PATIENT AND MEDICATION SAFETY

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Learning Objectives

This chapter seeks to prepare a pharmacy technician to:

- list three medication safety tools in use today in the health care environment.
- describe the value of close call reports to safety.
- describe the basics of root cause analysis and its use in health care safety.
- explain the Joint Commission's role in medication safety.
- identify three examples of good topics for an Failure Modes and Effects Analysis (FMEA) project.

Introduction

Long before the landmark Institute of Medicine (IOM) report released in 1999, pharmacists and other health care providers had been concerned with the safe care of patients.[1] Patient safety is not a new concept. The literature about medication error prevention spans decades, and medication safety is a core philosophy of pharmacy practice. So why is there so much discussion about safety recently? What has changed is organized health care's approach to safety. Numerous forces in health care, including the Joint Commission (TJC), and various state and national regulations have worked to encourage organizations to take a more systematic approach. Health care organizations across the country are using lessons learned from other industries, such as aviation, nuclear power and engineering, to make patient safety a part of the daily tasks of health care rather than a separate focus.

Medication safety and medication error prevention are not strictly the domain of pharmacists. They are fundamental parts of work processes in pharmacy practice, affecting both pharmacists and technicians alike. The process of formalized pharmacy technician education and certification began, in part, out of a need for well-trained and technically competent pharmacy technicians ready to help reduce the likelihood that medication errors would occur. The skill level required for many pharmacy technician positions exceeded that which could easily be taught on the job. There was also a need to standardize the approach to technician education. More clinical and workload demands put on pharmacists increases their reliance on pharmacy technicians, specifically well-trained and qualified pharmacy technicians.

Pharmacy technicians are in a key position to recognize and report safety issues because they are often the first to notice look-alike medications, sound-alike drug names and packaging/labeling that is confusing. Pharmacy technicians are often the first to see new medications coming into a pharmacy from wholesale or warehouse orders, responsible for removing medications from pharmacy shelves and responsible for selecting drugs to be dispensed based on information presented from a pharmacy's dispensing software. Pharmacy technicians are exposed to almost every potential failure in the medication system that could occur. Therefore, it is imperative for pharmacy technicians to have a solid background in the principles of medication safety in order to work with pharmacists in preventing patient harm. Because many pharmacists in practice may not be specifically trained in pharmacy school on the underlying science involved in medication safety, by virtue of completing this chapter, a pharmacy technician may actually have more training in medication safety than his or her coworkers. Dedicated and courageous pharmacy technicians who take the initiative to speak up about unsafe conditions or hazards have made numerous first-time discoveries that contribute to the practice's understanding of safe medication practices.

Systems Approach
Medicine has, traditionally, treated quality problems and errors as failings on the part of individual providers, support personnel or single factors. The **systems approach**, by contrast, takes the view that most errors reflect predictable human failings in the context of poorly designed systems (e.g., expected lapses in human vigilance in the face of long work hours, predictable mistakes on the part of relatively inexperienced personnel faced with situations requiring complex thinking, or unregimented procedures that encourage incautious and repetitive execution of tasks). Rather than focusing corrective efforts on reprimanding individuals or pursuing remedial education, the systems approach seeks to identify situations or factors likely to give rise to human error and implement systems changes that will reduce the occurrence of errors or minimize the impact of errors on patients. This view holds that efforts to catch human errors before they occur, or block them from causing harm, will ultimately be more fruitful than those that seek to somehow create flawless providers.

Reporting Systems
One feature of a well-designed medication safety system is a **medication event reporting system**. Often referred to by different names (e.g., medication error reports, variances, incident reports, etc.), the focus remains the same: collect information on errors or events that occur in order to improve the system and prevent the same, or a similar issue from occurring. Various methods exist to report an event, ranging from online reporting, paper reporting and anonymous reporting to hotlines using voice mailboxes. No matter how the information is gathered, there are some general principles that can be followed to help make the collection program more successful.

- Safety reporting systems are based on a belief that employees do NOT come to work to hurt patients. The vast majority of safety issues are systems-based rather than caused by individuals trying to do the wrong thing on purpose. Even with violations of procedures, the safety system asks why the employee has trouble following the procedures and does not see the lack of following a procedure as the true root cause of an event. In other words, there must be something deeper than the obvious procedure violation, such as a lack of appropriate training, exhaustion of the person or an outdated or unclear procedure, etc.
- Good systems accept information from all sources. It can be conversation in a hallway, a phone report or an official incident form, but all information is considered important.
- A good system is nonpunitive to the reporter and the employee(s) involved. The information is used to make things safer; it is not used to punish employees, otherwise, no one will report events and any safety efforts are stymied. Punitive work environments are counter-productive to safety improvement because employees can be fearful of being shamed or disciplined for their involvement in an adverse event.
- In order to sustain the system, follow-up must be initiated with the reporter to alert him or her to what was learned and how the information was used to improve care. This encourages reporting because reporters see that there is value in submitting event or error information.

