Improving Staff Training in a Cytotoxics Preparation Unit

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What was done ?

Implementation of a training program for the Cytotoxics Preparation Unit (CPU) focusing on product and staff safety.
Key steps were hand washing and simulated disinfection with fluorescent gel, media fill and simulated preparations with fluorescent dye. Wipe sampling of cytotoxic contamination is now performed routinely and is considered as an indirect performance indicator.

Why was it done ?

Improved processes were required due to PIC´s (2) requirements and workplace safety legislation. Moving to new CPU facilities was also a trigger for this improvement.
The training program started in 2013 and the aim was to change from an informal training to a program where minimal qualification standards were achieved despite heavy workload and budget constraints.

How was it done ?

Absence of national experience required literature review and support from other hospital in Europe.
Lack of commercial products and budget constraints led to adoption of more affordable solutions like in-place compounding of fluorescein vials, and use of standard sodium chloride IV bags for the media fill test. Other resources were procured externally and adapted.
Staff motivation was enhanced with their Involvement in the goals and open discussion of results.

What has been achieved ?

All relevant staff went through the training and reached the qualification thresholds.
Hand wash and disinfection were performed twice, before and after a formal presentation. In the discussion with staff between sessions, besides lecturing, there was a critical review of results and a training video was shown, with a clear focus on improvement. Second session had better results.
All pharmacy technicians successfully performed media fill test (no microbial growth), and fluorescein test (no dye spots counted).
Surface cytotoxic contamination (8 drugs tested in 5 locations) is mostly in line with reference values.

What next ?

Training program is to be repeated yearly, as well as the monitoring processes. Future steps will also focus on cleaning procedures and related training requirements. Despite budgetary and staff constraints, a sustainable training program can be implemented with adaptation of published sources, resulting in adhesion to good practice.

References
(1) USP <797> –Pharmaceutical Compounding–Sterile Preparations
(2) PIC/S guide to good practices for the preparation of medicinal products in healthcare establishments. PE 010-3, October 2008.
(3) Kiffmeyer TK [et.al.] Application and Assessment of a Regular Environmental Monitoring of the Antineoplastic Drug Contamination Level in Pharmacies - The MEWIP Project. Ann OccupHyg (2013) 57 (4):444-455

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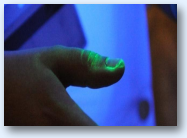
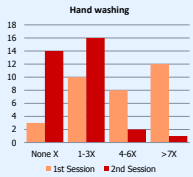
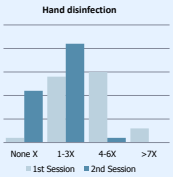
HAND WASHING AND DISINFECTION







Hand washing: X = number of spots with fluorescence; Hand disinfection: X = number of spots without fluorescence; n=33 (10 Pharmacists, 10 Technicians, 13 Others); Score: None X "Excellent technique", 1-3X "Good technique", 4-6X "Sufficient technique", <7X "Insufficient technique".

Hand washing: *there was an improvement in the second session (1st session Mo = <7X "Insufficient technique"; 2nd session Mo = 1-3X "Good technique").* ***Hand disinfection:*** *there was an improvement in the second session (1st session Mo = 4-6X "Sufficient technique"; 2nd session Mo = 1-3X "Good technique").*

MEDIA FILL TEST AND ENVIRONMENTAL MONITORING

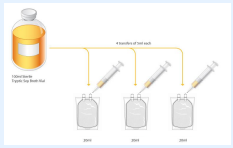
Air monitoring (Settle plates, 4 h, performed twice on different days, during media fill test)

Sample location (Grade)	Number of cfu	Vs. PIC's	Sample location (Grade)	Number of cfu	Vs. PIC's
LFC 1 (A)	0	OK	LFC 1 (A)	0	OK
LFC 2 (A)	---*	---	LFC 2 (A)	0	OK
LFC 3 (A)	1	Out of Limit	LFC 3 (A)	0	OK
LFC 4 (A)	0	OK	LFC 4 (A)	0	OK
LFC 5 (A)	0	OK	LFC 5 (A)	3**	Out of Limit
Room 1 floor (B)	2	OK	Room 1 floor (B)	3	OK
Room 2 floor (B)	0	OK	Room 2 floor (B)	0	OK

Glove fingerprints (after media fill test)

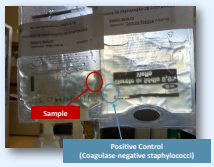
Pharmacy technician	cfu/left hand gloove	cfu/right hand gloove	Median Vs PIC's
1	1	1	Out of Limit
2	0	1	OK
3	0	0	OK
4	0	1	OK
5	1	2	Out of Limit
6	0	0	OK
7	0	0	OK
8	---*	---	-----
9	0	0	OK

