STUDY SUMMARY

Preparing for United States Pharmacopeia USP ‹800› compliance: Evaluating the effectiveness of two closed system transfer devices (CSTDs) on preventing hazardous drug surface contamination

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PURPOSE:

In order to prepare for upcoming USP ‹800› CSTD compliance guidelines, we conducted an evaluation of two CSTD systems. The study was designed to evaluate how well each CSTD would fit into existing pharmacy and nursing workflows and measure the level to which each system was able to minimize environmental contamination.

METHODS:

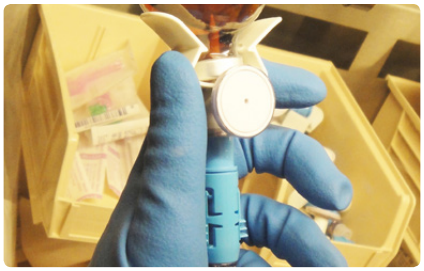
Our first steps were to review all practices and policies from preparation to administration. We researched several CSTD systems and narrowed the trial down to two systems, ChemoLock® (by ICU Medical) and OnGuard™ (by B. Braun). The systems were evaluated based on safety, compliance, and cost effectiveness.

Part of the review included a surface contamination analysis using wipe kits at our outpatient cancer center. The first wipe sample was collected while our center used the OnGuard CSTD system during drug compounding only. The second wipe sample was collected eight months later after we had implemented the ChemoLock CSTD system for both compounding and administration.

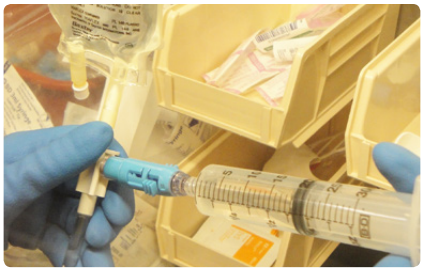
Surface wipe samples were taken from a shelf where chemotherapy is stored, a pharmacy drug preparation counter, the deck of the compounding aseptic containment isolator, a courier box used to transport chemotherapy, a nurse's station computer keyboard, and an IV pole used to hang chemotherapy drugs during administration.

The drugs identified for analysis consisted of paclitaxel, fluorouracil, cyclophosphamide, ifosfamide, and methotrexate. Analysis occurred by liquid chromatography coupled with tandem mass spectrometry. The lower limit of detection for these assays was 10 nanograms per square foot and concentrations less than this were considered non-detectable.

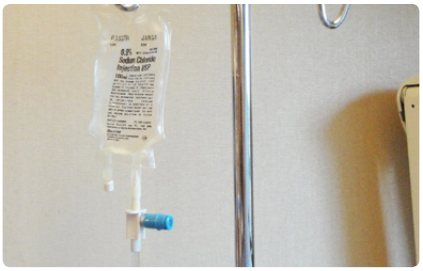
CHEMOLOCK SYSTEM CHOSEN AS BEST SYSTEM TO MEET USP ‹800› COMPLIANCE



ChemoLock's click to lock design ensures safe, easy compounding.



ChemoLock bag spike, for use with primary tubing, allows pharmacy to follow current workflow.



ChemoLock hazardous drug bag is spiked and primed in pharmacy making it easier for administration.

RESULTS:

We found that both CSTD systems were safe and easy to use during the compounding process; however, we found that the bonded CSTD administration components with the ChemoLock CSTD system added an additional layer of safety by ensuring there were no accidental disconnects. Both wipe sample analysis results showed non-detectable levels for all drugs and wipe samples tested (Table 1).

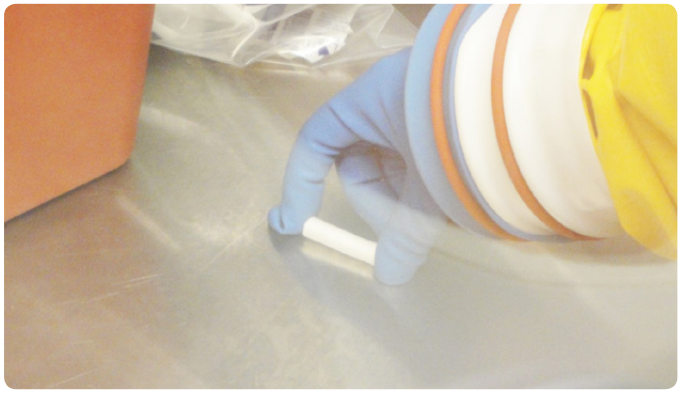


TABLE 1. SUMMARY OF IDENTICAL SURFACE WIPE RESULTS FROM BOTH AUGUST 7, 2015, FOLLOWING THE USE OF ONGUARD (BY B. BRAUN), AND APRIL 11, 2016, FOLLOWING THE USE OF CHEMOLOCK (BY ICU MEDICAL) (NG/FT^2 AND NG/CM^2)

Wipe ID	Location	Department	Paclitaxel Concentration ng/ft^2 (ng/cm^2)	5-FU Concentration ng/ft^2 (ng/cm^2)	Cyclophosphamide Concentration ng/ft^2 (ng/cm^2)	Ifosfamide Concentration ng/ft^2 (ng/cm^2)	Methotrexate Concentration ng/ft^2 (ng/cm^2)
1	Nursing Station Computer Keyboard	Oncology Suite	ND	ND	ND	ND	ND
2	Nursing Station IV Pole	Oncology Suite	ND	ND	ND	ND	ND
3	Hood PEC #10	Pharmacy	ND	ND	ND	ND	ND
4	Pharmacy Prep Counter	Pharmacy	ND	ND	ND	ND	ND
5	Red Courier Box (inside)	Pharmacy	ND	ND	ND	ND	ND
6	Chemo Storage Shelf	Pharmacy	ND	ND	ND	ND	ND

CONCLUSION:

Preparing for USP ‹800› with a review of CSTD systems can help a facility be one step closer to USP ‹800› compliance. We evaluated two CSTD systems and implemented the ChemoLock CSTD system we tested as it met the needs of our pharmacy and nursing staff. Surface wipe analysis confirmed that the CSTD, along with work practices and procedures that were implemented, was effective in minimizing hazardous drug surface contamination, noting that the work practices and procedures may have contributed to the non-detectable levels as well.