April 2004 "Case Studies in Medication Error Prevention" 707-000-04-004-H04

THIS MONTH
"Medication
Errors"

**To obtain continuing education credit for this lesson,
you must answer the questions on the quiz
(70% correct required).**

**Quizzes may be returned via mail, FAX (847-945-5037)
or send us a conventional email with your answers
(info@wfprofessional.com).**

ALWAYS KEEP A COPY OF YOUR QUIZ.

This lesson reviews legal cases that have been brought against pharmacies & pharmacists, alleging harm to patients as a result of medication error. Additionally, techniques, hints & details that can be implemented for improvement are presented. Our goal is to describe procedures that will reduce prescription errors. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings.

The ACPE program ID # for this lesson is 707-000-04-004-H04. Our CE Provider Registered # with CE Broker.com is 50-3170-1. The CE Broker.com Tracking # for this lesson is 20-18731.

Pharmacists completing this lesson by April 30, 2007 may receive full credit.

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.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Illinois, Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

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

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1.   Describe the threats to quality that can lead to error in pharmacy practice.
2.   List the types of errors that have led to pharmacist liability in the past.
3.   Discuss the measures that pharmacists can take to reduce medication errors.
4.   List the attributes of an effective error prevention program.
5.   Describe the research results from studies of medical errors.List the steps necessary to put research into practice in the prevention of pharmacy medication errors.

INTRODUCTION

The subject of patient safety has captured the attention of the public, health care practitioners and health care regulators. Although the actual extent of medical errors is unknown, there are estimates that place the incidence of these unfortunate occurrences in the realm of an epidemic. Medication error is just one subset of the overall field of medical error, but it is a very evident subset and has serious implications for pharmacists.

This lesson reviews legal cases that have been brought against pharmacies and pharmacists, alleging harm to patients as the result of medication errors. The point in reviewing these cases is not to criticize or embarrass anyone. The fact of error is unavoidable, and the professional approach to it is to evaluate each error with an eye toward steps that can be taken to prevent same or similar errors in the future. The motto of the patient safety movement is "Forgive and Remember." The only unforgivable error is the error from which no lessons were learned. This review of pharmacy errors will provide lessons for improvement, to reduce the likelihood that these and/or similar errors will occur in the future.

WRONG DRUG ERRORS

By far the most common pharmacy medication error is the dispensing of a drug other than the drug ordered by the prescriber. There are many reasons why the wrong drug might be dispensed, most of them having to do with a failure of communication in some way. Written communication and verbal communication may be ambiguous, and when they are, the wrong drug may be dispensed. The use of drug names that look and sound alike is a contributing factor to wrong drug errors in pharmacies. Consider the following case study from a lawsuit reported in Arkansas in 2003.

After working for thirty years in Dallas, Texas, a patient and his wife retired to DeQueen, Arkansas. While in Dallas, the patient had undergone bypass surgery. As of his last check-up in 1996, his cardiologist indicated that he had a life expectancy of five to ten years. When the couple moved to Arkansas, the patient switched to a new family practitioner.

Because the patient was overweight, the family practitioner prescribed Zaroxolyn to help reduce fluid retention due to the patient's diagnosis of congestive heart failure. On May 15, 1997 the patient took his Zaroxolyn prescription to a pharmacy to have it filled. The pharmacist on duty misfilled the prescription with Ziac rather than Zaroxolyn.

Shortly after May 15, 1997, the patient suffered from substantial weight gain due to water retention. He was eventually hospitalized in DeQueen on July 15, 1997, under the care of his family practitioner. Over the course of several days, doctors were able to reduce his fluid retention and, hence, his excess weight. He was discharged from the hospital on July 20, 1997. At that time, the family practitioner was unaware of the pharmacist's mistake in filling the earlier prescription for Zaroxolyn, so he directed the patient to return home and double his dose of Zaroxolyn.

The patient complied with his doctor's instructions; however, because of the misfilled prescription, he proceeded to double his intake of Ziac instead of Zaroxolyn. Once again, the patient experienced a significant gain in weight due to fluid retention. This time, he was hospitalized in Texarkana on July 28, 1997. Upon admission to the hospital, the patient was diagnosed with a kidney illness. During this hospitalization, doctors treated him for the kidney condition and his weight gain due to fluid retention. When the patient

was dismissed from the hospital, he was directed to again increase his Zaroxolyn intake.

On August 28, 1997, only two doses remained of the May 15 prescription, so the patient returned to the pharmacy for a refill. The pharmacist who had originally misfilled the prescription examined the two remaining doses and discovered that he had mistakenly filled the prescription with Ziac. Upon discovering the error, he advised the patient that he would contact the patient's doctors. In fact, the pharmacist never did contact any of the patient's doctors, although he did make a call to a doctor's office.

The patient returned home with the properly filled prescription of Zaroxolyn, but without any tapering dose of Ziac. One week later, on September 4, 1997, the patient died of a myocardial infarction. The patient's spouse filed a lawsuit against the pharmacy. A jury awarded the family a total of $1.275 million. This award was upheld on appeal.

Several important lessons emerge from this case report:
- Drugs starting with the same letter are often confused with each other, especially those starting with a distinctive letter such as "V" or "Z" or "X."
- Look alike drugs should not be placed on the shelf together, because they are easily confused with each other.
- Patients who receive a new prescription should be told the name of the drug and the purpose—any indication from the patient that this is unexpected or inconsistent with the doctor's information should be followed up immediately.
- Upon discovering an error, the patient's doctor should always be contacted.

WRONG PATIENT ERRORS

Simply because a prescription has been accurately processed does not mean that the correct patient will eventually receive the prescription. Pharmacies are busy places and certain times of day are very confusing. Patients have similar names or the same name. They may end up receiving medication intended for a different patient. Consider the following case report from Arkansas in 2004.

A patient presented a prescription for Cephalexin and Claritin D 24 Hour at a Siloam Springs pharmacy on November 19, 1998. Instead of receiving his correct medication, the patient was mistakenly given a bag containing medication meant for another patient who had the same last name. The medications he received were triamterene/hydrochlorothiazide and Synthroid. The patient took these medications for approximately two days, allegedly ingesting six triamterene/hydrochlorothiazide doses and two Synthroid doses. The mistake was discovered by the patient's wife after his condition did not improve.

A lawsuit was filed against the pharmacy alleging that the error resulted in post-traumatic stress disorder for the patient. The jury awarded the patient and his wife a total of $840,000. This award was affirmed on appeal. The important lessons from this case include:
- Proper instruction of support staff in the need to identify patients accurately when medications are retrieved in "will-call."
- The process of identifying patients not just by name but also by telephone number and address as well. This assures that pharmacy records are up to date, and that patients with the same name are not confused with each other.
- Reaffirmation that the "show and tell" system used for new prescriptions gives the patient an opportunity to explain that she or he is apparently not the patient for whom medications have been retrieved.

PATIENT RESPONSIBILITY

Although pharmacists have primary responsibility to assure that patients receive the correct medications, patients share the responsibility to look out for their own best interests. One reason dosage units have different colors and shapes is so they will not be confused. A patient who receives a medication that does not look the same as one that has been prescribed for several years should speak up. Patients who do not understand something they have been told should say so. Patients who wish to be provided information about medications should accept an offer of counseling when it is made. The following case report from California in 2002 describes one circumstance in which a patient did not meet his responsibility to

protect himself from adverse drug effects.

