Addition of a Novel Qualitative Technique to Standard Quantitative Practices for Evaluation of Hazardous Drug Exposure in a Canadian Hospital Setting

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ABSTRACT

Background: Current recommendations from regulatory authorities suggest quantitative surface sampling for detection of hazardous drugs at least once every 6 months. A more frequent and efficient process for hazardous drug testing might reduce the safety risks associated with exposure to these agents.

Objectives: The primary objective was to assess the findings of surface testing based on traditional quantitative sampling methods relative to the findings of qualitative surface sample testing with the BD HD Check system. The secondary objectives included assessment of the ease of integrating qualitative sampling into pharmacy protocols and identification of opportunities to enhance patient and staff education and safety.

Methods: Samples from 23 unique surfaces were tested concurrently once a month for 5 months using a quantitative surface sampling method and the qualitative BD HD Check system on adjacent 12 inch × 12 inch (30.5 cm × 30.5 cm) surface areas. The presence or absence of cyclophosphamide, methotrexate, and/or doxorubicin contamination was assessed by each of the 2 testing methods. The BD HD Check system was also assessed for ease of use and efficiency.

Results: Ten areas of contamination were identified over the 5-month period. Nine were detected by the BD HD Check system and one by the quantitative system. The BD HD Check system was easy to use, with results available in less than 10 minutes per area tested.

Conclusions: The BD HD Check system allows for more timely identification of surface contamination with hazardous drugs than the standard sampling protocol. The discrepancy in results between the 2 methods of hazardous drug surface sampling requires further investigation.

Keywords: hazardous drug exposure, surface sampling, BD HD Check system, surface contamination, hospital employee safety

RÉSUMÉ

Contexte : Les recommandations actuelles des autorités de réglementation suggèrent de procéder à un échantillonnage de surface quantitatif pour la détection de médicaments dangereux au moins une fois tous les 6 mois. Un processus de test des médicaments dangereux plus fréquent et plus efficace pourrait réduire les risques de sécurité associés à l'exposition à ces agents.

Objectifs : L'objectif principal visait à évaluer les résultats de l'échantillonnage de surface basé sur les méthodes d'échantillonnage quantitatives traditionnelles par rapport aux résultats des tests qualitatifs d'échantillons de surface effectués avec le système de détection des médicaments dangereux BD HD Check. Les objectifs secondaires comprenaient l'évaluation de la facilité d'intégration de l'échantillonnage qualitatif dans les protocoles pharmaceutiques et l'identification des occasions d'améliorer l'éducation et la sécurité des patients et du personnel.

Méthodologie : Des échantillons provenant de 23 surfaces uniques ont été testés simultanément une fois par mois pendant 5 mois à l'aide d'une méthode d'échantillonnage de surface quantitative et du système BD HD Check sur des surfaces adjacentes de 12 pouces × 12 pouces (30,5 cm × 30,5 cm). La présence ou l'absence de contamination par le cyclophosphamide, le méthotrexate et/ou la doxorubicine a été évaluée à l'aide de chacune des 2 méthodes de test. La facilité d'utilisation et l'efficacité du système BD HD Check ont également fait l'objet d'une évaluation.

Résultats : Dix zones de contamination ont été identifiées sur la période de 5 mois. Neuf ont été détectées par le système BD HD Check et une par le système quantitatif. Le système BD HD Check était facile à utiliser et les résultats étaient prêts en moins de 10 minutes par zone testée.

Conclusions : Le système BD HD Check permet d'identifier plus rapidement la contamination de surface par médicaments dangereux que le protocole d'échantillonnage standard. L'écart dans les résultats entre les 2 méthodes d'échantillonnage de surface des médicaments dangereux nécessite une étude plus approfondie.

