CLOSED SYSTEM TRANSFER DEVICE (CSTD) EVALUATION: SURFACE WIPE STUDY TO MEASURE EXPOSURE OF HEALTHCARE PERSONNEL TO CHEMOTERAPY AGENTS

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Introduction and aims

Closed system transfer device (CSTD) mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapor concentrations outside the system. Various CSTDs are not equally effective.
We evaluated impact of the current ChemoClave and the new ChemoLock systems on the exposure of healthcare personnel to chemotherapy agents and how the new CSTD would fit in our workflow.
Environmental contamination with the cytostatic drugs cyclophosphamide (**CP**) and 5-Fluorouracil (**5FU**) was measured in the pharmacy.

Materials and methods

Wipe samples were taken from five position in the pharmacy according to the schedule presented in Table 1. In addition, eight vials were sampled at random and analysed for contamination on the exterior surface. The wipe areas were measured and surface sizes were calculated. The wipe samples were taken with Cyto Wipe Kits from Exposure Control Sweden AB.
Initial cleaning was performed with NaOH and HCl to get baseline contamination before each trial (ChemoClave and ChemoLock). Daily cleaning was performed per facility protocol at the end of the day: detergent and IPA and biocid B or C (KlerWipe). Once a week 0,05 M NaOH was used.
All samples were stored frozen after sampling and during transport until sample preparation and analysis. The wipe samples were prepared by adding 140 ml of a 0,03 M NaOH solution. After extraction, a part of extract was further cleaned up according to standard procedures. Cyclophosphamide (**CP**) was analysed using a GC-MS method. The samples were analysed on GC-MSMS system. Specificity and sensitivity are increased using GC-MSMS instead of GC-MS. The analysis of 5-Fluorouracil (**5FU**) was performed on a HPLC system with UV detection.

Results and discussion

After initial cleaning and before the use of ChemoClave, contamination with CP was found on three positions in the pharmacy. The highest contamination was measured on the scale. This indicates that initial cleaning did not totally remove the contamination (Chart 1).
After three weeks using ChemoClave contamination with CP was found on all positions except the counter. Scale and LAF surface showed the highest contamination. The results indicate release of CP during preparation (Chart 1).
After initial cleaning and before the use of ChemoLock, very low levels of contamination with CP were found on the scale and the floor. This indicates that the initial cleaning before the ChemoLock period was more successful (Chart 1).
After three weeks of using ChemoLock, contamination with CP was found only on the floor. The results indicate no release of CP during preparation (Chart 1).
Two out of four CP vials were contaminated on the exterior surface.
No contamination with 5-fluorouracil was detected.

TABLE1: Schedule of samples

DATE OF PERIOD	TIME	ACTIVITY
11 May 2016	15:30	Initial cleaning with NaOH and HCl
	15:45	Wipe sampling
12 May - 1 June 2016		ChemoClave in use for three weeks
1 June 2016	15:30	Wipe sampling 1-6
	15:45	Initial cleaning with NaOH and HCl
	16:00	Wipe sampling 7-12
2 - 22 June 2016		ChemoLock in use for three weeks
22 June 2016	15:30	Wipe sampling