The patient received two prescriptions, one for trazodone and one for Zoloft. On May 15, 1998 the patient dropped these prescriptions off at his pharmacy. The next day, when he picked up the medications, a pharmacy clerk noted that the patient had already been using Zoloft, but he asked whether the patient would like to speak with the pharmacist about trazodone. The patient testified that the conversation occurred this way:

"And so when I came up to the cashier, she took the prescription and looked on the screen, and she said, 'Oh, you have already been taking the Zoloft.' And she asked me if I wanted to speak to the pharmacist about the sleep aid. And I kind of joked with her and said you know, 'Oh I don't need to talk to him about a sleeping pill,' you know, and that was the end of our conversation."

The patient also testified that he had declined counseling from the pharmacist "because I thought of the sleep aid as a not very powerful drug. I mean, you could get sleep aids at 7-Eleven." And when asked at deposition, "Did you have any questions about the trazodone?" the patient responded: "No."

The patient also signed a form entitled "Patient Counseling/Eligibility Form" when he picked up his medications. Above his signature was checked a box next to the statement: "I do not wish to be counseled by the pharmacist and I do not have any questions."

At the time the patient picked up his medication, the pharmacy maintained a computer system with patient profiles from which it could be determined whether the patient was receiving a new prescription. With newly prescribed drugs, the pharmacy provided a written handout that, among other things, warned of the side effects of taking the drug. Nonetheless, transmittal of this information to the patient was not a pharmacy requirement. And the patient testified that he never received this written information.

After the patient took the drug at bedtime several days later, he awoke with an erection that did not subside. The pharmacy's written information for trazodone stated: "Males: notify your doctor immediately if you experience painful and prolonged erections." The patient was not treated for at least three days, and he sustained permanent injury.

The patient sued the pharmacy alleging that the pharmacy "negligently and carelessly compounded, prepared and otherwise dispensed" trazodone to him, that it "knew or should have known of the serious and foreseeable side effects of trazodone," and that it "negligently and carelessly failed to warn, advise or otherwise inform him of the known and knowable side effects of the drug trazodone."

The court dismissed the case against the pharmacy, ruling that the patient had waived his right to counseling under California regulations applicable to pharmacies. The court also ruled that the patient had waived any right to counseling that might exist under the law of negligence. This dismissal was affirmed on appeal. The case has several important lessons for medication error prevention:
- Be sure to offer counseling on all new prescriptions and do so in an audible and obvious way.
- Document all refusals of counseling with patient signature accompanying the documentation.
- Develop a policy of distributing warning leaflets with all new prescriptions to assure that patients have been put on notice of drug side effects, and have the policy available as proof that responsibilities are being met.

DRUG USE REVIEW

When the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) was passed, it was generally viewed as a uniform patient counseling requirement, but the section of the legislation requiring prospective drug use review (DUR) by pharmacists prior to dispensing was not given extensive attention. As it has turned out, the DUR provisions are more important than the patient counseling provisions. While patient counseling may be waived by the patient, DUR may not be. Under the DUR requirements, pharmacists must screen each new prescription to determine whether any potential problems with drug therapy exist, and these potential problems must be resolved before the medication is dispensed. The following case report from Illinois in 2004 describes how this DUR requirement was allegedly not met.

On August 4, 1993, a man went to a pharmacy and picked up a prescription for the drug Toradol, for

his wife. The prescription had been telephoned in earlier that day by the wife's physician. Computer information in the pharmacy showed that the wife was allergic to aspirin and ibuprofen. Neither the husband nor the wife was aware that Toradol was an NSAID, nor had they any reason to believe that the wife would be allergic to the medication.

According to the allegations of a subsequent lawsuit, the pharmacy computer system would have displayed a warning when the husband asked for the Toradol, because of the wife's allergies to NSAIDs. They further alleged that the pharmacy computer system would not allow a prescription label to be printed after such a warning, unless the pharmacist manually overrode the system. Also, they alleged that it was pharmacy policy to prevent the pharmacist from doing an override without first talking with the prescribing physician. The lawsuit contended that one or more pharmacy employees noticed the warning and knew that Toradol would have a harmful effect on the wife, but printed the prescription label nonetheless, intending to cause her harm.

After taking the Toradol, the wife suffered severe, long-term medical problems as a result of her allergic reaction to the drug. The lawsuit alleged that these problems resulted from the negligence of the pharmacy personnel, and that the pharmacy personnel had acted in a willful and wanton manner, intending to harm the wife. Thus far, the legal right to maintain this lawsuit has been upheld by the courts. While it is not yet known whether the patient or the pharmacy will ultimately prevail, the case does teach important lessons.

- Only pharmacists should accept responsibility for DUR overrides; support personnel must be taught to refer overrides to a pharmacist.
- Any time a DUR alert indicates a potential for harm to a patient, the prescriber should be contacted to assure that the prescription is safe for the patient.
- All DUR consults should be clearly documented in a record that can be located later, to provide assurance to those reviewing pharmacy actions that the actions were appropriate.

RESEARCH IN MEDICATION ERROR PREVENTION

Case studies provide a context for a discussion of pharmacy error, but basic research is the key to understanding how errors occur and how to prevent them. Research on medical errors has produced truths that are directly applicable to pharmacy error prevention. One of the most accomplished researchers in this area is James Reason. According to Reason, error is not random. Rather, error is largely predictable. Errors cannot be completely eliminated, but they can be reduced and managed. Error is not the monopoly of the unfortunate few. It happens to everyone.

According to Reason, there are four steps to the development of a safer medication system. These are **principles, policies, procedures, and practices**.

The basic **principle** of patient safety is that safety is everybody's business. Top management must accept occasional setbacks and anticipate errors. Safety issues should be considered regularly at the highest level. Past events should be reviewed and changes implemented to improve for the future. After an error occurs, management should concentrate on fixing the system, not on blaming the individual. To conduct effective risk management, one must collect, analyze and disseminate data. Management must be proactive in improving patient safety, by seeking out error traps, eliminating error-producing factors, and brainstorming new scenarios of failure.

Policies that must be implemented to improve patient safety require free flowing information from the top to the bottom of a management hierarchy. Meetings on safety should be attended by staff from all levels and all departments. Messengers should be rewarded, not shot. Top managers must create a reporting culture and a fair culture. Reporting must include confidentiality and the separation of data collection from disciplinary procedures.

Key **procedures** in the reduction of error focus on the training and recovery of errors. Feedback must be obtained on recurrent error patterns. There must be a flexible awareness that procedures cannot control all situations. On the spot training may be necessary when a procedure is inadequate. Protocols should be written with those who are actually doing the job. Procedures must be intelligible, workable, and readily available.

As these principles are put into **practice**, it is important to generate rapid, useful, and intelligible feed-

back on lessons learned and actions needed. Information provided from the "bottom up" should be seriously listened to and acted on immediately. When an error does occur, it is important to acknowledge responsibility, apologize, and convince the patient that lessons learned will reduce the chance of recurrence.

Reason's approach to error prevention is based on three assumptions:
- Fallibility is inherent in the human condition.
- We cannot change the human condition.
- We can change the conditions under which humans work.

