Evaluation of the Sterility of Single-Use Vials Undergoing Multiple Access Following Application of a Closed System Transfer Device (CSTD)

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BACKGROUND

- Closed system transfer devices (CSTD) such as Cyto-Set® (1), PhaSeal® (2), and Equashield® (3) are designed to reduce hazardous drug exposure from preparation to administration (4)
- While these devices protect staff and have been provided an ONB designation by the FDA, as a closed system they can also minimize microbial contamination because the devices are airtight and leak-proof, potentially preventing microbial ingress.
- Equashield® was rated favourably in terms of ease of use and therefore used as the chosen CSTD for this study (4,6)

OBJECTIVES

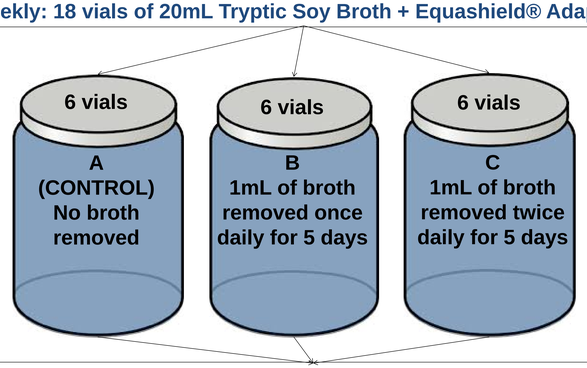
We undertook this study to test whether attaching Equashield® adaptors to simulated single-use vials (Tryptic Soy Broth 20 mL vials):

- Could prevent or minimize microbial contamination and extend the "use-by" date following multiple withdrawals under extreme-use-conditions
- Could verify the results of previously published data (5) applied to real-world conditions with multiple staff members and multiple areas at Sunnybrook Health Sciences Centre Pharmacy

METHODS

- Each lot of TSB growth medium was secondarily tested as a positive control by inoculation with less than 10^{-2} of S. epidermidis ATC 12228, incubation at 37ºC and review at 24 and 48 hours afterwards
- As a negative control, an unopened vial of TSB 20 mL from each lot was incubated for the duration of the study

Weekly: 18 vials of 20mL Tryptic Soy Broth + Equashield® Adaptor



Each vial group was placed in one of two settings for 5 day period:

1. BSC (biological safety cabinet Class II Type B2) running 24/7 (3 A/B/C vials)
2. Laminar airflow hood turned off nightly (3 A/B/C vials)

- At the end of day 5 each week, the vials were collected, incubated at 37ºC for 14 days and inspected visually every 2 days for microbial growth
- This process was repeated for 16 weeks for a total of 288 vials (32 vials per group)

FIGURE 1: Study Design Procedure

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RESULTS

Table 1: Distribution of TSB Vial Access and Positive Results (16 week period)

Area	AREA 1 (TWO BSCs RUNNING 24/7)			AREA 2 (ONE BSC RUNNING 24/7)			AREA 3 (THREE LAMINAR AIR FLOW HOODS, RUNNING DURING DAYTIME ONLY)		
	Vial A	Vial B	Vial C	Vial A	Vial B	Vial C	Vial A	Vial B	Vial C
Positive Results over number of accesses	0 / 32	0 / 160	0 / 320	0 / 16	0 / 80	0 / 160	0 / 48	0 / 240	0 / 480

- All positive control vials demonstrated growth within 48 hours
- All negative control vials showed no growth throughout the study
- All accessed vials remained sterile following storage at room temperature for 5 days and subsequent incubation for 14 days
- None of the 192 vials (B & C) accessed 1440 times showed evidence of contamination. The 95% confidence interval of the contamination rate is 0.000 to 0.035%
- None of 96 vials with CSTD attached but without broth removed demonstrated contamination

COST SAVINGS IMPLICATIONS

- Annual drug wastage in the cancer centre pharmacy, adhering to chemical stability and preparation in an ISO Class 5 environment, but not discarding partial vials after 6 hr as per USP<797> was ~$185,000 in 2014/15. This represents ~1% of drug expenditures.
- Annual estimates of drug wastage in 2015/16, abiding USP<797> would be in excess of $2.7M.
- If we were to use a CSTD on every single use vial in our system, the drug cost savings to our system is estimated to exceed $2.5M annually.
- The incremental cost of the CSTD within the outpatient oncology program is estimated at $400,000 annually, based on drug expenditures of $20.4M and approximately 25,000 patient treatment visits.
- Net cost savings would be ~$2.1M

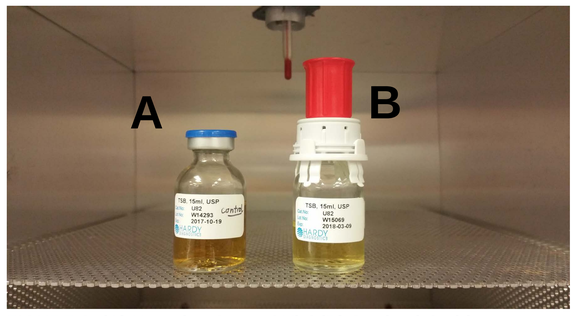
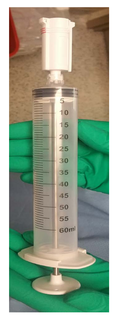


FIGURE 2: (A) Negative Control Vial (B) Study vial with Equashield® adaptor attached



(C) Equashield® syringe

CONCLUSIONS

- Attachment of a CSTD adapter to single-use vials within an ISO-5 environment has the ability to maintain sterility following multiple withdrawals
- These results were consistent when the vials were exposed to continuous ISO 5 air quality and when exposed to poorer than ISO 5 air quality (Laminar air flow hood off)
- These results remained consistent in the setting of multiple operators following training on the use of the CSTD

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