



Head-to-head evaluation of closed-system transfer devices in a health-system oncology clinic

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BACKGROUND

- USP <800> guidelines have increased the need to objectively evaluate closed-system transfer devices (CSTDs) in both the pharmacy and nursing sector¹
- Data suggests that any level of repeated hazardous compound exposure can lead to chromosome 5 and 7 abnormalities in health care workers, which are precursors to hematologic malignancies²
- A variety of data sources exist to help guide health-systems in their decision-making, including:
 - FDA ONB designation³
 - Industry-sponsored vapor containment studies⁴
 - Peer-reviewed, published data versus standard, needle-based preparation techniques^{5,6,7,8}
- NIOSH is poised to enter the CSTD evaluation space with the use of universal protocol, but this is limited to CSTDs that utilize a physical barrier for containment⁹
- Hazardous drug wipe testing is taking a larger role in the objective evaluation of hazardous drug contamination risk with the publication of USP <800>¹
- There is a paucity of non-industry-sponsored, peer-reviewed, published data on the evaluation of two different CSTDs in a head-to-head comparison using wipe testing as an objective measure of contamination

PURPOSE

The purpose of this project was to evaluate the safety of a new closed-system transfer device (B.Braun OnGuard) versus a legacy closed-system transfer device (BD Phaseal) in a head-to-head comparison of the two products in a live environment

METHODS

- Study performed over 2 week period in medium-sized clinic (average 17 infusion patients per day)
- Baseline contamination measured via validated third-party wipe testing for 6 hazardous compounds:
 - 5-fluorouracil
 - Cyclophosphamide monohydrate
 - Doxorubicin hydrochloride
 - Etoposide phosphate
 - Irinotecan hydrochloride
 - Paclitaxel
- Testing was conducted in the following areas:
 - Vertical flow hood, interior surface
 - Negative pressure room, floor
 - Negative pressure room, table top
 - Pass-through window, interior surface
 - Patient chair, arm support
 - Patient chair, floor directly in front
- Baseline wipe testing was performed by pharmacy personnel at the completion of a full infusion day prior to terminal cleaning of the space
- After samples were obtained, a two-step decontamination of the spaces to be evaluated was performed by pharmacy personnel
- Investigational CSTD was implemented in conjunction with on-site training/support
- Normal cleaning procedures were conducted for the entirety of the study period in accordance with health-system policies and procedures
- At the end of the trial, wipe testing was performed by pharmacy personnel at the completion of a full infusion day prior to terminal cleaning of the space
- After samples were obtained, a two-step decontamination was performed by pharmacy personnel

