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Surface Contamination by Antineoplastic Drugs in Two Oncology Inpatient Units

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Abstract

Background: Hazardous drugs pose risks to health care workers. To reduce the risk of occupational exposure for all workers, several protective and monitoring measures have been recommended and implemented over the past two decades. This study was undertaken to describe traces contamination with ten antineoplastic drugs in the oncology care unit of two university hospitals.

Methods: In this descriptive interrupted time series study, data was collected in two hospitals (a pediatric hospital and an adult hospital) in two consecutive years (12 December 2017 and 27 March 2018, defined as Period 1; 17 April 2019 and 12 June 2019, defined as Period 2). In both Period 1 and Period 2, 36 sites were sampled in each inpatient care unit to explore the contamination of surfaces with hazardous drugs.

Results: A total of 144 samples from the oncology care unit of the two hospitals were obtained for measurement. Overall, 40 % (58/144) of the sampling sites were positive for at least one hazardous drug. In the pediatric centre, 50 % (18/36) and 36 % (13/36) of the sites sampled in Period 1 and Period 2, respectively, were positive for at least one hazardous drug, whereas in the adult hospital, the percentage of sites that were positive for at least one hazardous drug was 19 % (7/36) in Period 1 and 56 % (20/36) in Period 2.

Conclusion: The surfaces of inpatient care units sampled in this study were contaminated with antineoplastic drugs, and contamination was present throughout the care units (including structures, furniture, medical equipment, and office equipment). Hospitals' environmental surveillance programs should encompass inpatient care units.

Keywords: hazardous drugs, trace contamination, environmental surveillance, occupational exposure

Introduction

Hazardous drugs pose risks to health care workers [1]. To reduce the risk of occupational exposure for all workers, several protective and monitoring measures have been recommended and implemented over the past two decades.

Recognizing that it is impossible to prevent or eliminate the presence of trace amounts of drugs, some organizations recommend periodic environmental monitoring for hazardous drugs [2–6].

Several environmental monitoring studies investigating National Institute for Occupational Safety and Health (NIOSH) Group 1 hazardous drugs (antineoplastic drugs) have been published [7, 8]. With the shift to ambulatory care in the healthcare sector over the past two decades, a substantial proportion of doses of Group 1 drugs are administered in the outpatient oncology setting. However, some protocols and clinical conditions require that these drugs be administered in an inpatient care unit, which may or may not be a unit specific to the provision of oncology care.

In Canada, an environmental surveillance program for antineoplastic drugs is proposed to hospitals since 2010 and targets 12 sampling sites, six in the oncology pharmacy and six in the outpatient oncology clinic [9]. None of these sampling sites are located in inpatient care units.

This study was undertaken to describe traces contamination with Group 1 hazardous drugs in the oncology care unit of two university hospitals.

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Methods

Design

This was a descriptive interrupted time series study.

Settings

The study was conducted at two tertiary university hospitals in the Montreal area: a pediatric centre and an adult hospital.

Sampling sites

To explore different sites of potential contamination with antineoplastic drugs, we mapped a typical inpatient care unit. From this map, we established a convenience sample of 36 sites divided into six zones: caregivers' workstation, teaching zone, corridor adjacent to targeted patient room, drug storage area in the oncology care unit, targeted patient room, and "other"). Sites were identified to sample a variety of surfaces with which the caregiver is in contact. Taking into account the proposed plan, revised sampling sites were identified to take into account the feasibility and availability of the measure.

Figure 1 schematizes the location of sampling sites in the typical care unit. Only 24 of the 36 sampling sites were paired between the two hospitals. A total of 50 distinct sites were identified and are shown in Figure 1. Some sampling sites were not measured in the two series for the same hospital given the feasibility of the sampling at the time of the study.

Timing

Data was collected on a two year period. In each facility, samples were collected for analysis on a single day for each year when at least one antineoplastic drug was administered to a patient in a specified patient room.

