Verifying Quality – The Keystone of a Quality Assurance System

Part II—The PASS Rx® Pharmaceutical Authentication Sensor System

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Incorporating PASS Rx® into the Quality Workflow

One tool every pharmacy should consider for incorporation into its continuous quality improvement (CQI) workflow is the PASS Rx® pharmaceutical authentication sensor system. A certain number of failures may be acceptable when manufacturing televisions or automobiles, but every patient expects their pharmacist and their prescription to be perfect every time.[1] Constant and consistent verification is a part of pharmacy practice. As part of the last step in the pharmacy workflow, each prescription must be checked and verified. The most effective way of doing this is through a combination of the pharmacist and technology. The most effective technology for verification is PASS Rx®.

Pharmacists are good at what they do. This is evidenced by the high ranking of pharmacists in the Gallup Poll asking participants to rank professionals according to honesty and ethical standards. In every recent Gallup Poll, pharmacists ranked just below nurses and above physicians as the most trusted professionals.[2]

Pharmacists, however, are not perfect. Once in a while, mistakes are made and occasionally, these mistakes reach the patient. Depending on how the studies are interpreted, this happens somewhere between one error for every sixty-three prescriptions and one in every one thousand prescriptions.[3] Pharmacists are good, but every pharmacist knows they are only human. There will be times when a pharmacist is tired, or the pharmacy is understaffed, or the pressure seems overwhelming. In these times and many more, pharmacists and pharmacy technicians can make mistakes. Even in slow times, mistakes can be made. That is why verification must be performed completely on every prescription. It must be a habit, done every time, all the time.

Technology provides effective tools because they can perform routine tasks in a programmed manner, time after time, every time. Pharmacists are the most important element in this process, because they can think and make decisions. No matter how advanced technological innovations are, including PASS Rx®, they cannot think or make decisions, but PASS Rx® can approach perfection in doing what it is programmed to do – analyze and verify. The PASS Rx® system, when used by the pharmacist as part of the final pharmacist quality check station, can decrease the risk of a medication error reaching a patient.

As impressive as the PASS Rx® system is, its effectiveness can be increased by the incorporation of other best practices into the pharmacy's CQI system. Every good CQI system will use several best practices, some multiple times, to reduce the risk of an error occurring, or to catch a near-miss before it becomes an error that reaches the patient. This report will not review all best practices, but will suggest one that, working in conjunction with PASS Rx®, can assist the pharmacist in reducing the risk of a medication error injuring a patient. It can prevent lawsuits, provide peace of mind, and save reputations.

A quality program can best be described and organized as a series of processes or stations, beginning with the receipt of the prescription or drug order and concluding with the delivery of the prescribed medication to the patient. At the first station, a prescription may be received in several ways, including by telephone, fax, electronic transmission or a patient walking into the pharmacy with a new prescription. Whatever the method, the technician taking the order is trained to check the completeness of the prescription order, including patient name, date of birth and address, and if necessary, legibility.

The second station is usually where the information from the prescription is entered into the computer system. The Auburn National Observation Study indicates that many errors have their beginnings in this part of the process.[4] If a pharmacy technician mistakenly enters the wrong strength of the prescribed drug into the computer, the mistake should be caught by the filling technician. Often, however, it is not. This oversight may be because when filling a prescription, a technician looks not at the new prescription to decide what drug and strength should be taken from the shelf and placed into the vial, but at the label that was generated by the entry technician. If, as in our example, there was a mistake during computer entry and the prescription is filled from the information on the label, the prescription is filled with the wrong strength drug because that is what was on the label.

The pharmacist should catch the mistake during the final quality check, but too often pharmacists have also fallen into the habit of checking the filled prescription against, not the new prescription, but against the label, which, in this example, calls for the wrong strength of the drug. PASS Rx® can be used as a check of computer input mistakes leading to wrong drug or wrong strength errors by using it in conjunction with a best practice that trains staff, technicians and pharmacists, to always fill a new prescription from the prescription itself and not from the information on the label.