PUTTING RESEARCH INTO PRACTICE

The pharmacy system is broken and needs fixing. Results of research by investigators such as James Reason can help in the development of practices to reduce the likelihood of pharmacy error in the future. All research results suggest that the best hope for pharmacy medication error prevention is the adoption of practices that reflect the principles of continuous quality improvement (CQI). Through CQI, errors of the past can be examined, and changes can be made in the system to promote successful, error-free pharmacy practice in the future. Errors cannot be completely eliminated, but they can be made very rare, and they can be forgiven when the very best efforts have been undertaken to prevent them. Pharmacy errors are always unfortunate, and at times they are tragic. But they are nonetheless "normal," because they happen to every pharmacist and in every pharmacy. Their occurrence is disappointing but not shocking. The principles of CQI require that pharmacy errors be incorporated into the other normal activities of a pharmacy, and that conscientious steps be taken to evaluate them for the purpose of developing error reduction strategies for the future.

THE CQI PROCESS

CQI is a health care application of the concept of Total Quality Management (TQM) developed by an engineer named W. Edwards Deming. In the early 1950s, Deming had a novel idea. He proposed that industry focus more on the quality of what it did than on the quantity of production. He suggested that it was more important to do it right than to do it fast. This was an idea that was laughed at by many managers, who said something like, "We don't have the time to do things well; we are too busy producing poor products to step back and focus a minute or two on the quality of what we do." So Deming took his idea to Japan, where it was warmly received. The electronics industry in Japan, and in other areas of Asia, was particularly interested in producing quality products, to offset a reputation that had developed for shoddy work in that area of the world. Today, there is no question that the best quality electronic merchandise comes from Asia, and it is the result of efforts by Deming to put TQM principles into practice.

Just as some in industry spurned Deming in the 1950s, many in health care also fail to see the point of quality-focused activities today. They say things like "We are too busy filling prescriptions, most of them correctly, to take time necessary to figure out how to fill all of them correctly." But the filling of a prescription incorrectly takes just as much time, eventually, as the CQI process initially takes to get it right the first time and avoid errors. And getting it right to begin with generates positive relations with patients as well as physicians. It boosts the self-esteem of pharmacists, who far less frequently must confront the embarrassment and humiliation of a serious, or potentially serious, error.

Following the lead of TQM, CQI requires taking a systems view. It shifts the focus from individual responsibility to shared responsibility. Pharmacists and pharmacy managers work together to develop ways of doing things that promote high quality practice, as error-free as it can be made. All individuals within the system are empowered to find group solutions to problems that threaten the quality of what everyone does.

WHAT DOES CQI LOOK LIKE?

It is not technically complex to develop a CQI system in a pharmacy. No new equipment needs to be bought, and no new personnel need to be hired. The key ingredient is "buy-in" from everyone. Cynical people who think a focus on quality can never work, or that there is no time for quality-oriented practice, must either change their view or be eliminated from the system. One weak link can break an otherwise

strong chain.

The first step in pharmacy CQI development is to define the procedures through which pharmacy is to be practiced at a specific facility. There are as many right ways to practice pharmacy as there are places to practice it. Nobody can tell a pharmacy what they should be doing. Rather, each pharmacy must decide what they do well and how they do it well. It must be committed to writing, and preferably a diagrammatic flow chart drawn. In most pharmacies, the personnel will discover that "stations" for specific activities must be identified. For example, there may be a station for receiving the prescription order, a station for data entry into the computer, a station for prescription assembly, a station for insurance claims resolution, a station for DUR, a station for patient counseling, and a station for delivery to the patient. At each of these stations, only those activities identified for the station are done. And they are done by people who are highly trained and highly motivated. If this seems insulting, because it resembles an automotive assembly line, consider the way surgery is performed at modern hospitals. The anesthesiologist, the scrub nurse, the surgeon, and the operating room technician (as well as many other participants, depending on the nature of the surgery) each have stations where they do what they do and nothing else. Nobody is telling surgeons that they are automotive technicians, and nobody says that to pharmacists who similarly organize their practice in this way.

The next step in CQI is to make a record of all "quality-related events." A quality-related event occurs any time anything out of the ordinary occurs in a pharmacy. It does not matter whether the patient received the medication or not. Even "near misses" (sometimes better thought of as "near hits") where patients almost received an erroneously filled prescription, need to be included as quality-related events. All such events must be recorded in a confidential record so that they are preserved for the future. Reliance on memory simply does not work. Nobody remembers things as they should, and errors are the easiest of things to forget.

The final step in CQI is to discuss the recorded quality-related events and develop a strategy for reduction of them in the future. Here is a guide for the conduct of a "quality consult" within a CQI program:

- Review the facts of each quality-related event.
  - o Review facts of the event itself: When? Where? Who? How?
  - o Review facts about the environment: What time of day? What day of the week? How busy was it that day? Did everyone show up for work on that day?
- Address the issues.
  - o Staffing issues: including training and coverage of breaks.
  - o Workflow issues: Are all stations fully functional?
  - o Communication issues.
- Review policies.
  - o Does everyone know his/her role?
  - o Are doctors being called when necessary?
  - o Are patients being appropriately identified at will-call?
- Problem solving.
  - o What is causing our quality-related events?
  - o What are the alternatives available to prevent errors in the future?
  - o Which of the alternatives is best for us today?
- Encouraging follow through.
  - o How will we know that our system is working?
  - o Who is on the team with us?
  - o When will we meet again to discuss quality improvement?

RESPONSE TO ERROR

No matter how hard pharmacy personnel work to develop systems that set up pharmacists for success, there will be occasional failures of quality. This is an unfortunate fact, but it is reality. When an error does slip through the system, there are steps to take to ameliorate the adverse effects of the error. Here are some suggestions for handling the errors that occur.

- Plan ahead for errors.
  - Develop a firm policy on compensation to patients who have been victimized by error.
  - Role play the resolution of an error so it is more comfortable to do the right thing when an error occurs.
  - Identify a quiet and confidential place in the pharmacy to discuss an error with a patient, so there is no "show" for the peanut gallery when an error must be discussed.
- Be sure that only pharmacists handle errors.
  - Store managers and pharmacy personnel should use a code word to quietly indicate that a situation of possible error has arisen.
  - Offer a safe apology that shows genuine concern but admits nothing.
  - Get back the erroneously dispensed medication so that a mistake does not continue to cause problems.
- Follow up after an error.
  - Find out what happened and call the patient's doctor.
  - Record the outcome of an error investigation, so lessons learned can be shared with others.
  - Report back to the patient and/or family. Many people will be understanding, and friends can be made this way.

MORE ON CQI—TECHNIQUES, HINTS, DETAILS.
THE CONTINUOUS QUALITY IMPROVEMENT PHILOSOPHY

The core philosophy of any medication error prevention program is a commitment to serving each patient, one patient at a time. It is perfectly acceptable for pharmacists and technicians to be conscious of a line of people waiting, and to be concerned with not keeping anyone waiting longer than is necessary, but best practices require that safety never be compromised. Never rush, if in rushing the opportunity for error is increased. In theory, the only acceptable error rate is zero. While as humans we may never reach that ideal, pharmacists always strive for that goal. Pharmacists must focus on constant quality improvement, because errors are inevitable, but preventable errors are unacceptable.

To effectively reduce errors, pharmacists must participate as team members in an organized effort to evaluate past failures of quality, and commit to the use of quality-related data to prevent future failures of quality. This approach asks of pharmacists that they adopt a new paradigm for professional practice. This new paradigm takes what is generally referred to as a "systems" view of patient care. Rather than viewing the providing of pharmaceutical products and services as merely a series of isolated individual events, the "systems" view is patient-oriented. In other words, "We don't just fill prescriptions, we help patients get and stay well." Pharmacy managers, individual pharmacists, and pharmacy technicians, should not be satisfied simply if they alone have achieved their personal goals of highest quality practice. They must continue to strive for the highest quality comprehensive system of pharmacy practice, so that all elements of the system are as good as they possibly can be. Success requires teamwork and cooperation.

