"Part 1: Medication Error Prevention Update"

March 2013

This is our biannual lesson on "Medication Errors." It's been divided into two portions. In this lesson we describe the outdated culture of punishment. Additionally, we discuss Root Cause Analysis & take a look at a couple of cases involving drug errors. In Part 2, we will review techniques & considerations for lessening medication errors.

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the problems presented by the culture of punishment as a response to medication errors.
2. Discuss the lessons that can be learned from recent cases associated with medication errors in pharmacy.
3. List the requirements of a Continuous Quality Improvement program.
4. Explain steps that can be taken to comply with a board of pharmacy CQI program.

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To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

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MEDICATION ERROR PREVENTION FOR PHARMACISTS: UPDATE

Pharmacists are human beings and human beings make mistakes. There is simply no avoiding this reality. Pharmacists try hard not to make mistakes. But imperfection is a part of the human condition and pharmacists are not perfect. This is the message we were all told many times as we grew up, when a mistake we made was met with the comforting response, "nobody is perfect." Medication errors by pharmacists are inevitable, although they certainly are undesirable, unpleasant and sometimes tragic. Pharmacist errors must be addressed in a systematic way to avoid harm to patients. Simply telling pharmacists to "be more careful" will not work. Pharmacists are already careful. But they are human and they just can't help making errors, particularly in the contemporary pharmacy practice setting where there is considerable stress, high prescription volume and countless distractions.

Dr. James Reason, and other experts who have studied errors made by health care professionals, have concluded that human error is "normal" in health care. In saying this, they do not mean that error is welcome, or that it is of no real consequence. In concluding that error is "normal," these experts are saying that the inevitability of human error requires that it be planned for in the sense that systems must be developed to identify, absorb, and prevent error. Human errors can be forgiven, but the failure to implement institutional procedures to prevent foreseeable errors cannot be forgiven. There is a difference between the pharmacist who has erred despite having done everything possible to prevent the error, and the pharmacist who has erred without having implemented any error prevention strategies in that pharmacist's practice.

THE OUTDATED CULTURE OF PUNISHMENT

Pharmacists are responsible health care professionals. When a responsible person makes an error, traditional thinking has been that the appropriate reaction is to punish the erring person. This can be done through action taken against a pharmacist's license, by discipline within the pharmacist's workplace, or via malpractice litigation. The culture of punishment in pharmacy is gradually being replaced with a culture of forgiveness and improvement, yet this is a slow process. Pharmacists who have been associated with an error are often still confronted by those who want to single out this pharmacist as the sole culprit, based on the outdated notion that "the buck stops here" and that a responsible pharmacist should be chastened into doing better in the future. In many ways, the oft-repeated saying attributed to a king of old, "the floggings will continue until morale improves," can be applied to punishment meted out after a pharmacy error.

To be responsible connotes that one is in a position to respond when goods or services are provided to another person in a way that indicates the possibility for harm occurring to the person (a patient, for example) who receives the goods or services. A pharmacist is in a position to respond when the final check of a prescription by the pharmacist indicates that the patient is about to receive the wrong drug, or the right drug in the wrong strength, or the right drug in the wrong dosage form, or that the directions for use are incorrect. A pharmacist is also in a position to respond when the accurate processing of a prescription, exactly as the prescriber has issued it, could cause harm to the patient through a drug-drug interaction, the emergence of a common and severe side effect, or any other adverse effect that can be foreseen by the pharmacist. This is what responsibility of the pharmacist means.

When a bad outcome like an adverse drug event occurs after the provision of products or services by a responsible pharmacist, the pharmacist will be held accountable. To be held accountable means that a pharmacist must provide a description by way of explanation. This

accounting will be evaluated by pharmacy management, a group of peers, an administrative agency, or a jury. The accounting may be judged completely acceptable, and the conclusion will be reached that the pharmacist met her or his responsibility despite the occurrence of an unfortunate, but unpreventable, bad outcome. Simply because something did not work out well does not mean the pharmacist failed to meet a responsibility. Alternatively, the accounting may be judged unacceptable based on the conclusion of the evaluators, and had the pharmacist acted appropriately the bad outcome would not have occurred. This is the process through which accountability is developed after responsibility has been established. The principle of accountability assures that pharmacists will be given the opportunity to provide an explanation after there is harm to a patient that may, but also may not, be the result of a failed responsibility.

