The Pharmacist Activist

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Editorial

Shame on CVS!

I remember the time when CVS sought and valued an image of professionalism. It was an advocate for the professional role of the pharmacist and emphasized communication of its pharmacists with patients and the value of pharmacist counseling. I used to encourage my students who were interested in chain pharmacy practice to explore employment opportunities with CVS.

Times have changed. Current and former employees of CVS observe that it is not the organization it used to be. From the standpoint of professionalism, bigger has not been better. I no longer encourage my students who are interested in chain pharmacy practice to consider CVS.

Some CVS pharmacists experience a high level of professional fulfillment and job satisfaction in their positions. Many others do not. These latter pharmacists are usually the ones in the high-volume, understaffed, and high-stress pharmacies that are commonplace, although CVS is not unique in having pharmacies like this. Although this situation alone is a basis for serious concern, it is an accumulation of concerns and negative publicity for CVS (and as a consequence for the profession of pharmacy) that prompt this editorial.

The concerns and criticisms voiced here are not directed to the pharmacists who are managing and staffing the CVS pharmacies. These pharmacists are usually remarkably effective, efficient, and professional as they carry out their responsibilities in what is often a very stressful workplace environment. Rather, my comments apply to those within the organization who have the authority for decisions such as staffing levels, company policies, product lines and promotions, and other factors that pertain to the professional role of the pharmacists. Some specific concerns are considered in the following discussion.

Sale of tobacco products to minors - Following numerous situations in which minors purchased tobacco products at CVS, it was announced in March that CVS had reached an agreement with 42 states and the District of Columbia that it would strengthen its efforts to keep minors from buying tobacco products. CVS should have used this as an opportunity to discontinue the sale of tobacco products, a practice that contradicts any message that it may try to convey that it wants to improve health care. Instead, CVS will check the identities of customers who wish to purchase tobacco products if they look younger than 27, will reconfigure its cash registers to alert clerks to check the age of customers who wish to purchase tobacco products, will not use self-service displays and vending machines to sell tobacco products, will hire an independent monitor to check compliance in all its stores across the country, etc. CVS has admitted to no wrongdoing (the kids who purchased the cigarettes must have looked old beyond their years and fooled the clerks) and has not revealed the cost of implementing the agreement (think millions). The willingness of CVS to sign the agreement was apparently prompted by threats of legal action by several states for past violations.

In the same news report regarding this agreement, it was also reported that CVS entered a separate agreement to pay up to $200,000 to settle complaints brought by the Attorney General of Massachusetts. These included accusations that tobacco products had been sold to 13% of minors who participated in sting operations in 2004 and 2005, and that CVS had continued to use self-service displays for tobacco products that had been banned in an earlier agreement.

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Target Provides some Good Examples

I am impressed with the manner in which Target values and promotes the professional role and responsibilities of its pharmacists. It actively encourages its pharmacists to personally speak with their patients ("guests") not only about their prescription medications, but also about the selection and use of nonprescription medications.

Target does not sell tobacco products. It is to be commended for not compromising the health care message and services provided by its pharmacists, and for not facilitating its guests' use of products that are so detrimental to health. Its example and leadership in this regard should be emulated by those pharmacies that continue to sell tobacco products.

For my students who are seeking an opportunity in chain pharmacy practice, Target is one of the organizations I encourage them to consider.

- Daniel A. Hussar

(CVS cont.)

Prescription errors - Following negative publicity in the lay press regarding prescription errors and an investigation by the Massachusetts Board of Pharmacy, the Board announced on February 9, 2006 that it had reached an agreement with CVS in resolution of 80 consumer complaints that the Board had investigated. The Board's investigation concluded that, of these 80 complaints, 62 errors or quality-related events had occurred. Areas of Board concern include the ratio of pharmacists to support personnel, an "offer to counsel" either not being provided at all or not being provided in accordance with Board regulations and statutes, improperly labeled inventory, inadequate storage and controls for Schedule II controlled substances, as well as other concerns.

The agreement requires CVS to engage the Institute for Safe Medication Practices (ISMP) to evaluate and monitor pharmacy practices, policies, and procedures at all CVS pharmacies in Massachusetts for a period of two years. ISMP is to provide CVS with a report of its findings and recommendations for improvement and adoption of best practices and error prevention strategies. The Board of Pharmacy will monitor the implementation of the recommendations and conduct unannounced on-site inspections. CVS must implement corrective active plans to address deficiencies identified during the inspections. The press release announcing the agreement between the Board and CVS includes the following observation by the Director of the Department of Public Health Division of Health Professions Licensure in Massachusetts:

> "The execution of this unprecedented agreement with CVS emphasizes that pharmacy corporations, pharmacists, pharmacy interns and pharmacy technicians all have critical roles and responsibilities in ensuring quality and safety in the delivery of pharmacy services."

