Risk Assessment of Occupational Exposure to Cytotoxic Drugs in an Outpatient Hospital Pharmacy

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BACKGROUND AND IMPORTANCE

Safe handling and dispensing of cytotoxic drugs in outpatient setting are of growing concern in Hospital Pharmacy. However, surface contamination studies mainly focus on the preparation areas. As oral therapy gains significance, it is critical to assess its role as a potential source of contamination in non-compounding environments.

AIM AND OBJECTIVES

a) Workflow analysis for a selection of critical sample sites;
b) Design of a risk matrix considering the contamination level (ng/cm2);
c) Implementation of corrective measures and sampling frequency according to the risk level.

MATERIALS AND METHODS

Two drugs were selected, 6-Mercaptopurine (6-MP) and Capecitabine (CPC), based on their potential risk for the operator (number of dispensations versus handling level) and four critical areas were identified (storage drawer; hood; repackaging bench; dispensing counter) **[Fig. 1]**.

The samples were collected by wipe sampling **[Fig. 2]** and sent to quantification analysis by LC-MS/MS, in a certified laboratory (IUTA)[1].

Two sampling periods were carried out (3+2 samples), before and after corrective measures.

RESULTS

Out of five samples collected, two presented results above the reference value of 0.1ng/cm2[1]: storage drawer (CPC) and hood (6-MP) **[Table 1]**.

Following a cleaning procedure in the storage drawer (CPC), a value of 0.014ng/cm2 was obtained **[Table 1]**.

The remaining results were below below the assay's limit of quantification (LoQ). **[Table 1]**.

CONCLUSION AND RELEVANCE

The storage areas were identified as of increased risk, however, the limited number of samples available for analysis conditioned the total mapping of the critical areas.

The analysis of the results led to the definition of risk levels **[Table 2]**. It is intended to extend the sampling to all dispensing pathways.

The development and evaluation of corrective measures and sampling frequency is still pending on future results, although the cleaning methodology has proven to be effective.

There is evidence of contamination from handling oral formulations of cytotoxic drugs. The lack of risk perception leads to the undervalue of routine procedures, such as cleaning, and proper use of Individual Protection Equipment (EPI), increasing occupational exposure.

This project aims to ensure that the occupational exposure level is reduced to a value as low as technically possible.

REFERENCES
[1] Kiffmeyer TK, et al. Application and assessment of a regular environmental monitoring of the antineoplastic drug contamination level in pharmacies-the MEWIP project. Ann Occup Hyg. 2013 May;57(4):444-55.

