Journal of Pharmacy Technology
2022, Vol. 38(3) 155–158

DOI: 10.1177/87551225211072743
journals.sagepub.com/home/pmt
SAGE

Evaluation of Current Hazardous Drug Exposure Control in Community Pharmacy

John Papastergiou, BScPhm[1,2,3] and Tom Smiley, PharmD[3,4]

Abstract

Purpose: To evaluate effectiveness of current hazardous drug exposure control practices in community pharmacies through identification of commonly contaminated surfaces. We also assessed the decontamination effectiveness of 5 different cleaning agents. **Methods**: This study was prospective and nonrandomized and conducted in 2 phases. In phase 1, 15 common areas used in the dispensing process were tested at each of 4 pharmacies in Toronto Ontario, Canada. Testing was conducted using the BD® HD Check System, a rapid, point-of-care, hazardous drug detection system that is able to identify contamination with methotrexate (MTX) and cyclophosphamide (CYP) and doxorubicin. In phase 2, 5 different cleaning agents (70% isopropyl alcohol, Lysol® spray, Ecolab® retail multiquat sanitizer, Ecolab retail multisurface and glass cleaner with peroxide, and Ecolab QSR heavy-duty degreaser) were tested for their ability to eliminate contamination. **Results**: All 4 pharmacies tested positive for contamination with MTX (25.8% of surfaces). Contamination with CYP was less frequent, with only 3 sites and 18.2% of surfaces testing positive. Of the 5 cleaning agents tested, only Ecolab QSR heavy-duty degreaser was able to eliminate contamination with MTX. None of the agents were successful against CYP. **Conclusions:** The results illustrate an unacceptable prevalence of hazardous drug contamination in community pharmacy settings. The BD HD Check System can serve to rapidly detect common high-risk areas for surface contamination. Decontamination protocols against MTX may include Ecolab QSR heavy-duty degreaser. Novel agents must be identified to remove contamination caused by CYP.

Keywords

hazardous drug detection, decontamination, community pharmacy

Background

Exposure to antineoplastic drugs and other hazardous drugs has been associated with short-term reactions such as flu'-like symptoms, skin rash, and headaches as well as more concerning issues such as increased risk for spontaneous abortion, fetal abnormalities, fetal loss, fertility impairment, and menstrual dysfunction, and increased risk for certain cancers.[1-4] The association between exposure to hazardous drugs and these negative outcomes is supported by studies that have revealed an increase in chromosomal damage in healthcare workers exposed to antineoplastic drugs.

In the pharmacy setting, surface contamination is an important source of exposure to hazardous drugs for anyone coming into contact with that surface.[1] This speaks to the importance of investigating and engaging in best practices for monitoring and removing hazardous drug contamination.

Objective

To identify surfaces in community pharmacies that are most commonly contaminated with hazardous drugs. Secondly, to explore the effectiveness of specific cleaning agents in decontaminating these areas.

Methods

This prospective, nonrandomized study was conducted in 2 phases. In phase 1, 15 common areas used in the dispensing process were tested for the presence of hazardous drugs at each of 4 pharmacies located in Toronto, Ontario Canada. A negative control area where contamination with drugs was known not to exist was also tested. Testing was conducted using the BD® HD Check System, a rapid, point-of-care, hazardous drug detection system that is able to identify contamination with methotrexate (MTX) and cyclophosphamide

[1]Shoppers Drug Mart, Toronto, ON, Canada
[2]University of Toronto, Toronto, ON, Canada
[3]University of Waterloo School of Pharmacy, Waterloo, ON, Canada
[4]Pharmavision Health Consulting Inc., Paris, ON, Canada

Corresponding Author:
Tom Smiley, President/Owner, Pharmavision Health Consulting Inc., 283 German School Road, Paris, ON N3L 3E1, Canada.
Email: phvision99@gmail.com

Table 1. Areas of Community Pharmacy Dispensary Assessed for Hazardous Drugs.