Everything happens for a reason. When reasons for failures of quality are identified, they can be evaluated. Systems can be improved in conformance with identified policies and procedures, to create an environment in which success is more likely to occur than is failure. The approach to medication error prevention described in this lesson cannot guarantee success in pharmacy practice, but it offers a proven system for error reduction.

Wouldn't it be nice if there were a perfection chamber into which a pharmacist could step at the beginning of a shift, push a button, and become perfectly error-free for the duration of the shift? Pharmacists who had become "perfected" in such a chamber would always reach for the right stock bottle from which to fill a prescription, they would always enter correct data into the computer, and they would always say the right thing to the patient.

Because no such chamber has yet been invented, pharmacists continue to struggle with the reality of imperfection, and a goal they may never quite reach. It is unreasonable to expect fallible humans to reach a state of perfection, yet it is perfectly reasonable to establish as a goal the management of the risk of patient harm caused by prescription error. The pharmacy manager and the pharmacy practitioner agree that the

goal of error prevention programs is risk <u>management</u> – and not risk <u>elimination</u>. On a practical level, pharmacists know that the pharmaceutical business is inherently a risky enterprise. Some level of risk must continue to exist in drug therapy, or else patients may be denied risky but potentially dangerous medications. The only way to eliminate prescription error is to eliminate medications from the health care system. Obviously this is a choice that simply will not work to the advantage of anyone. The better approach, the approach taken in this lesson, is to design a system that is conducive to success, so that threats to quality are recognized and resolved before patients are harmed by unavoidable error.

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PRACTICE GUIDELINE I
Standardized Pharmacy Workflow

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Overview

There are two basic elements of most pharmacy errors. The first element is the active defect, which is the human component – the negligent act. The second element is the latent defect. The latent defect is what sets up a human factor to commit the negligent act. An effective medication error prevention program must be designed to reduce the risk of error by working on both of these elements. The practice guidelines described here are intended to prevent the negligent act by incorporating a system of routines (organized workflow) and checks (risk management techniques) into everyday pharmacy practice. This guideline addresses the organization of workflow at pharmacies.

There are risk management techniques, which can be employed in pharmacy practice, that will reduce the likelihood of an error occurring, or which will allow a quality related event to be discovered before it reaches the patient and becomes an error. The trick is not in simply knowing these techniques, but in organizing them in such a fashion as to allow them to be used with each prescription. While the next guideline describes risk management techniques in detail, this first guideline describes a standard workflow process and it contains several techniques as examples of best practices to use in promoting quality. It is important to separate techniques from the workflow process. They are not the same. Use of the best techniques will fail to achieve error prevention goals, if the techniques are not organized within a standard workflow. However, techniques can be particularly effective in addressing threats to quality in pharmacy, if they are used within a standard workflow.

When one looks outside the pharmacy industry for successful risk management models, there is one particular system that immediately comes to mind - the airline industry. The safety record of the airline industry is in many ways remarkable. The airlines have achieved their enviable safety record by using many different approaches to quality improvement. Some of these approaches can provide a useful lesson for the business of pharmacy. For example, checklists describing a standard workflow can help assure that no important factor has been overlooked by humans within the system. Prior to each flight, the pilot and the co-pilot go through a checklist, determining the status of each component of the system. Regardless of the number of times the pilot and co-pilot have performed a similar routine, each go through the same list of tests. No step is omitted, nor is the order varied. The checklist is built into the system and into the mindset of the pilots. In his or her mind, no pilot could conceive of operating the airplane without having completed the checklist. If there is an accident in the airline industry, the cause of the accident is investigated. With each accident (or failure of quality), two questions are asked: "How did this happen?" and "What can be done to avoid this in the future?" In an effective medication error prevention program, an investigation occurs through the use of an audit form following each failure of quality. An effective program investigates each mistake, whether an incorrect prescription reaches the patient or not. If an incorrectly dispensed medication does not reach the patient, the incident is referred to not as an error, but as a quality related event, or QRE. A QRE may be thought of as a potential error. Each failure of quality and each error are used as a training tool and a statistical check on the system itself. QREs are free lessons from which a great deal can be learned, even though no harm occurred to a patient. Any time a medication order is processed in a way that varies from what was intended, or any time a pharmacy practice responsibility has not been met, a QRE has occurred. Every QRE represents an opportunity to learn and improve. A pharmacy practice site that is reporting a large number of QREs is considered a successful site, because without reports, the opportunity to improve is lost. A pharmacy practice site that has few QRE reports should be viewed with

suspicion, because there is a strong possibility that the pharmacists and other personnel at that pharmacy are not doing their best to learn from the past and improve in the future.

Understanding Workflow

Experience shows that when an assembly line approach to prescription order processing is used, confusion is reduced and problems with errors become manageable. It works well with pharmacy because all necessary steps in pharmacy practice are identified. Each individual within a pharmacy practice understands his or her role, as well as where within the process specific identified activities are undertaken.

In a successful medication error prevention program, workflow can be divided into the following stations:

A. Receiving the Prescription
B. Data Entry
C. Assembly of the Prescription
D. Professional Prescription Review
E. Delivery with Patient Counseling

Added to the basic workflow scheme is a "Special Care" Station. This Special Care station is created for prescriptions that require special attention, such as the need to contact a prescriber or to resolve problems or confusion over insurance coverage. When a patient's prescription develops the need for special care, the patient's basket is taken to the special care station. The patient is offered apologies for the need to take time for special care, and in the correct circumstances, can be given one dosage unit to get started with therapy until the existing concerns are resolved. It is important not to inconvenience a large number of patients while solving a complex problem for a single patient. At the first possible opportunity, an available pharmacist or appropriately trained and supervised pharmacy technician can attend to the special care prescriptions.

While there may be consistency between similar pharmacies, it is possible for one particular pharmacy, for a special reason such as its required physical layout, to place one station in a different order. Each station does not necessarily follow the one before it, and several processes may take place at the same, or nearly the same, time. For risk management purposes, however, each process at each station is considered separately from the others. This allows a pharmacy to view each step individually and thus to make minor changes to reduce the likelihood of errors. The purpose of a standardized workflow is to reduce errors, not merely to follow a process for the sake of doing so.

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PRACTICE GUIDELINE II
Risk Management Techniques

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Overview

Some pharmacy errors occur due to bad habits that can be corrected by using specific techniques to detect and absorb errors prior to delivery to the patient. Techniques themselves are not a systematic part of continuous quality improvement, but they can be used successfully within a program of continuous quality improvement. It is not mandatory that every technique in this second guideline be used every time a prescription is dispensed. However, pharmacists and management should consider these techniques as available methods of addressing quality-related events, and should implement them when a review of prior failures of quality suggests that they would be effective in preventing future failures of quality. There are many other techniques that have been already developed, but have not been included with the representative sample described in this guideline. In addition, new and useful techniques will be discovered by pharmacists, managers, and technicians, working together to improve the system. The point of this guideline is not to give anything approaching an exhaustive list of techniques. The point is that risk management techniques like these, work well, and pharmacy personnel should find the best techniques that work well for them.

