The Pharmacist Activist

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Editorial

MEDICATION ERRORS (AGAIN) – We Must be More Accountable!

On February 12, the front-page lead story in *USA Today* was "Rx for Error," written by Kevin McCoy and Erik Brady. Extensive coverage of this topic continued over the next two days. It was not pleasant to see the shortcomings of our profession splashed across the headlines. However, the writers had conducted extensive research and interviews, and their message was accurate. If you did not see this series of articles, I would encourage you to access them at www.usatoday.com. It is painful, but instructive, to read the details of some of the tragedies that have resulted from dispensing errors. Much of the coverage in the *USA Today* series pertained to errors made in Walgreens and CVS pharmacies. However, the information and perspectives are important for pharmacists in all pharmacies and practice settings.

Walgreens and CVS responses

The following are among the responses from executives/managers at Walgreens and CVS that are included in the *USA Today* series:

"Errors, as unfortunate as they are, are human errors." (Walgreens)

"No pharmacist ever has to fill a single prescription more during the workday than they feel is safe." (Walgreens)

"We have never dictated the time a pharmacist spends on a prescription." (Walgreens)

"We never compromise safety for speed." (CVS)

"It is not necessary or required for the pharmacy staff to work faster," in noting that pharmacists can extend waits (beyond the company goal [policy?] of 15 minutes) if a pharmacy is busy. (CVS)

Even if these statements can be considered to be technically accurate, many Walgreens and CVS pharmacists strongly challenge whether they represent reality in their busy and often stressful workplaces. Because I know so many of these pharmacists, I hear their concerns all the time.

Accountability

One thing that is very clear from the statements from Walgreens and CVS is that, when errors occur, they view them as human errors or, to be specific, pharmacist errors. I agree that pharmacists have the ultimate responsibility in preventing dispensing errors; however, I very strongly object when the management of chain pharmacies denies or ignores the role that their systems, policies, and workplace conditions have in contributing to the occurrence of errors.

As individual pharmacists and as a profession, we must accept accountability for the prevention of errors (of commission and omission) that are within the scope of our responsibility. One component of this accountability is to address our concerns with management when we believe that its systems and policies compromise patient safety and our ability to fulfill our professional responsibilities. If management does not respond in a positive and effective manner in addressing these concerns, we should actively seek another employment opportunity. Indeed, this is an important reason for which some chains have a continuing high turnover rate and shortage of pharmacists whereas others have waiting lists of pharmacists wanting to join them.

Chain pharmacies seemingly always have enough insurance to cope with lawsuits that result in awards or settlements that may amount to tens of millions of dollars. However, no amount of insurance will protect a pharmacist's license when

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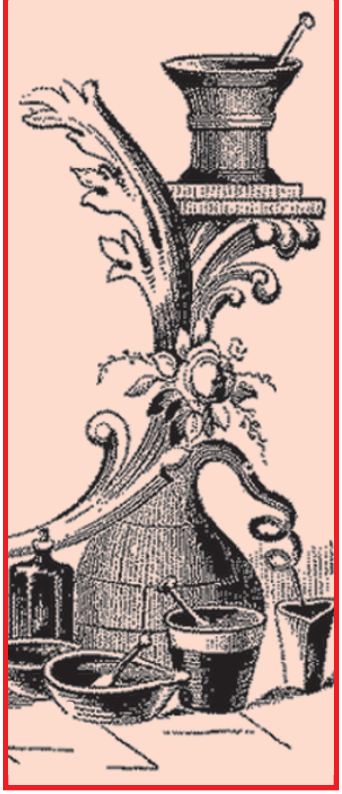

an error has occurred. When an error occurs, our primary concern must be the risk and harm to the patient who is the victim of the error. But, as pharmacists, our license, reputation, and livelihood may also be at risk whereas our employers stand to lose little more than money. We must be accountable and it is essential that we do much more to insist on working conditions that enable us to fulfill our responsibilities to our patients.

Our pharmacy associations and publications must also do much more to accept and promote our profession's responsibility and accountability for medication errors. Yes, there have been numerous articles and continuing education programs on this topic but, aside from the excellent programs and initiatives of the Institute for Safe Medication Practices (ISMP), as well as pharmacy law columns in some publications, there has seemingly been an unwillingness to address the working conditions and policies of some organizations that contribute to the occurrence of errors.

