

Environmental contamination with methotrexate in Canadian community pharmacies

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Abstract

Objectives: To evaluate environmental contamination with methotrexate, cyclophosphamide, and ifosfamide in Quebec, Canada, community pharmacies and to describe hazardous drug handling practices in these pharmacies.

Methods: Three standardized sites were sampled in each participating community pharmacy. Samples were analyzed for the presence of cyclophosphamide, ifosfamide, and methotrexate by high-performance liquid chromatography tandem mass spectrometry. The limits of detection were 0.10, 0.12, and 0.41 ng/mL for cyclophosphamide, ifosfamide, and methotrexate, respectively. Nine working practices were assessed.

Results: 20 community pharmacies participated in the study, and 60 samples were analyzed. No traces of cyclophosphamide or ifosfamide were detected. Traces of methotrexate were found in 12 of 20 pharmacies (60%). Of the 20 pharmacies, 8 (40%) had a storage space reserved for hazardous drugs and none had a preparation area reserved for handling methotrexate tablets. All of the participating community pharmacies had a tablet counter reserved for the handling of hazardous drugs, and all pharmacies cleaned their tablet counter reserved for handling hazardous drugs after use. None of the pharmacies cut or crushed methotrexate tablets.

Conclusion: The growing number of hazardous drugs represents a challenge for community pharmacies. Community pharmacists must be made aware of their presence and the need to comply with personal protection measures to reduce staff occupational exposure to hazardous drugs.

Keywords: Occupational exposure, environmental monitoring, community pharmacies, methotrexate.

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Since 2004, the U.S. National Institute for Occupational Safety and Health (NIOSH) has published an alert on the prevention of occupational exposure to hazardous drugs and a list of hazardous drugs. The list is updated regularly and now includes 167 drugs.¹ This growing number of hazardous drugs represents a challenge, particularly for the safety of community pharmacy staff.

In response to this alert, in 2008, a Quebec, Canada, association for workers' safety (Association paritaire pour la sant e et la s curit  du travail du secteur affaires sociales) published a prevention guide on handling hazardous drugs.² The prevention guide was mainly aimed at health care institutions, but it also can be applied to other sectors. In 2010, the Quebec Order of Pharmacists published recommendations for community pharmacies.³ They stated that gloves approved for handling hazardous drugs should be worn when counting antineoplastic drugs and that storage spaces for antineoplastic drugs should be identified with a cytotoxic hazard symbol.

Although many studies on environmental contamination with hazardous drugs have been conducted in hospital settings,⁴ very few have been conducted in community pharmacies.^{5–8} Given the paucity of literature available, our research group evaluated environmental contamination with hazardous drugs (methotrexate specifically) in Quebec community pharmacies.

Objectives

The main objective of this descriptive cross-sectional study was to evaluate environmental contamination

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with methotrexate, cyclophosphamide, and ifosfamide in Quebec community pharmacies. The secondary objective was to describe hazardous drug handling practices in Quebec community pharmacies.

Methods

Community pharmacies in the Montréal (Quebec, Canada) area were recruited on a voluntary basis using a list of contacts from two pharmacy groups. All of the surface samples were taken by a single research assistant between February 23, 2012, and March 23, 2012.

Evaluation of environmental contamination

The hazardous drugs to be quantified were selected based on the availability of an analytic method. Three standardized sites were sampled in each participating community pharmacy. The outer surface of a 2.5-mg methotrexate container (surface 66 cm²) was chosen because this hazardous drug is available in tablet form and is frequently handled by community pharmacy staff in Quebec. The tablet counter tray reserved for hazardous drugs (300 cm²) was chosen because it had been found to be the most contaminated site in an earlier study.⁸ The preparation counter (600 cm²) was chosen because this surface is frequently touched by workers.

Sites were sampled using a Wypall X60 wiper (6 cm × 8 cm; Kimberly-Clark Professional, Roswell, GA) moistened with 1 mL sampling solution (consisting of 10% methanol and 90% of 5 mmol/L ammonium acetate). Each wipe was analyzed at Quebec Toxicology Center (Institut National de Santé Publique du Québec) using ultra high-performance liquid chromatography tandem mass spectrometry. The analytical method was adapted from Larson et al.⁹ Each sample was quantified for cyclophosphamide, ifosfamide, and methotrexate. The concentration was measured in nanograms per milliliter and reported in nanograms per square centimeters based on the surface sampled. A sample was considered positive when the concentration found exceeded the limit of detection (LOD).

The LODs were 0.10, 0.12, and 0.41 ng/mL for cyclophosphamide, ifosfamide, and methotrexate, respectively. The limits of quantification (LOQs) were 0.33, 0.40, and 1.35 ng/mL for cyclophosphamide, ifosfamide, and methotrexate, respectively. Based on the

surface sampled, the LOD for methotrexate was 0.068 ng/cm² for the container, 0.015 ng/cm² for the tablet counter tray, and 0.0075 ng/cm² for the preparation counter.

The surface contamination was evaluated by taking into consideration the proportion of pharmacies with at least one positive sample, the proportion of positive samples, and the median value of contamination with hazardous drugs. For the calculations, when the measured concentrations were lower than the LOQ and higher than the LOD, we used the LOQ divided by 2.¹⁰ Similarly, for calculations when the measured concentrations were lower than the LOD, we used the LOD divided by 2.¹¹

Assessment of working practices in community pharmacies

Nine working practice aspects were assessed by the research assistant on the day on which the surface sampling was performed. The working practices to be assessed were chosen according to the prevention guide and the Quebec Order of Pharmacists recommendations.^{2,3}

Data analysis

Descriptive statistical analyses (mean, SD, median, interval, and quartiles) were performed. No comparative analyses were performed.

Results

A total of 20 community pharmacies participated in the study. Three sites were sampled in each of the community pharmacies, for a total of 60 analyzed samples. No traces of cyclophosphamide or ifosfamide were detected in any of the 60 samples. Traces of methotrexate were measured in 12 of the 20 pharmacies (60%).

Of the 60 samples, 13 (22%) were positive for methotrexate (2 [10%] from methotrexate containers and 11 [55%] from tablet counter trays used only for hazardous drugs; no samples from preparation counters were methotrexate positive). Table 1 presents concentrations of methotrexate in the participating community pharmacies.

Table 2 presents the results of the working practices that were assessed. Although the majority (six of seven)

Table 1. Profile of environmental contamination with methotrexate in 20 Quebec community pharmacies

Sample sites	Surface concentrations of methotrexate (ng/cm ²)		
	Median	75th percentile	Maximum
Exterior of a methotrexate container (n = 20)	<LOD-ct	<LOD-ct	0.07
Tablet counter tray (n = 20)	0.08	0.39	15
Preparation counter (n = 20)	<LOD-prep	<LOD-prep	<LOD-prep

Abbreviations used: LOD, limit of detection; LOD-ct, LOD for exterior of a methotrexate container; LOD-prep, LOD for preparation counter. LOD for methotrexate was 0.068 ng/cm² for the container, 0.015 ng/cm² for the tablet counter tray, and 0.0075 ng/cm² for the preparation counter.

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