Specific Risk Management Techniques

As a component of the quality improvement activities at pharmacies, all pharmacists, technicians, and managers must be continuously attentive to the occurrence of error, the causes of error, and the prevention of error. This focus on quality will lead to the implementation of many new and effective techniques to prevent errors. Because every pharmacy is different, it is impossible to know ahead of time which techniques will be effective in any particular pharmacy at any particular time. However, there are several standard risk management techniques that have proven useful over time at other pharmacies, and these techniques are provided in this guideline to facilitate improvements that may address quality-related events in a specific pharmacy.

The suggested techniques include:

- **Mark It—Move It:** Certain drugs in each pharmacy should be marked for special attention. The shelves on which they are placed can be marked with a piece of tape or a sign, to make sure anyone looking at them on the shelf understands that they are drugs for which special attention is necessary. A distinctive mark may be made on the regular shelving for a product, or the product may be moved to a separate shelf with distinct markings. These may be drugs that are often confused with each other, or drugs that, if a mistake is made, can result in injury. They may be drugs that appear often in professional liability claims. These may be drugs that are powerful agents that do exactly what they are designed to do, and a mistake with these is more likely to result in injuries and claims. Some of these drugs may be flagged for double check. Other drugs may cause problems in individual pharmacies. The following drugs were found significant in one study:

  Coumadin® (all strengths and brands of warfarin)
  Tegretol®
  Otic preparations (may be given in error when an ophthalmic is prescribed).
  Amitriptyline 100 mg (several reported claims involved 10 mg prescribed but 100 mg given)
  Anti-diabetic oral drugs
  Theophylline (dosage and strength should be double checked for child's prescription)
  Synthroid® (all strengths and brands of levothyroxine)

When the technician, or pharmacist, reaches for that part of the shelf with a flag, this person will briefly stop and reflect on what is called for in the prescription. The person will pause for one additional second and recheck the prescription. The flag should cause just a little apprehension—just enough to switch the mind from its "automatic filling mode" into a cautionary mode. One more caution, however. If too many products are flagged, the flags may become ineffective. There are many drugs, other than the ones listed here, that may cause problems with accuracy. Each pharmacy may, and should, have its own list. Pharmacists and technicians occasionally express the desire to flag all drugs in the prescription department. The value of flagging is uniqueness.

- **Basket System**: The " basket systems," introduced in many pharmacies, have reduced the likelihood of prescriptions of one patient becoming confused with prescriptions of another patient. When a prescription is received and passed to the filling area, all items with that patient's prescription(s) are placed in a basket. These items remain with the basket until the filling process is completed. In some pharmacies the basket will be used with the will-call system.
- **2 second rule**: As stated above, the " basket systems" in pharmacies reduces the likelihood of errors caused by interruptions. However, system errors occasionally occur when the technician, or pharmacist, counts tablets and places them in the bottle and is interrupted before the label is attached. Another label, from a different prescription, is then placed on the bottle. The result is the patient whose name is on the label receives the wrong medication. The "2 second rule" is a reminder that, regardless of the nature of the interruption, no prescription drug is allowed to remain in a bottle for longer than 2 seconds without a label. Even the most urgent request of the pharmacist or technician will have to wait for 2 seconds while the correct label is placed on the correct vial.
- **Sack check**: When clerks, technicians or pharmacists are hurried, mistakes are possible. One place an error is possible is when the prescription is placed in the bag (sack) and the receipt is attached. Several claims have been reported in the pharmacy literature, describing circumstances in which one person's prescription has been inadvertently placed in the wrong bag. "Sack Check" enables pharmacy technicians and pharmacists to perform one final check of the patient name on the label with the patient name on the receipt at the time of placing the prescription into the bag (sack). Open the sack, compare the vial with the receipt, verify the contents of the vial, and close the sack again.

- **Echo & Verify**: By their nature, telephone prescriptions rely on oral communication. The words can be misunderstood, or the speaker can be confused. If the pharmacist receives a prescription which is later found to be incorrect, it will be perceived as the pharmacist's mistake. If the physician or nurse calling in the prescription has misstated the drug, the pharmacist would like to find the error at the time of calling. If the pharmacist has misunderstood, that potential problem should be discovered as soon as possible.

    When any prescription is received by telephone, the pharmacists should always "echo" back the entire prescription before ending the conversation. "Let me make sure I got that right." As each part (patient name; drug name; dosage; directions) of the prescription is "echoed" the pharmacist places a checkmark on that part. The pharmacist then asks for verification, "Is that correct". When the nurse or physician indicates what the pharmacist "echoed" was correct, the pharmacist places a "V" (for verified) on the prescription face and places his or her initials next to the "V" and the date. If the pharmacist rewrites the prescription, these notes should be attached to the telephone prescription to be filed as a "hard copy".

- **Counseling**: Good pharmacy communication should be short and concise. The pharmacist must use his or her judgment to decide what two or three items should be mentioned to the patient at the time of counseling. Mention too many things, and the patient will remember none. Mention one or two or three, however; and the patient may remember and use the information.

    The Indian Health Service uses the question, "What did your doctor tell you this was for?" The pharmacist can discover if the patient knows what the medication is for and allow a final check on the prescription. For example, a serious problem was averted when the patient was shown a cold remedy but answered the question, "It is for my female problems." There had been a mistake. The doctor was holding the wrong chart in her or his hands when calling in the prescription.

- **New Rx filled from Rx** (not print out): A new prescription has an advantage over a refill. On a new prescription the physician's order is "out and available". When filling new prescriptions, it is tempting to fill from the information generated by the computer. It is easier to read. If, however, there is a mistake with computer entry, the mistake will be continued, and the prescription will be filled with the drug indicated on the computer information. On a new prescription, the prescription assembly station personnel should be taught to fill from the new order only, not from the computer generated information. This also allows a second interpretation of the physician's order. The NDC check will now discover any differences.

- **Pharmacist Only Questions**: Certain questions cause alarm when asked. One is "Why does this tablet look different than the last time?" A quick response is often "Its probably just a generic". It may be, but the system must assume there may be a mistake.   A mistake must be presumed until proven otherwise. Questions such as this should be reserved for the pharmacist on duty.

- **Double trouble:** Sometimes in a busy pharmacy, two vials of medication will become confused with each other, and the medication intended for one vial will end up being placed in the other vial. This type of error may happen for two medications being dispensed to a single patient, or it may be that the medications are dispensed to two different patients. If two patients receive the wrong medication, then it is unlikely that both will notice the error at the same time. One patient will probably contact the pharmacy with a question, and as the result of investigating this situation, the pharmacist will realize that an error has been made in putting Drug A in the vial intended for Drug B. At that point, the double trouble technique requires that the pharmacist investigate other prescriptions filled on that day to see how many patients were dispensed Drug A (particularly those whose prescription was filled at a time close to the filling of the prescription for Drug B). Each patient to whom Drug A was supposed to have been dispensed should be contacted to see if the patient received Drug B instead. This check can be done without the need of confusing the patient with a discussion of error; simply ask what the medication in the vial looks like.

Sometimes when patients complain that they received switched medications from the pharmacy, the

reality is that the medications were switched at home, and this possibility must always be considered before jumping to a conclusion that the pharmacy was in error. Patients may get home from the pharmacy and count out their medications on a kitchen counter to make sure that they received all dosage units to which they were entitled. If a patient contacts a pharmacy and contends that there was a switch of medications made at the pharmacy, or that two medications were put in the same vial at the pharmacy, the patient should always gently be asked what occurred when the patient arrived home from the pharmacy. If the patient indicates that as soon as he/she arrived home, the vials were emptied to examine their contents, then there should be a gentle suggestion that perhaps the confusion arose at home, not at the pharmacy.

