

Chemical contamination during the preparation of cytotoxics: validation protocol for operators in hospital pharmacies

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Background and objectives: The chemical contamination during the preparation of cytotoxics remains a serious problem in hospital pharmacies and the operators could contribute to this risk during their manipulations. A validation protocol was developed using a non-toxic, highly detectable tracer, quinine dihydrochloride.

Method: Further, a method for a high recovery extraction and quantification of this marker, and a protocol covering the critical operations of cytotoxic preparation, was developed and validated. Various devices were used to fill the syringes and perfusion bags. All the filled containers and used materials were collected at the end of the protocol and the tracer was extracted in water. The contaminated water was analyzed by fluorimetry. The number of spots on the working pads was counted under ultraviolet light. During a total of 28 sessions, the procedure was applied by 20 different operators.

Results: The mean cumulated quantities of contamination were 6.2 μL (0.6–23.8) and >10 spots (0–20), which was considered as high. No correlation was observed between the contamination rate and the operator's experience.

Conclusion: This validation protocol facilitates controlling the operators' working 'cleanliness' and helps to improve the initial and continuing training. This simple test presents an effective answer for the important issue of the chemical safety of operators.

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