Hazardous Drug Contamination

Presence of bathroom contamination in an ambulatory cancer center

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BACKGROUND: Many hazardous drugs (HDs) are excreted in urine and feces, and evidence has shown that bathrooms of patients receiving chemotherapy at home are contaminated with HDs. However, little information exists on bathroom contamination in ambulatory clinics where HDs are administered.

OBJECTIVES: This project aimed to determine the presence of HD residue in the patient and staff bathrooms of an ambulatory cancer center.

METHODS: A quality improvement project was initiated to examine potential contamination by the HDs 5-fluorouracil and oxaliplatin in a patient bathroom and a secured badge-access staff bathroom in the infusion department of an ambulatory comprehensive cancer center. Twice-daily wipe testing was conducted on the floor in front of the toilet and the flush handle for five consecutive days.

FINDINGS: Sixty-five percent of the samples from the floor of the patient bathroom were positive for at least one of the HDs. In the staff bathroom, 35% of the floor samples were positive for at least one HD. None of the flush handle samples were above the level of detection.

KEYWORDS
hazardous drugs; contamination; safe handling; ambulatory cancer center

HAZARDOUS DRUGS (HDs) ARE DEFINED BY THE NATIONAL INSTITUTE for Occupational Safety and Health (NIOSH, 2016) as having any of the following properties: carcinogenicity, genotoxicity, teratogenicity, reproductive toxicity, organ toxicities at low doses, and structure and toxicity profile of new drugs that mimic drugs previously determined to be hazardous. Studies in healthcare workers (HCWs) who compounded or administered HDs during the 1980s and 1990s demonstrated many adverse health effects ranging from nausea and vomiting to reproductive issues and spontaneous abortions (Fransman et al., 2007; Hemminki et al., 1985; Lawson et al., 2012; Lorente et al., 2000; Martin, 2005; Shortridge et al., 1995; Valanis et al., 1997). Currently, there are no acceptable levels of exposure to HDs, and NIOSH (2016) recommends the ALARA (as low as reasonably achievable) principle, which is used in radiation safety.

Environmental surface contamination with HDs has been described in a number of recent studies (Arnold & Kaup, 2019; Chauchat et al., 2019; Friese et al., 2015; Walton et al., 2020). In the standard on HD safety, USP General Chapter <800>, the U.S. Pharmacopeial Convention (USP, 2017) recommends performing an initial baseline wipe test and repeating at least every six months to help evaluate the potential source(s) of exposure and determine the effectiveness of practices and engineering controls. Research has suggested that environmental contamination can lead to dermal HD uptake with subsequent excretion (Hon et al., 2015). Many commonly used parenteral HDs are excreted in urine as an active drug or metabolites (Micromedex, 2020), and studies in hospitals have found HD residue in patient bathrooms (Böhlandt et al., 2017; Walton et al., 2020).

Two studies of patients receiving chemotherapy at home have also shown the presence of HD in the urine of family members sharing the same bathroom (Yuki et al., 2013, 2015). Unlike residential bathrooms, patient bathrooms in ambulatory clinics are subject to a high volume of patients receiving HDs. These bathrooms may also be used by HCWs. The lack of information on HD contamination in patient bathrooms and the effectiveness of standard cleaning procedures prompted a quality improvement project.

A multiphase quality improvement project was initiated to determine the presence of HD contamination in a patient bathroom and a staff bathroom in an ambulatory infusion department. Phase 1 involved wipe testing for HDs. If contamination was identified, phase 2 would consist of examining

current cleaning procedures, implementing necessary changes, and retesting the same locations six months later. Phase 1 was successfully completed at the end of 2019, and the results are reported in this article. However, because of the COVID-19 pandemic, phase 2 was delayed and is currently in progress.

Methods

Background

Although cyclophosphamide is often used as a marker drug in wipe-testing studies, the literature supports testing for HDs that are commonly administered in the clinical setting (Sessink et al., 1992). Based on pharmacy data, the two most frequently administered HDs were 5-fluorouracil (5-FU) and oxaliplatin. During the three months prior to testing, an average of 115 doses of these drugs were administered during a five-day period (96 doses of 5-FU and 19 doses of oxaliplatin). Both of these HDs are also renally excreted, with as much as 20% of 5-FU and 54% of oxaliplatin found in the urine (Micromedex, 2020). Although testing for multiple HDs would yield a more robust data set, doing so would have added to the project cost. Because no patient or staff information was collected, the project did not require institutional review board approval but was sanctioned by the research and quality departments.