Mots-clés : exposition à des médicaments dangereux, échantillonnage de surface, système BD HD Check, contamination de surface, sécurité des employés de l'hôpital

INTRODUCTION

Health care facilities where workers must handle hazardous drugs face unique challenges with respect to ensuring the safety of both staff and patients. Exposure to these agents can lead to short-term medical consequences such as flu-like symptoms, skin rash, and headaches.[1-4] In addition, studies have revealed an association between exposure to antineoplastic drugs and chromosomal damage, which may increase risks for spontaneous abortion, fetal abnormalities, fetal loss, fertility impairment, and menstrual dysfunction, as well as increased risk for some cancers.[1-3,5]

An important source of exposure to hazardous drugs in the hospital setting is surface contamination in and around the pharmacy where preparation and dispensing of these agents take place. The National Association of Pharmacy Regulatory Authorities (NAPRA) and Section 6 of United States Pharmacopoeia (USP) General Chapter <800> standards recommend that surface sampling be conducted at least every 6 months or more often if needed (e.g., if there is a spill).[6-8] Surface wipe sampling involves applying appropriate solvent to either the surface to be sampled or the sampling material, followed by wiping of the predetermined area in one direction and then perpendicularly to the initial wipe.[9] Currently, the wipes used for sampling at the study hospital are shipped to an analytical laboratory for analysis and returned up to 1 week later.[9,10]

Several studies reporting the results of testing for hazardous drug contamination in hospitals across Canada have established the need for better handling practices and better monitoring of hazardous drugs by testing for surface contamination.[11-19] The clinical pharmacy team at a major hospital in Toronto, Ontario, has recognized the need to test for the presence of hazardous materials more often, so that contaminants can be detected earlier and removed more quickly, and so that potential underlying causes of contamination can be addressed in a more timely manner. The BD HD Check system (https://www.bd.com/en-eu/offerings/capabilities/hazardous-drug-safety/hd-check-system) was identified as the only point-of-care detection method capable of showing the presence of surface hazardous drug contamination.

The primary objective of this study was to assess the results of hazardous drug testing on the same surfaces using traditional quantitative testing of surface wipe samples and qualitative testing with the BD HD Check system. It was assumed that if the hazardous drug findings aligned between the 2 methods, then application of the qualitative testing procedure at intervals of less than 6 months, while continuing the existing schedule of quantitative testing (every 6 months), would be useful for identifying surface contamination between the quantitative testing points. The secondary objectives were to assess the ease of integrating qualitative surface sampling into pharmacy protocols, to identify opportunities for education and training of patients and staff, and to determine incremental costs associated with use of the qualitative sampling method.

By conducting this study, we hoped to learn whether more frequent testing, by means of the BD HD Check system, of surfaces in areas at high risk of hazardous drug contamination would allow for better identification of surface contamination trends and assessment of current decontamination procedures. Quality improvement methods, such as further education and training, as well as additional policies and procedures could then be developed with the goal of reducing the risk of surface contamination, improving cleaning and decontamination methods, and enhancing patient and staff safety.

METHODS

This quality improvement study was conducted at a tertiary care hospital in Toronto, Ontario, which includes a busy oncology clinic. A total of 23 sampling sites were tested for contamination with 3 hazardous antineoplastic drugs (cyclophosphamide, methotrexate, and doxorubicin) with each of the surface sampling methods (see Table 1 for locations of sampling sites). Samples for quantitative testing (standard wipe procedure) and qualitative testing (BD HD Check system) were obtained concurrently from adjacent 12 × 12 inch (30.5 × 30.5 cm) areas at each of the sites once a month for 5 months during daytime working hours (0900 to 1700). The quantitative sampling protocol is summarized in Box 1. The limits of detection of the quantitative and qualitative sampling methods were approximately 0.01 ng/cm^2 and 0.1 ng/cm^2, respectively. Testing for cyclophosphamide and methotrexate was conducted at all 23 sites, whereas testing for doxorubicin was conducted at only 13 of the sites, because this drug is not used at the 10 inpatient pharmacy sites. Surfaces tested included those in areas used for sterile compounding of hazardous drugs; areas used for storage, dispensing, and treatment; administration locations within both the main pharmacy and the cancer care satellite pharmacy; and nursing areas. The selection of areas for testing was guided by recommendations in the USP <800> standards.[6,20]

Results of qualitative testing with the BD HD Check system were compared with results based on quantitative surface sampling in terms of the presence of hazardous contamination with the 3 antineoplastic drugs.

