

Dear college,

I recently spent four weeks in the psychiatric ward of my local hospital. During this stay the psychiatrist prescribed clozapine for me. I was quite concerned about the side effects of the medication. Initially I had difficulty with sedation but that improved with time. The most annoying part of treatment was the weekly blood work!

Once out of hospital I picked up a one-month supply of clozapine from my local pharmacy. I noticed that the pills looked slightly different from what I received in hospital but the pharmacist reassured me that it was clozapine.

Two weeks later I met with my case manager. I brought in my medication to discuss the changes with her. She told me that I got the wrong product and that I had been given too many pills at once. Now I am not sure that I should be taking them at all.

Confused about Clozapine

what Went Wrong

The pharmacist involved reports:

The patient brought in a prescription for a specific brand of clozapine 350 mg at bedtime for one month. Our pharmacy carries a different brand so I provided the brand that we carry. The patient commented on the different appearance of the tablets so I reassured her that it was another brand of the same drug.

Two weeks later the patient's case manager contacted me to ask whether a registration form had been completed. I was surprised by her question because I thought that would have been done by the physician. The case manager must have contacted the manufacturer's clozapine registry because they contacted me and requested a completed patient registration form. We do not handle a lot of clozapine prescriptions at our store.

Why does Health Canada require mandatory monitoring for clozapine?

Patients using clozapine have a small but significant risk of developing agranulocytosis. Mandatory monitoring through clozapine registries decreases this risk. Quick identification of patients who experience this adverse effect permits the physician to intervene in a timely manner.

Why is the issue of changing brands so important with clozapine?

The introduction of clozapine from multiple manufacturers has resulted in the establishment of manufacturer-specific registry, distribution, and monitoring systems.

Manufacturer-specific patient registration forms must be completed prior to starting a patient on clozapine. They are completed by the physician and the pharmacist and include patient consent. Pharmacists may not switch patients from one brand of clozapine to another without the completion of a new manufacturer-specific patient registration form signed by the prescribing physician. When brands are changed the physician must also obtain patient consent for the sharing of hematological data between clozapine registries. The prescribing physician is ultimately responsible for verifying a patient's hematological/non-rechallengable status so the physician must know which monitoring system the patient is registered in. The risk of harm due to agranulocytosis increases if there are gaps in the monitoring process.

If a patient is switched from one brand of clozapine to another, the frequency of hematological monitoring may continue unaltered unless a change is clinically indicated.

Confusion over the product brand change may increase the risk of non-compliance so thorough patient counseling explaining the substitution is crucial. All pharmacists involved in dispensing clozapine must be fully aware of these guidelines.

How much can I dispense at once?

Pharmacists signing the patient registration form are agreeing to provide clozapine on a weekly or two-weekly basis only. In addition, the pharmacist agrees to provide clozapine only after they have confirmed that the appropriate

lab work (CBC and differential) has been completed. No blood – no drug.

Lab work is required weekly for the first six months of treatment. After six months, if there have been no abnormalities in the lab work, the physician is able to extend the interval for lab work to every two-weeks and the pharmacist is permitted to dispense a two-week supply.

What happens if the patient misses their lab work and they are out of medication?

It is important that patients on clozapine stay on the medication. Abrupt discontinuation can result in rapid deterioration. The pharmacist may have to dispense a small emergency supply, refer the patient to the lab ASAP, and inform the physician. If a patient refuses lab work they will have to discontinue clozapine.

What if a patient wants to go on holidays for more than two weeks?

If the physician writes a prescription for a larger quantity of clozapine the pharmacy must contact the physician to ensure that the patient will be getting their blood tested while they are away. It may be prudent to get the patient to agree to this in writing with full disclosure of potential side effects.

Go www

www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2004/clozapine_hpc-cps_e.html

Situations like the one described above provide an excellent opportunity to reflect on your personal pharmacy practice and to make sure your pharmacy has a system in place to identify, prevent, manage, and report practice errors and omissions.