How many errors? No one knows!

Two sidebar commentaries in the USA Today series address issues that contribute to the frustration in understanding the extent to which medication errors occur. In the February 12 article in a column titled, "No One Counts Pharmacy Errors," the following observations are made:

> *"There are no comprehensive counts of prescription errors. Many go undetected or unreported. No federal agency tracks them. On the state level, where pharmacy boards monitor pharmacies and pharmacists, only North Carolina requires that all significant errors be reported."*

A column in the February 14 article is titled, "Many Lawsuits Against Pharmacies Settled In Silence." Many lawsuits regarding prescription errors are settled out of court. There typically is a confidentially agreement with respect to the terms of the settlement and a statement to the effect that there is no acknowledgment of wrongdoing on the part of the defendant. Because no wrongdoing is acknowledged, I must question whether these defendant pharmacies even count these incidents as errors.

As much as I do not want to see more publicity about pharmacy errors, I believe that the public has a right to know more than the information that is available to them now.

Explanations/excuses

Some contend that no one is perfect and that all pharmacists will make mistakes. However, our potential to commit errors must not deter us from establishing a zero-error goal. There are pharmacies in which significant errors have not been made. As the specific errors described in *USA Today* and other sources are reviewed, it is quickly evident that most of these problems could have been and should have been prevented.

Some contend that, in the context of several billion prescriptions being dispensed each year, the number of serious pharmacy errors is extremely small. However, we must not delude ourselves into thinking that any number of errors, however, small, is acceptable when disability and death can be the consequences.

Some contend that there are pharmacists who thrive on high prescription volumes and a fast pace, and are very accurate in their practice responsibilities and seemingly unaffected by stress in the workplace. Most of us, however, function better, and with greater accuracy and less risk, when we practice our profession in an environment and at a pace that is conducive to providing optimal services for our patients.

Actions needed

We must be much more accountable in reducing medication errors and demonstrate urgency in addressing these serious risks. I propose the following actions for the profession:

1. Every significant error (representing actual or potential harm to a patient) must be reported to the Board of Pharmacy. This includes errors that result in lawsuits that are settled out of court without an acknowledgment of wrongdoing. Pertinent information regarding errors that result in serious harm or death should be available to the public.

2. State Boards of Pharmacy should identify guidelines regarding the number of prescriptions a pharmacist can appropriately dispense per day or per shift of a certain number of hours. The North Carolina Board has acquired experience with a guideline of 150 prescriptions per pharmacist per day. This guideline is not intended to be monitored; however, when an error is made, the prescription volume/workload in the pharmacy is assessed, and disciplinary actions imposed when the conditions are considered to represent a danger to the public health. The North Carolina experience represents an excellent start and should be used as the basis for similar systems in other states.

3. Every serious error must be evaluated on an individual basis with consideration given to whether disciplinary action (e.g., suspension or revocation of a license, fines) for the pharmacist and pharmacy is warranted. Severe disciplinary actions should be taken against pharmacists and/or pharmacies responsible for multiple serious errors.

4. Pharmacists should participate in a minimum of two hours of continuing education programming on the topic of medication errors every two years.

5. When pharmacists encounter high prescription volumes and stressful workplace conditions as the norm, they must bring these concerns to the management of the pharmacy and document their discussions/communications. If these situations persist, the pharmacists should seek other employment rather than continuing in a situation in which patient safety and the pharmacist's license is at risk.

6. Pharmacists and pharmacy students who are pursuing a pharmacy practice employment opportunity should request information regarding matters such as the opportunity to counsel patients, prescription volume, staffing levels, working conditions, and job satisfaction.

7. The pharmacy associations must aggressively challenge the employers of pharmacists and the other organizations whose policies impact the scope and quality of our professional responsibilities and the safety of our patients. Some chain pharmacy executives, hospital administrators, insurance companies, and PBMs have hijacked our profession. In the interests of the safety of our patients and the preservation of our role as valued health professionals, we must take our profession back!