The PASS Rx® system uses three primary methods to verify that the prescription is accurate. One method is by scanning the bar code that is part of the label and checking this against the bar code information or the manufacturer's product code on the stock bottle. Adding the best practice, called "Original Only", to the third station, where the prescription is filled, allows the PASS Rx® scanning system to test the accuracy of the information entered into the computer.

Teaching the best practice "Original Only" is relatively simple. The filling technician is taught to fill all <u>new</u> prescriptions only from the information on the original prescription and never from the label. Using this best practice, the filling technician, reading from the new prescription itself, pulls the correct medication from the shelf and uses it to fill the prescription.

Even if the filling technician misses a label error, PASS Rx® will discover it and alert the pharmacist when the manufacturer's bar code is scanned and compared with the stock label bar code. Conversely, if the filling is wrong, that error is caught as well. PASS Rx® can also be made a part of the technician's filling process, in which case the potential error would be caught at that station.

Every pharmacist knows that their primary job when filling any prescription is to fill the prescription accurately. Ultimately, every error is the pharmacist's responsibility. It matters little where the mistake was made or by whom. It is the pharmacist's job to catch every medication error before it reaches the patient. The final station in the filling part of the workflow, before drug review and counseling, is the Pharmacist Final Quality Check. Every step here is critical. Yet, because most prescriptions are correct and because most checks reveal no errors, it is easy to occasionally skip steps in this final quality check. It is the routine nature of the quality check that intermittently allows a mistake to go through. Like all machines, however, PASS Rx® does not mind the routine. It does all of its processes each time, every time.

Using PASS Rx® as part of the Pharmacists Final Quality Check, the pharmacist's first step is to scan the label and the manufacturer's packaging using the scanner that is built into the PASS Rx® verifier. A picture of the correct tablet, in the correct strength, with identifiable tablet markings and a written description of the correct product is shown on the LCD screen. The prescription bottle is placed in the PASS Rx® verifier. Once the pharmacist pushes the "verify" button, PASS Rx® begins its work. Its built-in cameras take pictures of the contents through the bottom of the capped vial, which is used for additional verification along with the spectrographic analysis. The spectrograph provides a "chemical fingerprint" of the contents of the bottle. This is checked against the fingerprints embedded in the PASS Rx® database. Through the use of its multiple sensors, PASS Rx® then verifies the prescription. A record, including a picture will be available for confirmation of the scanned information and what was contained in the bottle at the time of filling.

Once the button on the PASS Rx® verifier is pushed, the pharmacist has eight seconds to complete his or her visual check of the prescription, including the typed directions. With a new prescription, the pharmacist checks the part of the label placed on the written prescription during filling against the original prescription:

PASS Rx
Pharmaceutical Authentication Sensor System

Directions verified – check; drug and strength verified – check; patient name – check. Following the check for mechanical errors, the pharmacist then performs the prospective drug review pursuant to the State's version of OBRA-90. The pharmacist may take more time here, but eight seconds is all of the time the PASS Rx® needs to complete its check and the LCD screen to display the results of the verification.

Most times a green indicator will display on the LCD screen – an indication that the prescription is verified as the correct drug and strength. The LCD display also shows the stock photo of the drug with its markings, the picture of the drugs in the vial, the NDC number, the trade name and the generic name of the medication. Any color other than green appearing on the LCD screen signifies that additional, manual checking is necessary.

A red screen, which is accompanied by an audible beep, indicates the verification failed. The pharmacist is now alerted to a possible error that must be further checked and probably corrected. Sometimes, the PASS Rx® will determine that the drug is correct (half of the screen is green), but the strength is wrong or, at least, cannot be verified (half of the screen is yellow). In each of these cases, the LCD screen will alert the pharmacist of a potential error, allowing the pharmacist to respond. Every time a pharmacist receives an alert indicating other than complete verification, the pharmacist knows possible disaster has been averted.

Liquids, injectables and ointments are checked through the scanned information using the NDC code or the manufacturer's identification numbers and the information entered into the computer from the original prescription. Whatever form of drug is being verified, if the scan, visual identifications and spectrographs are anything other than certain, such as if there are too few tablets to allow a complete verification, or the tablets are too small to produce certain confirmation, the LCD screen provides a message to the pharmacist that manual checking is necessary. While this is rare, it is an additional safety measure. The pharmacist knows that full verification is final and without exception.