RESULTS

Surface testing for the presence of contamination with cyclophosphamide, methotrexate, and/or doxorubicin was conducted at all designated test areas, as per the study protocol, once a month for 5 months in 2021 (on April 23, May 28, July 2, July 23, and August 26). Over the 5 months of testing, a total of 10 unique surfaces were found to be

TABLE 1. Locations of Sampling Test Areas for Specified Hazardous Medications

Sample Code	Test Surface	Medication Tested[a]		
		Cyclophosphamide	Methotrexate	Doxorubicin
Cancer clinic				
1	Shelving bin from storage cart in clean room	Yes	Yes	Yes
2	Shelving bin from storage cart in anteroom	Yes	Yes	Yes
3	Shelving bin from storage cart in staging room	Yes	Yes	Yes
4	Work surface on biological safety cabinet	Yes	Yes	Yes
5	Floor to the left outside of biological safety cabinet	Yes	Yes	Yes
6	"In" pass-through handles in staging room	Yes	Yes	Yes
7	"Out" pass-through door handle in clean room	Yes	Yes	Yes
8	Telephone in staging room	Yes	Yes	Yes
9	Computer keyboard for chair 14	Yes	Yes	Yes
10	Working desk in front of chair 14	Yes	Yes	Yes
11	Floor area at left side armrest of chair 14	Yes	Yes	Yes
12	Floor area waste bin next to chair 14	Yes	Yes	Yes
13	Side table surface next to chair 14	Yes	Yes	Yes
Inpatient pharmacy				
14	Shelving bin for storage of hazardous drugs	Yes	Yes	No
15	Storage cart in hazardous clean room	Yes	Yes	No
16	Work surface on biological safety cabinet	Yes	Yes	No
17	Door handle going into anteroom	Yes	Yes	No
18	Door handle to exit hazardous clean room	Yes	Yes	No
19	Door handle entering nonhazardous clean room	Yes	Yes	No
20	"In" pass-through handles in staging room	Yes	Yes	No
21	"Out" pass-through door handle in clean room	Yes	Yes	No
22	Work surface on packaging table of hazardous room	Yes	Yes	No
23	Storage bin for hazardous drug in transit to oncology pharmacy	Yes	Yes	No

[a]Yes = test surface was tested for the specified medication; No = test surface was not tested for the specified medication.

contaminated with one of the antineoplastic drugs (Figure 1). Nine of the contaminated surfaces were discovered with use of the BD HD Check system, whereas the 10th contaminated surface was discovered with use of the quantitative sampling protocol.

Four of the contaminated surfaces were discovered during sampling on August 26. On that date, the contaminant in all instances was cyclophosphamide, and all were identified with the BD HD Check system. In each case, no contamination of the immediately adjacent area was indicated by the quantitative sampling protocol. The surfaces that tested positive for cyclophosphamide were retested with the BD HD Check system 30 minutes after the initial test, at which time 3 of the 4 areas were again found to be contaminated with cyclophosphamide, while the fourth area tested negative. All 4 areas were then decontaminated and retested with the BD HD Check system. More specifically, of the 3 areas with positive results on retesting, 1 area was then decontaminated and cleaned with PeridoxRTU (hydrogen peroxide 4.4% plus peroxyacetic acid 0.23%; Contec Inc) and 70% isopropyl alcohol, whereas the other 2 areas were decontaminated and cleaned with Accel wipes (0.5% hydrogen peroxide; Diversey Inc). The 3 areas were then disinfected with PeridoxRTU, sterile water, and 70% isopropyl alcohol. Upon qualitative retesting, all 3 areas continued to test positive after deactivation, decontamination,

cleaning, and disinfection, while the area that tested negative for cyclophosphamide 30 minutes after initial testing remained negative after further decontamination.