Spontaneous reporting systems (e.g., medication event reports) are not a numbers game. Receiving more actual event reports (and perhaps more close call information) is not necessarily a bad thing. It could reflect an improved culture for reporting what is really going on rather than a reduction in the safety of care. The **National Coordinating Committee for Medication Error Reporting and Prevention (NCCMERP)** of the United States Pharmacopoeia issued a press release that does an excellent job of explaining the perils of using medication error reporting rates to benchmark organizations against one another.[2]

Safety Culture and Leadership
There is no question that the leadership in an organization sets the tone for the safety culture. If insufficient safety resources exist, there is punishment for reporting unsafe situations or purchases

and policies focus only on short-term economics, not safety or quality, then the overall functioning of the health care system is adversely affected. With a leadership team that is conscious of fostering a culture of safety, a safety program can become part of standard practice rather than a burdensome addition to daily routines. One mindset that can cause trouble for an organization is declaring that safety is a “priority”; this may sound like a reasonable stance, but it misses the reality of how safety needs to be viewed if patients are to be protected. Saying it is a priority assumes you can juggle it around and put something else first, and that it is a separate line item on an agenda. In order to be a true safety-minded organization, safety must be a core “value” of the organization and integrated into everything that the organization does, rather than declaring it a “priority.”[3] An individual person or organization’s values form their core belief system. These beliefs are immovable, and it is expected that the person, or organization, that holds such beliefs will be uncompromising in the pursuit of such beliefs. Creating a system of values, and learning how to work with one's values, is not an overnight process; organizations, and people, must work for years to develop and refine not just their values, but how holding those values translates into decision making.

Swiss Cheese Theory

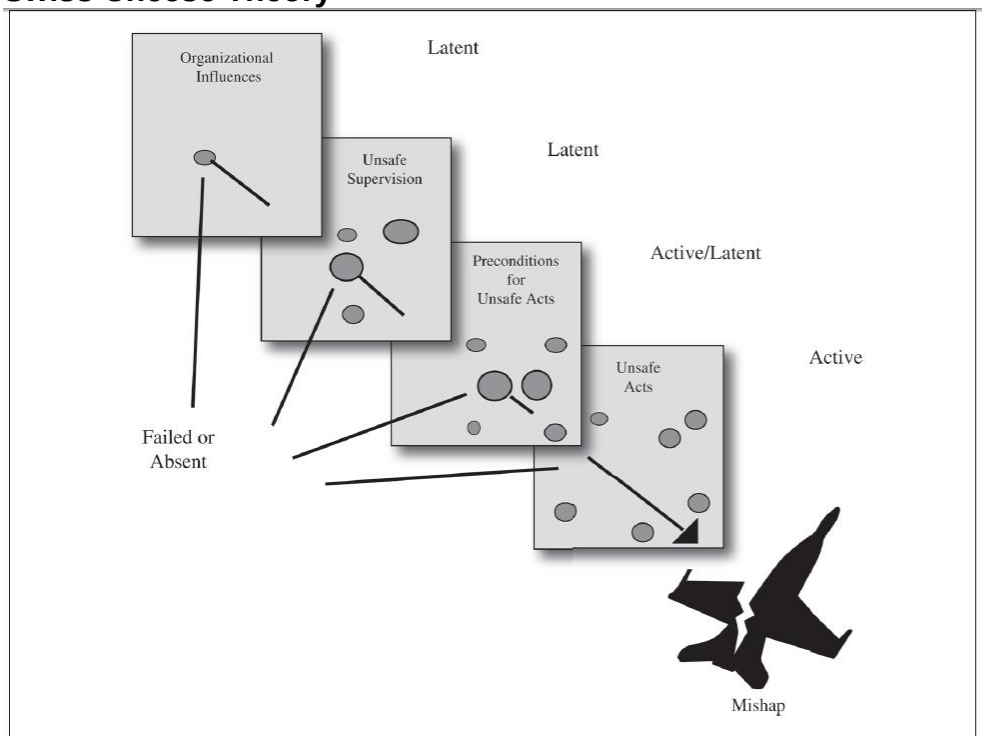


Figure 1
James Reason’s Swiss Cheese Theory of Organizational Accidents

James Reason developed what is known as the **Swiss Cheese Model of System Accidents** that can be seen in Figure 1. This theory illustrates the chance of multiple errors by examining the factors contributing to organizational accidents.[4] Imagine that there are many slices of Swiss cheese sliding past each other. The holes in the cheese have to line up just right in order for an event to cascade from a hazard to an actual accident. The slices of cheese represent systems, procedures and tasks within an organization. Each slice includes two types of holes: both latent (or passive) conditions that promote errors and active failures that occur because the conditions were right for the error to occur. A latent condition is a condition that is not itself an accident but that primes the system for failure because of its passive presence. Latent conditions are system defects such as a poorly maintained physical plant, a workplace culture that does not foster openness and transparency, or a technology that is implemented without proper training of all relevant staff members. In and of itself, there is no direct hazard in these situations existing; however, with the right trigger these conditions lead to disasters. An active failure is any action that goes awry because of a latent condition. For example, icy roads are a latent condition because they do not create accidents; however, they do contribute to accidents when people try to carry out their normal driving procedures in an environment with icy

roads. If there were no drivers, then the icy roads would just be icy roads. A driver attempting to operate a car in such conditions is required in order for the accident to happen.