Setting

Testing was performed in the main infusion floor at Seattle Cancer Care Alliance, an ambulatory comprehensive cancer center in Washington. The department consists of 51 infusion bays with eight patient bathrooms. A patient bathroom near the center of the department was chosen as the first testing site. A staff bathroom located behind a badge-access security door about 50 feet from the entrance to the infusion area was chosen as the second testing site. This bathroom is used by staff in the infusion and pharmacy departments, along with employees from other floors.

FIGURE 1.
CUSTOM TEMPLATE WITH NINE 10 CM BY 10 CM SQUARES

Note. Image courtesy of Seth Eisenberg. Used with permission.

> **"Because many HDs are excreted in urine, the bathroom floor is a potential reservoir for contamination that can be spread to other areas."**

Two identical locations inside the bathrooms were chosen for testing: an area on the floor in front of the toilet and the toilet flush handle. These areas were chosen based on studies that demonstrated HD presence in bathrooms of patients receiving chemotherapy at home (Yuki et al., 2013, 2015).

Procedures

Sampling area size is important in calculating the concentration of HDs. For many laboratories, the required size is 10 cm by 10 cm (100 cm^2) (Connor & Smith, 2016; Marie et al., 2017). However, based on measurements taken in patient bathrooms in the clinic, that size was deemed too small to capture the potential urine "drop zone" in front of the toilet. Therefore, a custom template comprised of nine 10 cm by 10 cm squares to cover an area of approximately 12 in. by 12 in. was used (see Figure 1). This template was approved by Bureau Veritas in Lake Zurich, Illinois, who performed all testing using tandem liquid chromatography–mass spectrometry, which can accurately detect HDs in urine (Mathias et al., 2017). Bureau Veritas also verified their ability to provide quantitative results from flooring substrate for the selected HDs. Because the results of an individual 100 cm^2 wipe was of less significance than knowing what was contained in the entire zone, data from the entire 12 in. by 12 in. template (consisting of the nine individual wipes) was aggregated and will be referred to as a single floor sample. The surface area of the toilet handles was smaller than 100 cm^2 (as determined by measuring the length and

diameter using a caliper), and this information was provided to Bureau Veritas for their analysis.

Samples were collected twice daily from both bathrooms, with the first wipes occurring between 6 and 6:30 am, prior to patient arrival in the clinic, and the second wipes occurring between 5 and 6 pm, when most of the regimens containing these drugs were completed. Testing was conducted for five consecutive weekdays in November 2019.

All testing was performed by the authors using the kit and instructions provided by Bureau Veritas. For each individual floor wipe, one Texwipe® Large Alpha® TX714A polyester swab was dipped in methanol and, after removing the excess liquid, wiped across one 10 cm by 10 cm square horizontally and vertically in a crosshatch pattern. Gloves were changed after each swab was used to avoid inadvertent contamination. A video demonstration of the wiping technique can be found at https://bit.ly/3lDcc7P. The swabs were then placed into individually numbered vials and stored in a freezer until the completion of the final test before being cold-shipped at the end of the week.

At the end of day 1, it was discovered that an insufficient number of swabs had been acquired for all the planned tests. After a discussion with Bureau Veritas, the procedure was altered for day 2, and the entire 12 in. by 12 in. floor template (covering 924 cm^2) was sampled using one swab for each bathroom in the morning and one swab for each bathroom in the afternoon. These four floor samples would be analyzed separately using the adjusted surface area because it was not known at the time how the larger area would affect accuracy of the test. Additional kits were shipped overnight, and testing for days 3 through 5 proceeded as originally planned. As shown in Table 1, a total of 168 swabs were sent for analysis.

TABLE 1.
NUMBER OF INDIVIDUAL WIPES BY LOCATION AND DAY (N = 168)

SURFACE	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
Staff bathroom					
Floor	18	2	18	18	18
Handle	2	2	2	2	2
Patient bathroom					
Floor	18	2	18	18	18
Handle	2	2	2	2	2
Subtotal	40	8	40	40	40

Note. All floor wipes covered a 10 cm by 10 cm area except for day 2, which covered a 12 in. by 12 in. area.

Findings

Bureau Veritas established the level of detection (LOD) in urine for both drugs as greater than 0.0056 ng/cm^2. Results for each of the daily floor samples reflect an aggregate of the nine 100 cm^2 squares per bathroom at both time points, with the exception of day 2, which consisted of two 924 cm^2 floor wipes for each bathroom. Twenty flush handle samples were also reported.