Filling counter[a]	Phone at filling station[a]
Pharmacist counter	Phone at pharmacist station[a]
Pick-up counter	Cytotoxic counting tray/spatula[a]
Counseling side of pick-up/counseling room counter	Area around keyboard at filling station (keyboard, mouse, mousepad etc.)
Compounding counter[a]	Electronic counting device[a]
Drop-off counter	Handles of doors (fridge, safe etc.)
Floor around filling station	Faucet/sink area
Injection vials[a]	Control area (known not to be contaminated)

[a]Areas that were found to be more commonly contaminated with hazardous drugs.

(CYP), 2 antineoplastic agents known for their cytotoxic effects. In phase 2, 5 different cleaning agents (70% isopropyl alcohol, Lysol spray, Ecolab retail multiquat sanitizer, Ecolab retail multisurface and glass cleaner with peroxide, and Ecolab QSR heavy-duty degreaser) were tested for their ability to eliminate contamination.

Results

All 4 pharmacies tested positive for contamination with MTX (25.8% of surfaces). Contamination with CYP was less frequent, with only 3 sites and 18.2% of surfaces testing positive. Common areas of contamination included electronic pill counters, telephones, counting trays, injection vials (MTX only), and filling and compounding stations (see Table 1). Older dispensaries had more sites of contamination than newer ones. Only Ecolab QSR heavy-duty degreaser was able to eliminate contamination with MTX. All other agents failed. None of the agents were successful against CYP.

Five different cleaning agents (70% isopropyl alcohol, Lysol spray, Ecolab retail multiquat sanitizer, Ecolab retail multisurface and glass cleaner with peroxide, and Ecolab QSR heavy-duty degreaser) were used in an attempt to decontaminate affected surfaces. Ecolab QSR heavy-duty degreaser was able to eliminate MTX contamination, while none of the cleaning agents used was able to eliminate CYP contamination. Ecolab QSR heavy-duty degreaser contains sodium carbonate (5-10%), tetrasodium ethylenediaminetetraacetic acid (EDTA) (1-5%), and sodium hydroxide (0.1-1%).

Discussion

The National Institute for Occupational Safety and Health (NIOSH) defines a hazardous drug as one that is associated with carcinogenicity, teratogenicity, or developmental toxicity, reproductive toxicity, organ toxicity at low doses, or genotoxicity.[1] As outpatient care continues to evolve, an increasing number of hazardous drug prescriptions are prepared in community pharmacies as it becomes more common for patients to receive their doses of chemotherapy, continuous antibiotic therapy and other hazardous drugs in their homes.[5] Methotrexate and CYP make up a high percentage of the hazardous drugs that are dispensed from community pharmacies as they are often dispensed in oral dosage forms. Pharmacists and pharmacy staff represent the largest occupational group exposed to antineoplastic agents with over 32,000 of these exposures occurring in community settings.[7] It is therefore imperative that pharmacists and staff be vigilant in maintaining the cleanliness and sterility of the environment where these drugs are prepared for the safety of both staff and patients.

Although the implementation of model standards for preparation of hazardous drugs is under the purview of the provincial pharmacy regulatory authorities, the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada has provided a comprehensive document entitled "Model standards for pharmacy compounding of hazardous sterile preparations" that has been adapted by each of the provinces.[6] Despite comprehensive standards, contamination studies have shown the presence of hazardous drug contamination on many surfaces in the workplace.[8] In fact, in a study of 83 oncology pharmacy and patient areas in Canada reported that 36% of samples tested positive for hazardous drug residue.[9] More than one type of antineoplastic drug residue was found in many of these samples.[9] This speaks to the importance of the implementation of established guidelines in community pharmacies for minimizing hazardous drug exposure. These guidelines should include the following[10]:

- Education and training of individuals on best practices for handling hazardous drugs.
- Limitation of access to areas where hazardous drugs are handled.
- Limitation of the time that each employee works with hazardous drugs.
- Handwashing before and after working with hazardous drugs.
- Best practices for identifying the location of hazardous drug residues.
- Effective decontamination of areas where hazardous drug residues are found.

