Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting

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Abstract

Background: Hazardous drug contamination (HD) in healthcare environments continues, placing healthcare staff at risk of significantly chronic health problems, despite the use of personal protective equipment (PPE) and closed system transfer device systems (CSTDs). **Objective:** This study's aim was to determine how HD might spread through touch after handling contaminated vials in simulated pharmacy and nursing environments. **Methods:** UV fluorescent powder Glo Germ (Glo Germ Co., Moab, UT), composed of melamine resin, was used to simulate HD. Following manufacturer's exact usage specifications, five commercially available CSTDs were tested in the simulated pharmaceutical preparation environment under controlled conditions. UV fluorescence was used to detect the test medium powder that simulated HD following each trial. Photographs, using a Nikon D40X (10.2 mp) camera, were taken at selected stages of testing to document the presence of HD. **Results:** Transfer of the HD testing medium (Glo Germ) to IV sets, pharmacy PPE, and nursing PPE was observed in 4 of 5 CSTDs tested. The only CSTDs that showed no observable contamination was the Allison Medical Safety Enclosed Vial Adapter (SEVA) system (Littleton, CO). **Conclusions:** Results show residue from HD vials spread as vial was handled in a pharmacy environment in 4 of 5 CSTDs, contaminating pharmacy PPE, ancillary products, and nursing PPE. No HD residue was detected on PPE, ancillary products, or nursing PPE in the pharmacy after using the SEVA system, providing an effective means to contain HD for drug transfer from vial to delivery system.

Keywords

antineoplastic drugs, surface contamination, cleaning, health care, pilot study

Introduction

Health care worker exposure to hazardous drugs (HDs), such as an agent with antineoplastic properties, antiviral agents, biological modifiers, and hormones, can cause workers to experience adverse reactions, including asthma, birth defects, miscarriages, and cancer.¹ Chemotherapy treatment for cancer, specifically the agents with antineoplastic properties, has been shown to potentially produce physiological and DNA-damaging effects since the late 1970s.² Contamination of work surfaces³ and personnel⁴ continues to create a health risk for pharmacy staff involved in antineoplastic drug preparation and for nurses involved in delivery of those drugs to cancer patients. Kiffmeyer et al demonstrated this issue's significance by testing 1269 drug preparation surfaces, and finding HD contamination on 744 of those surfaces.³ Their study most likely understated the issue, as the assay was

done for only 5 antineoplastic drugs, leaving the contamination created by alternative drugs undetected. Buschini et al reported 63 potentially exposed nurses at multiple centers in Italy.⁴ The comet assay study showed a significantly lower mean value for the percentage of DNA in the comet tail than a comparable group, suggesting chronic exposure to cross-linking antineoplastic drugs.⁴ Testa et al found a significant increase in chromosomal damage and aberrations in nurses

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exposed to antineoplastic agents, suggesting that current preventive measures may not provide adequate protection.⁵ The University of Maryland Medical Center conducted a study in 2010 on HD contamination documenting chromosomal effects in participating health care workers who worked with HD. Their study suggested low-level exposure, over an extended amount time, could cause significant chromosome damage. Furthermore, administrative HD therapy-related malignancies (myelodysplastic syndrome and acute myeloid leukemia) have been associated with signature lesions in chromosomes 5, 7, and 11 based on fluorescence in situ hybridization.⁶ DNA analysis of exposed health care workers in the study showed a statistically significant increased frequency of damage to chromosomes 5 and 7 ($P = .01$), and increased damage to chromosome 5 alone ($P = .01$).⁶

Antineoplastic drugs have been found to contaminate frequently touched surfaces in pharmacies, even after cleaning.⁷ These results suggest that contact with HD-contaminated surfaces is the most probable cause of transdermal exposure. Although standard cleaning procedures reduce the concentration of some HD surface compounds, others remained high. This indicated the importance of preventing HD exposure with resulting surface contamination during treatment preparation. This finding is especially concerning when considering the potential for cross-contamination of surfaces cleaned with the same cleaning materials. In addition, vials may arrive at health care facilities already contaminated with HD on their exterior surface. Massachusetts General Hospital conducted an extensive longitudinal study documenting a "chain of custody" to assess HD contamination from arrival at the hospital loading dock through use and disposal.⁸ They reported HD surface contamination was found on the majority of study areas along the entire "chain of custody." Studying this issue in the Swiss market, Fleurey-Souverain et al found 63% of arriving HD vials were contaminated on the vial surface or the septum, whereas 38% were contaminated only on the septum, and 21% were cross-contaminated with multiple agents.⁹