None of the toilet handles were above the LOD. However, one or both drugs were detected on the floor each day in either of the two bathrooms. Table 2 shows the levels for both bathrooms. In the staff bathroom, nine of the samples were above the LOD for 5-FU, and five were above the LOD for oxaliplatin. In the patient bathroom, four of the 5-FU samples and five of the oxaliplatin samples were above the LOD. A total of 13 samples for 5-FU and 10 for oxaliplatin were above the LOD for both bathrooms combined. Despite the larger surface area, samples obtained on day 2 demonstrated similar levels of contamination to the other four days.

Contamination did not appear to follow a pattern in either bathroom. On days when the staff bathroom was above the LOD for at least one drug, the patient bathroom was below the LOD. Similarly, oxaliplatin was undetected on certain days in both bathrooms where 5-FU was present. Of all samples, the highest level of contamination was for oxaliplatin in the patient bathroom on the evening of day 3; however, the staff bathroom was below the LOD for the evening test on that day. Only 30% of the floor samples were above the LOD for both drugs on the same day and time in both bathrooms despite both drugs being administered each day of the test. There was no association between the number of doses given each day and degree of contamination.

Discussion

During the five-day test period, 89 doses of 5-FU and 34 doses of oxaliplatin were administered. Depending on the chemotherapy regimen, patients can receive 5-FU without oxaliplatin (e.g., cyclophosphamide, methotrexate, and 5-FU) or with oxaliplatin (e.g., 5-FU, oxaliplatin, leucovorin, and 5-FU bolus followed by continuous home infusion). Because more 5-FU was administered during the testing period, it is not surprising that more samples were above the LOD despite having a lower rate of urinary excretion (Micromedex, 2020). Contamination in the patient bathroom was anticipated based on prior studies performed in hospitals (Viegas et al., 2018; Walton et al., 2020). However, the authors were surprised that the staff bathroom not only was contaminated with HDs, but also produced more samples above the LOD than the patient bathroom.

Hazardous drug residue can remain on surfaces for long periods of time and can be spread by cleaning practices (Chu et al., 2012; Gonzalez & Massoomi, 2010; Hon et al., 2014). It is impossible to determine precisely when contamination in either bathroom occurred because little information exists

regarding how long the HD residue from urine or other excreta can persist on flooring. Therefore, the authors do not know if contamination in either bathroom had occurred during the week of testing, was the result of cumulative contamination, or both. The presence of residue in both bathrooms with the initial 6 am test on day 1 suggests that the residue was not being completely removed or that cross-contamination from other areas had occurred.

The authors cannot definitively explain why 9 of 10 5-FU samples were above the LOD in the staff bathroom but only 4 of 10 were above the LOD in the patient bathroom. Several possible sources have been proposed for contamination in the staff bathroom. Direct transfer on the bottom of shoes from staff could not be ruled out because sampling of footwear or the floor immediately outside of the infusion and pharmacy departments was not feasible. Prior to and during the test period, several pharmacy staff were observed wearing protective foot covers into the staff bathroom. Again, because the footwear was not tested, it is unknown whether HDs were tracked from the pharmacy. It is also unknown whether any of the staff who used the bathroom were actively receiving treatment with these drugs prior to or during the testing period.

Spilled urine containing HDs can be spread across the floor via normal cleaning procedures (Kromhout et al., 2000). Prior to testing, it had been assumed that environmental services changed mop heads after cleaning each bathroom floor because that is the standard procedure when cleaning inside the pharmacy. However, the authors learned that the same mop and bucket was used for both bathrooms during the nightly cleaning. Although this is a possible source of cross-contamination, there were days where the patient bathroom was below the LOD, but the staff bathroom was not, reinforcing the theory that several factors contributed to contamination.

Because monitoring bathroom usage by staff or patients was not within scope of the project, the number of individuals using these respective bathrooms is unknown. However, no urine spills or falls in the patient bathroom were reported during the week of testing.

The days that either bathroom was below the LOD cannot be fully explained. Because methanol is commonly used as a wipe-testing solvent but has not been shown to adequately remove HD residue, it is unlikely that the testing procedure itself had a measurable effect on the results (Böhlandt et al., 2015; Simon et al., 2019). Both bathrooms were only mopped at night. It is impossible to determine whether the contamination was partially removed and subsequently recontaminated the following day. That contamination was not present for both drugs on all wipes would suggest the cleaning process may have reduced contamination to below the LOD, only to increase above the LOD with subsequent samples.

The proper products and techniques for removal of HD residue in bathrooms has not been identified, and cleaning solutions used for floors are not specifically designed for HD removal. The authors are actively investigating other products that claim to neutralize HD residue and plan to evaluate effectiveness with subsequent testing. Careful examination of cleaning techniques by environmental services staff may also help to ensure optimal removal of residue.