I have to think that CVS pharmacists are as capable, conscientious, and accurate as pharmacists working elsewhere. However, if a pharmacy has a high prescription volume and is understaffed, more errors will occur. CVS appears to give priority to how fast prescriptions can be dispensed, as reflected by a policy it has had that prescriptions are expected to be dispensed within 15 minutes from the time they are received from patients. This places added pressure on pharmacists who could be penalized if they do not dispense prescriptions within the 15 minute period, a formidable challenge in a busy pharmacy with some patients bringing in multiple prescriptions.

Disrespect for the professional role and responsibilities of pharmacists - I am aware of a lawsuit brought against CVS by a patient who experienced a serious and irreversible adverse event from a medication that was prescribed and dispensed over a number of years. The particular adverse event is a recognized complication of the use of this medication about which there are specific warnings in the package insert. A specific recommended duration of treatment is also identified.

The defense that CVS has presented is that it and its pharmacists have no responsibility with respect to the adverse event the patient experienced. The prescriptions were legal, were accurately prepared, and were dispensed in quantities and at a frequency that are consistent with the directions for use as noted on the prescriptions. The clear message from the CVS defense is that CVS and its pharmacists have no responsibility to patients beyond doing exactly what the prescriber has ordered. It demonstrates disrespect for the knowledge of its pharmacists, and ignores the responsibility of pharmacists to apply their knowledge in a way that will result in medications being used by their patients as effectively and as safely as possible. In the situation addressed in the lawsuit, timely intervention of the pharmacist would probably have prevented the serious adverse event. The CVS defense undermines the professional role and reputation of the very profession from which it derives its wealth.

The medication that caused the problem is not one of the more frequently prescribed drugs. Notwithstanding the seriousness of the adverse event, this information is not likely to appear as an "alert" on the computer at the time this prescription is being prepared. However, these observations do not remove the need for pharmacists to fulfill their responsibilities to patients. The information that could have been used in preventing this problem is readily available, probably even in the information leaflet provided to the patient.

Several questions arise: What is the likelihood that a pharmacist who is practicing in a pharmacy with a high prescription volume and limited staff support will seek out additional information regarding the medications being dispensed, in the absence of a computer alert? It is my observation that, for pharmacists practicing in a very busy and stressful workplace, the likelihood of their doing this is low.

With whom does the fault lie when a drug-related problem such as the one described above occurs? Pharmacists must carefully evaluate their personal responsibilities to patients. However, in some of the very busy and stressful pharmacy practice environments with which I am familiar, it would be very difficult, if not impossible, for the pharmacists to fulfill their professional responsibilities to each patient. Therefore, the primary focus of attention should be directed at the individuals (and the company) who establish the policies and make the decisions on matters such as the level of staffing in a pharmacy.

What should pharmacists who are confronted with challenging workplace situations do? They should bring their concerns to the attention of their manager/supervisor and persist in efforts to have appropriate changes made. The usual response to this admonition is that one individual in a large company will not be listened to and does not have any influence on decisions that are made. The effort must be made nevertheless. If each individual who has related concerns communicates them, there is an increased probability that the problems will be addressed. If repeated requests to address concerns are not successful, one should explore other professional opportunities.

The most compelling question is: How would you feel if a patient died or experienced a serious drug-related problem that resulted from a prescription error because you were so busy or the lack of information or an intervention that you could have provided but didn't? Considering and acting on this question now could be one of the best decisions you will ever make—for your patients and for yourself.

- Daniel A. Hussar

New Drug Review

Insulin detemir (Levemir)

New Drug Comparison Rating (NDCR) = 2
(significant disadvantage[s])
in a scale of 1 to 5, with 5 being the highest rating

Indications:

Once or twice daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Comparative drugs:

Insulin glargine (Lantus)

Advantages:

- None

Disadvantages:

- Duration of action may be shorter and twice-daily administration may be necessary for optimum control of hyperglycemia
- Less flexibility in the time of administration when administered once a day (i.e., administered with the evening meal or at bedtime, whereas insulin glargine may be administered at any time during the day [at the same time every day])

Conclusions:

Insulin detemir is classified as a long-acting insulin, as is insulin glargine. NPH insulin is classified as an intermediate-acting insulin and is usually administered twice a day. Insulin glargine is administered just once a day and is the standard for the treatment of patients with diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

The duration of action of insulin detemir is shorter than that for insulin glargine and, in some patients, it should be administered twice a day. In the clinical trial in which these two agents were directly compared, insulin detemir was administered twice a day while insulin glargine was administered once a day. There are insufficient data to conclude that once-daily administration of insulin detemir is as effective as once-daily administration of insulin glargine. This is reflected in the labeling for these agents as the labeled indication for insulin detemir is for once- or twice-daily administration, and the labeled indication for insulin glargine is for once-daily administration.

