error occurred, and what steps need to be taken to prevent the re-occurrence of the error. Even though health care is a field, like air traffic controls, where errors are highly likely to occur, we can anticipate where failures are probable and learn from those that do occur.

The beauty of CQI is that it focuses on the system or process, rather than the individual. Designed properly, it will make it easier, or natural, for the individual to do the right thing, rather than an erroneous action. Ideally, it promotes the need for objective data to analyze and improve processes.

CQI is also dynamic. Unintended variation in processes can lead to unwanted variation in outcomes. The ideal system reduces or eliminates unwanted variation. Nearly all pharmacies have their own unique specific routine or work flow. It could remain unchanged for months. However, occasionally change happens to the environment such as the introduction of new technology, such as a bar code scanner. Perhaps the addition of an additional printer has changed the normal flow of the prescription filling process. Even changing the location of prescriptions that are waiting to be picked up would be cause to reassess your current CQI system. You don't wait until a mistake or error is made because the process has been slightly altered. Continuous improvement is most effective when it becomes a natural part of the way every day work is done.

It is strongly recommend that every pharmacy has some version of a CQI program in place, even if it's just minimal. Every pharmacy has made medication errors, or will make a medication error in the future. Each error is a teachable moment, an opportunity to scrutinize your current work flow procedure and the technology you use. It's your opportunity to ask how, and why the medication error occurred. As you proceed with the root cause analysis of the error, you'll ask the "why" questions several times to fully appreciate the steps in your filling process, and how they can be tweaked to prevent a future error.

The rise in the electronic transmission of prescriptions in both the community and hospital settings has prompted many pharmacies and large employers to further scrutinize their CQI programs. As a result the HITECH Act, which calls for achievement of certain measures (meaningful use) partially through the transmission of e-prescriptions, numerous physician

practices and hospitals are changing the mode of prescription delivery to the pharmacy. Traditional delivery of a hand written and hand delivered prescription to a pharmacy is now increasingly done instantly in a computerized, digital, paperless format. While this legislation set forth a plan to improve the quality of care and enable changes in delivery systems essential to health care reform, it also created new errors not seen with traditional paper prescriptions. Despite the broad adoption of technology to improve medication safety, reports of adverse drug events in hospital inpatients continue to occur at a high rate.[2] A recent report cites poor technology design and poor integration into the clinical environment as reasons for technology's lack of impact on medication safety.[8]

For a deeper understanding of how CQI and RCA applies to pharmacy and the healthcare industry, you might want to read CQI in Health Care, probably the most sought reference on this topic.

Emily Jerry's death was not in vain. Thousands of health professionals have made changes in their practice and checking procedure as a result of this tragic accident. Additionally, all pharmacy technicians in Ohio must now be certified, as a direct result of legislation created with the assistance of the Jerry family. We urge you to visit Emily's website, The Emily Jerry Foundation, http://emilyjerryfoundation.org

Report and Share All Errors and Near Misses

Management and other staff should be made aware of all errors or near misses, even when harm could not or does not occur to the patient. In the Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report, only 42% of pharmacists (n=6,743)

responded that they agreed or strongly agreed that near misses in their organization were reported, 51% agreed or strongly agreed that errors without the potential to cause harm were reported, and 72% agreed or strongly agreed that mistakes having the potential to harm the patient were reported. In the area of near misses and errors with no potential for harm, pharmacists were the group that responded the least favorably to reporting errors when compared to other positions within a hospital organization (administration, physicians, nurses, therapists, technicians, etc.)[27] As one of America's most trusted professions, why are pharmacists so reluctant to report errors? Some may fear punishment, others fear being viewed as incompetent. Pride may have a place in other areas of life, but error reporting is not one of them. Every near miss and error should be scrutinized to gain a better understanding of the how, what, when, where, and why questions that contribute to deviance from a process intended to create a correct product or outcome. Event reporting provides extensive insights into safety and quality which can be meaningfully used to mitigate risks.[28]

Aside from reporting within the organization, errors should also be reported to a national tracking system such as the ISMP Medication Errors Reporting Program (MERP) at 1-800-233-7767 or the U.S. Food and Drug Administration's MedWatch Reporting Program at 1-800-FDA-1088. By reporting errors to a nationwide tracking service, trends in errors can be analyzed and if necessary, changes may be imposed at the level of the Food and Drug Administration (FDA) with actions such as changes to warnings and precautions of particular drugs or even letters to prescribers and other healthcare professionals to report problems with a particular drug. Sharing information is way that we can help others learn so that the same mistakes that have occurred in one practice site can be prevented in another.

Improve Patient Safety Culture in the Pharmacy Setting

From patient safety culture surveys, it is evident that there is a direct link between poorly perceived safety cultures and increased error rates.[26] The safety of the patients we serve can only be ensured when everyone involved in care is dedicated to promoting a culture of transparency, improvement, and prevention of errors. According to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network there are several key features that make up a culture of patient safety.

The first is the acknowledgement of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations.[26] Close scrutiny of the way prescriptions are received, input, prepared, checked, and delivered is essential to the safe operations of a pharmacy. Deviations from what is considered a safe process could harm a patient.