Taking into account the availability of the research team, the institution, and the study's inclusion criteria, samples were collected for analysis on 12 December 2017 and 17 April 2019 in the pediatric centre, and on 27 March 2018 and 12 June 2019 in the adult hospital. The samplings on 12 December 2017 and 27 March 2018 were

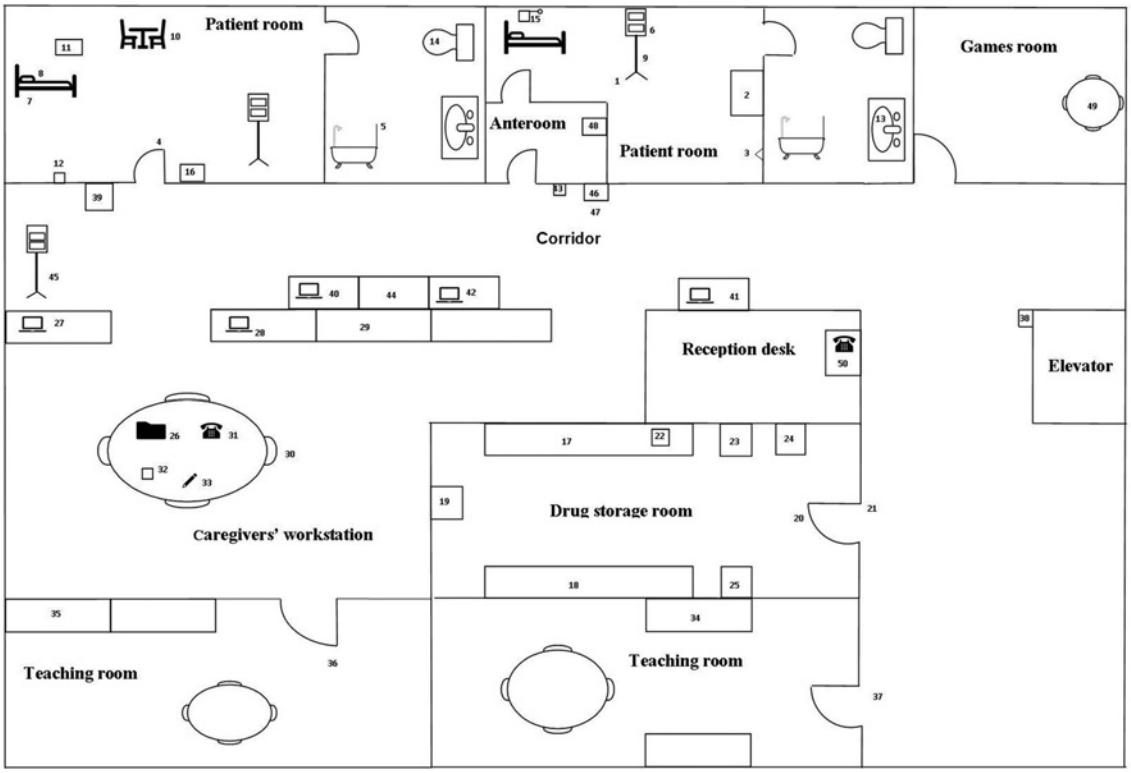

Figure 1: Map showing the 50 distinct sampling sites.

defined as Period 1. The samplings on 17 April 2019 and 12 June 2019 were defined as Period 2.

Analytical method

Each surface was sampled with a single 6 cm × 8 cm WypAll × 60 wipe (Kimberly Clark Professional, Newton Square, Pennsylvania). Before sampling, the wipe was moistened with 1 mL of sampling solution (10 % methanol and 90 % ammonium acetate 5 mmol/L). An area of about 600 cm^2 on each surface was wiped once horizontally and once vertically and with each side of the wipe (4 times in total). The sampling method was adjusted if the area of the surface was smaller or larger than 600 cm^2. The various sites were sampled before surfaces were cleaned.