The surfaces that most commonly tested positive were around the biological safety cabinet, particularly on the floor (n = 3) and inside the cabinet (n = 3). The BD HD Check system identified methotrexate once, on April 23 at sample site 2 (see Table 1 for site locations), and cyclophosphamide a total of 8 times: on May 28 at sample sites 4 and 5; on July 2 at sample sites 4 and 12; and on August 26 at sample sites 5, 11, 12, and 16. The single positive result by quantitative analysis identified cyclophosphamide on April 23 at sample site 5.

The BD HD Check system was easy to use and was easily integrated into existing pharmacy protocols. Qualitative testing took approximately 10 minutes from beginning to end. At the time of manuscript preparation, the cost of quantitative testing was $260 per wipe (where one wipe covers all 3 hazardous drugs), and the cost of qualitative testing with the BD HD Check system was $72.50 per wipe (where a separate wipe is needed for each of the 3 hazardous drugs, for a total of $217.50 to test one surface for all 3 hazardous drugs).

BOX 1. Qualitative Surface Sampling Protocol with the BD HD Check System

Features of system

- Uses lateral flow immunoassay (LFIA) technology[15]
- Employs template enclosing 12 × 12 inch (30.5 × 30.5 cm) surface for testing

Method

- Wipe surface systematically with premoistened swab[15]
- If surface area is unsuitable for use of the template (e.g., door knob), apply the swab in a freeform fashion[15]
- When swabbing is complete, place the swab inside a transfer vial and fully invert 5 times
- Place 4 drops of solution from the vial onto each of the 3 assay cartridges (marked for cyclophosphamide, methotrexate, and doxorubicin, respectively)[15]
- After 5 minutes, place each LFIA assay cartridge into the BD HD Check analyzer
- Result (positive or negative) will be indicated on the screen, according to whether the contaminant exceeded or did not exceed the detection threshold of 0.1 ng/cm^2 (or a total of 93 ng if freeform swabbing method was used)[15]

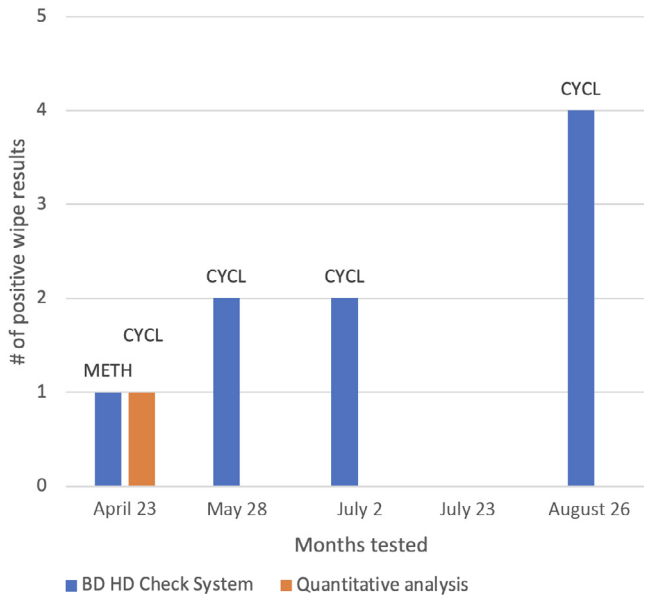

FIGURE 1. Number of surfaces that tested positive for cyclophosphamide (CYCL) or methotrexate (METH) with the BD HD Check system and the quantitative surface sampling protocol.