Reliable and efficient identification of the location of hazardous drug residues is a critical step in the efficient and effective removal of these contaminants. Traditionally, surface wipe sampling coupled with wipe sample analysis has been used as a component of quality assurance programs aimed at minimizing exposure to hazardous drugs.[10] A study that included 338 pharmacies, mostly in the United States, found that overall hazardous drug contamination was reduced with repeated surface wipe sampling through identification of specific areas where contamination existed.[11] The issue with traditional surface wipe sampling lies in the time, effort and expense required to ship samples to a laboratory for analysis. High-performance liquid chromatography, gas chromatography, and ultra high-performance liquid chromatography partnered with mass spectrometry are the most common methods for detecting hazardous drug residue in these samples.[11] Delivery of results can take a number of weeks with the traditional wipe sampling protocol.

The introduction of a portable hand-held hazardous drug detection device (the BD HD Check System) has made the process of hazardous detection much more efficient and provides timely identification of contamination with MTX and CYP, 2 of the more common oral anticancer drugs dispensed in community pharmacies that are known for leaving hazardous drug residues. Doxorubicin, a common intravenously administered antineoplastic agent is also detected. Results from the BD HD Check System take 10 min to deliver. This makes it ideal for use in community pharmacies where these hazardous drugs are used most often.

The BD HD Check System uses competitive lateral flow immunoassay technology to detect the presence of MTX, CYP, and doxorubicin with 95% or greater sensitivity and specificity to detect the drugs at a level above the limits of detection.[10,11] It is currently the only rapid HD detection system available.[10] The testing system consists of a template that is placed over the testing location, a swab used to collect the sample, assay cartridges, and an analyzer that tests the sample.[10] A positive result, available in less than 10 min, indicates that the HD drug is present at a level above the detection threshold of the device.[10,12]

In this study, the most common areas of contamination were electronic pill counters, telephones, counting trays, injection vials (MTX only), and filling and compounding stations. Older dispensaries had more sites of contamination than newer ones. Identification of these areas of contamination allowed for attempts at eliminating the contamination from the surfaces. Ecolab QSR heavy-duty degreaser was able to eliminate MTX contamination, while none of the cleaning agents used (70% isopropyl alcohol, Lysol spray, Ecolab retail multiquat sanitizer, Ecolab retail multisurface and glass cleaner with peroxide, and Ecolab QSR heavy-duty degreaser) was able to eliminate CYP contamination. This speaks to the importance of further research aimed at identifying novel cleaning agents that will be able to decontaminate affected surface areas.

The ASSTSAS is a Canadian joint-sector, nonprofit association for health and occupational safety of the social sector.[13] They have developed a "Prevention Guide for the Safe Handling of Hazardous Drugs." The guide states that existing literature is not clear on the products that should be used for eliminating drug-related contamination.[13] This notion is supported by the more current "USP General Chapter <800> Hazardous Drugs—Handling in healthcare setting" guidelines published by the United States Pharmacopoiea.[14] As with this study, previous studies using alcohol have found that the solution does not appear to be very effective for chemical decontamination. National Institute for Occupational Safety and Health and the American Society of Hospital Pharmacists (ASHP) have suggested using sodium hypochlorite (bleach), which inactivates some but not all drugs. Concentrations ranging from 2 to 5.25% have been used in various studies with action times ranging from 5 min to 1 h.[13] However, the safety risks (e.g., inhalation, splashing into eyes, or skin) must be taken into consideration as well as effects on surfaces (especially stainless steel) such as corrosion and discoloration of fabrics and surfaces. In most situations, the ASSTSAS recommends the use of detergent and water, a microfibre cloth and a rubbing action.[13] Additional evidence-based recommendations await the outcomes of further studies.

The limitations of this study include the ability of the BD HD Check System to detect only 3 HDs. While MTX and CYP are 2 of the most commonly used HDs in community pharmacies, other HDs would escape detection. A second limitation is associated with the limited number of cleaning agents that were used in an attempt to decontaminate the surfaces. This is an area where more detailed research is in order. Finally, the number of community pharmacies included in the study was limited to 4 and all were within 1 geographical area in Canada. Although the study did demonstrate important issues with the presence of HD contamination in typical community pharmacies, a larger sample size would have provided more robust results.