A well-implemented safety program does not blame the driver for the accident; instead, it looks at the accident and asks questions about the road conditions, the vehicle and the decisions made by the driver that seemed appropriate but led to the accident. Further, each organization must decide how much of its resources will be spent addressing the decision-making processes of the "drivers" and how much of its resources will be spent in addressing the "icy roads." Back in the Swiss cheese model, spending time addressing the icy roads reduces the number and size of the holes in each slice of cheese; spending time on the decision-making processes is more about preventing the holes from lining up to allow an error to occur as each slice slides past the other slices. A well-designed program focuses on both parts of the cheese model.

Human Factors Engineering

Human factors engineering (HFE) is a discipline in science that studies the interaction of humans with and within systems. The field of HFE involves the study of factors, and the development of tools, that facilitate the achievement of the goals of reducing errors, increasing productivity, enhancing safety and improving comfort.[5] Just as microbiology is the core science for infection control, HFE is the "-ology" or core science of patient safety.

Human factors engineering professionals are employed in aviation, aerospace, nuclear power, website and software development companies, and with the federal government in any setting where interaction between the human and the system is critical for safety or efficiency. They work on equipment design (e.g., battleship control panels, cockpits, medical instruments, etc.), task design (e.g., trying to prevent workers from work-related injury), environmental design (e.g., bringing together lighting, temperature and noise control concepts) and training (e.g., better preparing the worker for working conditions through teaching, instructional design and policies).

Until recently, very few medical professionals learned about HFE in their medical training programs. This training is still not commonplace. Health care products and processes, such as the medication-use system, medical devices (like intravenous pumps and glucose meters) and information systems, were designed using the best efforts of technically-skilled professionals and designers. The design was completed based on what made sense to the individual(s) familiar with that product or the design engineer. In essence, many technologically-savvy people did the design and focused on features using the latest technology rather than collaborating with current users of the technology to ensure safe, user-friendly, intuitive integration of the technology into common practice. Often those designs did not consider the learning curve to become familiar with the system or the challenge of integrating rotating employees and students into the process and then out of the process. The design often did not factor in the appearance of buttons, labels and controls or the consistency of the new product with other products already in use. For example, those who have ever had difficulty programming or using a video cassette recorder (VCR), home theater system or cell phone have probably been the victim of a design that is focused on technology rather than on usability.

User-centered design (a design centered on humans and their capabilities and limitations) demands a more consistent, and simplified, approach to all tasks within a system. If everything had a user-centered design, then all VCR's would be configured similarly, as would all cell phones and home theater systems. There might be models that only have basic features but these basic features, regardless of the model, would always function the same way and be in the same place to ensure that anyone trained to use one VCR, mobile phone or home theater system basically would be able to use them all. Taking this idea to a more complex system, can you imagine the safety hazards if all airplane cockpits were still designed differently? Through its analysis of safety events, the aviation industry has employed human factors design concepts into aircraft and cockpit. Now, contrast that

with an intensive care unit in a hospital and observe the technical complexity. Buttons flash, monitors beep and printouts spew from the machines; but, if each of these processes and machines is designed with a user-centered model in mind, then any trained nurse, physician or pharmacy technician can know at least how to basically operate each of these machines. Unfortunately, health care has been slower than other industries to see the value in such designs, and so each intensive care unit functions differently than most others – one must be completely retrained to work in each new unit when going between facilities. Someday, a nurse will be able to work in any intensive care unit after being trained to work in a single unit, much like people walk up to automated teller machines almost anywhere in the world and know exactly what to do because they all function in a similar way. In a well-designed system, the user just knows what to do based on the simple and obvious design of the machine. Such systems are often multilingual and even include Braille so that no matter how one communicates, they can interact with these simply designed devices.

HFE can be a valuable tool to improving the medication use process. Areas where HFE could be useful include:

- the design of medication labels and packaging.
- the design of workflow.
- the design of the computer system to mimic the natural work processes of filling a prescription.
- the layout of screens in the computer system so that the correct patient, or correct medication, is easier to select within menus.
- the human computer interface for automated dispensing equipment, such as robots and counting devices, is designed to be intuitive for the human rather than intuitive for the machine.

A comprehensive discussion of HFE in the medication use process can be found in a publication from the American Society of Health-System Pharmacists entitled, “Medication Safety: A Guide for Healthcare Organizations.” This publication contains an entire chapter on HFE in medication use and is a valuable resource for any pharmacy technician seeking to be a more effective part of a safe medication use system.[6]

Root Cause Analysis

One way that HFE is used in health care is in the process of conducting **root cause analysis (RCA)**. RCA is the systematic and organized analysis of a safety event in order to determine what happened, why it happened and what can be done to prevent it from happening again.[7] Often occurring after catastrophic events in health care and other industries (e.g., plane crashes, chemical plant explosions and nuclear incidents), RCA is a formalized way to investigate the systems issues that contribute to an event. It is the backbone of most safety programs; however, industries that are safety-wise don’t wait to analyze actual events. They realize that systems learning and improvements can come from the analysis of events that almost happened but, by happenstance, never came to be. These events are often referred to as near misses but are more accurately termed close calls. Analysis of these events puts the safety learning in place without waiting for accidents, or the death of a patient, to make a change.