DISCUSSION

This quality improvement study was designed to address potential issues associated with long waiting periods between quantitative testing to detect the presence of hazardous drugs in high-traffic areas that could result in patient and/or occupational exposure to toxic drug effects. Approximately 450 doses of cyclophosphamide, 1400 doses of methotrexate, and 400 doses of doxorubicin are prepared annually in the study hospital. The study was designed to assess whether testing once a month with the BD HD Check system, in addition to standard quantitative testing with the surface wipe sampling method every 6 months, might result in identification of surface contamination with hazardous drugs during the intervals between standard testing. If so, this modified protocol could lead to more timely decontamination of contaminated surface areas and enhanced staff and patient safety.

The assessment was carried out by comparing the results of qualitative surface sample testing, in terms of presence of hazardous contamination, with the BD HD Check system and the results of quantitative surface sample testing conducted in the same areas once a month for 5 months. Testing for contamination took place after standard decontamination, deactivation, cleaning, and disinfection of the test sites, around midday on the prespecified testing days. Although an analysis of the potential role of the BD HD Check system in identifying surface contamination with hazardous drugs was published recently,[21] to our knowledge this is the first quality improvement study comparing outcomes of the BD HD Check system with those of a standard wipe sampling technique in terms of presence of hazardous contamination in a Canadian hospital.

The BD HD Check analyzer has been validated, so there is 95% certainty that a positive result is truly positive and 95% certainty that a negative result is truly negative.[22] The steps required to complete surface testing with the BD HD Check system, as outlined in the Methods section and Box 1, were found to be very user friendly and time-efficient, with 10 minutes or less needed for analysis of each sampling area.

In this study, on the 5 separate days of surface testing conducted concurrently on adjacent areas by the quantitative and qualitative methods over a 5-month period, a total of 10 unique areas of contamination with a hazardous drug were identified. Nine of these areas of contamination were identified by the BD HD Check system only, with the remaining area identified by the quantitative surface sampling protocol only. Nine of the positive tests were for cyclophosphamide, and one was for methotrexate. There were no known spills of any drugs before testing. The finding of cyclophosphamide as the most common antineoplastic contaminant is consistent with previous reports focused on testing for the presence of hazardous drugs in hospital settings.[1,12,23] The surfaces that most often tested positive were located around the biological safety cabinet, particularly on the floor ($n = 3$) and inside the cabinet ($n = 3$). These findings are also consistent with previous reports of the areas most commonly found to be contaminated with hazardous drugs. For example, Poupeau and others[12] reported that hazardous drug samples were most commonly found around the compounding hood, on biological safety cabinets, on the floors, and on gloves used to prepare antineoplastic agents. In our study, cyclophosphamide proved difficult to decontaminate with existing methods. This finding is also consistent with the literature; for example, Soubieux and others[24] reported difficulty in removing 100% of cyclophosphamide traces.

Both NAPRA and the American Society of Health-System Pharmacists recommend that when hazardous drug contamination is detected, the site be evaluated and potential sources of contamination identified.[1,8] The area should then be decontaminated, cleaned, and disinfected. Finally, the area should be retested to determine the success of mitigation.[1,8] It is imperative to ensure that staff members who are compounding and dispensing hazardous drugs wear the correct personal protective equipment.[8] It is also important to follow institutional procedures and protocols for cleaning of spills, donning/doffing of personal protective equipment, and performance of sterile compounding and to ensure that opportunities for improving the environment, procedures, and practices are implemented. Regular environmental monitoring appears to be the best way to validate the effectiveness of existing preventive measures and to assess strategies for ongoing quality improvement.

