Sequential Wipe Testing for Hazardous Drugs: A Quality Improvement Project

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BACKGROUND: Monitoring for the presence of hazardous drug (HD) residue is recommended as part of a comprehensive HD safety program. However, a single wipe test provides limited information without the ability to evaluate interventions.

OBJECTIVES: This quality improvement project was designed to evaluate the benefits of performing sequential HD wipe testing during a six-month period in an ambulatory cancer center.

METHODS: Four areas in the pharmacy department and two areas in the infusion department were selected for testing, which was conducted at three time points. Cyclophosphamide, doxorubicin, 5-fluorouracil, methotrexate, and paclitaxel were tested using liquid chromatography coupled with tandem mass spectrometry.

FINDINGS: The initial test demonstrated HD contamination on the legs of the IV pole and the pharmacy transport bin. All other areas were below the limit of detection. Changes were made to cleaning practices in the pharmacy and infusion departments prior to the subsequent tests at the three- and six-month time points, which produced levels below the limit of detection.

KEYWORDS
chemotherapy; hazardous drugs; safety; USP <800>; nursing; contamination

DIGITAL OBJECT IDENTIFIER
10.1188/23.CJON.267-273

DANGERS ASSOCIATED WITH OCCUPATIONAL EXPOSURE to hazardous drugs (HDs) have been well documented and include reproductive toxicities (spontaneous abortions, fetal abnormalities, impaired fertility, learning disabilities in offspring of exposed mothers), acute toxicities (nausea, vomiting, nasal irritation, rash), and an increased risk of cancer development (Connor et al., 2014; Fransman et al., 2014; Nassan et al., 2021; Ratner et al., 2010; Roussel et al., 2019; Valanis et al., 1993a, 1993b). During the compounding of HDs, handling contaminated vials and using vial pressurization techniques can result in environmental contamination, particularly inside the containment primary engineering control (C-PEC) or biologic safety cabinet (BSC) (Power & Coyne, 2018). During drug administration, the priming, connecting, and disconnecting of IV tubing, along with spills and loose connections, significantly contribute to the presence of contamination in patient care areas (Eisenberg, 2016, 2018; Hon & Abusitta, 2016; Polovich & Olsen, 2018; Power et al., 2014).

HD Guidelines and Standards

Because of these risks, safe handling guidelines have been published by the National Institute for Occupational Safety and Health, the American Society of Health-System Pharmacists, and the Oncology Nursing Society (ONS) (National Institute for Occupational Safety and Health, 2016; Polovich & Olsen, 2018; Power & Coyne, 2018; U.S. Pharmacopeial Convention [USP], 2019). In 2016, the USP, a nonprofit scientific organization focused on medication standards, published the USP General Chapter <800> (referred to as USP <800>), with best practice recommendations and standards addressing HD safety for compounding and administration (USP, 2020). USP standards are enforceable, although the specific enforcement agency or entity depends on the state (Polovich, 2017). A summary of USP <800> can be found in Table 1.

However, despite practice guidelines and the use of closed-system drug transfer devices (CSTDs), studies continue to demonstrate HD contamination in pharmacy and drug administration areas (Bartel et al., 2018; Chauchat et al., 2019; Palamini, Gagné, et al., 2020; Salch et al., 2019; Walton et al., 2020). Surface contamination is a significant concern because dermal absorption may lead to uptake, as evidenced by subsequent urinary excretion (Hon et al., 2014, 2015). In one study, contamination was found on the hands of hospital employees who were not directly involved in patient care, with 55% testing above the limit of detection (LOD) for HDs in their urine (Hon et al., 2015).

USP <800> recommends routine environmental surface wipe testing for HD residue. An initial test should be performed to establish a baseline, followed by subsequent testing at a minimum of every six months (USP, 2020). Repeated or sequential wipe testing is also recommended by a panel of international experts (Gabay et al., 2021). Surface wipe testing is a method of quantifying contamination in a given area (typically 100 cm^2). Healthcare organizations are able to perform their own testing because user-friendly kits are now offered by laboratories. Using a laboratory-supplied kit helps reduce cost, which continues to be a significant barrier. A study by Eisenberg et al. (2021) that tested for only two drugs in a patient bathroom and a staff bathroom for five days cost $20,000. Therefore, it is not surprising that a one-time wipe test may be preferred from a financial perspective.

