USING A CLOSED-SYSTEM TRANSFER DEVICE LEADS TO BETTER CONTROL OF OCCUPATIONAL EXPOSURE IN ROUTINE PRACTICE

PP-015

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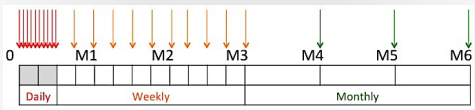
Background: Closed-system transfer devices (CSTD) are promoted in all recommendations to reduce the occupational exposure to antineoplastic drugs during compounding process. Numerous *in vitro* studies have shown that using the PhaSeal® system (Becton-Dickinson) may limit the chemical contamination.

Purpose: To compare the chemical contamination inside isolators between a standard (S) and a PhaSeal® (P) compounding process in routine practice (20000 preparations/6 months)during a prospective survey.

Material and methods

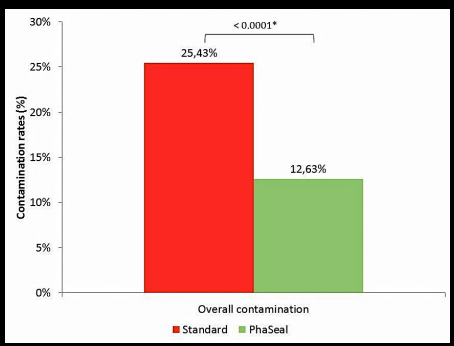
- Prospective study (6 months) started at the opening of a new compounding unit
- Compounding in 2 isolators with 2 workstations
  - Isolator S with standard devices (needles and spikes)
  - Isolator P using only the PhaSeal® devices
- 10 drugs (cyclophosphamide, cytarabine, dacarbazine, doxorubicine, 5-FU, ganciclovir, gemcitabine, ifosfamide, irinotecan, methotrexate) alternatively compounded in each isolator
- Sampling process: wipe sampling of 3 surfaces (gloves, window (inner surface), worktop) before and after daily cleaning process
- Samples progressively spaced:



- Dosage by LCMSMS (Xevo TQD, Waters).
- Statistics: Contamination rates (% of samples revealing contamination) were compared using a Chi² test and the drug amounts by a Mann-Whitney test. Significance was defined for p<0.05.

Results

- No contamination before study beginning
- No significant difference in the drug amount compounded in each isolator excepted for methotrexate (S:612±1759 vs. P:1782±2736 mg) and cytarabine (S:1040±1807 vs. P:1564±1872 mg)
- Significant difference in the overall contamination rate (see below)



- Two drugs were never retrieved (methotrexate and doxorubicine)
- Only traces (< LLOQ) of two drugs were retrieved (dacarbazine, irinotecan)
- Isolators were essentially contaminated with gemcitabine (S: 224.7 vs. P: 295.9 ng; p<0.67) and cyclophosphamide (S: 575.8 vs. P: 139.7 ng; p<0.03)

Discussion – Conclusion

- The importance of the compounded amount has no direct impact on the measured contamination as demonstrated with cytarabine and methotrexate
- Using a CSTD leads to reduce significantly the overall contamination on all surfaces and during all the study
- This intermediate analysis will be implemented by the analysis of the handled drug amounts and the occurrence of incidents.

Conflict of interest: Becton-Dickinson had partially supported the study in paying for samples dosing and provided PhaSeal devices

Keywords : Security, Antineoplastic drugs, compounding, closed-system transfer devices, chemical contamination