On the final testing date of this study (August 26, 2021), the BD HD Check system identified 4 areas of cyclophosphamide surface contamination, of which 3 remained positive upon qualitative retesting 30 minutes later and upon further retesting after additional deactivation, decontamination, cleaning, and disinfection, as described in the Results section. It is likely that the level of cyclophosphamide contamination was reduced by the decontamination process but not to a level below the limit of detection for the BD HD Check system (0.1 ng/cm^2). A previous study found that at least trace amounts of drug contaminants are evident even after multiple cleaning procedures.[12] The BD HD Check system can provide a quick point-of-care result after decontamination procedures to increase the likelihood that an area has been decontaminated of cyclophosphamide, methotrexate, and doxorubicin. However, to avoid a false sense of security, staff should be made aware that trace amounts of a hazardous drug (below 0.1 ng/cm^2) may be present on a surface even if the qualitative method yields a negative result.

At the time of manuscript preparation, the cost of adding regular qualitative testing to the standard quantitative testing protocol was $72.50 per wipe per drug tested. The total added cost per time period would depend on how often qualitative testing was desired (e.g., once per month, once every 2 months) and the number of spills for which surface sampling was required during that particular period.

This study had a few limitations that may help to explain the lack of correlation in results between the BD HD Check system and the quantitative surface sampling protocol. First, it was impossible to simultaneously test exactly the same site with the 2 systems. Therefore, surface sampling for the traditional quantitative test was conducted in an area immediately adjacent to the area tested with the BD HD Check system. Nonetheless, this represents a study limitation, especially given that the areas tested were fairly large (12 × 12 inches). The possibility exists that contamination was present in one area and not the other. Future studies could involve biweekly testing with alternate wipe sampling methods on exactly the same area for a more accurate comparison of results. In addition, the single area that tested positive with the quantitative analysis did not test positive with the BD HD Check system. This may have been related to differences in the limits of detection of the 2 methods. In this instance, the quantitative test result was cyclophosphamide 0.06 ng/cm^2, which is below the limit of detection of the BD HD Check system (0.1 ng/cm^2); in contrast, the limit of detection for the quantitative sampling system is approximately 0.01 ng/cm^2.

Another important limitation relates to handling and shipping of the quantitative surface wipe sample kits. Although the samples were refrigerated, as per manufacturer's instructions, they were not always shipped for analysis on the same day as samples were retrieved, and some were not received at the analysis laboratory until 7 days after surface testing (range 2–7 days). Drug deterioration during shipping, which would yield a negative test result, is therefore a possibility. This may have contributed to the fact that 9 of the 10 samples that revealed surface contamination were detected by the BD HD Check system and not by the quantitative surface sampling protocol.

Although the outcomes of this study associated with detection of hazardous drugs were not as expected, a number of important strategies for quality improvement in hazardous drug testing and cleaning of identified areas of contamination could be implemented at this large hospital

centre as a result of the study findings. The BD HD Check system was found to be a very efficient method of identifying areas of hazardous drug contamination. Point-of-care hazardous drug testing can be used in conjunction with regular quantitative testing to reduce the risks associated with dispensing and administration of hazardous drugs in clinical settings.

Only one positive test result was found with the quantitative surface sampling protocol versus 9 with the BD HD Check system. It is unlikely that this discrepancy is due only to the testing of adjacent areas (as opposed to exactly the same area), especially given that the quantitative system has a lower limit of detection than the qualitative system. A comprehensive review of the surface wipe sampling protocol, from sample collection to laboratory delivery, should be undertaken. Policies and procedures related to integration of the BD HD Check system into routine testing for hazardous drugs, as well as for handling of hazardous drugs and decontamination of areas, should be developed and updated following further investigation into the factors that influenced the results of this study.

CONCLUSION

The BD HD Check system was easy to use and easy to integrate into pharmacy protocols, and the test results were available quickly. The device was able to provide timely qualitative results in terms of the presence or absence of hazardous drug contamination (with a limit of detection of 0.1 ng/cm^2) for cyclophosphamide, methotrexate, and doxorubicin. More research is needed to understand the inconsistency in outcomes between the qualitative and quantitative analyses, especially with respect to the BD HD Check system identifying more areas of contamination than the quantitative system, despite having a higher limit of detection.

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