The next step in the outdated culture of punishment is to ascribe culpability to a responsible person whose explanation by way of accounting is not judged acceptable. Culpability designates as blameworthy the responsible person whose explanation has failed to justify exoneration. Blame carries with it connotations of unworthiness and carelessness. Sometimes referred to as the "blame and shame" approach, the outdated culture of punishment usually singles out a specific person, the person closest to the error, and designates that person as the sole culprit in the production of the bad outcome. To borrow a sports metaphor, it is similar to the scorer in a baseball game who identifies the shortstop as the erring player after a muffed play. The coach may have instructed the shortstop to play the position too deeply or too shallow, the catcher may have called the wrong pitch, the pitcher may have thrown a poor pitch, or the hit ball may just have spun in a completely unpredictable way. Regardless of whether the shortstop did everything that humanly could have been done to prevent the error, or that any other competent shortstop could have made the same error, the scorer will blame the shortstop. It is a rule of the game. Fortunately for the shortstop, baseball is only a game. No such luck for the erring pharmacist. When a pharmacist muffs a prescription, the patient may die.

The last step in the culture of punishment is liability. A culpable pharmacist may be liable for discipline by a licensing agency, for professional malpractice, and under very rare circumstances may be criminally liable. Liability is a step that is essentially a determination of causality. A responsible pharmacist, whose accounting is unacceptable, and who is determined to be culpable, will be liable only if the patient's harm would not have occurred in the absence of the pharmacist's inappropriate conduct. If the patient's harm was the result of other factors, such as the patient's underlying disease, or the failure by the patient to use medications as instructed, then the pharmacist will usually not be held liable.

There are several advantages of punishment as an approach to addressing error. Punishment is quick and easy. It appears to be responsive to societal requirements that wrongs be righted, and it may mollify the vengeful patient or the patient's family. In theory, punishment can serve as a deterrent to careless pharmacists who become more careful for fear that their errors may lead them to liability. On the other hand, punishment has its disadvantages. It really does not work because pharmacists do not need an additional incentive to avoid errors—they already try their best to avoid errors. Non-volitional errors cannot be deterred through threats of punishment, because threats require that a volitional choice be made to effectively deter errors. Since pharmacists do not choose to make mistakes, the threat of punishment is not an effective deterrent. Punishment has the disadvantage of deterring risky but beneficial therapies (like anticoagulation or pain management, for example) that are necessary to promote good

outcomes for patients but may lead to problems if done erroneously. Finally, punishment leads to the cover-up of errors and the loss of opportunities to develop error reduction techniques.

A famous story is told of a tragic airline crash that could have been avoided had federal airline authorities not supported a culture of punishment at the time the crash occurred. According to the story, a TWA flight was approaching Washington Dulles Airport, and had followed directions to navigate to a particular place in preparation for landing. The directions given by air traffic control were confusing and the captain went to the wrong place. As the airplane descended through clouds, the sky cleared and it became obvious that an error had occurred because the airplane was about to crash into a hill. The pilot corrected the error and the airplane landed safely. Shortly thereafter, the captain posted a notecard in the crew break room in St. Louis, advising his colleagues of the potential confusion in that approach to Dulles Airport, and instructing them on the appropriate way to make the approach safely.

Several months after this near-miss, a USAir captain made the same mistake, going to the wrong place in the sky, but this time the cloud cover was lower and the mistake was not recognized in time. The airplane crashed into the hill and all on-board died. In their investigation, federal agents learned of the notecard posted in St. Louis. They located the captain who had posted it, and asked him why he had not brought this problem to their attention. The agents accused the captain of causing the USAir crash by not reporting his near-miss, and pointed out to him that federal law required reporting of all flight errors. The captain explained to them that their policy was to punish those who made mistakes, even if the mistake had led to a near-miss rather than a crash, so out of self-preservation he had decided not to report it. The federal authorities learned from this experience. They abandoned the culture of punishment and encouraged flight crews to report errors so the system could be fixed and future errors prevented. As a result, reports of piloting errors have risen dramatically and the system has been improved, with a significant reduction in lives lost due to pilot errors. The health care regulatory system, and more specifically the pharmacy regulatory system, has followed the model of aviation. It has adopted continuous quality improvement rules that mimic the lesson learned in aviation.

