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EVALUATION OF THE EFFECT OF CLOSED SYSTEM TRANSFER DEVICE SYRINGE ADAPTOR CONNECTION IN THE ISOLATOR ON CYTOTOXIC RESIDUE CONTAMINATION DURING INTRAVENOUS ADMINISTRATION

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Background and Importance:

The European Biosafety Network recommends that cytotoxic drug surface contamination in pharmacy and patient wards not exceed 0.1 ng/cm^2. Among other mitigations, closed system transfer devices (CSTDs) are recommended in several guidances in the US, Europe, and UK for reduction of surface contamination. In the UK, CSTDs are not part of standard cytotoxic preparation procedures in isolators, but the NHS recommends the use of CSTD syringe adaptors (SAs) with syringes used for intravenous administration. At University Hospitals Birmingham, standard practice is to connect Luer caps in the isolator and remove them for administration.

Aims and Objectives:

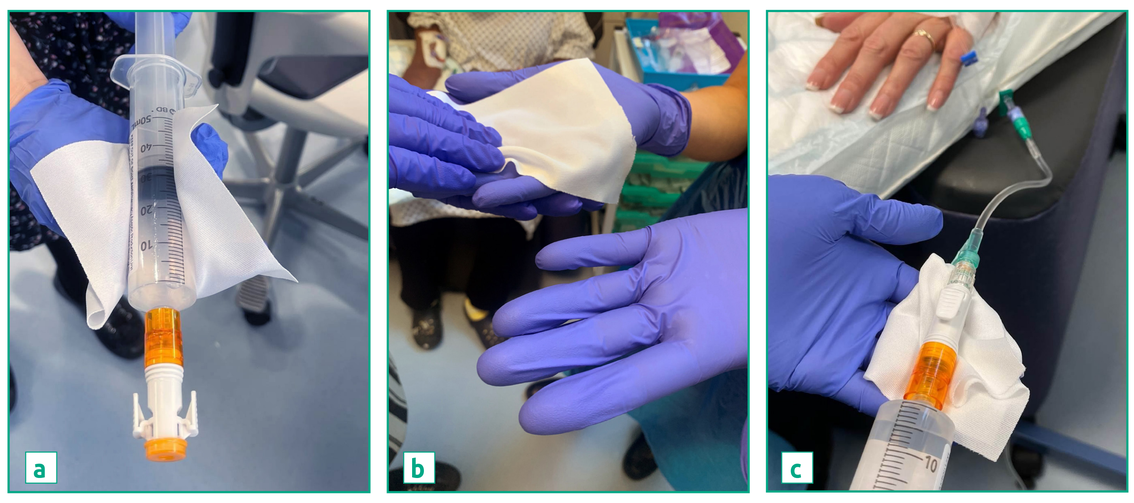
The aim was to determine if the addition of a CSTD SA in the isolator reduces cytotoxic residue contamination during intravenous bolus administration.

Materials and Methods:

Surface contamination of syringes, gauze pads placed at the administration site, and nurses' gloves were compared between the two procedures: connecting AMD hub caps in the isolator and removal in the ward vs. connecting a SIMPLIVIA® SA Locks (SALs) in the isolator during preparation.

In a negative pressure isolator, 25 cyclophosphamide syringes were prepared with hub caps and 25 with SALs. Syringes were wiped with 50% methanol prior to removal from the isolator. In the ward, syringes were swabbed. Gauze pads placed under connection sites for bolus administration were collected (Figure 1). Following administration, nurses' gloves were swabbed. Cyclophosphamide on swabs and gauze pads was quantified by LC/MS.

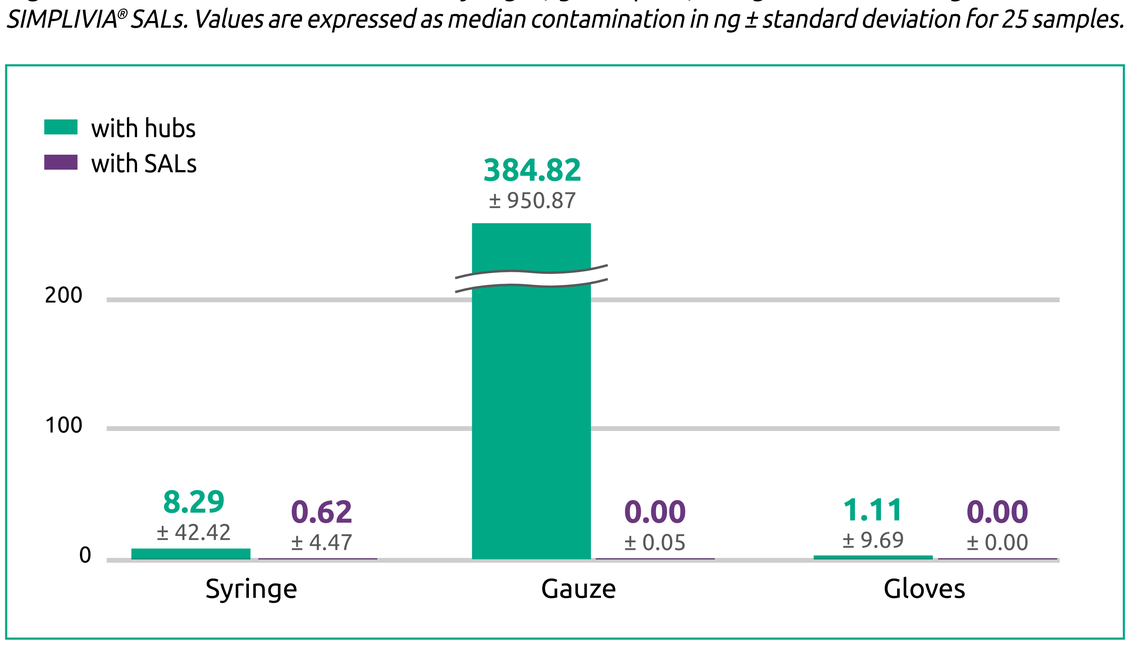
Figure 1. *Sampling of (a) syringe surface, (b) gauze pads, and (c) gloves with SAL. The same procedure was performed with hubs.*



Results:

When SALs replaced hub caps: median cyclophosphamide contamination decreased from 8.29 ng to 0.62 ng on syringes, from 384.82 ng to 0.01 ng on gauze pads; and from 1.11 ng to 0.00 ng on gloves (Figure 2). When hub caps were used, 12/25 syringes, 19/25 gauze pads, and 2/25 gloves exceeded the recommended limit of 0.1 ng/cm^2, while with SAL, no samples exceeded this limit.

Figure 2. *Contamination detected on syringes, gauze pads, and gloves when using Luer hubs vs. SIMPLIVIA® SALs. Values are expressed as median contamination in ng ± standard deviation for 25 samples.*



Conclusion and Relevance:

Addition of SIMPLIVIA® SALs to syringes in the isolator reduced cytotoxic residue on syringe surfaces, nurses' gloves, and on connect/disconnect, compared to the addition of standard hub caps. Thus, SIMPLIVIA® SALs are beneficial in reducing cytotoxic drug exposure to nurses administering IV syringes and may reduce the risk of mutagenic adverse events.

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