The second key feature of a culture of patient safety is a blame-free environment where individuals report errors or near misses without fear of reprimand or punishment.[26] It is easy to acknowledge that incompetence and direct negligence are rarely the cause of an error. In most cases there are many contributing factors, as in the case of Eric Cropp. It seems unreasonable that the process breakdown that contributed to the error in his case was not viewed more openly as just that, a system breakdown. Instead, Eric Cropp was thrown into a world of pharmacy board hearings which revoked his license and civil court hearings which required him to serve jail time. The fine line between blame-free and accountability is hard to define in cases such as these where death or serious injury occurs to the patient. A blame-free environment promotes error reporting and looks for process breakdown with a balance of accountability for

risky behavior. Without error reporting the cascade of negative outcomes is inevitable. In an optimal culture of patient safety, the actions of all pharmacy staff are held to a standard and the outcome is not what is judged, but rather behavior associated with the error. For example, employees skipping steps in any part of the workflow process would be accountable for their actions regardless of whether skipping the step created a negative outcome or not. Workflow is in place to prevent negative outcomes (errors) with the assumption that positive outcomes will occur as long as the established process is followed. Any deviance from the workflow is a risky behavior that is not in line with optimal patient safety. Again, error reporting is not intended to facilitate blame, but rather to seek ways of preventing the process breakdown or contributing factors from occurring again.

The third key feature of a culture of patient safety is the encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems.[26] When collaboration occurs, systems and processes can be improved and appropriate behavior can be determined. The ultimate goal of patient safety is to prevent avoidable harm by proactively identifying and mitigating risk events, conducting investigation and root cause analyses to prevent the recurrence of such events, and redesigning systems and processes accordingly.[28] Collaboration begins with open and honest communication.

The fourth key feature of a culture of patient safety is organizational commitment of resources to address safety concerns.[26] If staffing and breaks are a major concern of those who collaborate, management at an organizational level must acknowledge the safety concerns and provide the resources necessary to provide appropriate coverage in the pharmacy.

Communication failures often contribute to preventable patient harm events. [28] Without this communication and commitment, it would be difficult to implement improvements within the pharmacy. In the Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report, 6,743 pharmacists from 355 hospitals were surveyed and the findings expose just how much further we have to go toward achieving a culture of patient safety. Although 87% of respondents positively report (either agreed or strongly agreed) that their organization is actively doing things to improve patient safety, 56% of respondents felt that hospital management seems interested in patient safety only after an adverse event happens.[27] In the pharmacy setting, reduction of medication errors is the very minimal that every pharmacist can strive toward in order to optimize patient safety.

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ACTIVITY TEST

1. Adverse events can be classified as:

A. Preventable
B. Due to a medication error
C. Non-preventable
D. All of the above

2. According to a poll conducted by the National Patient Safety Foundation, what percent of respondents had been affected by a medical error?

A. 60%
B. 26%
C. 42%
D. 18%

3. Which statement regarding error rates is not accurate?

A. Error rates are determined at an organization level based on voluntary reporting.
B. Organizations with good error reporting systems often appear to have high error rates.
C. In general, pharmacists are most likely to report almost all errors and near-misses
D. Error rates at an organization are a measure of the number of reported errors, not the quality of care given or actual number of errors that occur.

4. Which of the following accounts for 41% of fatal medication errors?

A. Giving wrong drug
B. Giving the wrong route of administration
C. Administration of an improper dose
D. None of the above

5. Which group has an increased risk of adverse effects due to medication errors due to altered pharmacokinetic parameters and lack of published dosing information?

A. Males
B. Females
C. Pediatrics
D. Adults

6. All of the following are strategies to reduce medication errors except:

A. Encourage prescribers to include a diagnosis or indication on each prescription.

B. Use the Teach Back method during patient counseling to be certain that the patient understands how to properly use their medication.

C. Spend extra time with geriatric and pediatric prescriptions to review appropriate dosing before dispensing

D. Decipher handwriting by looking in the patient profile to see what was filled last month.

7. Open-ended counseling questions can be answered with a "yes" or "no" answer.

A. True

B. False

8. Challenges associated with SALA drugs include all of the following except:

A. Illegible handwriting makes it more difficult to determine correct drug

B. Differences in pronunciation can make it more difficult to verbally transmit drug orders

C. ISMP, NACDS, and Joint Commission all have created SALA lists

D. All SALA drug pairings are in the same therapeutic category

9. Which of the following drug abbreviations have been reported to cause problems?

A. MgSO4

B. HCL

C. MSO4

D. All of the above have been misinterpreted

10. What rule does the ISMP use for determining what letters are differentiated in a drug name?

A. CD3 rule

B. Consonant - vowel rule

C. Vowel plus 2

D. None of the above

11. Which of the following drug category is not a high alert medication?

A. Antivirals
B. Anticoagulants
C. Oral hypoglycemics
D. Antiarrhythmics

12. It is the responsibility of every employee to ensure patient safety and the prevention of medication errors.

A. True
B. False

13. The principles of a Continuous Quality Improvement Program includes which of the following?

A. Determine the cause of an error and analyze how it occurred
B. Actively identify methods to prevent the re-occurrence of the error
C. Anticipate where failures are probable
D. All of the above

14. When death or serious injury does not occur to the patient, Continuous Quality Improvement does not need to be employed.

A. True
B. False

15. The electronic transmission of prescriptions has virtually eliminated wrong-drug errors.

A. True
B. False

16. According to the Hospital Survey on Patient Safety Culture: 2014 User Comparative Database Report, what percentage of pharmacists agreed that near misses in their organization were reported?

A. < 25%
B. < 50%
C. > 50%
D. > 75%

17. Every near miss should be scrutinized even if the near miss did not have the potential to cause harm.

A. True
B. False

18. From patient safety culture surveys, it is evident that there is a direct link between poorly perceived safety cultures and increased error rates.

A. True
B. False

19. Key features that make up a culture of patient safety include all of the following except:

A. Collaboration to seek solutions to patient safety problems
B. Acknowledge the high risk nature of dispensing medications
C. Lack of resources to address patient safety concerns
D. A blame-free environment conducive to reporting errors

20. Skipping steps in a workflow process because of time constraints would be considered what type of behavior?

A. Outcome driven
B. Risky
C. Process driven
D. Patient Safety conscious

Please submit your final responses on freeCE.com. Thank you.