However, conducting a wipe test as an isolated event, even in multiple locations, affords only a snapshot of contamination during a specific time point and may not provide sufficient information for evaluating CSTDs, policies and procedures, or staff adherence (Gabay et al., 2021). For example, a chemotherapy spill from a dislodged IV catheter or a broken drug vial during compounding can produce measurable HD contamination but does not imply a systemic problem. In contrast, testing performed at multiple time points provides a broader overview of the organization's HD safety program and the impact of changes to practice, policies, and equipment. Sequential wipe testing aligns with the Plan-Do-Check-Act model for continuous quality improvement (Comfere et al., 2020).

> **"Hazardous drug contamination is an invisible safety concern that can affect the healthcare team, visitors, and patients."**

Purpose

As part of the organization's HD safety program, a quality improvement wipe-testing protocol was jointly developed by the nursing and pharmacy departments to evaluate the benefits of performing sequential HD wipe testing. Prior to this initiative, the institution had performed random wipe testing in the pharmacy and nursing areas.

Methods

Project Design and Setting

Testing occurred in an ambulatory National Cancer Institute–designated comprehensive cancer center during a six-month period. Members of the HD team determined that testing would occur at three time points in six specific locations (four areas in the pharmacy and two areas in the infusion department). Both departments were open seven days per week, for 15 hours per day from Monday through Friday and for 10 hours per day on Saturday and Sunday. On average, between 150 and 200 patients were seen for a variety of infusions during the week, and between 70 and 120 patients were seen on each weekend day. Depending on regimen acuity, nurses cared for two to three patients at a time. During the six-month study period, a total of 20,619 HDs were compounded in the pharmacy and administered in the infusion department. The pharmacy technicians and infusion nurses received annual HD safety training as required by state law and in accordance with professional guidelines and USP <800> requirements. Given the varying work schedules and the number of staff, different pharmacy technicians were involved in compounding, and different nurses cared for patients in the selected infusion bay.

The following four specific pharmacy locations were chosen for testing: the floor of the negative pressure HD buffer cleanroom where personal protective equipment (PPE) is doffed, a plastic bin for transporting HDs and finished preparations in and out of the cleanroom, the floor in front of a class II type A2 BSC/C-PEC, and the C-PEC airfoil grate. These areas were chosen based on known locations where contamination has been found in published studies (Gabay et al., 2021; Hilliquin et al., 2019; Power & Coyne, 2018).

In the infusion department, a telephone handset at a nursing station and the legs of an IV pole in a patient bay were selected for testing. The pole was labeled for identification in case it was inadvertently moved to another patient bay. The telephone (located in close proximity to the infusion bay with the IV pole) was specifically chosen by nursing leadership because staff are not permitted to wear gloves when making telephone calls and telephones had been identified as a source of contamination in prior studies (Ladeira et al., 2014; Palamini, Hilliquin, et al., 2020; Salch et al., 2019; Viegas et al., 2018; Walton et al., 2020).

Sample

The drugs selected for testing were based on frequency of use and included cyclophosphamide, doxorubicin, 5-fluorouracil, methotrexate, and paclitaxel. These drugs are common treatments for different cancers and are well represented in wipe-testing studies

(Chauchat et al., 2019; Fleury-Souverain et al., 2014; Salch et al., 2019; Viegas et al., 2014).

Except for the doxorubicin syringes, which were compounded and dispensed with the ChemoClave™ CSTD, the remaining drugs were compounded using the ChemoLock™ CSTD and administered as IV piggyback infusions using a short secondary tubing containing a CSTD on both ends. A CSTD was also placed on the distal (patient) end of the primary tubing. Based on nursing policy, the doxorubicin syringes were connected directly to the IV pump cassette or manually pushed into the Y-site of the primary IV tubing for patients with peripheral IVs.

Project Outcomes

The goals of the project were to evaluate the benefits of performing sequential wipe testing by obtaining baseline HD contamination measurements in the selected areas, implementing any necessary changes, and evaluating the effectiveness of those changes based on subsequent test results.

Data Collection and Procedures

Surface sampling kits were obtained from ChemoGLO™. Pharmacy wipe samples were performed by the quality assurance compounding pharmacist, and nursing samples were obtained by the author. Areas were sampled between 7 am and 8 am in both departments. In the pharmacy, wipe testing was done prior to the morning decontamination procedures. The two areas in the infusion department were tested prior to patient arrival. HD gloves were changed between each wipe sample to prevent inadvertent cross-contamination. The initial wipe test (referred to as test day 1 [TD1]) occurred in December 2020. The process was then repeated in March and June 2021 for a total of three sequential tests over six months.

