The Pharmacist Activist

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Editorial

Pharmacy FAILS Drug Interaction Investigation!

Pharmacists: Be on Guard and Stand Your Ground Against Metrics!

On December 15, 2016, the *Chicago Tribune* (Sam Roe, Ray Long, and Karisa King) published an article titled, "Pharmacies miss half of dangerous drug combinations." It is the third in a series of articles on the subject of drug interactions, and describes an investigation conducted by its reporters. The results of the investigation are shocking and alarming! This series of three articles should be required reading for every practicing pharmacist, and it is now required reading for my students.

The investigation

Chicago Tribune reporters visited 255 pharmacies, most of which are in Chicago and its suburbs, and presented two prescriptions for medications with a known potential to interact with serious consequences. The five pairs of drugs used in the study are:

1. Clarithromycin and Ergotamine
2. Simvastatin and Clarithromycin
3. Colchicine and Verapamil
4. Tizanidine and Ciprofloxacin
5. Norgestimate/ethinyl estradiol and Griseofulvin

The reporters presented two prescriptions at a pharmacy and typically waited for them to be completed. A pharmacy was considered to have failed the test if there was not an attempt to contact the prescriber about a drug interaction or orally warn the "patient." Leaflets placed inside the bag or attached to the bag were not considered sufficient to "pass" the test. Thirty pharmacies in each of the large chains in the Chicago area were visited, as were 32 independent pharmacies. The failure rates in this investigation are noted below:

Independent pharmacies	72%
CVS	63%
Target	62%*
Kmart	60%
Costco	60%
Walmart	43%
Jewel-Osco	43%
Mariano's	37%
Walgreens	30%

*Only 13 Target pharmacies were visited as the study in these pharmacies was stopped when CVS acquired Target pharmacies during the study.

The *Chicago Tribune* article is very comprehensive and, in addition to providing the results of the investigation, considers other important issues in sections titled:

- How the Tribune conducted the tests
- Last line of defense
- Speed vs. safety
- 'Scorecard' pressures
- Squeezed by chains
- Major pharmacy chains vow safety improvements

The drugs

A pharmacist friend who is aware of my interest and publications regarding drug interactions asked my opinion regarding the potential severity of the interactions that could occur with the pairs of drugs used in the investigation. To support my responses, I started by looking at the package inserts (i.e., the FDA-approved product labeling) for at least one of the drugs in each pair of medications. In the package insert for clarithromycin, it is noted that ergotamine and simvastatin are among the drugs for which concurrent use of clarithromycin is *contraindicated*. In the package insert for tizanidine, concurrent use with ciprofloxacin is contraindicated. In the package insert for colchicine, it is recommended that the dosage of colchicine be reduced by one-half when verapamil is used concurrently. The interaction between norgestimate/ethinyl estradiol (oral contraceptive) and griseofulvin is not as well documented but the current package inserts contain information about potential problems with this combination. It often takes a considerable period of time before even clinically important interactions are eventually included in the prescribing information/package inserts. The facts that the medications used for the investigation have been available for many years and that the potential interactions are sufficiently well recognized to be included in the most widely available and easily accessible source of information (i.e., the package inserts) justify the selection of the pairs of drugs that were used.

The results

The failure rates of pharmacies in identifying potentially serious or even fatal drug interactions are abysmal and alarming. Regular readers of The *Pharmacist Activist* are aware of my strong advocacy for independent community pharmacies. Therefore, it was very surprising and disappointing that independent pharmacies had the highest failure rate. However, not only independent pharmacies (collectively), but also every chain that was included in the investigation *failed*. The very critical and widespread publicity regarding these failures is an embarrassment for our entire profession.

There have been some attempted explanations/excuses (and my observations) for the high failure rates that have been reported, including the following:

- "We are too busy." (to protect patients from harm? Would a jury agree?)
- "There are too many alerts – alert fatigue." (More time and a better alert system are needed.)
- "Not all the drugs used in the investigation are 'common' medications as some have suggested." (Whether common or uncommon, pharmacists have a responsibility to identify and intervene to prevent important drug interactions.)
- "The interactions involving the 5 pairs of drugs are not 'no-brainers' as suggested by one of the pharmacist consultants working with the *Chicago Tribune*." (Certain of the interactions will be identified more readily than the others, but all should be identified.)
- "The pairs of medications presented were not 'run through insurance.'" (This factor requires further evaluation but it is the pharmacy, and not an insurance company/program, that is supposed to identify interactions.)

Notwithstanding these "explanations," pharmacies failed this investigation, and there must be no excuses!

