Evaluation of Real-World Hazardous Drug Wipe Test Data to Assess Surface Contamination Following the Use of an Air Cleaning Closed System Transfer Device

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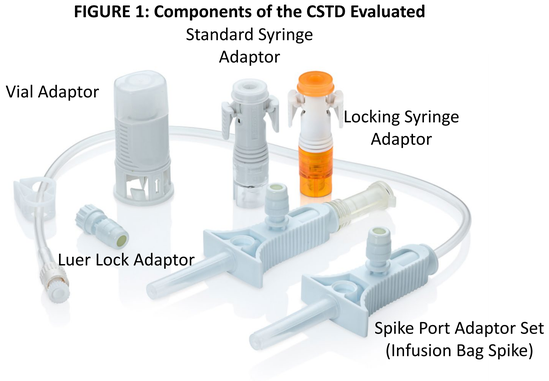
INTRODUCTION

- Antineoplastic drugs are known to be hazardous to healthcare professionals (HCPs) as accidental exposure may lead to detrimental health effects such as an increased risk of developing certain cancers, organ damage, an increased risk of infertility, and neonatal health defects.[1]
- Increased awareness regarding the risks and detrimental health effects caused by occupational hazardous drug (HD) exposure to patients and HCPs has led to risk management guidelines utilizing engineering, administrative, and personal protective equipment controls.[1]
- Despite such guidelines, multiple studies have reported measurable concentrations of HDs present in the urine of HCPs and across various workspace surfaces.[2]
- The air-cleaning closed-system transfer device (CSTD) evaluated in this assessment consisting of four interconnected components: a vial adaptor, syringe adaptor, an infusion bag spike, and Luer-lock adaptor designed to prevent the escape of HDs or metabolites outside the system, offer increased protection HCPs through the stages of handling HDs, from compounding to administration **(Figure 1).**[1,3]
- United State Pharmacopeia (USP) <800> advises the use of CSTDs when compounding and requires it for administration of HDs, it does not strictly define or enforce the acceptable concentrations of the commonly assayed HDs (cyclophosphamide, ifosfamide, methotrexate, 5-fluorouracil, and platinum-containing drugs).
- Wipe testing is the preferred method for determining workplace surface drug contamination.

FIGURE 1: Components of the CSTD Evaluated



OBJECTIVES

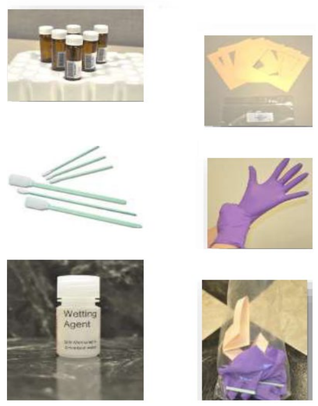
- The objective of this project was to perform an analysis of Real-World wipe test data from multiple hospitals and outpatient facilities based in the United States (US) following the implementation of an air-cleaning CSTD.
- The analysis assessed and summarized the incidence of HD surface contamination with the use of air-cleaning CSTD at several hospital systems and/or outpatient facilities.
- Wipe-test data collected from 2018 through 2022 were analyzed by drug type, frequency, and location of HD contamination using a surface-sampling wipe kit.

METHODS & MATERIALS

This analysis utilized a preexisting database of wipe test information containing real-world antineoplastic HD surface contamination. This data included multiple sample wipe tests collected using marketed surface sampling wipe kits after the implementation of the CSTD assessed **(Figures 2A-2B).**

Figure 2A: Wipe Test Kit

Figure 2B: Wipe Test Kit Components



Key Kit Components: Shipping container, pre-labeled barcoded vials, swabs, wetting agent, 100 cm^2 sampling templates, Nitrile chemo gloves, chain of custody form.

- **Data Collection:** During data collection, there were inconsistencies in the naming of facilities and locations. Thus, prior to analysis, 43 individual hospital systems and outpatient facilities were consolidated into 18 new systems based on facility names and affiliations, and the 507 individual areas/locations of sample collection were consolidated into nine locations using similar individual location descriptions. Data were collected from 2018 -2022.
- **Sampling:** Sites provided wipe test submissions every six months for three years. Up to five samples per submission were tested for cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. The threshold for detection was > 5 ng. Samples were collected from multiple locations and grouped as follows :

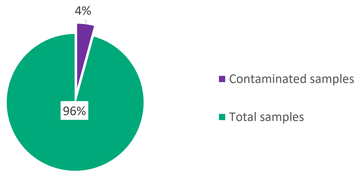
a) Biosafety Cabinet Hood
b) Infusion Area/Room
c) Nursing Area
d) Patient Admin/Room
e) Pharmacy
f) Receiving Room
g) Staging Area
h) Unpacking Area/Room
i) Other

- **Analysis:** The initial analysis utilized all results. After review, a single data point, approximately 60 times greater than the mean population, was determined to be a significant outlier. The outlier was removed, and the data were reanalyzed.
- Overall contamination was summarized using occurrence (percentage), mean level (ng) of contamination, and mean time from collection to analysis (days). The occurrence of contamination was also summarized by hospital system, analyte, and physical location of sample collection.
- The database was given to an outside vendor for a second analysis .