The ChemoGLO wipe-sampling procedure requires two sponge swabs for covering an area of 30.48 cm by 30.48 cm (929 cm^2), which is significantly larger than the more typical 100 cm^2 area specified by other laboratories (Gabay et al., 2021). One swab is used vertically and the other horizontally over the same area. Each swab is placed into its own vial containing a proprietary solution before beginning the vertical or horizontal wipe. Two of the pharmacy areas (the working surface of the BSC and the floor of the doffing area) were sampled using a 929 cm^2 template provided by ChemoGLO. For the airfoil grate and the transport bin, an area of 929 cm^2 was measured and sampled.

Because the area of the telephone receiver was 116 cm^2, only one swab was used vertically to obtain a sample. The IV pole had six legs, each leg totaling 194 cm^2. For TD1, a swab was used vertically and another horizontally to obtain a sample from all six legs. However, after further telephone consultation with ChemoGLO, it was recommended that TD1 be repeated using one vertical swab and one horizontal swab for each of the six legs. This was performed one week later, and results for both of those TD1 sampling techniques are reported here. The revised IV pole technique was used for test day 2 (TD2). Because of an insufficient number of available swabs, for test day 3 (TD3), one vertical and one horizontal sponge was used for a pair of legs (total combined surface area of 232 cm^2). This approach was also approved by ChemoGLO.

Data Analysis

All collected samples were stored overnight in a refrigerator until shipped. Sample analysis was subsequently performed by ChemoGLO using liquid chromatography–tandem mass

TABLE 1.
SUMMARY OF USP <800> GUIDELINES

GUIDELINE	DEPARTMENT AFFECTED
Maintain a list of HDs and provide access to all affected staff.	P, N
Establish written policies and procedures covering all aspects of HD handing.	P, N
Conduct annual HD training based on job responsibility to include compounding, decontamination procedures, drug administration and disposal, and spill management.	P, N
Obtain written confirmation from personnel of reproductive capacity regarding the risks associated with HD handling prior to HD-handling activities.	P, N
Follow specific requirements for unpacking and storage of HD vials.	P
Establish a designated individual to be responsible for overseeing the organization's HD program.	P or N
Provide HD safety education and training to all staff who handle or may come in contact with HDs.	P, N
Provide engineering controls for compounding (e.g., containment primary engineering control such as biologic safety cabinet) and supplemental engineering controls (e.g., closed-system drug transfer devices for administration).	P, N
Recommend environmental wipe testing.	P or N
Use appropriate PPE based on HD-handling activities, including the following: HD receipt, transport, compounding, administration, deactivation, decontamination, cleaning, disinfecting, spill management, and disposal.	P, N
Institute proper disposal of used PPE during the previously mentioned activities.	P, N
Review HD policies and procedures at least annually.	P, N

HD—hazardous drug; N—nursing; P—pharmacy; PPE—personal protective equipment; USP—U.S. Pharmacopeial Convention
Note. Based on information from USP, 2020.

spectrometry (LC-MS/MS). Based on the results of each sequential test, the HD team determined that the pharmacy and nursing departments would discuss necessary changes in procedures, education, or equipment and would reevaluate those changes after the subsequent test(s). Potential improvement opportunities included revisions to the staff training plan regarding decontamination or cleaning processes and whether the CSTDs were providing the expected level of safety.

Results

ChemoGLO establishes the LOD for the tested drugs as 0.01 ng/cm^2. Results from TD1 revealed HD contamination greater than the LOD in two of the six locations. Neither TD2 nor TD3 (at three months and six months) found results greater than the LOD at any of the areas in either the pharmacy department or the nursing department. Overall, 2 of the 18 total wipes exceeded the LOD. A summary of all tests is presented in Table 2.

Pharmacy Department

HD residue from 5-fluorouracil was found on the transport bin in the pharmacy (0.10 ng/cm^2). It is difficult to determine the origin of the TD1 transport bin contamination, although, after discussion, the institution's pharmacists believe it may have been the result of a contaminated vial that had been placed in the bin. Studies have found that many HD vials arrive from the distributor with exterior contamination (Cotteret et al., 2022; Redic et al., 2016). The department had also recorded a broken 5-fluorouracil vial in the week prior to TD1, although it was unclear whether this was related to the bin contamination. Although decontamination and cleaning procedures included the transport bin, inconsistent staff adherence was identified. Additional education was provided, and procedural changes were implemented by including the transport bins in the tracking system for decontamination and cleaning procedures. These changes appear to have been effective because HD residue was less than the LOD at TD2 and TD3.