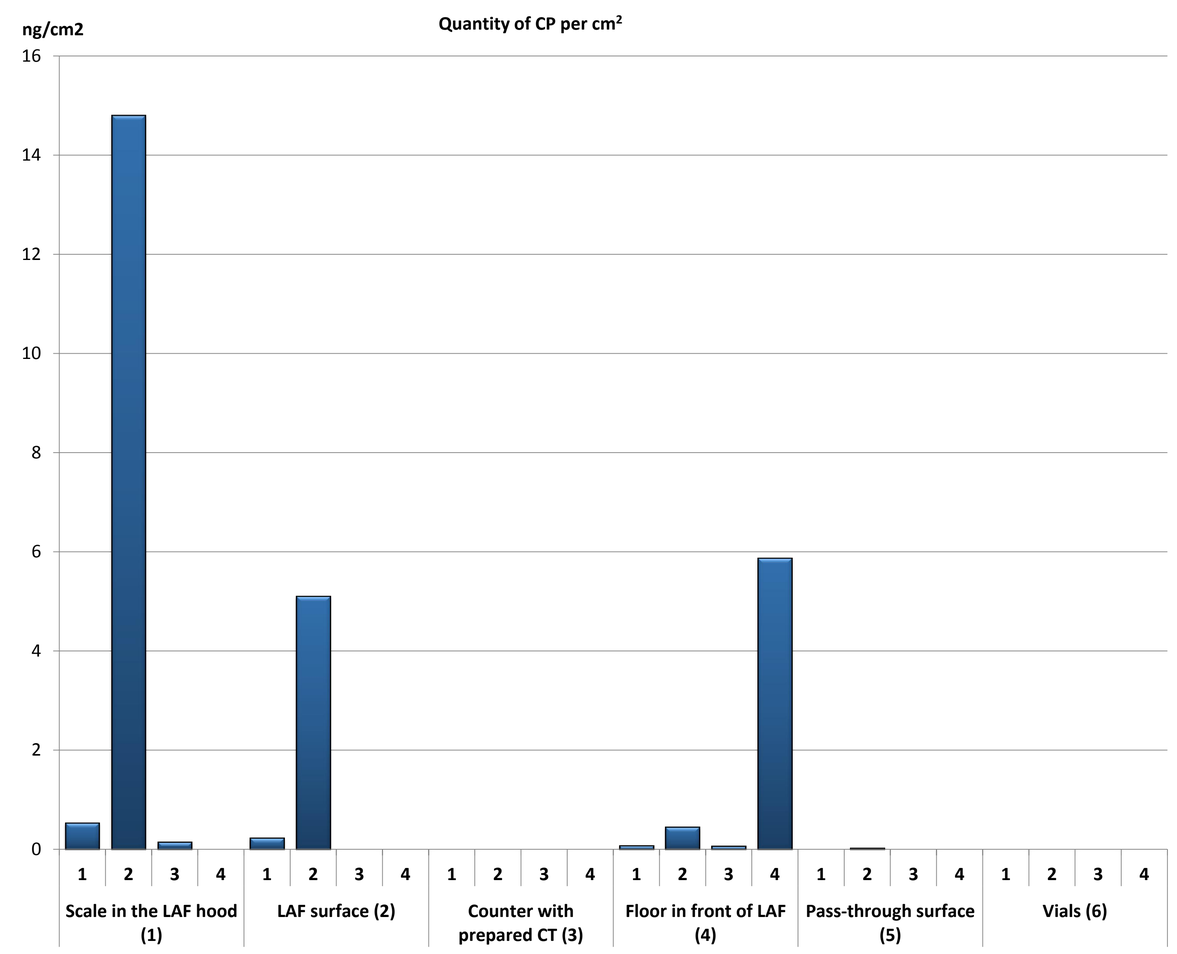
TABLE 2: Number of preparations and weight of CP and 5FU in them

12 May - 1 June 2016	No. of preparations	Weight of API (mg)
5FU	210	369.716
CP	89	114.684

2 - 22 June 2016	No. of preparations	Weight of API (mg)
5FU	207	589.765
CP	87	118.696

Results and discussion

CHART 1: Results of the study



1: 11 May 2016 (after initial cleaning)
2: 1 June 2016 (after three weeks of ChemoClave)
3: 1 June 2016 (after initial cleaning)
4: 22 June 2016 (after three weeks of ChemoLock)

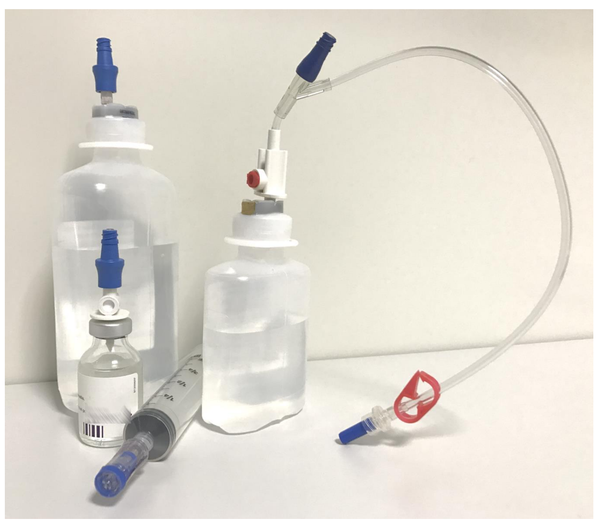


FIGURE 1: ChemoClave Needlefree Closed System Transfer Device

FIGURE 2: ChemoLock Needlefree Closed System Transfer Device

Conclusion

We found that both systems are easy to use, while the new CSTD system provided enhanced safety by ensuring compliance without an option to bypass the system. The limited surface wipe sample analysis shows that cleaning (especially because the external factors can lead to downstream contamination) and workflow are important factors in minimizing exposure of healthcare personnel to chemotherapy agents. With current CSTD system cyclophosphamide contamination was found on surfaces 1, 2, 4 and just detectable on 5 and 6. No contamination with 5-fluorouracil was found. With new CSTD cyclophosphamide contamination was found only on surfaces 4 and 6 that has little or no correlation to compounding. No contamination with 5-fluorouracil was found.
The study demonstrated that the new CSTD system ensures compliance, fits in our workflow and can help minimize exposure of healthcare personnel to chemotherapy agents.