The National Institute for Occupational Safety and Health (NIOSH) released an Alert in 2004, titled, "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings."¹ In 2009, NIOSH presented the results of an extensive multifacility study providing a comprehensive evaluation of potential sources of HD exposure in the workplace.¹⁰ The study included surface sampling in pharmacy and nursing areas, self-report exposure diaries, and urine and blood sampling of health care worker participants. Results were consistent with an earlier study where HDs were detected on all tested sites with the percentage of HD-contaminated surfaces in the 2009 study and were nearly identical to that found in the 1999 study.¹⁰ Both studies found 75% of surfaces sampled in pharmacies had detectable residue of at least one HD marker. These results show a 10-year span of efforts by NIOSH and US

Pharmacopeial Convention, in combination with common closed system transfer devices (CSTDs), have not resulted in a measurable difference in safety handling of HDs. In April 2011, a letter to hospitals in the United States, written by the Occupational Safety and Health Administration and the Joint Commission, reiterated the need for safe practices in the handling of HDs.¹¹

Although many studies document the continuing issue of HD contamination, resulting in health care worker exposure, few studies have attempted to identify why efforts to control HD spread have not been successful. A recent study of nurses sought to explain this issue and one of the findings in a study indicated that, despite the fact that nurses are knowledgeable about the risks of handling HD and the dangers of chronic HD exposure, adherence to suggested precautions during HD use and disposal was low.¹²

Successful removal of HD contamination by standard cleaning methods has been proven to be difficult. Connor showed that conventional cleaning procedures and the use of protective sleeves (monoaxial, stretched, high-shrink polyethylene terephthalate film) reduced HD contamination by 90%, demonstrating the need for more effective methods of containment and the institution of modified cleaning protocols.¹³ It, however, has been observed by the authors that the use of these sleeves during HD handling is labor intensive, and contributes to HD migration. Furthermore, Hon et al found an average of 10.4% of HD contamination on stainless steel remains after a single-step cleaning process and, after a second step of cleaning, 9.7% still remains.¹⁴ These findings suggest that a significant amount of HD is spread via fomite contamination. Fomite contamination has been well documented outside of patient care areas, including elevator buttons, as stated by researchers involved in the study.⁸ These studies are often cited; however, no method for the prevention of such spread has been documented to date in a formal study.

The study of this article was designed to investigate preparation and handling methods of HDs in simulated pharmacy and nursing environments. It was used to track the spread of an HD test contamination medium placed on exterior vial surfaces to downstream surfaces. It was done using commercially available engineering devices that were selected based on the leading market share at the time, along with standard procedures and controls.

Methods

HD Testing Protocol

Ultraviolet (UV) fluorescent powder Glo Germ (Glo Germ Co, Moab, Utah), composed of melamine resin, was used to simulate HD contamination. Fifteen drug vials, containing only sterile saline, were placed in a separate room and coated with the Glo Germ powder at 90% coverage. They were then

Figure 1. Pharmacy, nursing, and intravenous set of (a) contaminated and (b) uncontaminated images in OnGuard CSTDs and Allison Medical's Safety Enclosed Vial Adapter (SEVA).

brought in and placed on a new disposable absorbent barrier pad near the pharmaceutical hood in a clean room. UV fluorescence was used to detect the test medium powder that simulated HD contamination following each trial. Fluorescence detection used a 365-nm-wavelength, hand-held UV lamp. HD contamination testing was conducted in a simulated pharmacy and simulated nursing environment in a single clean room. Before entering the room, the drug prep technician donned a clean gown, bouffant, surgical mask, and nitrile gloves (personal protective equipment [PPE]). Each of these items was replaced before the start of each test repetition. The pharmaceutical prep bench included a containment hood and the sterile work surface was cleaned with a dimethyl benzyl ammonium chloride disinfectant, wiped with an isopropyl alcohol cloth, and inspected under UV light prior to drug preparation, to ensure that no UV light response was present. Photographs (Figure 1) were taken under UV light of all PPE before drug preparation to ensure that no Glo Germ fluorescence could be detected. New absorbent barrier pads were used for each test to prevent cross-contamination between products tested prior to starting the test protocol.