- **Partner check:** Computers have vastly improved the quality and efficiency of what pharmacists do. They free up time for pharmacists to review drug therapy, and they remove the tedium of typing labels, as well as improve the likelihood that labels will be correct when they are placed on a vial. On the other hand, the principle of "garbage in-garbage out" is an important one to remember. If data entry is not done accurately, a computer will produce results as inaccurately as it has been told to by the operator. Self-checking is a notoriously poor way to review one's own work. When a label is reviewed immediately following the generation of it, there is a bias that causes the viewer to see what is supposed to be there rather than what really is there.

The partner check technique is one in which a pharmacist who comes on duty compares the computer information on all new prescriptions from the previous shift, with the original prescriptions. It may be that the reviewing pharmacist is the same pharmacist as the one who worked the previous shift, but usually it will be a different pharmacist. In partner check, it is possible to determine whether the information entered into the computer is the information that should have been entered into the computer.   Wrong drug, wrong strength, and wrong direction errors can be detected during partner check, and patients can be notified to determine what information they were given and whether a potential problem needs to be solved. Prescription refills are far more likely to reflect what the patient was supposed to receive on the initial filling when the partner check procedure is used. A properly trained and supervised pharmacy technician may perform partner check if time constraints make it impracticable for a pharmacist to do so.

PRACTICE GUIDELINE III
Peer Review Documentation

Overview
The checks and balances placed into a program to prevent future problems should reflect what has been learned in the past about particular weak links in the chain of drug distribution.   Although a chain is only as strong as its weakest link, a strong link may contain a mechanism for strengthening an earlier link, when the subsequent strong link detects a problem with the earlier weak link. Improvements built into a particular link are based on knowledge of prior errors at another earlier link.

The most important step in any risk management program is to monitor the program put into effect, and constantly improve. Peer Review audits are a mechanism for pharmacists to help themselves improve, to help each other to improve, and to help management see where resources need to be enhanced to facilitate safe pharmacy practice. No program of peer review can be successfully undertaken without documentation of quality-related events. The audit system described in this third practice guideline shows how to make a record of past failures of quality, not for the purpose of punishment, but for the purpose of future improvement.

Must Know About Errors - The Importance of Audits
Unless there is knowledge of what errors are occurring and why, no systematic improvements can be done to absorb error.   It is imperative that all failures of quality are recorded, so that they can be evaluated, and changes can be made to prevent them in the future.

When Dr. W. Edwards Deming developed his Total Quality Management concept, he felt the most important part of the program was statistical control. In order to improve, it is necessary to establish a benchmark and to then compare present quality with past quality. If the program is improving in quality, the number of quality related events should decrease with time. In addition, by analyzing errors or "quality-

related events," it is possible to discover where work is needed to improve the system.

In order to accomplish this crucial measurement and comparison of past with present, an effective medication error prevention program must contain a system of audits, kept daily and analyzed regularly. It is from these audits that pharmacists, pharmacy technicians, and managers learn what they need to know to constantly improve.

Determine What Caused The Error

The diagnosis of an error requires asking hard questions about the circumstances of the error, and the people who were connected with it. Every error is different. Quality improvement efforts require asking not only how an error occurred, but also how it could have occurred. To the extent that there are multiple causal factors for any error, solutions must be found for each factor.

The information from each error or "quality-related event" (QRE) is used in the pharmacy. When the pharmacist notes, during the Pharmacists Final Check, that a QRE occurred, the pharmacist indicates it to the technician or technicians involved. Correction is made to the prescription. During a convenient time, as soon as possible, however, the pharmacists and the technicians then discuss the QRE – where in the process it happened, how it occurred and what could have been done to prevent it. This information is recorded on an Audit Form. The answer may be to move or mark two look-alike or sound-alike drugs or it may be "we must not have used the NDC check," but whatever the answer, the situation produces an excellent learning opportunity. Opportunities are lost when documentation is not done through executed audit forms.

The Peer Review Audits

When constructing and using an Audit Form, one can think of a great deal of information that could be useful. However, a look at forms used in most successful pharmacies shows that only a minimal amount of information is requested. This is purposeful. Pharmacists will not use forms that they perceive as taking too much time or are too intrusive. Therefore, the information selected should be the minimum thought necessary.

The pharmacist preparing an Audit Form should be asked to indicate how he or she discovered a quality related event (QRE) by indicating the Audit Type being used when the QRE was found. There are four basic Audit Types: (1) Periodic Self Audit, (2) Partner Check, (3) Will-Call Check, and (4) Other.

Over time pharmacists at each individual pharmacy will learn which audit helps them the most in reducing errors. Managers may ask several important questions: Should we concentrate on training and the pharmacy personnel's time on partner check or on will-call checks? If a pharmacist complains that the partner check takes too much valuable time, how should a competent manager answer? With information from the audits, the answer will become clear.

In order to change the process, it is important to discover the root cause of any QRE. Possible causes should be included on an Audit Form to give pharmacists a shorthand way of considering and recording what they perceive to have caused a QRE. The "causes" can be grouped to provide information concerning where in the process, or workflow, the QRE occurred and what caused it.

The USP Severity Code table is often included on audit forms to enable pharmacists who know of the effect of a quality-related event to document it. Seldom, however, does the pharmacist have access to information indicating the extent of harm resulting from an error.

Capturing information regarding errors and near misses is necessary to improving pharmacy practice. Yet, once they have been used in an analysis of past concerns, audit reports need not be retained. The retention of audit reports may convey the impression that the pharmacy is focused on the past, and that those whose unsuccessful efforts have been documented in the reports are likely to suffer the consequences of the regrettable occurrences. Destruction of the audit reports, after they have been evaluated and used for improvement purposes, conveys the important message that there is no penalty for reporting a QRE.

There are two keys to the value of the audit reports. First, all pharmacists must take the time to fill them out every day. When the data begin to be evaluated, it is easy to determine who is complying and who is not. Also important, however, is accuracy and "buy-in." Pharmacists may initiate the use of a new audit

form on a regular basis, but note consistently that there are no QREs to report. Any such claim should be viewed with suspicion, as few practice sites are fortunate enough to completely escape QREs when a concerned observer is watching for them. Pharmacists will learn quickly that an appropriately designed medication error prevention program is not punitive, and that a QRE documented on an audit form is an opportunity to improve.

The second key is using the information in a meaningful manner. This means quarterly analysis, discussion by a peer review team and feedback to everyone in the system. The information may be compiled into a database, which can be used to generate meaningful charts, tables and summaries. There is no need to record the names of pharmacists, pharmacy technicians, or patients on an audit form. There is nothing to be gained by identifying a person to be blamed for an error. Ultimately the success of a medication error prevention program lies with the pharmacists and technicians who make it work. A non-threatening and supportive environment will lead to success with any medication error prevention program.

PRACTICE GUIDELINE IV
Quality Improvement Coordination

Overview

No solution is effective unless it addresses a real problem. A medication error prevention program is not designed as a "quick fix" reaction to a difficult problem. Quick fixes may make people feel as if they have done something valuable and appropriate, but most errors in pharmacy can be traced to several complicated factors that defy an easy solution. A medication error prevention program provides the opportunity to analyze the pharmacy system as well as pharmacy practice in general using "five quality factors". The standard workflow is designed using these factors, and the peer review program that evaluates performance within the standard workflow focuses as well on these five quality factors.

