The Pharmacist Activist

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Editorial

Drug Interaction Investigation: Part 2

There Must be Mandatory Reporting of Serious Medication Errors and Prohibition of Confidentiality Agreements that Restrict Disclosure!

In the January 2017 issue of *The Pharmacist Activist* (www.pharmacistactivist.com) I reported on the investigation of potential drug interactions that was conducted by reporters of the *Chicago Tribune*, and provided some recommendations for pharmacists and our professional associations. However, even with committing all four pages of the January issue to the editorial, and omitting the review of a new drug that I would typically include, there was not enough space to adequately address this important problem. Thus, Part 2!

The *Chicago Tribune* investigation has received extensive publicity and response. Governor Bruce Rauner of Illinois proposed requiring pharmacists to give counseling when a person obtains a medication for the first time or when prescriptions change. I strongly support this concept as one that should be part of the standards of practice expected of pharmacists. However, it is very unfortunate that elected officials must consider requiring an action of pharmacists that we should be providing as part of our basic responsibilities. It is unacceptable that so many pharmacists have such intolerable working conditions that they do not feel they are able to take the time to counsel patients, and that there are some pharmacists who choose on their own to not fulfill such responsibilities. But the fact that these situations are so common makes it unsurprising that some have concluded that laws must be enacted to require pharmacists to provide services that will help protect patients from drug-related problems.

Such laws must apply to all situations in which medications are provided for self-administration by patients, including local community pharmacies, hospital outpatient pharmacies, specialty pharmacies, and mail-order pharmacies. When medications are provided through the mail, a pharmacist must counsel the patient in a telephone discussion. An email message or a leaflet in the package is not sufficient. A mail-order pharmacy must be no less accountable in complying with a law than a local pharmacy.

Also in Illinois, Representative Mary Flowers has introduced a legislative proposal that would restrict the

number of hours a pharmacist could work in a day, limit the number of prescriptions they can fill each hour, require break time during a pharmacist's shift, and provide whistleblower protection if they identify safety problems. Rep. Flowers notes that whistleblower protection is necessary "…because right now they're all afraid to speak," and that they have an "amazing" fear of retaliation. What a sad, but accurate, commentary on the employers and workplaces for so many pharmacists.

Other responses

I received many responses from pharmacists to my editorial. All voiced strong concerns about the problems exposed by the investigation, but a number of them were pessimistic that any meaningful changes would result. As one pharmacist observed, "This problem may continue to get attention in Illinois but, in most other parts of the country, it will soon be forgotten or ignored until the next investigation is conducted." A pharmacist who was so frustrated in her position with a large chain pharmacy that she left to work in several independent pharmacies, voiced strong concern about the inadequacies of the computer systems and drug interaction information sources used in some of these pharmacies. Retired Pennsylvania independent community pharmacist Michael Hornick made the following observations:

> "It is my firm belief that direct face to face counseling is the only way in which pharmacists can improve patient adherence to medication regimens and prevent medication misadventures. Interacting with the patient gives the pharmacist a better ability to discover poly-pharmacy, prescribing errors, and drug interaction problems. It was my practice to counsel all of my patients whether they asked for it or not. I refused to dispense a medication without counseling even if the patient resisted. The loss of a sale was of no consequence, much like the burning of our tobacco products back in 1979. I am not surprised by the percentages who failed the Tribune test. At a continuing education program I attended on the topic of aerosol inhalers, the speaker asked the participants to raise their hands if they gave personal instructions on the proper use and care of their inhalers. Of the approximately 60 pharmacists attending, only 2 or 3 of us raised our hands. I was surprised and shocked as you were with the Tribune results."

The many readers of *The Pharmacist Activist* who, like myself, had the very valuable experience of having G. Victor Rossi as our teacher at the Philadelphia College of Pharmacy, will have a flashback of his wisdom, eloquence, and wit from his response to my editorial:

> "Shocking, alarming – yes. Disappointing – yes. Surprising – no. Your expectations are very high – perhaps unrealistically so. I regard over-prescribing to be a much greater health hazard – especially among those further along the time span continuum (present company excluded). My kid brother (84) lives in Florida – the stories he relates from 'Dinosaur Park' – notably regarding the number of medications being taken by his friends and neighbors is 'shocking and alarming' – surprising – no, especially given the constant stream of TV commercials that conclude (after a hurried listing of adverse reactions) with 'Ask your doctor if Hemlock is right for you.'"

Serious errors must be reported

There are situations in which the medical problems of patients are so complex that they may experience serious or fatal complications that are caused by an error that is not recognized and/or acknowledged to the patients and their families. In certain of these events, the errors are covered up. Some years ago a large chain of hospitals was in the process of acquiring a Philadelphia-area hospital that was experiencing major financial problems and potential bankruptcy. During the financial deliberations it was necessary for the hospital being acquired to identify actual and potential liabilities, and some of the liabilities disclosed included the potential for lawsuits in situations in which patients died or were disabled as a consequence of errors. A newspaper reporter gained access to this information and, in developing her story, contacted family members of the patients who had been victims of the errors. She was shocked to discover that neither the patients (who survived the error) nor their families had ever been informed of the error that the hospital considered serious enough to identify as a potential liability. Some other explanation had been provided.

(Continued on Page 4)

New Drug Review

Patiromer sorbitex calcium

(Veltassa – Relypsa) *Agent for Hyperkalemia*

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

Indications:
Treatment of hyperkalemia; should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Comparable drug:
Sodium polystyrene sulfonate (e.g., SPS, Kayexalate).

Advantages:
- Less risk of serious gastrointestinal adverse events (e.g., intestinal necrosis);
- Less risk of sodium and fluid retention;
- Is administered once a day (whereas sodium polystyrene sulfonate is administered multiple times a day in some patients).

