VALIDATION OF OPERATORS FOR CHEMICAL CONTAMINATION DURING PREPARATION OF CHEMOTHERAPY INJECTABLES

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OBJECTIVES

The chemical contamination of the operators during the preparation of cytotoxic is a hot topic. Besides the external surfaces of vials, the operators themselves can also contribute to this problem during the manipulations. We developed a validation protocol using a non-toxic, highly detectable and easy to quantify tracer to measure the level of contamination produced by operators.

METHODS

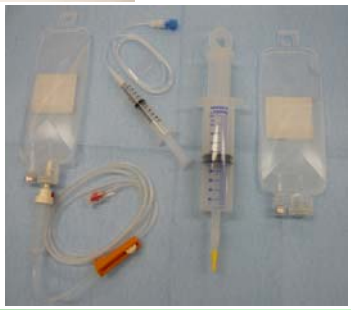
Using a complete protocol including critical operations of cytotoxic preparation, 12 operators were tested. Each operator used vials of quinine diHCl powder, resulting in a 0.1 M solution after reconstitution. Different devices were used to fill syringes and perfusion bags, with or without an administration set. For each operator, all the filled containers and material were collected at the end of the protocol and washed by a validated method. The obtained solution was analyzed by fluorimetry (LOQ=0.5 µL) for the rate of contamination. The number of spots on the working pad was counted under UV light.

Negative pressure isolators : preparation environment

UV Lamp (CAMAG)

Fluorimeter Perkin Elmer LS 40

20 Vials of Quinine diHCl to reconstitute and fill these material



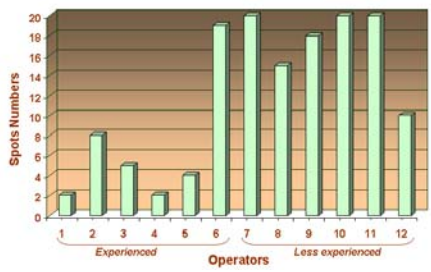
Material used for the validation of the operators

RESULTS & DISCUSSION

The total quantities of contamination after the whole procedure (1 hour) had a mean value of 3.0 µL (1.7 to 5.2) and 10 spots (2 to 20). 4/6 experienced (> 5 years) operators had contamination levels below the mean values for both criteria (mean 1.8 µL, 4 spots), whereas for less experienced operators, 6/6 were above the mean value for at least one parameter (mean 4.3 µL, 15 spots), and 4/6 for both.

According to FDA* : Acceptable level of contamination

= 0.1% of the daily dose



* FDA Guide to inspections validation of cleaning processes, http://www.fda.gov/ora/inpect_ref/igs/valid.html

This **"Acceptable level"** calculated for less active and highly active substances :

5-FU: 50mg/mL solution, Daily dose : 1000 mg
« acceptable level » → **1 mg**
Equivalent detected level further to operators results : **min → 58 µg**
max → 220 µg < 1 mg

Vincristine: 1mg/ml solution, Daily dose : 2000 µg
« acceptable level » → 2 µg
Equivalent detected level further to operators results : **min → 1.2µg**
max → 4.4 µg > 2 µg

Therefore, training must be done for less performing operators further to their contamination rate results.

CONCLUSION

A validation protocol for chemical contamination, using a non-toxic tracer, permits to control the working "cleanliness" of the operators and their abilities to avoid contamination. These evaluations will help us to improve our initial and continuing training and preparation methods, even for experienced operators. Following the well-known schemes of media-fill tests for microbiological contamination, this new test answers to the important issue of chemical security of the operators.

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Conflict of interest : nothing to disclose