EXPOSURE CONTROL
monitoring and consultancy

MONITORING CONTAMINATION ON INNER WALLS OF SYRINGES USED FOR PREPARATION AND ADMINISTRATION OF HAZARDOUS DRUGS

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Aim of the study

To evaluate contamination on inner walls of barrel syringes used for preparation and administration of hazardous drugs by means of wipe sampling.

Background

When a syringe is filled with a hazardous drug, the inner surface of the syringe is directly exposed to the drug that may react and stick to the surface. After transferring the drug to its final container or after administration, the inner wall remains fully exposed to the environment and the process of hazardous drug evaporation to the working environment may take place. Furthermore, the syringe plunger may get contaminated either by contact with the inner wall of the syringe or the drug may infiltrate onto the plunger during manipulation of the syringe if the syringe is used for multiple manipulations. Such contamination could be transferred via gloves of the operators to other surfaces resulting in spread of contamination in the working environment. Obviously, this should be prevented as much as possible.

Study design

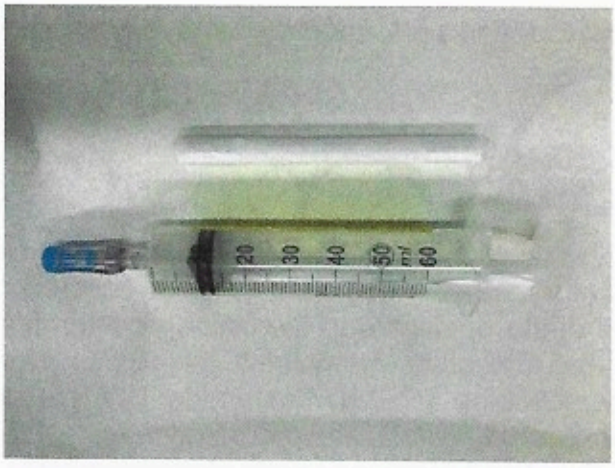
Between 4 and 7 October 2020, forty-three 50 ml BD Plastipak luer lock syringes (actually 60 ml) were collected by the hospital pharmacy of the University Hospital Leuven in Belgium.

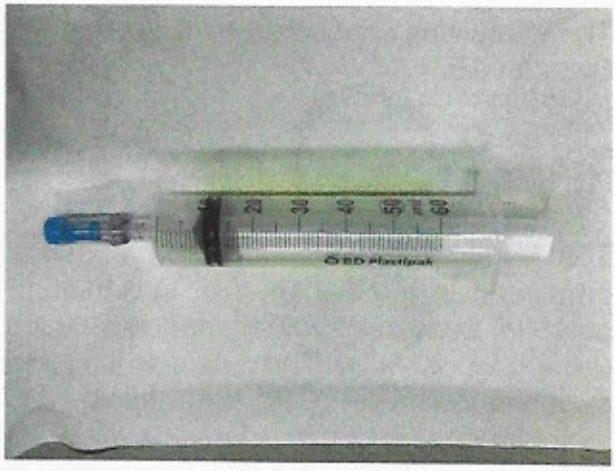
The syringes were collected after single use for the preparation of hazardous drugs. The drugs were transferred from the vials to the infusion bags using the ChemoClave and Spiros CSTD (ICU Medical). Drug volumes transferred varied from 36 to 60 ml. Fourteen pharmacists and technicians were involved in the preparation of the syringes (coded A – N).

The inner walls were wiped for each syringe using standard Cyto Wipe Kits for surface wipe sampling. Wiping with prewetted tissues (5 ml 0.1% formic acid solution and for cisplatin 5 ml 0.5 M HCl solution) and analysis were performed at the laboratory of Exposure Control in the Netherlands. The shape of the wipes was adapted to perform wiping on the inner walls of the syringes (Figure 1). The plunger was set at 10 ml to have sufficient access into the syringe barrel to perform the wipe sample. The wipe sample was taken by turning around the plunger to make sure the prewetted tissue contacted the total surface of the inner wall of the syringe.

Six hazardous drugs were tested because physical and chemical properties of drugs differ, and this could produce different results. Only 50 ml syringes were collected for testing to allow convenient access with the wipes. Considering the 50 ml requirement, the following drugs fitted into the study: 5-fluorouracil (50 mg/ml), cyclophosphamide (20 mg/ml), ifosfamide (40 mg/ml), methotrexate (100 mg/ml), doxorubicin (2 mg/ml), and cisplatin (1 mg/ml). Two till ten tests of each drug were performed depending on availability of the syringes during the collection period.

Figure 1: Tissue for wiping and syringe (left) and tissue inside syringe barrel (right)





Touching the plunger shafts was not allowed to avoid contamination on the inner walls of the syringes caused by the gloves of the operators during preparation. Only the external knob on the end of the plunger was used for holding. To ascertain this has not happened, the wipe samples were also analysed for nine other drugs in addition to the drug handled and transferred, except for cisplatin as the sample clean up procedure and the analysis was different compared to the other five drugs tested.

Materials and methods

The syringes were collected after single use and individually packed in a plastic mini bag. The syringes were still connected to the Spiros CSTD to avoid spills with the drugs. Each syringe was provided with a unique code and details are registered in the Tables 1-6. The syringes were stored at 2-8°C until sample preparation and analysis at the laboratory performed 14, 15 and 19 October 2020.

The wipe samples were taken with Cyto Wipe Kits from Exposure Control Sweden AB [1].

Before analysis, all wipe samples were extracted by adding 20 ml 0.1% formic acid solution. For cisplatin 20 ml 0.5 M HCl solution was used. Total extraction volume for the wipe samples was 25 ml.

LC-MS/MS was used for the analysis of cyclophosphamide, cytarabine, docetaxel, doxorubicin, etoposide, 5-fluorouracil, gemcitabine, ifosfamide, methotrexate and paclitaxel [2]. Platinum analysis of cisplatin was performed with stripping voltametry [3]. 0.5 ml of the extract was destructed using hydrogen peroxide, hydrochloric acid and UV-light resulting in the formation of platinum (PT) ions. Finally, the platinum ions were analysed instead of cisplatin. Samples were analysed in duplicate (including destruction). Mean values are reported.