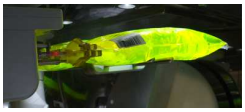
ASSESSING SURFACE AND CROSS CONTAMINATION AFTER AN INTENSE USE OF A ROBOTIC SYSTEM FOR THE CHEMOTHERAPY COMPOUNDING

C. Bufarini[1], R. De Palma[1], S. Guglielmi[1], A. Marinozzi[1], D. Paolucci[2]
[1]Pharmacy, A.O. Ospedali Riuniti – Ancona (Italy) | [2]Loccioni humancare – Moie di Maiolati, Ancona (Italy)

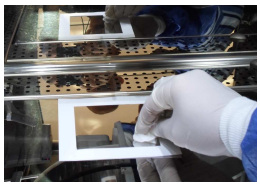
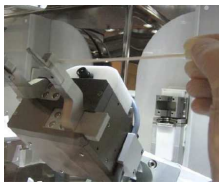
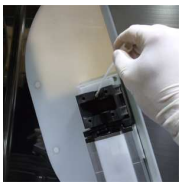
BACKGROUND

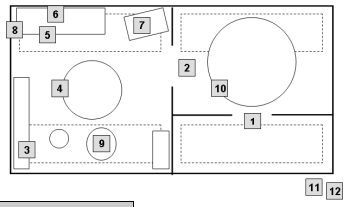
The verification of chemical contamination is a fundamental requirement to ensure the safety of operator and patient. Robotic systems are designed to minimize the risk of chemical and microbial contamination. The main source of chemical contamination turns out from the cytotoxic drugs handling and depends mainly on the working procedures applied.
In this work, we wanted to evaluate the level of environment contamination and cross-contamination generates during a thorough use of the robotic system.



MATERIAL AND METHOD



Threshold Guidance Values for environmental contamination with cyclophosphamide (CP). [2]				
	Strive risk level			Prohibitory risk level
Urine (µg/24h)	<0.02	0.02-0.2	0.02-2	>2
Surface cont. (ng/cm2)	<0.1	0.1-1	1.0-10	>10

Fluorescein was chosen as marker for the chemical contamination verification due to its high fluorescence that, analysed by means of chromatography (HPLC with fluorimetric detector), allows the detection of minimum traces (LOD=1ppb). The protocol provided for the simulation of hospital pharmacy day activity,[1] including the worst case conditions. Drug-like fluorescein vials at 1mg/ml concentration in NaCl 0,9% solution were used in different vial formulations: single-dose and multidose liquid solution, powder. Wipe tests were carried out at the end of the activity, without performing any cleaning procedures, and involves surfaces of the inner chambers of APOTECAchemo, external surface of the compounded bags, touch-screen monitor, handle of the barcode scanner. The cross contamination is verified by detecting the marker inside test preparations compounded simultaneously with those having the tracer, but compounding only NaCl 0,9%.
Finally, the data were analysed using the Sessink's threshold, [2] the first based on healthcare safety considerations. The study correlates the contamination level of the urine samples of heathcare workers with that of the related surfaces.

RESULTS

None of the surfaces sampled outside the robot showed contamination (values < LOD), including the external surfaces of the bags compounded. As expected, low levels of contamination (between 0,02 and 0,06 ng/cm2) were recorded in some internal surfaces of the compounding room. These positive samples are well below the safety limit identified by Sessink.
Concerning the cross contamination, no detectable traces of fluorescein were recorded either inside or outside the "control" bags without the marker, but compounded simultaneously with those having it.

Test	Surfaces	Result
1	Manual Load/Unload area	<0.01 ng/cm²
2	Automated load/unload area of the internal warehouse	<0.01 ng/cm²
3	Internal parking of the compounding area	0.03 ng/cm²
4	Robot electronic gripper	0.06 ng/cm²
5	Surface under the dosing device	0.02 ng/cm²
6	Dosing device	<0.01 ng/cm²
7	Scale	<0.01 ng/cm²
8	Lateral surface close to the dosing device	<0.01 ng/cm²
9	Powder drug reconstitution mixer	0.02 ng/cm²
10	Sector of the automated warehouse dedicated to unload partially-used vials	<0.01 ng/cm²
11	Touch-screen monitor	<0.01 ng/cm²
12	Handle of the manual barcode reader	<0.01 ng/cm²
13	Clamp adapter for bags and elastomeric pumps	<0.01 ng/cm²

Test	Final products	Result
14	Internal volume of bag 8 (cycle 7)	<1 ng/ml
15	Internal volume of bag 15 (cycle 14)	<1 ng/ml
16	Internal volume of bag 18 (cycle 18)	<1 ng/ml
17	External surfaces of bag 1	<0.01 ng/cm²
18	External surfaces of bag 2	<0.01 ng/cm²
19	External surfaces of bag 3	<0.01 ng/cm²
20	External surfaces of bag 4	<0.01 ng/cm²
21	External surfaces of bag 5	<0.01 ng/cm²
22	External surfaces of bag 6	<0.01 ng/cm²
23	External surfaces of bag 7	<0.01 ng/cm²
24	External surfaces of bag 9	<0.01 ng/cm²
25	External surfaces of bag 10	<0.01 ng/cm²
26	External surfaces of bag 11	<0.01 ng/cm²
27	External surfaces of bag 12	<0.01 ng/cm²
28	External surfaces of bag 13	<0.01 ng/cm²
29	External surfaces of bag 14	<0.01 ng/cm²
30	External surfaces of bag 16	<0.01 ng/cm²
31	External surfaces of bag 17	<0.01 ng/cm²

CONCLUSION

A systematic protocol to assess drug contamination was designed and carried out. No relevant contamination was recorded after a massive amount of drug reconstituted. This work represents the first step to point out that robotic compounding can be considered as a safe level for environmental and cross contamination. Next steps provides for extending this approach to cytostatic drugs, such as fluorouracil and cyclophosphamide.

Reference:

[1] 36 preparations (14 syringes, 18 bags and 4 elastomeric pumps), using 23 ready-to-use solution vials (both single and multidose) and 14 powder vials.

[2] Sessink PJM, Environmental contamination with cytostatic drugs: past, present, future, Special Edition Fall 2011, 2-5 (http://www.ppme.eu/About-PPME/Current-Activities/Supplements/Safety-Considerations-in-Oncology-Pharmacy).

Azienda Ospedaliero Universitaria OSPEDALI RIUNITI Umberto I - G.M.Lancisi - G.Salesi Ancona

c.bufarini@ospedaliriuniti.marche.it
d.paolucci@loccioni.com

LOCCIONI humancare