Conclusions

The results of this study illustrate a prevalence of hazardous drug contamination in community pharmacy settings that is not acceptable. The BD HD Check System can serve to rapidly detect common high-risk areas for surface contamination. Based on study results of a select group of cleaning agents, decontamination protocols against MTX may include Ecolab QSR heavy-duty degreaser while novel agents must be identified against CYP. Evidence-based recommendations on best decontaminating agents for hazardous drugs found on community pharmacy surfaces awaits the outcomes of further research.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research has been supported by an unrestricted educational grant from BD.

ORCID iD

Tom Smiley https://orcid.org/0000-0002-9414-7067

References

1. American Society of Hospital Pharmacists. ASHP guidelines on handling hazardous drugs. Accessed October 8, 2021. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx.
2. BC Cancer Provincial Health Service Authority. Safe handling of hazardous drugs. Published September, 2021. Accessed October 8, 2021. http://www.bccancer.bc.ca/pharmacy-site/Documents/Safe%20Handling/2%20%20Module%201_Safe%20Handling%20of%20Hazardous%20Drugs.pdf.
3. Cavallo D, Ursini CL, Perniconi B, et al. Evaluation of genotoxic effects induced by exposure to antineoplastic drugs in lymphocytes and exfoliated buccal cells of oncology nurses and pharmacy employees. *Mutat Res*. 2005;587:45-51. doi:10.1016/j.mrgentox.2005.07.008.
4. McDiarmid MA, Oliver MS, Roth TS, Rogers B, Escalante C. Chromosome 5 and 7 abnormalities in oncology personnel handling anticancer drugs. *J Occup Environ Med*. 2010;52:1028-1034. doi:10.1097/JOM.0b013e3181f73ae6.
5. Lombardo J, Roussel C. Highlighting the risk of occupational exposure to hazardous drugs in the health care setting. *Pharmacy Times*. November 15, 2018. Accessed October 8, 2021. https://www.pharmacytimes.com/view/highlighting-the-risk-of-occupational-exposure-to-hazardous-drugs-in-the-health-care-setting-
6. National Association of Pharmacy Regulatory Authorities. Model standards for pharmacy compounding of hazardous sterile preparations. Ottawa, ON, Canada. Published 2016. Accessed October 12, 2021. https://napra.ca/general-practice-resources/model-standards-pharmacy-compounding-hazardous-sterile-preparations.
7. CAREX Canada. Antineoplastic agents occupational exposures. Accessed October 12, 2021. https://www.carexcanada.ca/profile/antineoplastic_agents-occupational-exposures/.
8. Schulz H, Bigelow S, Dobish R, et al. Antineoplastic agent workplace contamination study: the Alberta cancer board pharmacy perspective. *J Oncol Pharm Pract*. 2005;11:101-109.
9. Chauchat L, Tanguay C, Caron NJ, Gagné S, Labrèche F, Bussières JF. Surface contamination with ten antineoplastic drugs in 83 Canadian centers. *J Oncol Pharm Pract*. 2019;25:1089-1098. doi:10.1177/1078155218773862.
10. Sarna K. Best practices for monitoring hazardous drug contamination. A guidance for health care institutions. *Pharmacy Practice News*. July 23, 2020. Published 2020. Accessed October 15, 2021. https://www.pharmacypracticenews.com/Review-Articles/Article/07-20/Best-Practices-for-Monitoring-Hazardous-Drug-Surface-Contamination/58875.
11. Salch SA, Zamboni WC, Zamboni BA, et al. Patterns and characteristics associated with surface contamination of hazardous drugs in hospital pharmacies. *Am J Health Syst Pharm*. 2019;76:591-598.
12. Canadian Association of Pharmacy in Oncology (CAPHO). Can you identify hazardous drug contamination in less than 10 minutes? Accessed November 3, 2021. https://www.capho.org/article/news/bdr-hd-check.
13. ASSTSAS. Prevention guide: safe handling of hazardous drugs. Published 2008. Accessed October 18, 2021. http://asstsas.qc.ca/sites/default/files/publications/documents/Guides_Broch_Depl/GP65A_hazardous_drugs.pdf.
14. USP General Chapter <800> Hazardous Drugs. Handling in healthcare settings. Accessed October 18, 2021. https://www.usp.org/sites/default/files/usp/document/our-work/health-care-quality-safety/general-chapter-800.pdf.