ROOT CAUSE ANALYSIS

A system is a combination of parts incorporated into a unitary whole, with coordination of inputs and outputs to achieve established goals. Traditionally there has been no comprehensive system of pharmacy practice. Each practice site has either developed its own system or has muddled through without a system. Many factors with which pharmacists must deal present significant challenges to a systematic practice of pharmacy. Orders from physicians to pharmacists are often unclear. Physicians are often unavailable to clarify these orders. The names of drugs ordered are similar and are easily confused with each other. The packaging of stock bottles of very different drugs is very similar, and the traditional way to organize stock is to place look-alike, sound-alike drug containers right next to each other. There are no clear standards for the management of potential problems such as drug-drug interactions or drug-disease contraindications, and computer systems over warn pharmacists about potential problems of a trivial nature. In many states there are no standards for pharmacy technician training. Patients believe that the best pharmacy is the fastest and cheapest pharmacy. Third party payers constantly seek ways to compensate pharmacies at lower and lower levels, while they establish administrative barriers for pharmacists who want to do the right thing for their patients. Given the many system problems, it is a true wonder that pharmacists make so few errors.

Despite a strong record of success in practice and empirical evidence that pharmacy errors

are quite low, the public expectation of pharmacists is one of perfection, and the profession strives to achieve that unreachable goal. No pharmacy is satisfied that it makes only very few errors or that only a tiny percent of its patients are harmed by pharmacy errors. Pharmacies take a systems view and look for ways to eliminate errors that can be controlled through system improvements. Within this activity, management works on the system to provide tools, training, equipment and materials. Pharmacists and other pharmacy personnel work within the system to follow established procedures and evaluate how the procedures work and when they should be changed. It is teamwork that makes the systems approach effective. Management cannot rely on pharmacy personnel to solve all of their own problems, and pharmacy personnel cannot wait for management to bring them solutions on a silver platter. Together they can achieve at a level that would be impossible to reach separately.

Case Studies In Pharmacy Error And Quality Improvement

Case studies drawn from actual litigation against pharmacies and pharmacists provide an opportunity to learn how errors may occur in pharmacy, and what can perhaps be done to improve pharmacy systems to avoid similar errors in the future. Two of these case studies are reviewed below, not to cast aspersions on the pharmacists involved, but to promote a better understanding of how pharmacy errors occur and how they can be prevented through system improvements.

Case No. 1: *Bookman v. Ciolino* (Louisiana, 1994)

The patient in this case had been prescribed two drugs, Restoril and Prozac. The pharmacy filled both prescriptions, and allegedly placed the intended contents of each prescription in the vial of the other. Thus, the patient took Restoril according to directions for Prozac, and vice-versa. After being hospitalized and recovering, the patient sued the pharmacy contending that the pharmacists were overworked and that the error occurred due to the stress caused by their being overworked. The court noted as follows:

> *"In 1990, three full-time pharmacists were employed at C's, with Steven Ciolino filling in part of the time. The drugstore filled about 800 prescriptions per day. Based on the average eight-hour day, counsel for the plaintiff figured, and Skinner agreed, that the average number of prescriptions filled per hour was 28.5, or one prescription every 2.1 minutes. This took a great deal of concentration, and if interrupted during the process, he would have to start over again. He was often interrupted to answer questions or to answer the telephone."*

The court ruled in favor of the pharmacy in this case, based on confusing testimony from the patient that suggested she was the one who had switched the medications and not the dispensing pharmacist. Nevertheless, the case stands for the important lesson that distractions can cause errors and pharmacy practice sites should be designed to avoid unnecessary distractions. Fortunately, the intervening two decades have produced technological innovations that make it less likely that interruptions will adversely affect the quality of a pharmacist's practice. Nevertheless, the problems created by distractions continue to be a challenge for pharmacists who develop error-reduction strategies.