Although a potential exists for insulin detemir and insulin glargine to have different frequencies of responses such as hypoglycemia, injection site reactions, and weight gain, comparative data are not available at the present time to permit a conclusion that either agent has an advantage over the other with respect to the occurrence of adverse events.

When insulin detemir is administered once a day it should be administered with the evening meal or at bedtime. The effectiveness of once-daily administration of insulin glargine has been demonstrated when it is administered at various times during the day. Accordingly, it may be administered at any time during the day at the same time every day, and this greater flexibility in administering the drug may be advantageous for some patients.

Insulin detemir has no documented advantages when compared with insulin glargine, but does have disadvantages. Insulin glargine is the best choice for the treatment of patients with diabetes mellitus who require a long-acting insulin.

Discussion

Insulin detemir (Levemir-Novo Nordisk) is a human insulin analogue with a long duration of action following subcutaneous administration. It is produced by recombinant DNA technology and differs from human insulin in that the amino acid threonine in position B30 has been omitted, and a C14 fatty acid chain has been attached to the amino acid B29. The properties of insulin detemir are most similar to those of insulin glargine (Lantus).

The mean duration of action of insulin detemir ranged from 5.7 hours at the lowest dose to 23.2 hours at the highest dose. Following subcutaneous administration, insulin detemir undergoes slow systemic absorption from the injection site as a result of strong self-association of the drug molecules and albumin binding.

Insulin detemir is indicated for once- or twice-daily administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. Insulin glargine has the same labeled indication with one exception—its longer duration of action precludes a need to administer it more often than once a day, and its indication is for once-daily use.

In the clinical trials, insulin detemir was administered once a day (at bedtime) or twice a day (before breakfast and at bedtime, before breakfast and with the evening meal, or at 12-hour intervals), and was compared with NPH human insulin, administered once or twice a day, or insulin glargine administered once a day. Glycemic control attained with insulin detemir was generally similar to that attained with NPH human insulin and insulin glargine, as measured by glycosylated hemoglobin. However, the data are insufficient to conclude that once-daily administration of insulin detemir is as effective as once-daily administration of insulin glargine because in the study in which they were compared, insulin detemir was administered twice a day while insulin glargine was administered once a day.

The primary concern with the use of any of the insulins is the potential for hypoglycemia, and glucose monitoring is recommended for all patients. The occurrence of hypoglycemia with insulin detemir was similar to that with NPH human insulin. The risk of hypoglycemia may be increased by other medications such as the salicylates, and the concurrent use of one of these agents with an insulin formulation should be closely monitored. Caution should be exercised in patients treated with insulin who are also taking certain beta-adrenergic blocking agents (e.g., propranolol [e.g., Inderal]) because the latter may mask the symptoms of hypoglycemia in some patients.

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The insulins may cause injection site reactions in some patients. Mild injection site reactions occurred more frequently with insulin detemir than with NPH human insulin and usually resolved in a few days to a few weeks. Other adverse events associated with the use of the insulins include allergic reactions, pruritus, weight gain, and lipodystrophy. In the clinical studies, insulin detemir was associated with somewhat less weight gain than was observed with NPH human insulin. However, the studies were not designed in a way to permit a conclusion regarding possible differences between the drugs with respect to this parameter, and the clinical importance of any observed differences has not been established.

Insulin detemir is classified in Pregnancy Category C, as is insulin glargine. Caution should be exercised if either of these agents is administered to a nursing mother.

Insulin requirements may be increased by the use of medications that may increase glucose concentrations (e.g., thiazide diuretics, corticosteroids), and the concurrent use of these agents should be closely monitored.

Insulin detemir is administered subcutaneously and must not be administered intramuscularly, intravenously, or via insulin infusion pumps. For patients who are to be treated once a day, insulin detemir should be administered with the evening meal or at bedtime. In contrast, the once-daily dose of insulin glargine may be administered at any time of the day, at the same time every day. For patients who are receiving insulin detemir twice a day, the first dose is administered in the morning and the second dose with the evening meal, at bedtime, or 12 hours after the morning dose. The dosage of insulin detemir should be individualized, appropriately balanced with the dosage of a shorter-acting insulin that may also be needed and adjusted based on blood glucose determinations.

Insulin detemir should be administered by subcutaneous injection in the abdominal wall, thigh, or upper arm. Injection sites should be rotated within the same region. The new drug should not be diluted or mixed with other insulin preparations, a precaution that is also recommended for insulin glargine.

Insulin detemir injection is a solution that contains the drug in a concentration of 100 units/mL, and is supplied in vials (10 mL), PenFill cartridges (3 mL), and prefilled syringes (3 mL; FlexPen or InnoLet). Unopened insulin detemir formulations should be stored in a refrigerator, but should not be frozen. If the products are stored at room temperature, they may be used for up to 42 days. Opened formulations should be used within 42 days of opening. Opened cartridges and prefilled syringes must not be stored in a refrigerator.

- Daniel A. Hussar

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