The pharmacy department has defined HD work practice processes as described in USP <800>. These processes include the use of appropriate PPE, C-PECs and containment-controlled environments for HD sterile compounding, CSTDs during drug preparation whenever possible, and appropriately scheduled decontamination and cleaning procedures. Because wipe testing was performed prior to morning decontamination procedures, the use of CSTDs may have played a role in the negative tests, as evidence suggests that compounding with a needle, even within a C-PEC, still results in contamination (McDiarmid et al., 2018; Power & Coyne, 2018; USP, 2020).

Infusion Department

The legs of the IV pole were positive for paclitaxel (0.03 ng/cm^2) using the initial TD1 technique, although the results were below the LOD when the legs were retested a week later using the revised technique. The presence of a low concentration of paclitaxel at TD1 on the IV pole legs using the first technique but not with the revised technique raises several possibilities. Normal infusion bay cleaning procedures include wiping the surfaces of all equipment with germicidal wipes after each patient discharge. The polished chrome (vertical) section of the IV pole was wiped down with special attention to areas of patient contact, but cleaning practices did not routinely include the legs attached to the wheels. In addition, the cleaning process is intended as an infection prevention measure and not for HD remediation. The use of disinfectant wipes has not been shown to be effective in removing HD residue, although no studies have been published on the optimal cleaning product for use outside of pharmacy surfaces. However, recommendations to nursing leadership were subsequently made for routine cleaning of the IV pole legs using bleach wipes because strong oxidizers can neutralize some HDs (Soubieux et al., 2020).

The most likely source of IV pole leg contamination was from a loose secondary tubing connection at the pump. The

TABLE 2.
SUMMARY OF RESULTS FROM SEQUENTIAL WIPE TESTING OF HAZARDOUS DRUGS

TIME POINT	CLEANROOM FLOOR	TRANSPORT BIN	FLOOR IN FRONT OF BSC	C-PEC AIRFOIL GRATE	TELEPHONE HANDLE	IV POLE LEGS
TD1 (December 2020)	Less than LOD	0.10 ng/cm^2 (5-fluorouracil)	Less than LOD	Less than LOD	Less than LOD	■ 0.03 ng/cm^2 (paclitaxel) ■ Less than LOD on repeat test
TD2 (March 2021)	Less than LOD	Less than LOD	Less than LOD	Less than LOD	Less than LOD	Less than LOD
TD3 (June 2021)	Less than LOD	Less than LOD	Less than LOD	Less than LOD	Less than LOD	Less than LOD

BSC—biologic safety cabinet; C-PEC—containment primary engineering control; LOD—limit of detection; TD1—test day 1; TD2—test day 2; TD3—test day 3
Note. The LOD for hazardous drugs in this study was established as 0.01 ng/cm^2.

department recorded three HD spills during the six-month wipe-testing period, and although one was because of a loose connection, the affected bay and drug were not specified in the report. That missing information highlighted a gap in the spill reporting procedure and the need for further staff education. It is also unknown how long the contamination might have remained on the IV pole legs because HD residue can persist for extended periods of time (Connor et al., 2002).

ChemoGLO hypothesizes that the three subsequent negative results on the IV pole legs (including the retest one week after TD1) could have occurred because the amount of contamination on the first TD1 wipe was marginally higher than the LOD (0.03 ng/cm^2 versus 0.01 ng/cm^2). Although it is generally difficult to remove HD residue from surfaces (Anastasi et al., 2015; Böhlandt et al., 2015; Roberts et al., 2006), the friction and proprietary solvent used with the initial TD1 swab may have removed the residue.

Discussion

Based on best practice guidelines, organizations should consistently evaluate the effectiveness of safety procedures and equipment as part of their HD exposure program (Olsen et al., 2019; Power & Coyne, 2018). Because no acceptable levels for HD exposure have been established, the ALARA (as low as reasonably achievable) principle has been suggested (Connor et al., 2016). Because HD contamination is always a possibility, monitoring for contamination is recommended in USP <800> (USP, 2019).

Several factors can contribute to the presence of HD residue in healthcare facilities. Studies have demonstrated that HD vials can arrive from the distributor already contaminated and that this residue can be spread through the pharmacy and beyond (Power & Coyne, 2018; Power et al., 2014). Spills can occur at the bedside as a result of loose connections, accidental peripheral IV dislodgement, and defective equipment (Eisenberg, 2018; Friese et al., 2015). Practice drift can occur over time, which can affect the culture of safety within an organization (Polovich & Clark, 2012).

