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 OBN 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 ATCC 12228, incubation at 37°C 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.

**RESULTS**

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).
3. Three laminar airflow hoods, running during daytime only.

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**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.

**REFERENCES**