As has been noted above, quality improvement requires evaluation of failures of quality in the past, before one can move to the implementation of systems improvements focused on the future. This is best accomplished by considering the "five quality factors" set forth below. The five quality factors are:

1. Who — person (pharmacist, technician, clerk, customer, caregiver, other). Note: We do not mean the actual person, but the position of the person.
2. Where — the process and the sequence of processes, i.e.: the pharmacy workflow.
3. What — equipment, material.
4. When — time, method of work.
5. How — environment (lighting, noise, interruptions), work load, external stress & internalized stress.

THE PRACTICE OF PHARMACY IS A SYSTEM OF PROCESSES

Most errors can be attributed to a failure of process. Correcting the process is the goal. All acts taken in remedy should be aimed at improving the process in the future rather than dwelling on problems in the past. They should be remedial, not punitive. An analysis of the five quality factors tells us where to look in the process to allow a technique to prevent a quality related event.

Implementing Peer Review

A commitment to quality in pharmacy practice requires both acceptance of the concept that everything can be improved no matter how good it may be, and adoption of a method to evaluate and change systems so as to achieve improved quality. Pharmacists, technicians, and management can improve quality and reduce error by working cooperatively within an established framework for problem identification and problem resolution.

In many ways implementing a program can be the most difficult part. Using the workflow method to form habits, however, should make this process easier for the individuals involved. Checklists are useful in training, but are too cumbersome to use regularly in day-to-day practice. Complete reliance on checklists is less than totally effective in the long run. Eventually technicians and pharmacists begin to mentally see the

task as checking off the box, therefore boxes are checked, but the task (e.g. NDC check) may not have been done.

Taking a Systems View

A system is a collection of interrelated processes that are intended to complement each other in the pursuit of a common goal. Never does the outcome of any activity depend on the success of a single person at a single time. Within any pharmacy system, many people have a role to play in creating an acceptable result. The absence of an acceptable result means simply that the system did not operate as it was intended to. And the productive response to such a failure of quality is to determine how the system can be used to produce better results in the future.

A systematic approach to pharmacy practice, based on standard policies and procedures, can reduce the likelihood that a mistake will occur. Haphazard and disorganized pharmacy practice increases the likelihood of error. By taking a systems view of quality, and organizing the system of pharmacy practice, procedures can be developed that, if adhered to, will reduce error. The most effective risk management technique is to develop and utilize an organized system, such as the suggested workflow, that has definite starting and endpoints, with recognizable intermediate points along the way. Within such a system, a pharmacist is less likely to ask, "let's see, now where was I?" and miss a step that results in error.

Fix The Problem, Not The Symptoms

Superficial explanations of error such as, "I guess I just wasn't paying attention" are unacceptable when one adopts a systems view of quality. The failure to pay attention is a symptom of some systematic problem. It leads to the question, "What was it about the system that caused you to not be paying attention?" When looking for explanations of error, as a first step in solving a problem, it is important to identify the real problem, not simply the symptom of the problem. Fixing symptoms does nothing to resolve the underlying problem.

An active act of negligence by an individual may directly result in an error. In most active acts of negligence, however, there is a latent defect in the system that allowed the quality related event to occur. Since merely telling an individual human being to "be more careful" is unlikely to prevent many future errors. Medication error prevention efforts are better directed on discovering what latent defect allowed the error to occur or what techniques we could add to a process to discover the quality related event before it reaches the patient and becomes an error.

For example, if a technician fills a prescription written for an ophthalmic preparation with an otic preparation, it is important to ask what system factors allowed the error to be made. Through problem analysis, it may be discovered that ophthalmic preparations were located right next to the otics, and that each is labeled in a confusingly similar manner. While there may be little control over the labels themselves (the manufacturers make them the way they make them), the problem may be solved at the pharmacy level by storing the otics physically away from the ophthalmics. In addition, it may help to mark the otic shelf with colored tape to alert a technician reaching for this shelf to "Stop – check one more time". Also, emphasizing the need for an NDC check in the workflow may help a pharmacist to catch an error, either at the point of assembling the prescription or during the pharmacist's final check stage, or both.

Sometimes after a mistake has been made, pharmacists are admonished to put the past behind them, look to the future, and to simply "forgive and forget." As tempting as it might be to avoid the unpleasantness of evaluating past failures of quality, and to be oblivious to problems that may continue to exist, quality improvement requires that past failures of quality be remembered, so that the improvements they prompted will reduce the likelihood of future problems.

This is not to say that those involved with past problems are made to remember them and suffer the shame of them as some sort of penance for a sin. Rather, the approach is one of remembering the past but forgiving it. A successful medication error prevention program adopts the "forgive and remember" motto to emphasize the point that quality improvement is not about assigning blame and shame, but it is about learning from mistakes and using this information to avoid problems in the future. Past failures are used to improve in the future, without casting aspersions on anyone who was involved with a failure of quality in the past.

Some errors cannot be prevented by a system, but they can be "absorbed" into the system. This can

occur when a step later in the system is designed to detect and rectify an error that occurs earlier in the system. As an example, consider the switch of otic for ophthalmic suspension, and how the NDC check can be added to "catch" the quality related event before it reached the patient to become an error. Checking for errors to rectify them should not be used as a replacement for the prevention of errors to begin with, but it can serve as an effective second line of defense when the reality of error is recognized.

PRACTICE GUIDELINE V
Day-to-Day Risk Management Practice

No matter how good a pharmacy's system of quality assurance may be, and no matter how hard a pharmacist may try to adhere to policies within the system, failures of quality will continue to occur. Patients will receive inaccurately filled prescriptions, they will be inadequately counseled, and obvious problems with drug therapy will be undetected by prospective drug use review. When problems of this sort do occur, patients will understandably become upset, and the person who will be confronted by the patient, or a representative of the patient, will be the pharmacist. This initial confrontation is the best opportunity to avoid litigation by means of an appropriate response by the pharmacist, and it is the time at which litigation can be guaranteed through an inappropriate response by the pharmacist. It is the defining moment in risk management.

Pharmacists should always do whatever they can to assist in resolving a pharmacy error and minimizing the impact of it. This includes notification to anyone whom the pharmacist suspects may have been the object of an error, and absolute openness with information necessary to ensure a good outcome for the patient. The patient's physician should be contacted any time there is reason to believe that a pharmacy error may have affected the patient's health. Patients should be made to know that their safety and welfare are the most important concern. Many times patients have said, "I understand that anyone can make a mistake, but what upsets me is that the pharmacist didn't seem to care when I asked him to talk with me about the mistake he made." A patient who feels this way may file a lawsuit for malpractice, or a complaint with the board of pharmacy, simply to get the pharmacist's attention. Reacting to patient concerns in a way that does not show respect and caring is poor professional judgment and a poor risk management technique.

Pharmacists must ensure that, when they react to a problem with drug therapy, the things they say and the things they write are done in ways that are sensitive to risk management issues. Otherwise, the words spoken and written may come back to haunt them in a lawsuit.