No matter how good a pharmacy's quality prescription system is, mistakes can be made. There is no one answer to solving the problem of medication errors, but a complete and consistent Pharmacist Final Quality Check system is the keystone of any quality program. The PASS Rx® pharmaceutical authentication sensor system can take this important station to a new level. PASS Rx® is not magic. It is dependable science. It provides quality and consistency that can be verified and information that can be stored as later evidence. The bottom line is PASS Rx® can assist pharmacists to protect their patients. Ultimately, that is what pharmacy is about.

A Final Thought

Pharmacists have been granted a special place within the healthcare system. Pharmacists have, by law, been given the almost exclusive right to oversee the distribution of dangerous drugs in the United States. This monopoly in dispensing prescription drugs did not always exist, but has evolved over the past two centuries.

There are two primary reasons for the existence of our current pharmacist/patient relationship: the rise of more powerful, effective and potentially toxic or dangerous drugs and, equally important, pharmacists have earned the respect of their patients and the nation. Patients have faith that the prescription they picked up from their pharmacist will be correct. The expectation is perfection.

That absolute trust is one reason that when a pharmacist does make a mistake, it is such a shock and such a sensational story. As journalists say, "It is a good story." Most times, what they mean is, it is a particularly bad story that will sell a lot of papers. No one reports when billions of prescriptions are filled correctly every year. The story is the other one-tenth of one percent that may contain an error.

Pharmacists are expected to be perfect. The only acceptable error rate for a pharmacy is zero. Yet, every pharmacist knows they are not perfect. Every pharmacist has made and will make errors. When it happens, the consequences can be disastrous, first, and most importantly, for the patient, but also for the pharmacy, the pharmacist, and the pharmacy technician personally.

This report was prompted by a request to review PASS Rx®, a new product designed to reduce the number of pharmacy medication errors that reach the patient. I have reviewed many quality related products that can have a positive effect on the number of medication errors, but this one impressed me as few others have.

I originally reviewed PASS Rx® for Pharmacists Mutual® Insurance Company, which has an obvious interest in any product that can reduce the risk of medication errors. Pharmacists Mutual® wanted to know if this product could deliver on what it promised. It exceeded my expectations and my report to Pharmacists Mutual® was that if a pharmacy consistently used PASS Rx®, the number of medication errors could be reduced significantly.

I have reviewed many products for Pharmacists Mutual®, both in my earlier role as General Counsel, Senior Vice President and later as a consultant. I have reported favorably on many of these, including robotic systems, and found many valuable in reducing medication errors.

However, PASS Rx® is different. It is a verification tool that can be integrated into every pharmacy's quality assurance program. Every pharmacy needs a well designed continuous quality improvement system and PASS Rx® should be part of that system. Pharmacists can reduce the number of medication errors. PASS Rx® pharmaceutical authentication sensor system can assist.

[1] Pharmacists and pharmacy technicians will not be surprised to learn that according to the *Wilson Rx 2008 Pharmacy Satisfaction Digest*, patients indicated that the most important service a pharmacy can provide is filling their prescriptions accurately.

[2] For the latest Gallup Poll, see http://www.gallup.com/poll/2287/Nurses-Remain-Top-Honesty-Ethics-Poll.aspx

[3] The best study on errors was by professors Flynn, Barker and Carnahan at the Auburn University College of Pharmacy. These numbers come from that study. See, Flynn, EA, Barker, KN and Carnahan, BJ, National Observational Study of Prescription Dispensing Accuracy and Safety in 50 Pharmacies, JAPhA, Vol. 43, No. 2 March/April 2003. The wide range is dependent upon where all errors are counted, (1.8%) or just significant errors, ones that have the potential to cause serious injury or death (0.1%).

[4] See, Flynn, EA, Barker, KN and Carnahan, BJ, National Observational Study of Prescription Dispensing Accuracy and Safety in 50 Pharmacies, JAPhA, Vol. 43, No. 2 March/April 2003, pg 193.