RESULTS

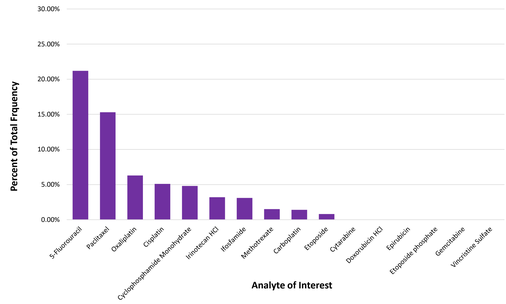
- **Total Analyses**: Of the 5,531 wipe analyses performed from 2018-2022, 246 (4.45%) were positive for HD contamination. The average level of contamination in these 246 tests was 54.8 ng, with a range of 5.1 ng to 3,430.0 ng or 41.0 ng, ranging from 5.1 to 653.0 ng after removing the outlier **(Figure 3).**

Figure 3: Overall Contamination



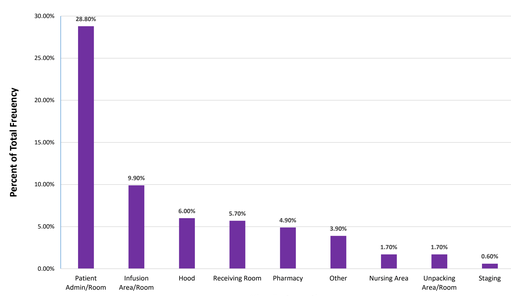
- **Contamination by Year:** Tests were relatively equally distributed over 2018-2022, with **c**ontamination rates ranging from 2% to 8% annually.
- **Major Contributors:** 76% of contaminated tests came from two hospital systems
- **Major Contaminants:** After removing the outlier, the highest occurrence of contamination was reported for 5-Fluorouracil (5-FU) analytes, with 20.9% (N=53/254) of wipe tests showing a mean 42.7 ng level of contamination. The highest level of contamination measured for a single analyte was Paclitaxel at 79.4 ng). See **Figure 4**.

Figure 4: Occurrence of Contamination by Analyte



- **Contaminant by Location:** The highest occurrence of contamination was reported in the Patient Admin/Room, with 28.8% of the tests showing contamination **(Figure 5)**. The average level of contamination was also highest in the Patient Admin/Room (224.7 ng). The occurrence of contamination was lowest in Staging locations (0.6%), whereas the lowest mean level of contamination was observed in the Unpacking Area/Room (6.6 ng).

Figure 5: Occurrence of Contamination by Location



RESULTS (Continued)

- **Potential Covariates:** A simple linear regression model showed that neither pooled Hospital System/Outpatient Facility, Analyte, Year of Collection, nor Time from Collection to Analysis are significant predictors of the overall level of contamination (**Table 1**). However, the highly significant p-value for Location suggests that it is a significant predictor of level of contamination.

Table 1: Linear Regression Results for Level of Contamination

Simple Linear Regression Results for Level of Contamination					
Source	**DF**	**Type III SS**	**Mean Square**	**F-Value**	**P-value**
Pooled Hospital System/ Outpatient Facility	15	8977.17	598.48	0.24	0.9988
Year	4	6660.42	1665.10	0.66	0.6190
Analyte	15	60586.76	4039.12	1.60	0.0646
Time from Collection to Analysis	1	145.24	145.24	0.06	0.8102
Location	**8**	**252854.9**	**31606.9**	**12.55**	**<0.0001**

CONCLUSION

- This Real-World Data evaluation of HD wipe test data shows an extremely low contamination of 4.45%, with most of the contamination coming from 2 hospital systems. Suggesting that preparing and administering HDs using this air-cleaning CSTD minimizes surface contamination and decreases potential exposures of HD to healthcare professionals.
- While all locations utilized the CSTD, observed variations in levels of contamination amongst different facilities could be attributed to different surface cleaning and HD handling practices, emphasizing the need for these facilities to evaluate their cleaning and HD handling to accommodate best practices.
- Results from the statistical vendor supports the initial analysis, ensuring the reporting of unbiased results from the retrospective data.

ACKNOWLEDGEMENTS

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CONTACT/DISCLOSURES

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