Drug interaction databases

No pharmacist, or anyone else, can remember all of the important drug interactions that have been identified and, as a result, pharmacists greatly depend (sometimes to an excessive extent) on the information provided when the data for a patient's prescription(s) are entered into an electronic system. But to what extent can the pharmacist rely on the information/alert provided to be adequate, complete, timely, and pertinent to a particular patient's situation?

The pharmacist consultants working with the *Chicago Tribune* reviewed the information/alert that was generated by three drug safety databases for the pairs of interacting drugs. With the first four pairs of drugs, the interactions were identified as major, severe, or contraindicated. The oral contraceptive and griseofulvin pair of medications was identified as moderate, major, and severe in the three databases. Presumably, a high-level alert would have been provided when the names of the medications in each pair were entered into a pharmacy's computer. However, how specific and how strong was the recommendation provided to the pharmacist with respect to the action that should have been taken? For example, if a potential interaction for which a high-level alert is provided is identified as being "suspected" rather than "probable" or an even more definitive characterization, should that influence how a pharmacist should respond?

A "contraindication" is the strongest designation in the "official" labeling/package insert for a medication with respect to risk and potential harm for a patient. I very strongly recommend that pharmacists NOT dispense a medication for which the concurrent use of a medication they are taking or will take is contraindicated. I do not rule out the possibility of very exceptional situations in which a patient needs both types of medications, and

alternative therapies with less risk are not available. The pharmacist must contact the prescriber to discuss the risk of concurrent therapy for the patient and consider alternatives. The pharmacist should only dispense the potentially interacting medication if the prescriber provides convincing information/explanation that the patient would be at *greater* risk if the two medications were not used together. The discussion must be thoroughly documented. An explanation from a prescriber that he/she has used the medications concurrently in other patients without any problems does not suffice. The pharmacist's first responsibility is to the patient, and not to the prescriber.

Other questions that are important with respect to drug interaction databases/alert systems are: Who evaluates and develops the pertinent information and, on how timely a basis is new information included in these databases? When I think of the topic of drug interactions there are two individuals – Phil Hansten and Dave Tatro - who come immediately to mind as the pharmacists (or all health professionals) who have the greatest expertise on this topic. For a number of decades they have been the experts who have published the most authoritative and comprehensive references on drug interactions. However, the publishers of their books/databases have been acquired by huge publishers and, to my knowledge, they are no longer involved in the development and review of content for these reference sources. But who now has that responsibility, and what experience and expertise do they have in the area of drug interactions? I don't know, but the pharmacists who depend to such a great extent on the quality, comprehensiveness, timeliness, and recommendations of these references should know and be able to have complete confidence in the information provided. Additional questions regarding the drug interaction databases can be raised but are beyond the scope of this commentary.

The responses

Pharmacists Carmen Catizone, executive director of the National Association of Boards of Pharmacy, NCPA CEO Doug Hoey, and APhA CEO Tom Menighan were absolutely on target with their responses. In the *Chicago Tribune* article, Catizone observes, "Anytime there's a serious interaction, there's no excuse for the pharmacist not warning the patient about that interaction," and Hoey notes, "It's something that shouldn't happen – both for chains and independents; even one is too many." Menighan's letter that was published in the *Chicago Tribune* is titled, "For pharmacists, patient safety must always come first."

The reporters involved in the investigation subsequently spoke with a number of pharmacists and many of their comments are very insightful with respect to the emphasis of management on metrics and speed. Management of the chains in which the investigation was conducted were also contacted. Some declined to comment but others did, and some responses from executives/managers of CVS, the chain with the highest failure rate, are provided below as examples from the *Chicago Tribune* article:

- "There is a very high sense of urgency to pursue this issue and get to the root cause." (comment from the CVS vice president of pharmacy professional services)
- The company will improve policies and its computer system to "dramatically" increase warnings to patients.
- CVS officials declined to be interviewed about metrics but issued a statement and answered questions in writing. The company said prescriptions do not have to be filled quickly, but it expects pharmacists to have medications ready by the time promised to the customer.
- The color indicators on computer screens are meant to help pharmacists with prioritizing their work.
- CVS said it will change its policies and computer system to require pharmacists to call the prescribing doctor or warn the patients when a serious drug interaction is flagged.
- In the future, the computer alert system will not allow pharmacies to dispense certain flagged medications unless the pharmacists document in the computer that they have called the doctor or counseled the patient.
- CVS said its pharmacists will undergo a comprehensive training and certification program on the new rule, to be implemented in early 2017.
- CVS said it will change its approach to the "offer to counsel," and will require a more robust and explanatory communication.
- CVS said that the new wording has not been finalized but that the company's 50,000 technicians will be trained in the new policy.