Disadvantages:
- Rectal administration has not been evaluated (whereas sodium polystyrene sulfonate has been administered as an enema when oral administration is not feasible);
- Product should be refrigerated.

Most important risks/adverse events:
Worsening of gastrointestinal motility (should be avoided in patients with severe constipation or bowel obstruction or impaction, including abnormal post-operative bowel motility disorders); interactions with other oral medications (boxed warning; binds with many orally administered medications which may reduce their absorption and effectiveness; other oral medications should be administered at least 3 hours before or at least 3 hours after patiromer); hypomagnesemia (serum magnesium concentrations should be monitored).

Most common adverse events:
Constipation (7%), diarrhea (5%), nausea (2%), abdominal discomfort (2%), flatulence (2%), hypomagnesemia (9%), hypokalemia (5%).

Usual dosage:
Should be administered with food but should not be added to heated foods or liquids; recommended starting dosage – 8.4 grams once a day; dosage may be increased at 1-week or longer intervals, in increments of 8.4 grams, up to the maximum dosage of 25.2 grams once a day.

Product:
Powder for oral suspension; single-use packets – 8.4 grams, 16.8 grams, 25.2 grams (should be stored in a refrigerator; if it is stored at room temperature, must be used within 3 months of being taken out of the refrigerator); doses should be prepared immediately prior to administration; the contents of a packet should be emptied into a glass or cup containing about 1 ounce of water; the mixture should be stirred thoroughly and an additional 2 ounces of water should be added and thoroughly mixed; the powder does not dissolve and patients should be instructed to drink the mixture immediately.

Comments:
Hyperkalemia is characterized by a serum potassium concentration greater than 5.0 mEq/L. It is most often experienced by patients with kidney disease or heart failure, particularly in those who are taking medications that inhibit the renin-angiotensin-aldosterone system (RAAS) such as angiotensin-converting enzyme inhibitors (ACEIs; e.g., lisinopril), angiotensin receptor blockers (ARBs; e.g., valsartan), the direct renin inhibitor aliskiren (Tekturna), and aldosterone antagonists (spironolactone, eplerenone). The cation-exchange resin sodium polystyrene sulfonate has been used orally or as an enema in the treatment of hyperkalemia. However, it may cause serious gastrointestinal adverse events and sodium and fluid retention.

Patiromer sorbitex calcium consists of the active moiety, patiromer, a non-absorbed potassium-binding polymer, and a calcium-sorbitol counterion. When administered orally, the calcium-sorbitol counterion is exchanged for potassium that binds with patiromer in the lumen of the gastrointestinal tract. This exchange results in increased fecal potassium excretion and reduced serum potassium concentrations. Its effectiveness was evaluated in hyperkalemic patients with chronic kidney disease and/or type 2 diabetes who were taking at least one RAAS inhibitor. Within 4 weeks of initiation of treatment, most patients experienced a reduction in serum potassium concentrations to the target range of 3.8 mEq/L to less than 5.1 mEq/L.

Daniel A. Hussar

Laws and policies regarding the disclosure/reporting of healthcare-related errors vary widely among states and companies/organizations (e.g., hospitals, pharmacies). Patients who are affected by the errors and, as appropriate, their families, must be informed. There is both a need and expectation for healthcare professionals and our employers to be transparent in identifying serious errors. There must also be a system in which all serious errors are reported. Everyone has committed errors although, fortunately, many do not have consequences. The system for reporting errors that should be established should be for educational purposes and the improvement of healthcare practices, and it will be of value in alerting and assisting healthcare professionals in being diligent in observing the precautions that prevent errors. Its purposes should not be for disciplinary or punitive actions, although gross negligence and/or repeated/consistent negligence must not be ignored and does warrant disciplinary action.

With respect to the practice of pharmacy, the state boards of pharmacy come to mind first as the organizations to which serious errors should be reported. However, as regulatory agencies with the authority for licensing pharmacists, state boards of pharmacy would be viewed by many as having a focus on disciplinary action. An alternative would be for the Institute for Safe Medication Practices (ISMP) to collaborate and contract with state boards of pharmacy in the development of an error reporting and education system. Such a system would involve state boards enacting rules/regulations that require the reporting of serious errors to ISMP which would serve as a central source for the collection, evaluation, and dissemination of information and warnings that would be of value for pharmacists and their patients. The discovery of failures to report serious errors to ISMP on a timely basis would be the basis for disciplinary action by the board of pharmacy. The information reported to ISMP would include the specific details regarding the error, contact information for the individual reporting the error (e.g., to obtain clarification), and additional pertinent information (e.g., action taken by the employer or a patient who was harmed). This information would be considered confidential to ISMP, and the educational communications it would disseminate would not include disclosure of the identities of patients, pharmacists, or pharmacies. There are some errors that have such serious consequences (e.g., death, disability) that the specifics should be reported to the state board of pharmacy. The ISMP and boards of pharmacy, in consultation with national pharmacy organizations, should identify the criteria for which the most serious errors must be reported to both ISMP and the particular board of pharmacy.

Confidentiality agreements

Some serious errors result in lawsuits and I have had experiences as an expert witness in such litigation. In the vast majority of situations, the lawsuit is settled out of court and a confidentiality agreement prevents the disclosure of any information regarding the error and the financial and other terms of the settlement. Information that could help other pharmacists avoid making similar errors is suppressed with the motivation that secrecy regarding the event will reduce negative publicity and the possibility that other patients of the pharmacy who have experienced errors will also consider a lawsuit. It is also very likely that state boards of pharmacy are not aware of such errors.

Confidentiality agreements should be prohibited in situations such as these in which the disclosure of pertinent information, risks, and warnings could help prevent other individuals from experiencing similar harm!

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