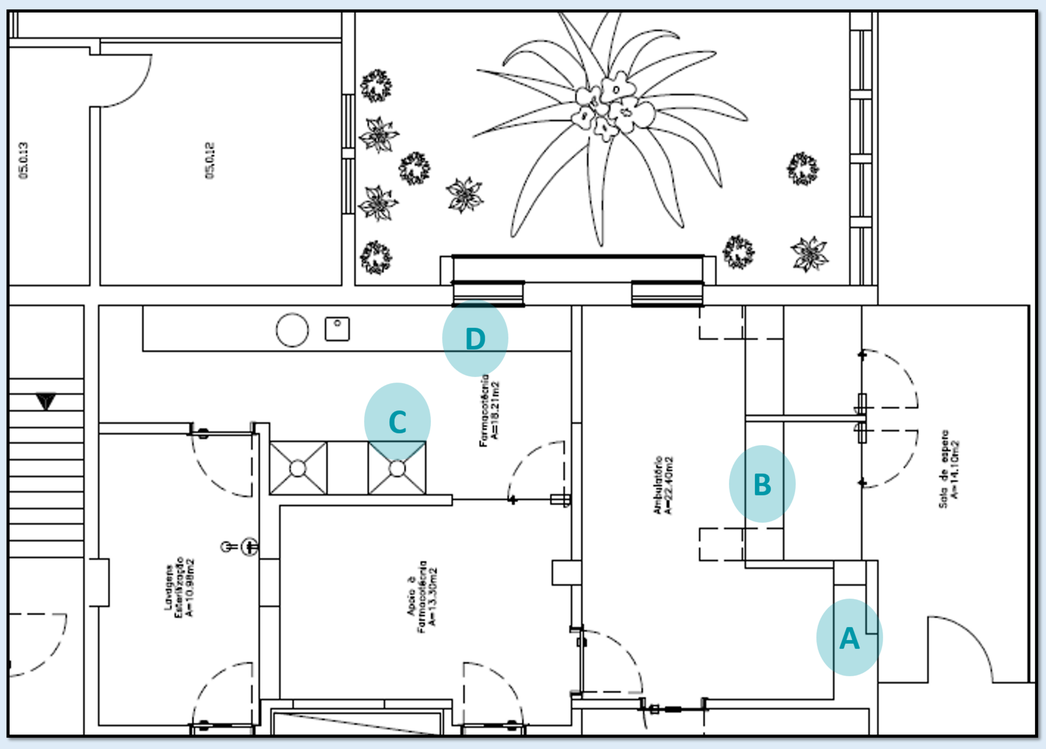

Figure. 1 Sample location plan.

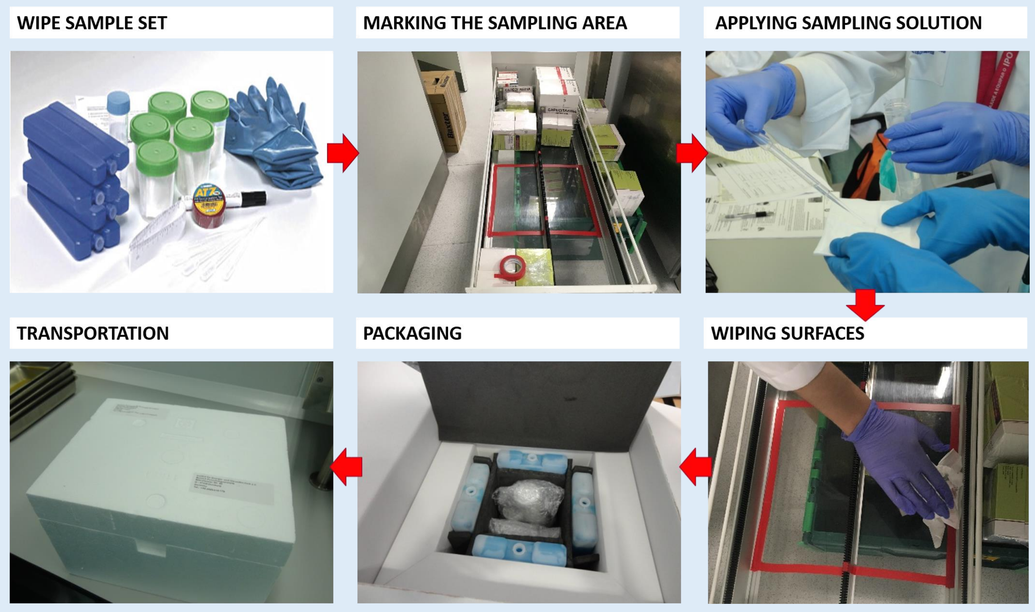

Figure. 2 Wipe Sampling method.

SAMPLE NUMBER	1	2	3	Corrective Measures (Cleaning)	4	5
LOCATION	Storage drawer (A)	Dispensing counter (B)	Hood (C)		Storage drawer (A)	Repackaging bench (D)
CAPECITABINE (CPC) (ng/cm²)	0,51*	<0,004	N/A		0,014	<0,004
6-MERCAPTOPURINE (6-MP) (ng/cm²)	N/A	N/A	32*		N/A	N/A

*Results above the reference value (0,1 ng/cm²);
Limit of Quantification (LoQ) of the assay for CPC and 6-MP: 0,004 ng/cm2.

Table 1. Results by sampling location.

	QUANTIFICATION (ng/cm²)		
	< 0,004	0,004 – 0,1	> 0,1
RISK LEVEL	LOW	MEDIUM	HIGH

Table 2. Risk levels matrix: Capecitabine and 6 – Mercaptopurine.

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