Closed System Transfer Devices

Five commercially available CSTDs were tested in the simulated pharmaceutical preparation environment under

controlled conditions. The testing procedure required each CSTD product be used exactly as specified by the manufacturer. Each step in the overall testing procedure was evaluated for each CSTD with some steps excluded if not required by that manufacturer's protocol. Any variations in methods for specific CSTD are reported in Table 1 where an "x" indicates which step applies to the corresponding CSTD, and NA indicates which step in the testing procedure was omitted based on the specific prescribed manufacturer's protocol.

Each CSTD tested was stored on a separate tray prior to each test and sequestered to avoid incidental contamination. When test ready, each CSTD was then placed on a new absorbent barrier pad near the hood. A previously contaminated test vial was then moved from the absorbent barrier pad and placed on the second clean pad in the hood. Manufacturer's instructions were followed for each brand of CSTD during the transfer of 5 cc of water from the contaminated test vial into an intravenous secondary set (IV set; Table 1). After being filled, the IV set was put into a large plastic zipper bag, which was then placed on a clean tray outside of the hood. The tray was carried a minimum of 10 m before being placed on a separate testing surface. The IV set was removed from the bag and placed on a metal IV stand with the bag remaining on the tray. The IV tube was primed, and then the IV set was removed from the IV stand, and placed on a separate tray. Pictures were taken under UV light of all PPE. The zipper bag and IV set were then photographed under UV light. All

Table 1. Drug Preparation Steps Corresponding to Individual Commercial Closed System Transfer Devices.

Method	ICU medical	Allison Medical	BD PhaSeal	B. Braun Medical	CareFusion
Products placed on the pad near the hood	x	x	x	x	x
Vial moved into the hood on the pad	x	^a	x	x	x
Vial stopper disinfected	x	^a	x	x	x
Vial adapter attached to the vial	x, Texium Vial Adaptor	^a	x, PhaSeal Vial Adaptor	x, Tevadapter Vial Adaptor	x, CareFusion Vented Vial Adaptor
Connector attached to the vial adapter	x, SmartSite Connector	x, Smartsite to SEVA Vial Adapter	x, PhaSeal Injector/Connector	x, OnGuard Vial Adapter	x, Texium Dripless Connector
Syringe attached to connector	x, Spiros Syringe Adaptor	x, Texium with Cinch Syringe Adaptor	x, PhaSeal Syringe Adaptor	x, Tevadapter Syringe Adaptor	x, Texium Syringe Adaptor
Syringe and adaptor/connector attached to the SEVA kit	NA*	x	NA*	NA*	NA*
Five-milliliter solution from the vial to syringe	X	x	x	x	x
Syringe and connector disconnected	x	x	x	x	x
Syringe and connector placed back on the pad	x	x	x	x	x
Secondary IV set attached to a separate adaptor	NA*	NA*	x, PhaSeal Connector Luer Lock	x, Tevadapter Luer Lock to SmartSite	NA*
Secondary IV set attached ("spiked") to the IV bag	x	x	x	x	x
IV set primed and placed on the same pad	x	x	x	x	x
Syringe and connector attached to the IV set	x, SmartSite IV Connector	x	x	x	x
Five-milliliter solution injected from the syringe into the IV bag	x	x	x	x	x
Syringe and connector detached and placed back on the pad	x	x	x	x	x
IV set placed into 1-gallon zipper bag	x	x	x	x	x
Zipper bag placed onto the tray outside of the hood	x	x	x	x	x
Tray carried 10 m	x	x	x	x	x
Tray placed on a separate testing surface	x	x	x	x	x
IV set removed from the zipper bag	x	x	x	x	x
IV set hung on the metal IV stand	x	x	x	x	x
IV set drip chamber filled to the mid level	x	x	x	x	x
IV set removed from the IV stand and returned to the tray	x	x	x	x	x

Note. "x" indicates that the method is applicable to the corresponding product. ICU = intensive care unit; BD = Becton, Dickinson; NA = the device did not perform specified function.

^aUnique Safety Enclosed Vial Adapter (SEVA) steps: alcohol prep opened using the tether, vial picked up with the SEVA sleeve and placed into the SEVA bag, SEVA bag zipper sealed, vial cap removed and stopper disinfected, SEVA bag spike inserted into the vial, spiked vial and bag placed on the pad in the hood.

Figure 2. Contamination by process (fluorescing pixels in thousands).