The court also made an observation about the manner in which prescriptions were processed at the pharmacy:

> *"When filling a prescription, Skinner would first receive a computer-generated, three-part label; he would then read the prescription to check for accuracy of the information. The first*

portion of the label is attached to the prescription; the second part of the label contains refill information and the pharmacist's name along with the name of the medication, directions, etc. Skinner would then get the medicine, bring it to the counter and check it against the prescription, check it against the computer-generated document, count the pills, and put them in the bottles. After stamping his (pharmacist's) name on the bottle, the contents are again checked to make sure that the medication has been correctly dispensed. When filling more than one prescription for the same patient, both medications are pulled at the same time; each one is filled separately, as outlined above. After so doing, the bottles are again opened and checked before handing the prescriptions down. Each pharmacist is responsible for checking his own work."

Lessons to learn from this description of workflow suggest opportunities to improve both at the front end and the back end of the dispensing process. First, the pharmacist usually should not retrieve both stock bottles at the same time. In doing so, the pharmacist has both medications and both labels available concurrently, and the chance of a switched label medication error is increased. If the pharmacist instead fills one prescription completely, returns the first stock bottle to the shelf, and then fills the second prescription completely, the chances of a switch are reduced considerably. Second, self-checking is notoriously ineffective. One tends not to notice one's own mistakes. Having another person check the accuracy of what has been done by the person actually filling a prescription can dramatically reduce errors.

Case No. 2: *Harco v. Holloway* (Alabama, 1995)

In the case that first recognized the responsibility of pharmacies to initiate sufficient institutional controls over the manner in which medications are dispensed, the court was critical of both the pharmacy that had created a challenging work environment and the pharmacist whose error led to litigation. Here is what the court said:

"There was evidence that (1) the prescription was illegible; (2) the pharmacist knew that the prescribing physician was an oncologist (a cancer specialist); (3) the pharmacist gave the patient Tambocor, an antiarrhythmic drug used by cardiologists to treat arrhythmias and other serious heart ailments, although it is undisputed that the prescription actually called for Tamoxifen, a cancer-fighting drug; (4) the pharmacist admitted that she realized at the time that she was giving the plaintiff Tambocor, a heart medication; (5) the pharmacist did not attempt to call the physician to verify the accuracy of her reading of the prescription and did not even try to question Ms. Holloway about why her oncologist was supposedly prescribing a heart medication for her; (6) the pharmacist did not re-read the prescription to verify the accuracy of her reading of it."

The court suggests in this passage that misfilled prescriptions can frequently be prevented if the pharmacist talks with the patient or requests clarification from the prescriber. Any time a prescription is illegible, the pharmacist should first ask the patient what the physician has explained about the medication. Sometimes things become crystal clear with the addition of a tiny piece of new information from the patient. Should the patient's information still not be adequate to clarify what drug has been prescribed, then the pharmacist must contact the prescriber. To guess what the medication probably must be is to invite disaster. Accuracy in pharmacy requires pharmacists to make certain of what they do, and not take chances with patients' medications.

ERROR REDUCTION & PREVENTION

State Board of Pharmacy Continuous Quality Improvement Programs

To protect the public and to assist pharmacists in the reduction of errors, approximately two-thirds of the states have now implemented some sort of requirement for a program that will monitor system failures, promote system improvements, reduce the occurrence of errors, and demonstrate that pharmacists who make a mistake were trying hard to prevent errors. The Florida Board of Pharmacy was the first state to adopt such a program, and its program serves as an example of how most programs are conducted. The Florida Board of Pharmacy is authorized by the Legislature of the State of Florida to promulgate administrative rules that establish standards of practice for the profession of pharmacy. This is a compliment to the pharmacy profession on its ability to self-regulate in the public interest, and it is an opportunity for the profession to solve its own problems without well-intentioned but uninformed outside intervention. Pursuant to this legislative authority, the Board of Pharmacy has responded to the problem of errors in pharmacy, through the development of its CQI rule. The enabling language from the Florida Pharmacy Act reads as follows:

465.0155 Standards of practice.– *Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.*

The specific language of the Florida Board of Pharmacy CQI rule is as follows:

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

1. "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

2. "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;

2. Incorrect drug strength;

3. Incorrect dosage form;

4. Incorrect patient; or

5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;

2. Therapeutic duplication;

3. Drug-disease contraindications;

4. Drug-drug interactions;

5. Incorrect drug dosage or duration of drug treatment;

6. Drug-allergy interactions; or

7. Clinical abuse/misuse.

3. (a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.