Sampling wipes were stored between 2 and 8 °C in 50-mL polypropylene tubes. In Period 1, seven antineoplastic drugs were quantified: cyclophosphamide, ifosfamide, methotrexate, cytarabine, gemcitabine, 5-fluorouracil, and irinotecan. Three additional antineoplastic drugs were detected but not quantified: docetaxel, paclitaxel, and vinorelbine. In Period 2, cytarabine was removed from the quantitation method for purposes of optimization. The method used in this study is also that used for a Canadian environmental monitoring program and the withdrawal of cytarabine helps to optimize not only the analytical procedures but also the costs of analysis. One negative control per group of 12 samples was also obtained, for a total of six for both series.

Quantification and detection of the antineoplastic drugs in the sampling extract was conducted by Ultra performance liquid chromatography – tandem mass spectrometer (UPLC-MS/MS) (Acquity UPLC® chromatographic system coupled with a Xevo TQ-S tandem mass spectrometer, Waters, Milford, MA, USA). Chromatography was carried out on a C18 Acquity UPLC HSS T3 column (2.1 × 100 mm, 1.8 µm; Waters, Milford, MA, USA) using an acetonitrile–formic acid 0.1 % medium with gradient increasing from 2:98 to 60:40 over 3 minutes).

With this analytical method, the limits of detection (LODs) for the various antineoplastic drugs were as follows: cyclophosphamide = 0.0010 ng/cm^2, cytarabine = 0.02 ng/cm^2, docetaxel = 0.30 ng/cm^2, 5-fluorouracil = 0.04 ng/cm^2, gemcitabine = 0.001 ng/cm^2, ifosfamide = 0.004 ng/cm^2, irinotecan = 0.003 ng/cm^2, methotrexate = 0.002 ng/cm^2, paclitaxel = 0.04 ng/cm^2, and vinorelbine = 0.01 ng/cm^2. The limits of quantification were as follows: cyclophosphamide = 0.0033 ng/cm^2, cytarabine = 0.079 ng/cm^2, docetaxel = 0.30 ng/cm^2, 5-fluorouracil = 0.14 ng/cm^2, gemcitabine = 0.001 g/cm^2, ifosfamide = 0.0055 ng/cm^2, irinotecan = 0.006 ng/cm^2, methotrexate = 0.006 ng/cm^2, paclitaxel = 0.12 ng/cm^2, and vinorelbine = 0.012 ng/cm^2.

Only descriptive statistics were calculated.

Results

Table 1 presents the characteristics of the two hospitals. Both hospitals are teaching institutions but the pediatric centre is smaller with fewer antineoplastic preparations.

Table 1: Characteristics of the two study hospitals.

Characteristics	Pediatric centre	Adult hospital
Year of opening	1995	2017
No. of beds	≈500	≈800
No. of inpatient beds on oncology unit	44	36
Population type	Pediatric	Adult
Removal of outer packaging upon receipt	No	Yes
Cleaning of vials of Group 1 drugs after receipt	No	Yes
Priming of antineoplastic IV tubing in pharmacy	Yes	No
Use of closed-system transfer device	No	No
No. of antineoplastic preparations		
Fiscal year 2017-2018	7 819	28 840
Fiscal year 2018-2019	7 149	30 319
Group 1 drug administered in the targeted patient room in Period 1	CP, MTX	Cytarabine
Group 1 drug administered in the targeted patient room in Period 2	CP	MTX

A total of 144 samples were obtained and analyzed. Taking into account the paired sampling sites between the two hospitals, a total of 50 distinct sampling sites were evaluated in the two hospitals.

For the sampling day in Period 1, cyclophosphamide and methotrexate were administered in the targeted patient room of the pediatric centre (12 December 2017) and cytarabine in the adult hospital (27 March 2018). For the sampling day in Period 2, cyclophosphamide was administered in the pediatric centre (17 April 2019) and high-dose methotrexate in the adult hospital (12 June 2019).