DISCUSSION

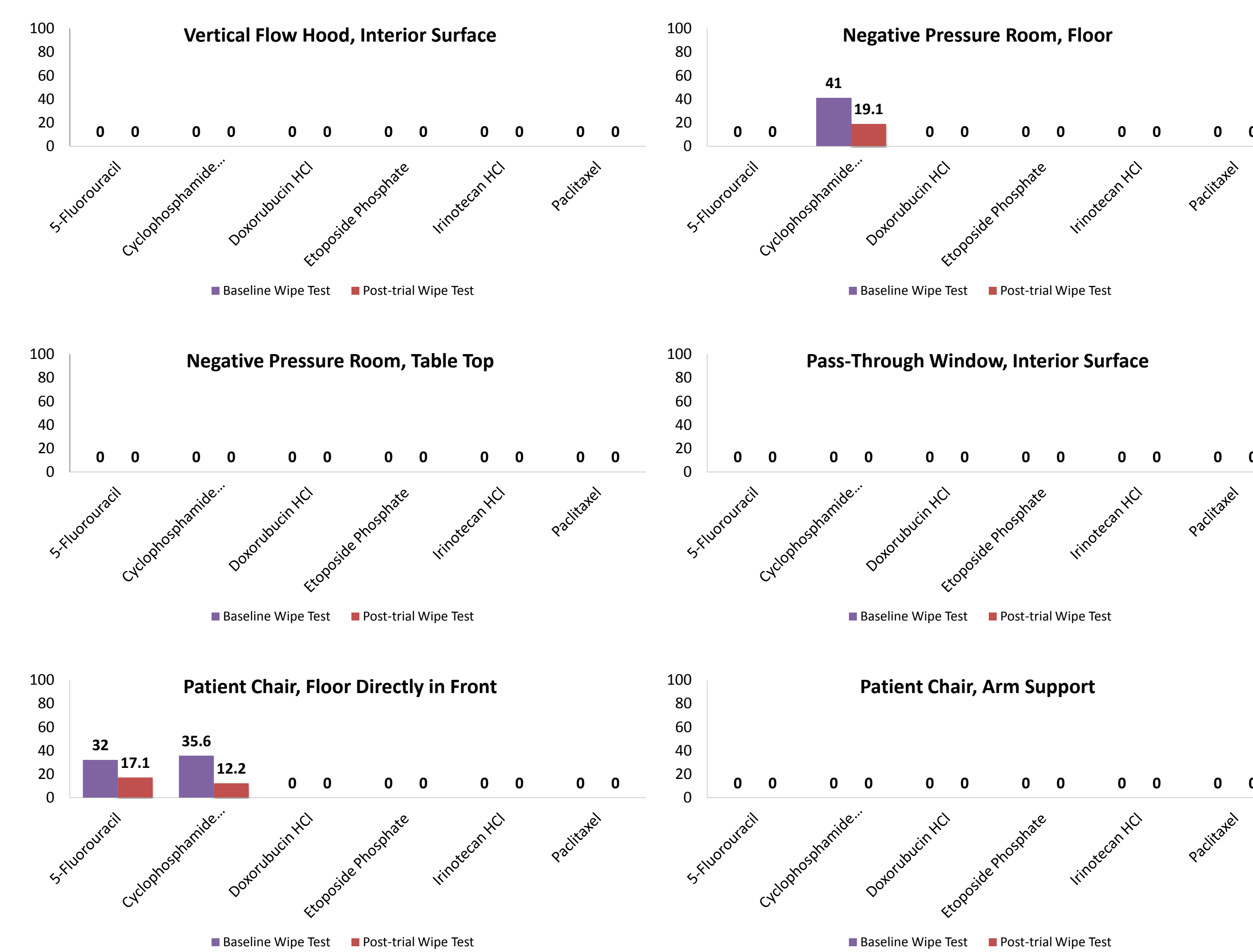
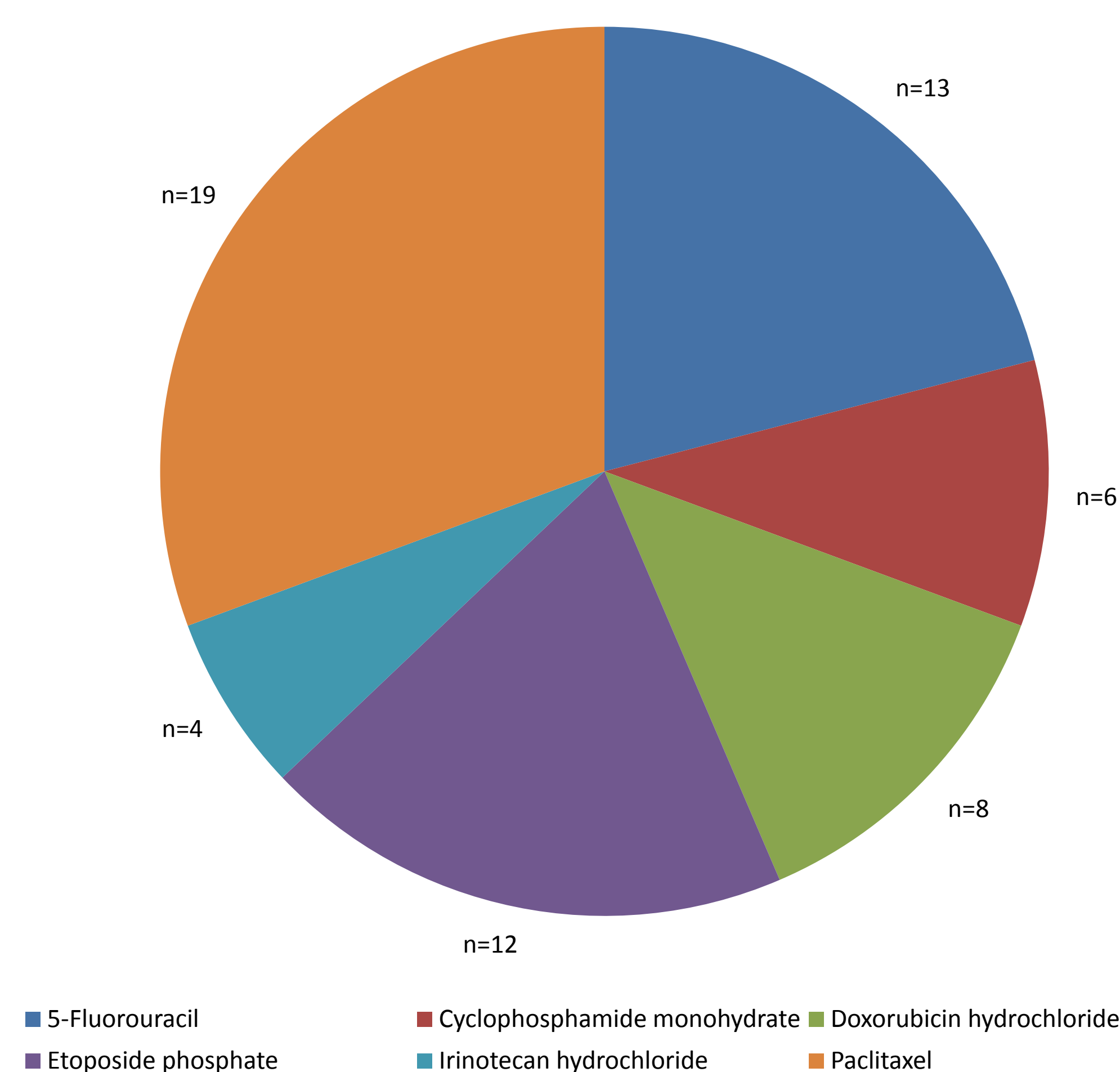
- Based on the independent wipe testing, the B.Braun OnGuard system is equivalent to the BD PhaSeal system in terms of hazardous drug containment
- Both systems showed measurable hazardous compound levels, which underscores the importance of decontamination and cleaning
- As a result of this trial, a CSTD change was made at the health-system level, as safety was confirmed to be equivalent and cost-savings were obtainable

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RESULTS

Preparations, by measured hazardous compound



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:

- M. Jay Brown: Nothing to disclose
- Rolanda Davis-Lowery: Nothing to disclose
- Brian Wallace: Nothing to disclose