It is noteworthy that, in all of the CVS comments about changes and plans they will make, there is no mention made about considering increased staffing of pharmacists and technicians. Similarly, there is no indication that they will abandon or reduce the metrics and, if anything, the metrics could very well increase as policies are changed. I will offer to serve as an unpaid consultant to help CVS identify the "root cause" of the problems that it says it wishes to identify. Indeed, I can identify the root cause without an investigation, based on what I know already from comments of CVS pharmacists. The root causes are understaffing and management's obsession with metrics. *Chicago Tribune* reporters also interviewed current and former CVS pharmacists. It is remarkable, but not surprising, how very different their comments are compared to those made by CVS management.

Recommendations

The *Chicago Tribune* investigation is a strong indictment of the failures of the profession of pharmacy to assure that the risks of using medications are as low as possible. As much as I dislike our profession being viewed so negatively, my conclusion is that this criticism is valid and needed. "Needed" from the standpoint that this investigation can prompt the actions that will result in our protecting the safety of

our patients in the manner that we say we are capable of doing, but very often have not. I have the following recommendations:

1. The APhA, NCPA, the National Association of Chain Drug Stores, and the American Society of Health-System Pharmacists should appoint a task force of pharmacists and selected others who have the greatest expertise and clinical judgment on the subject of drug interactions, and who will be paid for their expertise and service. This task force should evaluate existing electronic and print drug interaction references/databases for their adequacy and timeliness in enabling pharmacists to prevent harmful drug interactions. This activity should initially focus on medications that are dispensed in community pharmacies, and subsequently be extended to include medications that are usually only used in the hospital setting. The task force should identify the drug interactions that have the highest risk of harming patients and provide specific recommendations for pharmacist intervention, including the identification, where possible, of alternative medications that have less risk. The adequacy of the availability and use of drug interaction information should be assessed in the context of how patients obtain prescription and nonprescription medications (i.e., from local pharmacies, mail-order pharmacies, etc.). For example, does a pharmacy have the electronic database needed to prevent interactions, or does the database of a pharmacy benefit manager or insurance company have more complete information? If it is the latter, pharmacies must insist on being provided with the most complete information, and the profession must act in addressing and calling the attention of the public, and their employers and unions, to the greater risk associated with obtaining certain medications from mail-order pharmacies, in addition to medications obtained from local pharmacies.

2. Independent pharmacists should take the actions necessary to identify the best available database/reference, a combination of these sources, as well as the additional information they can obtain, to evaluate and use in the prevention of drug interactions and other drug-related problems. Owners of independent pharmacies have the authority and ability to act immediately in addressing the concerns identified.

3. Chain pharmacies should also take the actions necessary to prevent the occurrence of drug-related problems. However, very unfortunately, for certain chain pharmacies, interactions and other drug-related problems, and the resultant lawsuits, are viewed as a cost of doing business rather than a concern about the consequences experienced by their customers. Yes, some chain pharmacies will respond with additional policies but, unless they provide additional staffing and abandon or substantially reduce their metrics, the additional policies could exacerbate an already stressful workplace environment. If there is any question that current metrics are intended to be of benefit for anyone other than the chain pharmacy company, with the mutually beneficial exception of bonuses for pharmacists, would there not be metrics for the number of situations in which pharmacists commit the time to contact a prescriber, speak directly with patients, acquire additional pertinent information, and intervene to assure optimum drug therapy with the least risk for their patients? If such metrics do exist, I would appreciate learning about them.

Pharmacists must stand their ground against metrics that are counterproductive to providing the best care for their patients! We must insist on having the time needed to fulfill our primary responsibilities to patients in the manner of which we are capable. And we should also take the time to document these situations and our interventions. If the lines of patients waiting to obtain prescriptions get even longer, so be it.

Yes, there will be risks, not only for our patients but also for ourselves. Pharmacists might be faced with a demotion or other disciplinary action, or even the loss of their jobs. If such an action would be taken, a complaint with your supportive documentation should be filed with the State Board of Pharmacy, with copies provided to your professional organizations and, as appropriate, your local newspapers and legislators. If legal assistance is needed, it can be obtained and your situation should prevail.

Our greatest concern is for our patients, but pharmacists also have basis for concern if our license is jeopardized because of decisions/errors of commission or omission. And if your license is revoked or suspended, how will the pharmacy employer respond? It will hire another pharmacist to replace you!

Our patients, our profession, and we as pharmacists deserve our best effort, and it will be for the benefit of all!

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