Implications For Practice

HD contamination is an invisible safety concern that can affect the healthcare team, visitors, and patients. Determining the presence of HD contamination has a particular benefit for nurses and supportive personnel because HD PPE is not used for all patient care activities. Although wipe testing is not a requirement, USP <800> recommends it as a quality indicator for evaluating the effectiveness of staff education, policy adherence, and engineering controls such as CSTDs. In this study, the sequential testing process provided an opportunity to identify two specific areas in need of improvement and allowed for the validation of subsequent changes. Contamination did not recur in either of the two previously positive areas, nor was it detected in any other locations. Repeatability and sustainability are key components of ongoing quality improvement processes. The identification and remediation of two vulnerabilities within the system helped validate the goal of the project, which could not have been attained with a single wipe test. The concept of sequential testing is transferable to any healthcare organization where HDs are compounded and administered and can assist in benchmarking improvements. Deficiencies in equipment or decontamination procedures must be identified to initiate corrective action.

IMPLICATIONS FOR PRACTICE

- Implement routine sequential wipe testing in areas where hazardous drugs are handled.
- Review testing results with an interprofessional team consisting of nursing, pharmacy, and environmental services.
- Educate nurses regarding the need for detailed documentation of any hazardous drug spills.

As HD safety awareness has increased over the years, so has the desire to better understand the safety risks within areas where nurses are employed. Over the past four decades, the author has spoken to nurses at ONS Congress® and other nursing conferences, as well as at ONS chapter meetings across the country, who have expressed concerns about the safety of their work environment. Sequential testing can provide valuable information about areas where improvements are needed and communicate to staff that the work environment is being evaluated. The relatively low amount of HD contamination identified in this project suggests that although there was room for some improvement, most of the safety measures and procedures were working as intended, which served to reinforce a positive message to staff about their environment and practices. In light of the continued nursing shortage, this messaging is universally valuable in all clinical settings.

Limitations

Although functioning as a quality improvement component of the HD safety program, several weaknesses in the testing protocol itself were subsequently identified. First, the project included only six wipe-sampling areas. Although commonly referenced areas in the pharmacy department were tested (Bartel et al., 2018; Janes et al., 2015; Roland et al., 2017), only two areas in the infusion department were chosen, although the department has 40 bays, 6 nursing stations, and more than 24 telephones. Lack of HD residue on one telephone may not be representative of the nursing unit as a whole, and similarly, a single IV pole may not be indicative of the remaining 39. The computer keyboards in the bays and the IV pumps were not wiped, but other studies have reported HD contamination in these areas (Hon et al., 2013; Janes et al., 2015; Roland et al., 2017; Walton et al., 2020). Although testing these additional locations would have provided a more robust picture, it would have also added to the cost and labor involved in the project.

Because of a change in computer systems during the course of the study, the authors were unable to track the individual number of HDs administered. However, based on the overall volume of

drugs administered throughout the year, it was concluded that a sufficient number of the five agents were both compounded and administered. The difference in sampling techniques used for the IV pole legs is a potential variable. However, because the initial TD1 sample was positive but all the subsequent wipe tests (which covered less surface area per swab) were below the LOD, there was no concern about a false-negative result. Wiping a smaller area per swab typically produces a higher drug recovery rate (Gabay et al., 2021). Finally, better tracking of spill data might have provided more insight as to the cause of the IV pole contamination.

Conclusion

Surface wipe testing is a valuable component of an HD safety program as described in USP <800>. This project demonstrated that sequential testing can identify HD safety vulnerabilities while providing the opportunity to validate the effectiveness of changes over time. This project's results suggest that there is value in organizations establishing sequential testing projects, with an emphasis on areas where HDs are administered.

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The author takes full responsibility for this content. This article was funded, in part, by ICU Medical. The article has been reviewed by independent peer reviewers to ensure that it is objective and free from bias. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Society.

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QUESTIONS FOR DISCUSSION

USE THIS ARTICLE FOR JOURNAL CLUB

Journal club programs can help to increase your ability to evaluate the literature and translate those research findings to clinical practice, education, administration, and research. Use the following questions to start the discussion at your next journal club meeting.

- Based on the description of sequential hazardous drug (HD) wipe testing in this article, if similar testing was performed in your clinical oncology environment, what do you think the results would be?
- Targeting areas/surfaces in your clinical oncology environment, where would sequential HD wipe testing potentially reveal HD contamination?
- In your healthcare facility, how would you advocate for regular sequential HD wipe testing of surfaces/areas in your clinical environment?
- What can you do to encourage your clinical colleagues to prevent HD contamination in the clinical oncology environment?

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