3. A planned process to record, measure, assess, and improve the quality of patient care; and

4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

4. Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

5. Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Interpreting the Board of Pharmacy CQI Rule

All records generated as part of the CQI process are confidential and are protected from discovery by an opposing party in either an administrative or civil action. Once a meeting has been held to consider the effects on quality of factors such as staffing levels, workflow and

technological support, the pharmacy must create a summarization document that contains an analysis of remedial measures undertaken following documented QREs. The rule specifies that no patient or employee name shall appear in this summarization document. The purpose of the document is not to learn who is at fault and whom to blame. The focus is entirely away from people and their errors. **The summarization document focuses on the system and on what is being done to improve the system to prevent QREs in the future.** Some knowledge of the past is necessary to improve in the future. But past QREs are used as information to guide a choice of what to do to improve, not as evidence of whom to punish. Contents of the summarization document may vary considerably from one pharmacy to another. But each pharmacy should use this document to provide strong evidence that an effective CQI program is in place and that it is being used consistently to prevent harm to patients. The summarization document, including the recommendations for future improvements, must be maintained in the pharmacy for two years.

As a model, compliance with the Florida pharmacy CQI rule is not onerous. Any pharmacist who has 20 hours to review the literature and study her or his practice site can develop a plan that works well for any site. The goal of the Florida Board of Pharmacy is to enable success by individual pharmacy permittees, not to prescribe the specific keys to success for every permittee.

All pharmacy CQI programs should be different, because all pharmacy practices differ to some degree. There is no single "right way" to practice pharmacy, so there is no single "right way" to conduct a pharmacy CQI program. Every pharmacy's P&P manual should be unique; every CQI program should function differently; and every CQI meeting should be conducted in a new and different way so it can lead it to a higher level of success than the meeting before it. Given the basic premise that there is no "generic" program of pharmacy CQI, the recommendations in this lesson are intended to illustrate one possible way to comply with the CQI rule such as the one that exists in Florida. Even within this general template there is room for considerable individual variation based on the unique characteristics of each pharmacy practice site. The steps will be presented in the next lesson.

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LESSON EVALUATION

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

1. Does the program meet the learning objectives?

Describe the culture of punishment as a response to drug errors	YES	NO
Discuss the lessons that can be learned from recent drug errors cases	YES	NO
List requirements of a CGI Program	YES	NO
Explain steps that can be taken to comply with a board approved CQI program	YES	NO

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

	Poor			Average			Excellent
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____
5. What did you like least about this lesson?_____

Please Mark the Correct Answer(s)

1. **In what manner must pharmacist errors be addressed in order to facilitate & increase patient safety.**
   A. Casual B. Radical
   C. Systematically D. Disciplinary
2. **Pharmacist responsibility includes:**
   A. Accurate processing of prescriptions
   B. Responding to potential prescription drug-drug interactions
   C. Providing input regarding common drug side effects
   D. All of these
3. **In a world of "punishment," a pharmacist might have liability for:**
   A. Professional malpractice
   B. Criminal liability
   C. Discipline from board of pharmacy
   D. All of these
4. **The "bottom line" result of *Harco v. Holloway* was that it recognized pharmacies' responsibilities to incorporate error control programs & systems**
   A. True B. False
5. **Dr. James Reason & other experts have concluded that in healthcare, human error is "normal." What do the experts mean by "normal" error?**
   A. Errors must be planned for
   B. Errors are welcome
   C. Errors are no big deal
   D. Errors have no real consequences
6. **What had traditional thinking been regarding the appropriate reaction to an error by a pharmacist?**
   A. Ignore the error & proceed
   B. Punish the erring pharmacist
   C. Forgive the error immediately
   D. Humiliate the pharmacist
7. **A pharmacist being "accountable" means he/she must provide an accounting by way of explanation, when an adverse event occurs.**
   A. True B. False
8. **Self-checking of a prescription that a pharmacist has filled by himself or herself is less effective than having another person check the prescription.**
   A. True B. False
9. **According to the Florida CQI rule, how is a Continuous Quality Improvement Program described?**
   A. As an unfunded mandate
   B. As a bureaucratic burden
   C. As a system of standards & procedures
   D. As a guarantee means to eliminate all pharmacy errors
10. **Under the Florida CQI law, how frequently must the CQI Committee review QREs at each pharmacy?**
    A. At least once a week
    B. At least once a month
    C. At least every 3 months
    D. At least once every 6 months

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