Overall, 40 % (58/144) of the sampling sites in oncology care units of the two targeted hospitals were positive for at least one antineoplastic drug. In the pediatric centre, 50 % (18/36) and 36 % (13/36) of the sites sampled in Period 1 and Period 2, respectively, were positive for at least one antineoplastic drug. In the adult hospital, the percentage of sites that were positive for at least one antineoplastic drug was 19 % (7/36) in Period 1 and 56 % (20/36) in Period 2. In most cases, positive samples included traces of the antineoplastic drugs administered in the targeted patient room (e. g. in the pediatric centre, 100 % (18/18) in Period 1 and 69 % (9/13) in Period 2 and in the adult hospital, 86 % (6/7) in Period 1 and 100 % (20/20) in Period 2).

Table 2 presents a profile of trace contamination with the antineoplastic drugs in the oncology care units of the two university hospitals. Of the 36 targeted sites, 24 occurred in both hospitals and were considered equivalent. Additional sites were sampled in each hospital to bring the total number of samples to 36 for each year. Thus, the number of sampling sites per zone varied by hospital.

The proportions of sites with antineoplastic drug contamination by zone (both hospitals combined) were as follows: targeted patient room, 48 % (12/25) of samples in Period 1 v. 77 % (20/26) of samples in Period 2; storage areas, 42 % (5/12) v. 25 % (3/12), respectively; corridor adjacent to targeted patient room, 36 % (4/11) v. 31 % (4/13), respectively; caregivers' workstation, 20 % (3/15) in both series; teaching rooms, 0 % (0/5) v. 67 % (2/3), respectively; and other areas, 25 % (1/4) v. 33 % (1/3), respectively.

In Period 1, the number of sites with contamination by individual antineoplastic drugs were as follows (in decreasing order): cyclophosphamide, n = 17 (14 for the pediatric centre v. 3 for the adult hospital); methotrexate, n = 17 (16 v. 1, respectively); cytarabine, n = 6 (0 v. 6, respectively); ifosfamide, n = 3 (3 v. 0, respectively);

Table 2: Results of surface sampling in inpatient units.

		Contamination (ng/cm^2)			
		Pediatric centre		Adult hospital	
Site no.	Sampling site	Period 1	Period 2	Period 1	Period 2
	Patient room				
1	Floor under the intravenous pole	NA	NA	CP = 0.0017 CYT = 0.147	MTX = 3.8
2	Work surface	NA	NA	<LOD	MTX = 0.031
3	Gown hook	NA	NA	<LOD	<LOD
4	Handle of inside door	MTX = 0.19	<LOD	<LOD	MTX = 0.018
5	Support bar in shower	<LOD	MTX = 0.005	<LOD	MTX = 0.02
6	Medication pump	CP = 0.012 MTX = 0.006	<LOD	<LOD	MTX = 0.02
7	Safety bar for bed and its remote control unit	MTX = 0.004	IF = 0.015	CP = 0.0053	MTX = 11
8	Mattress	<LOD	IF = 0.04 MTX = 0.002	<LOD	MTX = 0.024
9	Bar of the IV pole	NA	NA	CYT = 0.020	CP = 0.0087 MTX = 12
10	Chair (base and armrest)	CP = 0.040 IF = 0.023 MTX = 0.2	CP = 0.056 IF = 0.11	<LOD	MTX = 0.49
11	Mobile table	CP = 0.031 MTX = 0.011	CP = 0.002	CP = 0.0017 CYT = 0.040	MTX = 0.54
12	Main light switch	<LOD	<LOD	<LOD	<LOD
13	Tap for sink	<LOD	<LOD	CYT = 0.040	MTX = 4.9
14	Base of toilet	CP = 0.83 IF = 0.04 MTX = 0.35	CP = 0.0035	CYT = 0.13	CP = 0.0048 MTX = 62
15	Blood pressure cuff	NA	NA	NA	MTX = 0.1
16	Cover of the soiled cloth container	NA	NA	<LOD	MTX = 0.071

(*continued*)

Table 2: (*continued*)