RCA is a “retrospective” look at an event; it occurs after the event or close call happens~~does~~. It involves the formation of an interdisciplinary team to thoroughly analyze the event and determine exactly what happened, why it happened and what can be done to prevent it from happening again. Such teams generally interview witnesses, interview the patient and interview relevant staff members. Further, the team often visits the site of the accident to get a sense of the environment in which the accident occurred. Then, the team will prepare a report discussing the system, how it failed to prevent the error from occurring and how the system can be strengthened to prevent the error from recurring.

RCA reports are generally kept confidential; however, some organizations chose to disclose their events and subsequent analysis so that others may learn from their work. As part of the accreditation process, discussed elsewhere in this manual, TJC has the right to review RCA documents on selected events known as “reviewable sentinel events”, such as inpatient suicide, serious medication errors leading to permanent harm, patient falls leading to permanent injury or death and surgeries performed on the wrong patient or the wrong part of the patient.[4] Table 1 is an example of the common elements of an RCA report.

For further information, there are examples of RCA reports posted on the Internet and published in many journals. There are also training courses available, and materials from various organizations available, to the novice. Pharmacy technicians who find themselves in a position to interact with an RCA team are encouraged to look further into this topic.

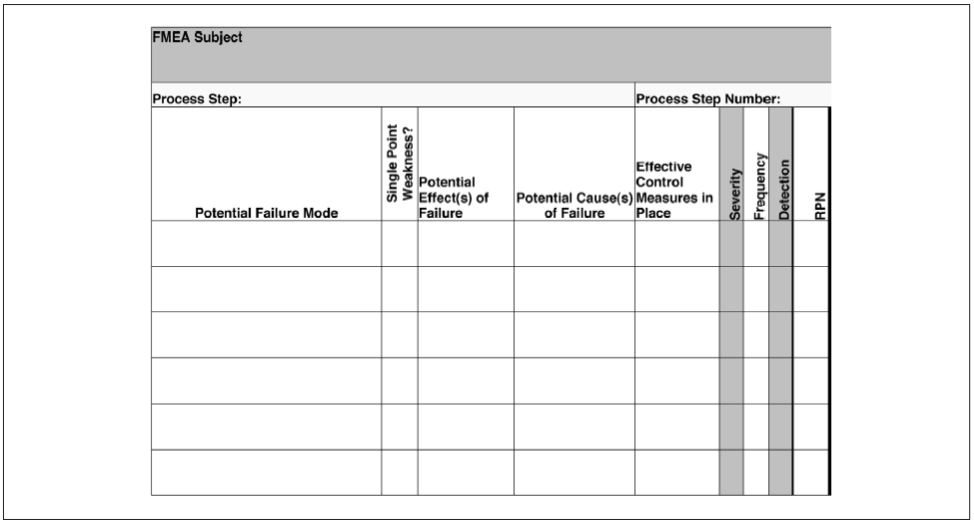
Failure Mode and Effect Analysis

Organizations interested in preventing events prospectively often conduct what is known as **failure mode and effect analysis (FMEA)**. FMEA is a proactive, prospective, technique used to prevent process and product problems before they occur. This safety tool looks not only at what problems could occur, but also at how severe the effects of the problems could be and how often they could occur. FMEA is not new. It has been used since the mid-1960s in aerospace. By the 1970s and 1980s, FMEA had gained widespread use in other fields, including nuclear and chemical power, electronics and food processing. The automotive industry also began using FMEA and has relied upon that process as an integral part of improved vehicle quality and safety.

FMEA in health care has become more commonplace since the TJC requirement to prospectively perform risk assessment was implemented in July 2001. FMEA is one method of proactive risk assessment that can be used by organizations to meet that TJC standard. FMEA is well suited to analyze the following situations:

- Implementation of a new computer system
- Patient identification in outpatient pharmacy
- Allergy information processing
- Telephone (verbal) orders from physician offices
- Restocking the robot with oral solid medications
- Patient-controlled analgesia

These topics are complex systems and tend to be problem-prone for most organizations. The emphasis is not on elimination of errors (although that is a lofty goal) but rather the prevention of harm to the patient. Systems can be made safer by reducing the frequency of errors, making errors more obvious and reducing the severity of an error. Many safety systems in place in everyday life (such as seat belts, baby safety devices and traffic safety interventions) capitalize on those factors. Typical steps in an FMEA are shown in Table 2. An example of one page of a medication-related FMEA is included in Figure 2.