Pharmacy, intravenous set, and nursing for Allison Medical Safety Enclosed Vial Adapter (SEVA) are displayed vertically for clarity; however, all are reported 0.0 and should be understood as such.

absorbent barrier pads, trays, gowns, masks, bouffants, and gloves were replaced before starting the next test.

Data Collection

Photographs using a Nikon D40X (10.2 mp) camera were taken of the components used in the drug preparation process under UV light at selected stages of the testing procedure to document the presence of fluorescence indicating HD contamination. The drug prep technician was framed the same in the field of view at a specified distance to standardize photo size and resolution. Photo pixel analysis was used to quantify the amount of Glo Germ present using Adobe Photoshop to determine the number of pixels that fluoresced in each photograph.

Results

Transfer of the contaminated HD testing medium (Glo Germ) to IV sets, pharmacy PPE, and nursing PPE was observed for 4 of the 5 CSTD systems tested. The only CSTD system that showed no observable contamination was the Allison Medical SEVA system. Simulated HD contamination followed a pattern that found the pharmacist's gloves most heavily contaminated, followed by the IV sets, and, finally, the nurse's gloves after setting up the IV for patient use

(Figure 2). This pattern follows the order of HD handling during treatment preparation with a decreasing amount of HD contaminant available to being spread during the next handling step.

An analysis of fluorescing pixels during the handling process for each CSTD was used to provide a quantitative evaluation of the extent of HD contamination on the PPE. Results revealed a wide range of HD contamination levels depend on the CSTD system used and provide baseline data indicating the relative extent of contamination during drug handling and treatment preparation (Table 2). Fluorescing pixels range from a low of 0, using the Allison Medical CSTD SEVA system, to a high of 76 000 or 6.22% of the total photograph area for the Braun Medical CSTD Onguard system at the pharmacy handling step. Table 2 also shows the extent of the dilution effect as the simulated HD contamination moves through the preparation process.

Discussion

Although the B. Braun Medical CSTD system was considered the highest level of simulated HD contamination on the pharmacist's gloves and, subsequently, to the IV set and nurse's gloves. When the results in Table 2 are compared based on the number of manipulation steps for each CSTD system, they indicate the level of handling complexity has a

Table 2. Contamination Levels for 5 Commercial Closed System Transfer Devices at 3 Different Steps During the Hazardous Drug Handling Procedure.

Products	Condition	Total pixels	Pixels indicating test medium	Percent indicating test medium
Onguard	Pharmacy	1 228 800	76 469	6.22
	Nursing	1 228 800	10 808	0.88
	IV set	1 228 800	52 062	4.24
PhaSeal	Pharmacy	1 228 800	63 514	5.17
	Nursing	1 228 800	7816	0.64
	IV set	1 228 800	20 714	1.69
Safety Enclosed Vial Adapter (SEVA)	Pharmacy	1 228 800	0	0.00
	Nursing	1 228 800	0	0.00
	IV set	1 228 800	0	0.00
Spiros/Genie	Pharmacy	1 228 800	51 227	4.17
	Nursing	1 228 800	10 443	0.85
	IV set	1 228 800	24 939	2.03
Texium	Pharmacy	1 228 800	66 393	5.40
	Nursing	1 228 800	7891	0.64
	IV set	1 228 800	27 562	2.24

moderate effect on the HD contamination level. The exception was the BD PhaSeal CSTD, which was reported by the technicians as the most difficult product to use of the 5 CSTD systems.

The Allison Medical CSTD system, however, required an additional step of using the SEVA sleeve to pick up the vial and deposit it into the SEVA bag. Although the alcohol prep was already accessible in the bag providing some labor savings, the additional step of placing the vial in the bag added another manipulation when using the SEVA system, particularly when compared with the CareFusion Texium CSTD and the ICU Medical Spiros/Genie CSTD. If increasing the number of product manipulation steps was a primary factor in HD cross-contamination, the act of picking up the vial using the SEVA sleeve and SEVA bag should have increased HD contamination rather than reduced it (Table 2). The Allison Medical SEVA added minimal additional time when compared with the other CSTDs. PhaSeal requires the use of a proprietary lever, which aids in attaching the vial adapter to the vial. Other products require about the same amount of time as conventional vial adapters, as Spiros (ICU Medical) is often used with a conventional vial adapter. SEVA, depending on the user, added an additional 5 to 10 seconds per use; most of that time is taken up when placing the SEVA bag over the vial, sliding the vial into the bag, and sealing the bag.