TABLE 2.
RESULTS FOR LEVELS OF DETECTION AND TOTAL DOSES ADMINISTERED BY DAY, DRUG, TIME, AND LOCATION

	DAY 1		DAY 2		DAY 3		DAY 4		DAY 5	
VARIABLE	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**
Staff bathroom										
5-FU	0.0127	0.0373	0.0147	0.007	0.0731	0.0086	0.0132	0.0067	0.0103	–
Oxal	–	–	–	0.0067	0.0148	–	–	0.0058	0.0344	0.0126
Patient bathroom										
5-FU	0.0227	0.0626	–	–	–	0.0898	0.0301	–	–	–
Oxal	–	0.1083	0.0113	–	–	0.3262	–	0.0112	0.0157	–
VARIABLE	**5-FU**	**OXAL**	**5-FU**	**OXAL**	**5-FU**	**OXAL**	**5-FU**	**OXAL**	**5-FU**	**OXAL**
Total doses administered	22	10	28	13	17	6	11	4	11	1

5-FU—5-fluorouracil; oxal—oxaliplatin
Note. Values below the level of detection are 0.0056 ng/cm^2 or less. Blank cells indicate values below the level of detection.

Limitations

Studies have shown that the ability to detect HD residue is affected by a number of variables, including the type of surface being tested (Böhlandt et al., 2015; Hedmer et al., 2004; Pretty et al., 2012). Floors in particular are subject to the accumulation of more dirt and debris than other traditional wipe-testing areas (e.g., counters), which can decrease the efficacy of the swabs. It is possible that this debris contributed to samples that were below the LOD. In addition, because the patient bathroom and staff bathroom had different flooring materials and textures, a direct quantitative comparison between the two bathrooms is not possible. Although 148 floor swabs were evaluated, their aggregate equates to only 20 floor samples over a period of five days. This relatively small snapshot may not be indicative of contamination over a longer period or in other areas of the bathrooms (e.g., sink faucet, doorknob). The authors do not have data regarding how many times the bathrooms were used by patients and staff or if any employees were being treated with either drug. Finally, because only two drugs were tested, it is unknown what the results would be for other HDs administered in the department.

Implications for Nursing

The Occupational Safety and Health Act (Occupational Safety and Health Administration [OSHA], 2011) requires employers to provide a safe and healthful work environment. Although HD bathroom contamination is not mentioned by either OSHA or NIOSH or discussed in USP General Chapter <800>, preventing the spread of HD contamination is an important component of an HD safety program (NIOSH, 2016). Once contamination has been acknowledged, current practices can be scrutinized. The current authors' testing revealed vulnerabilities that had not been previously identified, which resulted in changes to practice. In addition to halting the practice of wearing protective foot covers outside of the pharmacy, the environmental services team has changed to using single-use, disposable mop heads when cleaning bathroom floors to eliminate potential cross-contamination. In addition, they are looking into alternative cleaning products.

The relatively simple design of this project makes it easy to replicate in other healthcare facilities as part of a comprehensive HD safety program. It can assist in identifying areas of potential vulnerabilities within facilities and prompt necessary practice changes that might not otherwise have been initiated. As a result of this project, several practices in the cancer center were scrutinized that might not have been otherwise. In addition, it reinforced that environmental services personnel, typically responsible for cleaning, do not always receive the requisite HD safety education and are a potentially vulnerable population (USP, 2017). This creates an opportunity for sharing HD safety knowledge with supportive personnel within the organization.

IMPLICATIONS FOR PRACTICE

- Include wipe testing in bathrooms, particularly those used by staff, in a comprehensive hazardous drug safety plan.
- Review cleaning practices with environmental services personnel to ensure hazardous drug residue is not being spread.
- Implement a comprehensive hazardous drug safety plan using a multidepartmental approach, including members from disciplines outside of pharmacy and nursing.

Conclusion

Because many HDs are excreted in urine, the bathroom floor is a potential reservoir for contamination that can be spread to other areas. Although wipe testing is usually performed where HDs are compounded and administered, it can also be a valuable tool in identifying contamination in bathrooms. To the authors' knowledge, this is the first published report of HD contamination in a staff and patient bathroom in an ambulatory cancer center. Detection of HD residue in one of the staff bathrooms demonstrates how contamination can be found in an unanticipated location and suggests that cleaning procedures and other factors may have contributed. Although eliminating all bathroom HD contamination may not be a realistic goal, quality-based projects such as this can help identify concerns and improve employee safety.

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