FMEA Subject								
Process Step:				Process Step Number:				
Potential Failure Mode	Single Point Weakness?	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Effective Control Measures in Place	Severity	Frequency	Detection	RPN

Figure 2
Sample FMEA
Data Collection
Sheet

Medication Safety Self-Assessment

Another valuable tool in the medication safety toolbox is the task of doing a self assessment. The **Institute for Safe Medication Practices (ISMP)**, a nonprofit safety agency, has produced several **m**edication **s**afety **s**elf-**a**ssessment (MSSA) documents. The first was for hospitals in 2000. Subsequently, the ISMP produced an outpatient pharmacy tool and one for assessing the readiness of an organization to implement bar code drug distribution. In 2004, there was a follow-up survey for hospitals; and in 2005, a self-assessment for anti-thrombotic care (covering anticoagulant use) was released. Experts in the field of medication safety develop these MSSA tools and the questions come from known safety practices and a collection of events and close calls that have occurred in health care around the world. The process to complete a MSSA includes the formation of a multidisciplinary team. The team goes through the MSSA document question by question. It rates the organization on each facet covered by the question. The questions state the concept that represents the safest practice and the team decides if this is applicable to that organization; if it is, the team decides how close the organization is to having a full implementation of the practice. For example, an item such as "Medication orders cannot be entered into the pharmacy computer system until the patient's weight has been entered (weight is a required field)," is discussed among the team members and then scored as follows: no activity to implement; considered, but not implemented; partially implemented in some or all areas; fully implemented in some areas; or fully implemented throughout. Pharmacy technicians are valuable members of the assessment team given their day-to-day exposure to the exact conditions being assessed. Pharmacy technicians may also read the assessment tools to find out what constitutes best practices in medication safety and use this information to suggest positive changes in the work environment.

Once the team scores the various items, the scores are entered into a Web site and then collected and compared to other organizations based on similar demographics. The MSSA is designed to weigh certain items more heavily, and the total results are scored electronically. The participating organization can review how it does against the national average, any other organizations in its own system and how it is doing against itself over time as the assessments are repeated. Generally, organizations do a "gap analysis" to find out which areas have the biggest gaps between ideal situations for safety and the actual conditions of that organization. From the gap analysis, the organizations usually develop an action plan to close those gaps identified. More information can be found on the ISMP Web site at www.ismp.org.

Teamwork and Communication

Many studies on the factors contributing to safety events have pointed to communication failures and the erosion of teamwork. In fact, communication failure has been implicated in as many as 80 percent

of safety-related events. This has long been recognized by the military and aviation industries, where such failure can lead to catastrophic events. To counteract these vulnerabilities, the concept of **crew resource management (CRM)** evolved. Health care organizations are now beginning to use similar methods, such as **medical team training (MTT)**, to reduce communication failure and teamwork erosion related events. There are many methods, but some common elements, to conduct MTT. First, an entire workplace is trained simultaneously. The training of the staff is a large commitment of resources because often the normal workplace is closed or operates under reduced services while the workers are being trained. The theory is that after the training and repeated use that the behaviors trained in the coursework will become more automatic. Second, MTT is aimed at teaching health care professionals how to communicate with each other in a more organized and structured way. They introduce the concepts of briefings and debriefings and also teach individuals how to better state their portion of information that contributes to patient care. An important factor is teaching people how to accurately and succinctly challenge another person, even though that person might be in a higher position, or of a higher rank, than the employee doing the challenging. It also involves employees and physicians taking team responsibility for the care of patients and constantly checking each other to make sure that no one has strayed off course (lost situational awareness). By this constant checking and adjusting (course corrections), the theory is that the care of the patient will be better and safer.

Areas that typically utilize MTT include intensive care units, emergency departments, operating rooms and ambulatory clinics; but, almost any workplace in health care would benefit from the program. Within pharmacy practice, a pharmacist might be involved in MTT for the ICU or any other area where that pharmacist is a part of the medical team. Within the pharmacy itself, the MTT could be useful in those areas where there are hand-offs and high stress levels or highly technically complex areas (such as the dosing services, during shift changes and the intravenous admixture area). Pharmacy technicians can and must be part of this training if the opportunity for that training exists.

Measuring Medication Safety[9]

The organization that makes system changes for safety has the added challenge of measuring what has changed to see if there is improvement. There are whole organizations that function around implementation and measurement of change, but it is important for pharmacy technicians to have a basic grasp of the principles. Often, a pharmacy technician may be asked to collect the information needed to assess the success of the change.

There are several types of measures in complex systems.

- **Outcome measures** can be thought of as the end-of-the-road effect of a change. Has the change resulted in a better outcome for the patient such that the change reduced the overall harm to patients from adverse drug events? Think of this as the destination on a trip. Did you get where you wanted to go?
- **Process measures** are the steps taken to make changes in the systems and subsystems in the hopes that those improved steps will lead to a better outcome. When you measure a process change, it is generally measuring that the steps to perform tasks were done correctly (you can do all the steps right and still not have a good outcome). Think of this as measuring how you did on a long-distance trip. Filling the car with gas, keeping air in the tires and driving the speed limit can be measured and increase the likelihood that a traveler would arrive at a destination safely.
- **Balance measures** are performed to determine if an improvement in one part of the process has had negative consequences somewhere else. In the example of driving across the country, a traveler might choose to drive safely but take a longer route. If the individual was absent from his or her job for an additional week to get to the destination, the balance measure would be to measure if he or she was also following the work rules of his or her job. This individual might get to the destination, but may get fired in the process.

Examples of outcome measures related to medication use could include the percentage of admissions to the hospital that had an adverse drug event or the presence or absence of bleeding events during anticoagulation care.