Daniel A. Hussar

New Drug Review

Etravirine
(Intelence – Tibotec)
Antiviral Agent

New Drug Comparison Rating (NDCR) = 4
(significant advantages) in a scale of 1 to 5, with 5 being the highest rating

Indication:

In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor (NNRTI) and other antiretroviral agents.

Comparable drugs:

Non-nucleoside reverse transcriptase inhibitors (NNRTIs): Delavirdine (Rescriptor), efavirenz (Rescriptor), nevirapine (Viramune).

Advantages:

- Is effective in some patients who have become resistant to other antiretroviral regimens;
- Not likely to cause hepatic adverse events (compared with nevirapine that has a boxed warning in its labeling regarding this risk);
- Not likely to cause central nervous system and psychiatric adverse events (compared with efavirenz);
- May have less risk when used during pregnancy (is in Pregnancy Category B; compared with delavirdine that is in Category C and efavirenz that is in Category D);
- Certain drug interactions may be of lesser clinical importance (e.g., compared with efavirenz for which certain interacting drugs are identified as being contraindicated);
- Is administered less frequently (compared with delavirdine that is administered three times a day).

Disadvantages:

- Use is limited to treatment-experienced patients with evidence of resistance to other agents;
- Is administered more frequently (compared with efavirenz that is administered once a day);
- Is not indicated for pediatric use (compared with efavirenz and nevirapine that are indicated for use in children as young as 3 years and 2 months, respectively).

Most important risks/adverse events:

Severe and potentially life-threatening skin reactions, including Stevens-Johnson syndrome, erythema multiforme, and hypersensitivity reactions (treatment should be discontinued if a severe rash develops); immune reconstitution syndrome; fat redistribution; should not be included in a regimen with another NNRTI as concurrent use has not been demonstrated to be beneficial; should not be co-administered with tipranavir (Aptivus)/ritonavir, fosamprenavir (Lexiva)/ritonavir, atazanavir (Reyataz)/ritonavir, ritonavir (600 mg twice a day), or other protease inhibitors without the co-administration of low-dose ritonavir; is a substrate of the CYP3A4, CYP2C9, and CYP2C19 metabolic pathways, an inducer of CYP3A4, and an inhibitor of CYP2C9 and CYP2C19; and the concentration and activity of etravirine may be altered by the concurrent use of other agents that are substrates,

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New Drug Review (cont.)

Most important risks/adverse events (cont.):

inducers (e.g., carbamazepine [e.g., Tegretol], rifampin [e.g., Rifadin], St. John's wort), and inhibitors (e.g., clarithromycin [e.g., Biaxin]) of these pathways; the action of certain statins, immunosuppressants, antiarrhythmic agents, and sildenafil may be decreased by the concurrent use of etravirine, whereas the action of warfarin may be increased.

Most common adverse events:

Rash (17%), nausea (14%).

Usual dosage:

200 mg twice a day following a meal.

Product:

Tablets – 100 mg.

Comments:

Etravirine is the twenty-fifth antiretroviral agent to be marketed for the treatment of HIV infection and the fourth that is classified as a NNRTI. However, it is effective in some patients with HIV-1 strains that are resistant to other NNRTIs and is indicated for use in antiretroviral treatment-experienced patients who have evidence of viral replication and HIV-1 strains resistant to a NNRTI and other antiretroviral agents. As with the other most recently-approved antiretroviral agents, it is not indicated for use in initial regimens in treatment-naïve patients. The effectiveness of etravirine was demonstrated in two placebo-controlled trials in patients who had already been treated with three types of antiretroviral agents (NNRTIs, nucleoside/nucleotide reverse transcriptase inhibitors [N(t)RTIs], HIV protease inhibitors). Sixty percent of those treated with etravirine plus a background antiretroviral regimen were identified as virologic responders (viral load less than 50 HIV-1 RNA copies/mL) at week 24, compared with 40% of those treated with placebo plus the background regimen.

Severe and potentially life-threatening skin reactions, including Stevens-Johnson syndrome, erythema multiforme, and hypersensitivity reactions, have been reported infrequently (less than 0.1%) with the use of etravirine, and treatment should be discontinued if a severe rash develops. As with many other antiretroviral agents, etravirine may interact with numerous other medications, including certain of the other antiretroviral agents.

Daniel A. Hussar