PIC's recommended limits for microbiological monitoring of clean areas in operation: Settle plates,diam. 90mm (cfu/4hours) Grade A <1; Grade B = 5); Glove print, 5 fingers(cfu/glove) Grade A <1
cfu – colony forming unit; LFC #– Laminar flow cabinets (# from 1 to 5)
** Contaminated in the lab; ** not used in media fill session*



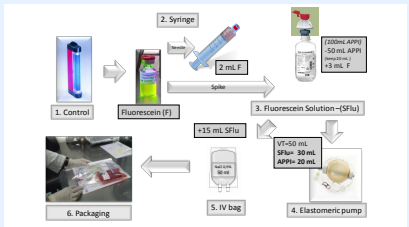
Media fill test (n= 9 technicians)

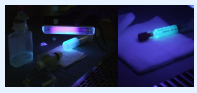
Number of samples with microbiological growth (incubation at 30ºC)	
Day 1	None
Day 2	None
Day 3	None
Day 7	None
Day 14	None



Staff Media fill test results were adequate. None of the samples prepared had evidence of microbial growth (turbidity). As IV bags are not fully transparent, the USP adapted technique was confirmed by seeding the third sample of each operator in blood gelose plate. No cfu's were observed.
Air monitoring and fingerprint showed some out of specification results that were investigated. This enhances the need for careful review and improvement of training, equipment and cleaning procedures.

FLUORESCEINE TEST



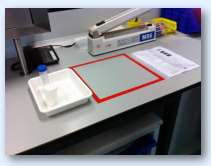


Fluorescein test (n= 9 technicians)

Check points	Number of Dye Spots Counted Using UV Light		RESULT
	TARGET	ACHIEVED	
Syringe	0	0	OK
Fluorescein Solution	0	0	
Elastomeric pump	0	0	
Infusion bags	0	0	
Packaging	0	0	

Cytotoxics handling technique was adequate regarding staff safety. No spots were detected. The target of zero spots was defined based in previous work with pharmacy staff.

SURFACE CYTOTOXIC CONTAMINATION



Results are in line with bibliography (3). Some results were higher than expected, which shows the need for improved cleaning procedures and continuous monitoring

July 2014

SAMPLE		1 Floor in front of LFC 1	2 Work surface outside the preparation area 1	3 Computer keyboard outside the preparation area	4 Storage area (5-Fu)	5 Transport box
AREA	cm2	900	900	594	840	182
IUTA REF		M 140801/01	M 140801/02	M 140801/03	M 140801/04	M 140801/05
	PROJECT MEWIP (90th Percentil) UNIT					
5- FLUOROURACIL	ng/cm²	0,12	<0,009	**0,041**	<0,01	**0,37**	<0,05
GEMCITABINE	ng/cm²	0,035	<0,004	<0,004	<0,006	<0,004	<0,02
METHOTREXATE	ng/cm²	<0,004	<0,004	**0,011**	<0,006	<0,004	<0,02
IFOSPHAMIDE	ng/cm²	0,014	**0,017**	<0,004	<0,006	<0,004	<0,02
CICLOPHOSPHAMIDE	ng/cm²	0,048	**0,061**	**0,0066**	<0,006	<0,004	<0,02
ETOPOSIDE	ng/cm²	<0,007	<0,004	<0,004	<0,006	<0,004	<0,02
DOCETAXEL	ng/cm²	<0,02	<0,02	<0,02	<0,03	<0,02	<0,09
PACLITAXEL	ng/cm²	<0,04	<0,009	<0,009	<0,01	<0,01	<0,05

January 2015

SAMPLE		1 Floor in front of LFC 1	2 Work surface outside the preparation area 2	3 Refrigerator door inc handling	4 Storage area (5-Fu)	5 Transport box
AREA	cm2	915	900	900	840	648
IUTA REF		M 150204/35	M 150204/36	M 150204/37	M 150204/38	M 150204/39
	PROJECT MEWIP (90th Percentil) UNIT					
5- FLUOROURACIL	ng/cm²	<0,009	<0,009	<0,009	<0,01	<0,01
GEMCITABINE	ng/cm²	0,035	<0,004	<0,004	<0,004	<0,004	<0,005
METHOTREXATE	ng/cm²	<0,004	<0,004	<0,004	<0,004	<0,004	<0,005
IFOSPHAMIDE	ng/cm²	0,014	**0,019**	<0,004	<0,004	<0,004	<0,005
CICLOPHOSPHAMIDE	ng/cm²	0,048	**0,060**	<0,004	**0,12**	<0,004	<0,005
ETOPOSIDE	ng/cm²	<0,007	<0,004	<0,004	<0,004	<0,004	<0,005
DOCETAXEL	ng/cm²	<0,02	<0,02	<0,02	<0,02	<0,02	<0,03
PACLITAXEL	ng/cm²	<0,04	<0,009	<0,009	<0,009	<0,01	<0,01

The underlined results are above the reference value (0,1 ng/cm2 from the MEWIP project)