		Contamination (ng/cm^2)			
		Pediatric centre		Adult hospital	
Site no.	Sampling site	Period 1	Period 2	Period 1	Period 2
	Drug storage room				
17	Work surface 1	<LOD	<LOD	<LOD	<LOD
18	Work surface 2	CP = 0.007 MTX = 0.028	CP = 0.003	NA	NA
19	Refrigerator handle	CP = 0.026 IRI = 0.028 MTX = 0.026 VRB = présence	<LOD	<LOD	MTX = 0.003
20	Handle of inside door	MTX = 0.006	<LOD	<LOD	NA
21	Handle of outside door	NA	NA	NA	MTX = 0.0065
22	Calculator	<LOD	<LOD	NA	NA
23	Cytotoxic drug storage bin	NA	NA	<LOD	<LOD
24	Cover of the hazardous drug bin[a]	CP = 0.005 IRI = 0.005 MTX = 0.005	<LOD	NA	NA
25	Drug storage drawer	<LOD	<LOD	CYT = 0.005 MTX = 0.003	<LOD
	Caregivers' workstation				
26	Patient file	<LOD	<LOD	<LOD	MTX = 0.003
27	Keyboard	<LOD	<LOD	<LOD	<LOD
28	Mouse	<LOD	<LOD	<LOD	<LOD
29	Desk	<LOD	<LOD	<LOD	<LOD
30	Chair (base and amrest)	MTX = 0.002	CP = 0.002	<LOD	<LOD
31	Phone	CP = 0.0017	<LOD	<LOD	<LOD
32	Employee card	NA	NA	<LOD	<LOD
33	Employee pen	CP = 1.12 MTX = 12	<LOD	<LOD	MTX = 0.082
	Teaching room				
34	Desk 1	<LOD	CP = 0.002	<LOD	NA
35	Desk 2	NA	NA	<LOD	NA
36	Handle of inside door 1	<LOD	<LOD	NA	NA
37	Handle of outside door 2	<LOD	CP = 0.002	NA	NA
	Corridor				
38	Elevator buttons	<LOD	IF = 0.014	NA	NA
39	Cover of the clean cloth container	CP = 0.0011 MTX = 0.001	<LOD	NA	NA
40	Keyboard	<LOD	<LOD	<LOD	<LOD
41	Mouse	CP = 0.004 MTX = 0.012	<LOD	NA	NA
42	Touch-screen	NA	NA	<LOD	<LOD
43	Isopropyl alcohol solution support	<LOD	<LOD	<LOD	<LOD
44	Surface of cart	CP = 0.001 MTX = 0.002	<LOD	<LOD	<LOD
45	Bar of the IV pole	CP = 0.004	CP = 0.0036	NA	NA
46	Cover of the hazardous drug bin[a]	NA	NA	NA	MTX = 0.046

(*continued*)

Table 2: (*continued*)

		Contamination (ng/cm^2)			
		Pediatric centre		Adult hospital	
Site no.	Sampling site	Period 1	Period 2	Period 1	Period 2
47	Floor under hazardous drug bin	NA	NA	NA	CP = 0.001 MTX = 0.2
	Other sites				
48	Anteroom: cover of the hazardous drug bin[a]	NA	NA	<LOD	NA
49	Games room: table	CP = 0.014 IF = 0.013 MTX = 0.002	CP = 0.061 IF = 0.004	NA	NA
50	Reception desk: phone	<LOD	<LOD	<LOD	<LOD

[a]The specified surface was found in different locations in the two hospitals.
CP: cyclophosphamide; CYT: cytarabine; IF: ifosfamide; IRI: irinotecan; MTX: methotrexate; VRB: vinorelbine; LOD: limit of detection; NA: not applicable.

irinotecan, n = 2 (2 v. 0, respectively); and vinorelbine, n = 1 (1 v. 0, respectively). In Period 2, the numbers were as follows: methotrexate, n = 22 (2 v. 20, respectively); cyclophosphamide, n = 12 (9 v. 3, respectively); and ifosfamide, n = 5 (5 v. 0, respectively).