Examples of process measures related to medication use could include the number of pharmacy interventions (clarifications or therapy changes made by pharmacists) per 100 admissions or per day and the number of times an action step was taken (as part of a procedure), such as identifying the patient using two identifiers, collecting allergy information for patients, etc. Benchmarking facility to facility or one unit against another with their spontaneous medication error reporting is NOT a good idea for a number of reasons. A higher number of reports are not necessarily a bad thing, and the reporting rate going down may be a reflection of a negative change in culture rather than a positive improvement in safety. As previously mentioned, NCCMERP has a position statement that covers this antiquated view of medication error reporting.

The Joint Commission
This nonprofit organization accredits almost 20,000 health care organizations and programs in the United States. While TJC is not a governmental agency, having its accreditation is as important as having a government-issued license to practice. Health care organizations reviewed by TJC are expected to have programs addressing any form of adverse incident that occurs. Pharmacies in organizations surveyed by TJC are particularly interested in events involving medications. If an event involves the death, or serious physical or psychological injury, a **sentinel event** has occurred. The health care organization where the sentinel event occurs may be required to notify TJC and may have additional requirements to investigate the system failure that led to such an event. TJC also requires hospitals to develop and use an **adverse drug reaction (ADR)** reporting system and use the data obtained to improve the quality of care offered in the hospital. ADR's encompass both side effects and allergic reactions. Some of these reactions are mild, but some of them may be life-threatening.

TJC also establishes **National Patient Safety Goals (NPSG's)** that are specific programs, or processes, aimed at improving safety. These are safety ideas that are generally new. Once these ideas are vetted nationally, they may eventually be incorporated into the main standards manual. Examples of NPSG include methods for dealing with look-alike/sound-alike drugs, the use of two patient identifiers (e.g., name and date of birth) before administering medication and specific processes aimed at improving the safety of verbal and telephone orders.

Drug utilization evaluations (DUEs) are performance improvement studies used to evaluate and improve drug therapy outcomes for patients. These concurrent, or retrospective, projects are a valuable part of the oversight of medication use. DUEs generally include criteria for the use of the drug, and the cases are evaluated against the criteria. DUE reports are usually presented to the committee that has oversight of medication use in the organization. That is typically the Pharmacy and Therapeutics Committee.

Safety vs. Quality vs. Risk
Many organizations do not have separate medication safety resources and, as such, have integrated medication safety activities into performance improvement (quality) activities or risk management activities. Safety is a dimension of quality but the primary focus of risk management, quality improvement and safety assurance is different. Quality improvement focuses on the performance of the organization as a whole and may look at factors other than safety. Risk management focuses on reducing risk (via reduced malpractice claims) for the organization, but it may not look at safety as a primary focus. What distinguishes patient safety is the focus on the safety of the patient rather than having the focus on the organization. Ideally, these areas work cooperatively with the end result of making things better for everyone; but, too often, the organization forgets to weigh the needs of the patient above the needs of the organization. Quality improvement, by nature, is based on

measurement of actual events, while patient safety is based on preventing events from occurring. To quote Dr. James Bagian, MD, two time shuttle astronaut and former director of the Veterans Health Administration National Center for Patient Safety, “Not everything that matters can be measured; and, not everything that can be measured matters.” For example, rare safety events are often the once-in-a-lifetime confluence of events, not something that happens with any regularity. To say that the organization will “measure” to be sure month after month that the event has not happened again is nonsensical since, even by leaving the situation as is, it might not recur for five or 10 years. It doesn’t mean that you don’t fix what is known to be broken, but outcome measurement may not be a useful tool in that circumstance.

Imagine a large organization, with high prescription volume, that aims for a ”safety goal” of no more than 3.4 errors per one million prescriptions filled. One of the ways that an organization can determine such a goal is to find an average error rate for similar conditions and then try to be better than that average. A particular scheme for doing this is called the **6-Sigma method**; to achieve 6-Sigma means that the organization's level of performance is an adjusted six standard deviations from the mean performance. The traditional symbol used in statistics for standard deviation is the Greek letter sigma (σ). Although the computation of standard deviation is complex, and not applicable to this chapter, one must understand that the more standard deviations away from the average one gets, the more exceptional one gets. Further, to be six adjusted standard deviations away from the average (under normal conditions) translates to having only 3.4 errors for every million events. This is a great quality goal; however, if the organization fills three million prescriptions each week, then they could be harming 10 patients each week with a 3.4 errors/million rate. Achieving a 6-sigma level of performance does not assure all the patients are safe because, while the organization is performing remarkably well as a system or factory, from the patient safety perspective, 10 patients would dispute the safety record and tell you there are still improvements to be made.

Look-Alike/Sound-Like Drug Names (Confused Drug Names)
One of the most common factors in medication errors are problems with look-alike and sound-alike drug names and packages. Look-alike medication names can be problematic because humans often have trouble regularly discerning one name from the other when only a few characters differ. This is problematic for drug names within a class of medications such as benzodiazepines that often end in –am, or beta blocker medications that often end in –olol, or the myriad of drugs beginning with chlor- or meth-.