PROBLEMS AND PITFALLS OF RISK MANAGEMENT

Verbal communication and written documentation by pharmacists can be a cause of misunderstandings and resulting antagonism toward pharmacies and pharmacists. The things pharmacists say and the things they write have a way of coming up in lawsuits, and they can be difficult to explain. There is no question that some problems, which would have gone undetected otherwise, are made obvious through careless comments, and suspicions are cast on previously unidentified health care providers through a carelessly drafted written record. Yet the advantages of verbal communication and written documentation clearly outweigh the disadvantages. It would not be good risk management advice, and certainly not good patient care advice, to instruct pharmacists, "Don't ever say anything or write anything." Verbal communication is necessary to ensure that patients make good decisions about drug therapy, and documentation by pharmacists can prevent harm to patients. Both of these activities are positive from a risk management perspective because they prevent litigation. Nobody sues when harm does not occur. Even if harm does occur, documentation may show that a pharmacist did everything that could reasonably have been done for a patient and that the bad outcome was unavoidable. Litigation will be unsuccessful if it is based on harm that could not have been prevented, and a pharmacist's written record can refute the patient's contention that a medication error was preventable.

RULES FOR EFFECTIVE DAY-TO-DAY PATIENT CARE

In a successful medication error prevention program every pharmacist is a risk manager, and it is important to remember that there are certain approaches to verbal discussions and written notes that can

reduce exposure to liability. No set of rules can absolutely produce good risk management outcomes, but the following suggestions serve as the basis for an approach to patient care that is sensitive to the concerns of risk management.

1. Be Correct. The admonition to "be correct" reflects the fact that most errors in verbal communication or record keeping result from a failure to accurately convey information. Word usage is important. Consider the following statements that do not really say what was intended:

- o "Patient has difficulty walking on diazepam."
- o "Patient experiences difficulty swallowing tires easily."
- o "She moves her bowels roughly, three times a day."

Sometimes the placement of punctuation or voice tone can alter the meaning of a statement. Being correct also includes the notion that when things go wrong, one should tell it like it is. Cover-ups are never to be tolerated. The facts will speak for themselves eventually, so honesty is always the best policy.

2. Be Complete. That conversations and written documents should "be complete" means that they should include all information that is necessary to provide a continuing high level of care for the patient. Everything necessary to promote a good outcome for a patient should be spoken of and appear in the patient's record. A pharmacist who is wondering whether a particular piece of information should be mentioned in a conversation or included in a patient care record should ask whether the information is necessary to promote the patient's welfare. If the answer to that question is yes, then the information should be included.

3. Be Concise. Being complete does not mean saying whatever comes to mind or putting every known tidbit of information in the patient care record, because that would conflict with the rule to "be concise." Nothing that is not necessary for patient care should be spoken or appear in the patient care record. Some pharmacists confuse consults with other health care providers and notes entered on the prescription or other area of the patient care record with a miniature continuing education program. They photocopy articles from journals, send them to the physician, and then staple a copy to the prescription. They overdo the job of information provision, just to prove a point that does not need to be made. When the patient's physician has not followed pharmacy advice and a bad result has occurred, these pharmacists write "Told Ya So" on the prescription. This is a real problem, because notes in pharmacy records are fully available to the patient's lawyer if the patient decides to sue.

4. Be Consistent. To urge that pharmacists "be consistent" reflects the fact that once a pattern of verbal comments or documented remarks develops, a break from that pattern can be interpreted in a way that was not intended. Pharmacists should develop patterns of verbal observation and written documentation and adhere to them. If a pharmacist has a habit of recording a particular finding, and that information is not recorded, then the record overall will lead to the conclusion that the pharmacist did not observe something that should have been observed or that the pharmacist did not do something that should have been done. The pharmacist may in fact have acted appropriately, but to have omitted from the record a type of notation that is habitually made will be compelling evidence of inaction. Remember the saying, "If it isn't documented, then it didn't happen."

5. Be Cautious. A pharmacist's verbal statements and documentation must "be cautious" to avoid misinterpretation of even the most innocuous comments. In particular, pharmacists should be cautious enough to avoid beginning a conversation or written note with a word or phrase that "handcuffs" the attending physician. For example, to begin a note with "Recommend..." or "Strongly recommend . . ." has the effect of saying "You are committing malpractice if you don't do. . . ." This is obviously a risk management nightmare. Of course, there are some circumstances when strong language needs to be used and attending physicians need to be handcuffed. But caution dictates using softer beginnings for most pharmacy notes. The best approach for a pharmacist is to use a less demanding beginning to a conversation or a note, such as "Suggest . . ." or "Consider . . ." or even "Perhaps consider. . . ."

CONCLUSION

Case reports from lawsuits against pharmacists suggest that bad outcomes for patients will at times be viewed as the result of pharmacy error. When pharmacists have been in a position of responsibility prior to the occurrence of a bad outcome, they will be held to account for their actions within that position. If the

accounting is inadequate, they will be held liable. It is in the interest of everyone to reduce this liability by lowering the risk of error to patients.

Error prevention cannot occur in a blame-and-shame environment. Pharmacists do not want to make errors, and managers do not want them to make errors. It is the system that sets pharmacists up to fail, and it is the system that must be changed to reduce errors. Management and pharmacists, working together, can create a system in which conscientious and caring pharmacists can maximize their error reduction potential.

FLORIDA & NEW YORK PHARMACISTS.
THIS LESSON FULFILLS THE REQUIREMENT FOR
"MEDICAL ERRORS" CE.
FOR EVERYONE ELSE, THIS TOPIC IS OF SIGNIFICANCE,
NOT ONLY FOR APPROPRIATE PATIENT OUTCOMES,
BUT ALSO BECAUSE IT IS A HIGHLY VISIBLE SUBJECT
THAT CONSUMERS (AND THE PRESS)
ARE CONCERNED ABOUT.
OUR RESPONSIBILITY AS PHARMACISTS IS
TO BE OPEN-MINDED,
AND DO WHATEVER IT TAKES TO
REDUCE THE INCIDENCE OF ERRORS.

Fill in the information below, answer questions and return Quiz to: *CE PRN*®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015. (Or fax to 847-945-5037; or email answers to info@wfprofessional.com).

NAME_____I.D.#(1st line on label)_____

ADDRESS_____CITY_____STATE_____ZIP_____

CHECK IF NEW ADDRESS ❏ **ARE YOU LICENSED IN FLORIDA? IF YES FL LIC #**_____

EMAIL Address (we need this)_____

Please Select the Most Correct Answer

1. What is the purpose of reviewing past pharmacy errors?
   A. To embarrass the pharmacist who has erred.
   B. Humiliation of the pharmacy
   C. Criticism of inappropriate ways of practicing pharmacy
   D. Prevention of the same or similar error in the future

2. All refusals of patient counseling should be documented with patient signature with the documentation.
   A. True   B. False

3. Drugs that have look alike & sound alike names should be placed on shelf next to each other.
   A. True   B. False

4. Upon discovering a pharmacy error, the patient's MD should be contacted.
   A. True
   B. False

5. What factor(s) should be used to identify individuals picking up prescriptions in the will-call area?
   A. Name
   B. Telephone number
   C. Address
   D. All of these

6. What is the most common type of pharmacy error?
   A. Wrong drug
   B. Wrong patient
   C. Failure to counsel
   D. Inadequate DUR

7. Which of the following should be responsible for DUR?
   A. Pharmacists
   B. Technicians
   C. Clerks
   D. All of these

8. Within a pharmacy organization, whose business is safety?
   A. Management only
   B. Pharmacists only
   C. Pharmacists & technicians only
   D. Everyone

9. Individuals who submit pharmacy error reports should be rewarded.
   A. True   B. False

10. What steps should be taken when an obvious error occurred in a pharmacy?
   A. Acknowledge the error
   B. Apologize
   C. Convince the patient that lessons will be learned
   D. All of these

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