Connector integrity testing to assess the efficacy of multiple closed system transfer devices

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BACKGROUND

- The risks associated with compounding and administration of hazardous drugs (HD) has been evaluated and documented in the literature.
- USP 800 guidelines released earlier this year:
  - Require use of a closed system transfer device (CSTD) for HD administration.
  - Recommend the use of a CSTD for HD preparation.
- Since the development of CSTDs, several options exist for HD preparation and administration. There is limited data comparing all of the products in one study.

PURPOSE

- The purpose of this study is to determine how 6 different CSTDs that are marketed as leak-free behave when tested with actual drug.

METHODS

- To assess the integrity of CSTD connectors, 6 types of CSTDs were tested for leakage for up to 3 connections.
- Using sixty 5-fluorouracil (5-FU) vials, each fitted with one CSTD vial access device, a total of 10 samples were obtained for each of the 6 CSTD types.
- A 10 mL syringe was connected to the vial and 7 mL was withdrawn using a Pull-Push-Pull method to simulate air bubble removal. The vial was inverted upright to re-inject 5 mL into the vial and then the connectors were disconnected. The syringe was then reconnected to the vial and the remaining 2 mL of drug was injected in to the vial. This was repeated two more times with the same CSTD.
  - Testing Group 1 (TG1) investigated leakage from the vial (V) and syringe (S) during the 2nd and 3rd connection.
  - Testing Group 2 (TG2) investigated leakage during the 1st and 3rd connection.
- Leakage of the device was evaluated qualitatively using litmus paper to assess if there was visible leakage on the vial and syringe connector.

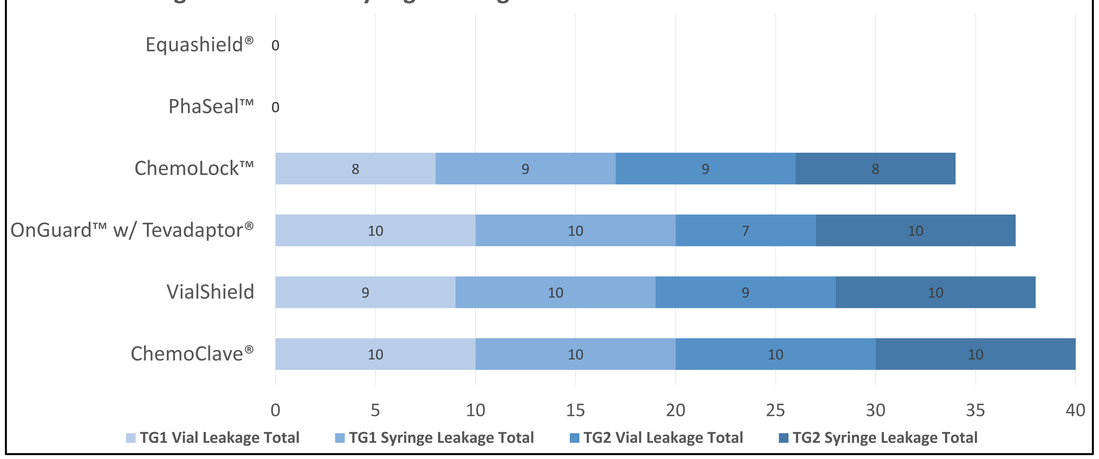
FIGURE 1. Separate syringes and vials were fitted with the CSTD being tested before manipulation of 5-FU.

FIGURE 2. Example of the table used to record leakage of the CSTD from the vial (V) or syringe (S).

5-FU Testing Group 1			5-FU Testing Group 2		
Device	Sample 1 2nd Connection	Sample 2 3rd Connection	Device	Sample 1 1st Connection	Sample 2 3rd Connection
1	V S	V S	6	V S	V S
2	V S	V S	7	V S	V S
3	V S	V S	8	V S	V S
4	V S	V S	9	V S	V S
5	V S	V S	10	V S	V S
Negative Control		NC	Positive Control		X

RESULTS

Figure 1: Vial and Syringe Leakage of 5-FU Detection on CSTD Connectors



- A total of 120 samples were prepared and assessed for litmus paper discoloration from either the syringe or vial connector of 6 CSTDs.
- The negative control was performed by wiping litmus paper on the 5-FU vial stopper and resulted in no color change. The positive control was performed by placing one droplet of drug onto the litmus paper and resulted in color change.

TABLE 1. Summary of each device tested.

Device	Manufacturer	Vial and Syringe Leakage Total (TG1 + TG2)	Rate of Leakage in 40 Samples (%)
Equashield®	Equashield, LLC	0	0
PhaSeal™	BD	0	0
ChemoLock™	ICU Medical	34	85
OnGuard™ w/ Tevadaptor®	B.Braun (Teva Medical)	37	92.5
VialShield	BD (CareFusion)	38	95
ChemoClave®	ICU Medical	40	100

FIGURE 2. ChemoClave® demonstrating leakage in both the syringe and vial connector during a sample run.

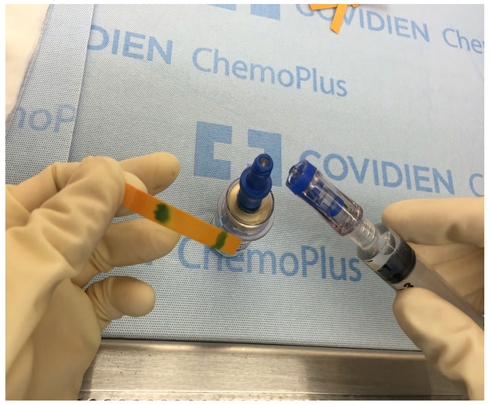
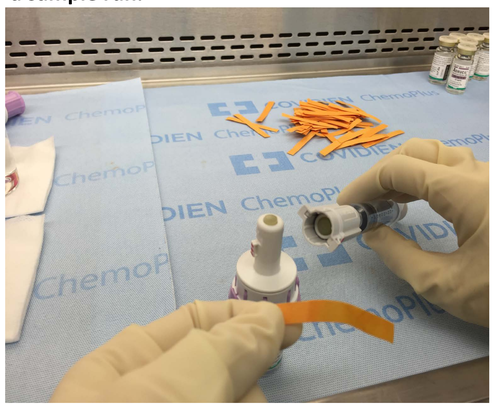


FIGURE 3. Equashield® demonstrating no leakage in the syringe and vial connector during a sample run.



CONCLUSIONS

- Out of 6 closed system transfer devices, 4 had detectable leakage while 2 had no visible leakage.
- Equashield® and PhaSeal™ are the two CSTDs that demonstrate a completely closed system.
- To improve patient outcomes and employee safety in chemotherapy preparation, CSTDs that demonstrate no leakage should be the m preferred choices.
- Limitations: Two technicians alternated testing for each different CSTD; however, both were trained in the same way. The litmus paper may have been wiped on the syringe and vial with varying force between two technicians.

DISCLOSURE

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: This research was funded through a grant from Equashield®