In the science of language and communication, there are fields of study that evaluate the similarity between words. **Phonology** is the study and measurement of the sound similarity of words. **Orthography** is the study of the similarity of the visual appearance and spelling of words. Those who study these topics are generally called upon to help industries, including health care, develop tools to minimize the impact of sound-alike/look-alike names. Further, most drug companies will design a brand name for newly developed products that attempt to avoid such errors. Occasionally, these efforts fail and a drug is forced to change its name due to errors that happen at an unacceptably high rate. One such example is the drug now known as Lovaza.® It was once known as Omacor®; however, that sounded, and looked, too close to Amicar.® So, the manufacturer successfully changed the product's name in collaboration with the FDA.

Packaging also plays a large role in drug mix-ups. Some companies produce products that are so similar that it makes it very difficult to discern one product from another. ISMP continues to work with the pharmaceutical industry and the FDA to improve the readability of the drug package labels. Further, ISMP has helped to create innovative ways to make packaging distinct for each drug and strength of drug available. Although the pharmaceutical industry has made great strides in recent years to assist in preventing mix-ups due to packaging, the ultimate responsibility for preventing these errors lies with each health care organization. Pharmacy technicians are in a unique position to

identify those drugs that are most prone to error and work with the entire pharmacy team to minimize errors related to these drugs. One strategy is to make sure that these drugs are physically separated from each other on pharmacy shelves. Another is to flag both drugs with a bright-colored sign alerting staff to the higher possibility of an error. One safety strategy that is already being employed by some pharmaceutical companies is the use of “tall man” letters on commercial labels. The name “tall man” refers to highlighting differences between commonly confused words by writing the letters that are different in all capital (tall) letters and leaving the similar parts in lower-case letters (e.g. topAMAX vs. topROL XL, DOBUTamine vs. DOPamine).

High Alert Medications

Year after year, there are a number of medications that continue to be involved in medication events that cause harm to patients. The ISMP has established a list of those medications that are continually involved in injury-related medication events. Those medications are called “High Alert” medications to signify that the consequences of misuse of the medication will more often result in an injury. The actual incidence of error is not more common with high alert medications, but the result is more severe than errors with other drugs. Additionally, because some high alert medications are also frequently used medications, several therapeutic categories appear as most frequently involved in injury. The usual top three most commonly associated with injury are insulin products, anticoagulants and narcotics.

The high alert medication list, which is updated every few years, is established through data drawn from reporting systems and through professional consensus. The updated list of these medications may be found on the ISMP website at www.ismp.org. The list began with medications commonly used in acute care hospitals, but there is ongoing work to develop a separate list more applicable to ambulatory care. If an ambulatory care list is released, it would be located on the ISMP website also.

Medication Safety Organizations

The National Patient Safety Foundation (www.npsf.org) is not only a patient safety organization itself, but it has compiled links to nearly all of the active, relevant, patient safety organizations that exist. A sampling of the organizations recognized by NPSF can be found in Table 3.

The Pharmacy Technician’s Role

Because pharmacy technicians are so crucial to the medication-use system, pharmacy technicians are crucial to the medication safety system. As illustrated throughout this chapter, medication safety impacts everyone in the medication use process. Pharmacy technicians are often the first in a pharmacy to encounter potential problems and in a unique position to recommend strategies to minimize the risk of errors. Some simple ideas that can be used to improve medication safety can be found in Table 4.

Conclusion

Pharmacy technicians are in a position to participate in medication safety activities regardless of their area of practice. The first step is being aware that, as a pharmacy technician, there exists a responsibility to be aware of potential errors and how to avoid them. This awareness will help foster a work culture that is rooted in patient safety and that encourages everyone to participate in keeping patients safe. Although the ideas in this chapter do not represent the entirety of the information available on patient safety, this chapter is a starting point that can be used to begin to transform workplaces into ones with patient safety built into every health care decision.

References

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Review Questions

1. Which of the following type of investigation must be performed by a hospital, accredited by TJC, after a reviewable sentinel event occurs?
    a. Failure mode and effect analysis (FMEA)
    b. Medication safety self-assessment (MSSA)
    c. Root cause analysis (RCA)
    d. Medical team training (MTT)

2. Which of the following is the science that studies the interaction of humans with and within systems?
    a. Psychometrics
    b. Human factors engineering
    c. Sociology
    d. Genetics

3. Which industry is most often used as a good example of safety improvements?
    a. Aviation
    b. Law enforcement
    c. Metallurgy
    d. Food manufacturing

4. Which patient safety organization listed below has published self-assessment tools that a pharmacy can use to determine, not only how their current practices compare to ideal safety practices, but also what a pharmacy can do to move towards implementation of these goals?
    a. The National Quality Forum
    b. The National Council on Patient Education
    c. The Institute for Safe Medication Practices
    d. The Institute of Medicine

5. Which of the following is one way a pharmacy technician can improve medication safety?
    a. Not telling anyone about dispensing errors that never reached the patient
    b. Scouting for look-alike and sound-alike medications

c. Not listening to patient complaints
d. Doing jobs for which you received no training

6. Which of the following potential drug mix-ups might be prevented if tall-man letters are employed on each drug's packaging?
    a. Apresoline® v. Atarax®
    b. Oxycodone® v. Oxycontin®
    c. Lipitor® v. Zestril
    d. Metoprolol v. Amlodipine

7. All of the following drugs are considered high alert medications by ISMP, EXCEPT:
    a. Warfarin
    b. Lantus®
    c. Morphine
    d. Azithromycin