Also noted, Texium and Smartsite are used as components in both the Allison Medical SEVA and the CareFusion CSTD systems. Protocol for the SEVA system is identical to the CareFusion CSTD system, except that the steps taken to prevent contamination are performed in the SEVA bag, which is an important difference when comparing these two CSTD systems. In Table 1, it is shown that multiple components are used in each CSTD and that when the Texium and/or

Smartsite are used with the SEVA, there is no contamination, but when they are used alone, there is significant contamination. More importantly, use of the SEVA sleeve and isolation bag significantly decreases the spread of HD contamination, despite the additional steps required when using this system. Furthermore, results demonstrate the act of providing a contamination barrier that fully encloses the HD contamination source is effective in the prevention of HD contaminants.

The 4 CSTD devices exhibiting HD contamination spread were designed to focus primarily on preventing the spread of HD contamination at their connection sites. Note that Equashield was not included in this study as it was relatively new at the time and had little market share. Although it has demonstrated a somewhat improved market position since then, it still has exhibited the same deficiencies of the other products tested in that HDs on the exterior of vials can still be transferred via touch contamination.¹⁵ All products currently on the market have the same deficiency in that none of them address HD contamination on vials. This suggests that any product system tested would likely have the same or similar results as found when compared with the Allison Medical SEVA product.

Other studies, especially those reported on the PhaSeal website,¹⁶ focus on comparing relative HD contamination on the small surface areas of competitive product connection site septas and release of vapors from vents (eg, B. Braun Onguard Vial Adapter¹⁷). In contrast, HD vial contamination focuses less on the comparatively large surface area on the vial exterior where HD may transfer to gloves and other PPE posing a previously unacknowledged risk to those who use such products on a frequent basis. The PhaSeal is also not a closed system in terms of providing an enclosure around a vial, neglecting to prevent HD contamination as a result of handling vials with HDs on the exterior of a vial. Despite use

of CSTD products, there has been little reduction of the risk of HD exposure since the 2004 NIOSH safety alert. Use of a sleeve and enclosure device, such as the Allison Medical SEVA system, may be one way to significantly improve HD exposure risk to health care workers. In terms of cost effectiveness for health care facilities, PhaSeal cost about \$5.00 at the time, and other vial adapters, such as Onguard, were around \$3.50 each. The Allison Medical SEVA system was priced to be competitive with the lowest priced safety vial adapters at \$3.50 each.

In recent years, findings suggest current HD handling products are insufficient, resulting in articles that tend to focus on testing for HD contamination, including areas outside oncology treatment areas, and improved cleaning to minimize said risks.¹³ Although such procedures are useful, at least for those who are not exposed in the process, the prevention of HD cross-contamination spread clearly provides a greater level of safety and likely a lower cost option to expensive testing and labor-intensive cleaning.

Conclusions

In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn, contaminated nursing PPE. When the Allison Medical SEVA system was utilized, vials were not handled directly. They, instead, were being handled by the SEVA sleeve, placing the vial directly into the SEVA bag, thus eliminating contamination of HD handlers. As a result of this protocol, no HD residue was detected on PPE in the pharmacy, on ancillary products, or on nursing PPE.

The Allison Medical SEVA system provides an effective means to contain the spread of HD contamination as a result of its unique use of a sleeve and enclosing zipper bag for drug transfer from the vial to the delivery system. The other 4 CSTD products tested resulted in the spread of the HD test medium to other surfaces, showing HD contamination on the vial exterior spread as a result of touch contamination. Although CSTDs provide a measure of exposure reduction, 4 of 5 CSTDs were insufficient in containing the spread of contaminants. Reports in the literature have indicated that the first source of contamination in the drug preparation sequence is the vials and that they arrive from the manufacturer with contamination on the surface.⁸ This would explain the effectiveness of the containment zip lock bag.

The results of this study illustrate why HD contamination resulting in health care worker exposure continues to be problem despite use of CSTDs along with the current methods to clean vials.¹⁸ HDs may be spread even through handling of contaminated transport bags, as well as other ancillary products, such as IV sets and IV bags. The spread

of HD contamination by this route can be ameliorated through the use of a closed barrier system, such as the Allison Medical SEVA, if proper sequestration techniques are used to load the IV delivery system. In conclusion of this study, the use of the Allison Medical SEVA products showed significant improvements in HD containment compared with other systems that require direct handling and touching of vials.

Declaration of Conflicting Interests

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