Worker exposure to antineoplastic hazardous drugs (AHDs) has been a long standing concern.1 Studies show that AHD surface contamination is prevalent in work areas where AHDs are mixed and administered and that marker AHDs are found in the urine of workers who handle these drugs.2 Closed system drug-transfer devices (CSTDs), adjuncts used in mixing and administration, have been shown to reduce contamination and worker uptake of AHDs.3 To date only one of the commercial CSTDs has been extensively studied and known to be effective with results published in peer-reviewed journals.4,5 The study presented here is the first to evaluate a new CSTD using a strict protocol for both mixing and administering AHs to allow reliability of results across multiple sites.

OBJECTIVES

- Evaluate performance of the new CSTD in reducing surface contamination during mixing and administration of a set protocol of marker AHDs cyclophosphamide (CP) and 5-fluorouracil (5FU) using wipe sampling in participating U.S. cancer centers
- Compare the performance of the new CSTD to similar studies of another CSTD in the literature
- Determine user satisfaction/ease-of-use of the new CSTD

METHODS

- Study sites were recruited from the National Cancer Institute (NCI) designated Cancer Centers and the members of the Association of Community Cancer Centers (ACCC) in the U.S.
- Nineteen U.S. cancer centers were selected to participate in the study; six sites were omitted based on exclusion criteria, including failure to provide required pharmacy and nursing staff, pre-contamination and/or expired drug samples unrelated to the study device, and a failure to comply with the study protocol
- A standardized protocol was followed by all participating centers
- Wipe samples of predetermined surfaces were collected in mixing and infusion areas to determine existing levels of surface contamination at each site
- Stainless steel templates of 100cm² and 47.5cm² (for the chair arm) were placed on previously sampled surfaces, and specific amounts of AHDs were mixed and infused over the templates, using the new CSTD system
- Wipe samples from the templates were collected after the tasks were done and analyzed for both marker AHDs: CP and 5FU
- Results were reported as ng/cm² with the limit of detection (LOD) of 0.002 ng/sample
- Study participants completed a questionnaire on satisfaction/ease-of-use of the new CSTD

RESULTS

Comparison to peer-reviewed literature

Only two multi-site studies, both done with the initial CSTD PhaSeal®, were sufficiently similar in methods and reporting of results to allow a reasonable comparison with the new CSTD. The CP and surface contamination found in the current 13 U.S. site study with the new CSTD is less than reported with PhaSeal® in 22 U.S. sites in a 2011 publication (Table 8). When compared with a second published study of compounding CP with PhaSeal® in 30 U.S. sites, the new CSTD in 13 U.S. sites resulted in less contamination overall (Table 4).

Satisfaction survey

To assess the CSTD’s impact on workflow, acceptance and ease of use, participants were given a survey rating the new CSTD from 1 to 5 (1 being extremely satisfied and 5 being extremely unsatisfied), 12/26 clinics scored Halo® as a 4 with the other 8 clinicians scoring a 4.

Conclusions

The new CSTD reduced surface contamination by the marker AHDs during both mixing and administration. Compared to the published results of both the new CSTD is superior in reducing surface contamination with marker AHDs as determined by wipe sampling of similar surfaces. Participants reported the new CSTD was easy-to-use which would support consistent and proper use of the CSTD.

REFERENCES

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