8. In the quality measure and evaluation system known as 6-sigma, to achieve a 6-sigma, the error rate must be at (or be better than):
    a. 1 error per 1000 events
    b. 3.4 errors per 10,000 events
    c. 3.4 errors per 1,000,000 events
    d. 1 error per 1,000,000 events

9. Which of the following combinations is at greatest risk for a “sound-alike” error?
    a. Xanax® v. Zantac®
    b. Zocor® v. Cozaar®
    c. Amoxicillin v. Cephalexin
    d. Mirthazapine v. Fluoxetine

10. An adverse event reporting system in a hospital captures data on which of the following?
    a. Side effects experienced by patients
    b. Allergic reactions experienced by patients
    c. Both of the above
    d. None of the above

Table 1
Elements of RCA

Element	Description
Event descriptions and flow charts	A description of what is known initially and the final understanding after a thorough analysis (time lines are often included)
Immediate actions taken	A description of what was done to contain the situation or help the patient right away before the analysis can occur
Resources used	What sorts of records and documents need to be reviewed for information
References consulted	A search of the literature to determine how often this has been reported and various methods of prevention of further events
Lessons learned	Knowledge gained along the way that may or may not have direct applicability to the event but which is important to pass on to others
Root cause/contributing factors identified	A listing of those things that failed to prevent the event and those things that enabled the event to occur (this is one area where HFE is helpful).
Action plans that facilities will implement	These are the organization's detailed plans to prevent future occurrences. Action plan design is another area where HFE is useful. Emphasis must be placed on hard fixes (like physical plant changes or redesigns vs. policy and procedure updates or more training).
Outcome measures that evaluate the effectiveness of each action	The method to measure and evaluate how effective those fixes have been

Table 2. Typical Steps in an FMEA[8]

Step	Description
Select a high-risk process and assemble a team	A topic is picked by the organizational leadership and an appropriate multidisciplinary team is selected (three to eight individuals).
Diagram the process	The steps of the process, as they actually occur, not how the procedure says they should be, are flow charted.
Brainstorm potential failure modes and determine their effects	Team members postulate how the process could fail no matter how off the wall the failures seem. Each failure mode developed must have a resultant effect of that failure mode. This portion examines what could happen.
Prioritize failure modes	Each failure mode is hazard scored for: • severity. (How severe is this failure to the system?) • detectability. (How easy is it to identify it before it happens?) • occurrence, probability or frequency. (How often would this failure occur?) These factors are scored from 1-10 and multiplied together to determine a criticality score. The higher the score, the more critical the failure mode.
Identify root causes of failure modes	For each failure listed, there is an accompanying cause or causes of that failure. This step identifies why the particular failure occurred.
Redesign the process	Using HFE concepts and systems theory, the system is redesigned to decrease the criticality
Analyze and test the new process	The team completes step 2, 3, and 4 of the new process and then pilot tests the changes. The criticality must be lower for the redesigned process.
Implement and monitor the new process	The new process is implemented, and its success is regularly measured

Table 3. Select Medication Safety Organizations

Organization	URL	Description
Institute for Safe Medication Practices (ISMP) Also visit their consumer medication safety page: www.consumermedsafety.org	www.ismp.org	The ISMP's newsletters and this Web site are some of the most complete reference sources for information about medication errors.
National Coordinating Committee for Medication Error Reporting and Prevention (NCCMERP)	www.nccmerp.org	This group includes representatives from a number of organizations. It publishes statements and information and it is linked to the United States Pharmacopeia, which is a drug standards organization.
American Society of Health-System Pharmacists (ASHP)	www.safemedication.com	This site includes information on medication safety geared for consumers.
Food and Drug Administration (FDA)	www.fda.gov	This Web site is a comprehensive source of information about drug safety. Any recall information and actions by FDA (such as seizure of counterfeit medications) can be found here. Additional detailed information can be obtained via a Freedom of Information Act (FOIA) request.

Table 4. Ideas for Improving Medication Safety

- Speak up. If unsafe working conditions are noticed or if orders/procedures do not seem to keep the patient's safety as the main focus, alert management and continue to pursue them until all concerns are addressed.
- Communicate with patients. Although the entire health care team is part of the safety net intended to keep patients safe, patients themselves are the last line of defense in preventing harmful medication errors. Encourage patients to ask questions, to be aware of changes to their medications and to consistently tell the entire health care team about all of their medications.
- Listen. The entire health care team, not just pharmacists and pharmacy technicians, are part of safe medication delivery. Be sure that safe medication practices include input from the entire team.
- Volunteer. Rather than leave the work of improving current procedures to someone else, volunteer to work on safety issues.
- Read and distribute. Whether it is the ISMP Newsletter or one of the many other publications on medication safety, keep up on current ideas for keeping patients safe and share them with colleagues.
- Be proactive. Always be on the lookout for new look-alike and sound-alike medications and be prepared to implement strategies to minimize errors involving these medications.
- Rest well. Come to work rested and healthy and take your breaks. Exhausted workers are much more likely to make mistakes.
- Don't give up. If a work environment is unsafe, find one where safety is considered more important or keep working with management until the environment is safe.