In terms of the concentration of the various antineoplastic drugs, the following ranges were measured: for cyclophosphamide, <LOD to 1.12 ng/cm^2; for cytarabine, <LOD to 0.147 ng/cm^2; for ifosfamide, <LOD to 0.11 ng/cm^2; for irinotecan, <LOD to 0.0279 ng/cm^2; and for methotrexate, <LOD to 62 ng/cm^2. Seven sites had contamination with measured value greater than 1 ng/cm^2 (presented in descending order): toilet seat (methotrexate 62 ng/cm^2 at adult hospital), caregiver's pen (methotrexate 12 ng/cm^2 and cyclophosphamide 1.12 ng/cm^2 at pediatric centre), intravenous pole (methotrexate 12 ng/cm^2 at adult hospital), bedside rail (methotrexate 11 ng/cm^2 at adult hospital), sink tap (methotrexate 4.9 ng/cm^2 at adult hospital), floor under intravenous pole (methotrexate 3.8 ng/cm^2 at adult hospital). Across the 144 samples, the 75th and 90th percentile values for every drug were below the LOD.

Discussion

In this interrupted time series study, traces of at least one antineoplastic drug were found in 40 % of the sampling sites in the oncology units of two hospitals in Period 1 and Period 2. This proportion of contamination is lower than what has been reported in most previous studies. For example, Stover and Achutan [10] reported positive results for 54 % (7/13) of sampling sites in a single patient care unit, and Ramphal et al. [11] reported positive results for 50 % (3/6) of sampling sites in another patient care unit. Hedmer et al. [12] reported positive results for 100 % (6/6) of sampling sites in 2 patient rooms (however, they did not detail the results for other areas sampled, such as the floor, work area, and "other areas"). Other authors have also reported highly variable results for proportion of surfaces contaminated with at least one antineoplastic drug, ranging from 17 % (Graeve et al. [13]) to 100 % (Koller et al. [14]; Lee et al. [15]; Ziegler [16]). In a systematic review, Gurusamy et al. [8] reported that the proportion of surfaces contaminated with cyclophosphamide was 44 % in areas dedicated to patient care (i. e. outpatient clinics and care units). However, in many other published studies, it is unclear whether the sampling sites were located in outpatient and/or inpatient areas.

For the six zones considered in the current study, the proportion of contaminated surfaces varied from 0 % to 77 %. Although the targeted patient rooms were the most contaminated areas in our study (48 % of positive samples in Period 1 and 77 % in Period 2), several sampling sites in each of the other zones were also contaminated. Of the 50 different sampling sites in the study as a whole, only 16 had no detectable traces of antineoplastic drugs. Traces of at least one antineoplastic drug were detected on various structures (e. g. door handle, floor, faucet), furniture (e. g. mattresses, toilet seats), medical equipment (e. g. pump, refrigerator handle, intravenous pole, medication cart, sphygmomanometer), and office equipment (e. g. nursing staff pen, telephone handset, patient file binder, children's playroom table). The results indicate that traces of antineoplastic drugs can be found anywhere, but they do not

allow discrimination among potential sources of contamination by site. For example, trace contamination can result from handling and administration of the drug, but also from patients' excreta. Traces of antineoplastic drugs probably spread through skin contact with contaminated gloves or hands that have come into contact with the various targeted sampling sites. Several studies have identified traces of antineoplastic drugs on various surfaces, suggesting that excretion from the skin and other areas of the patients' body who received a antineoplastic drug is an important source [6, 10–12, 14].

In this study, the pediatric centre had 18 and 13 sites with positive results for at least one antineoplastic drugin Period 1 and Period 2, respectively, whereas the adult hospital had 7 and 20 sites with positive results, respectively. A few hypotheses can be proposed to explain this variation. At the pediatric hospital, cleaning practices were changed after the first sampling date, with implementation of a high-touch cleaning sequence after administration of each dose of antineoplastic drug, in addition to regular daily cleaning. The high-touch cleaning sequence involved cleaning with a chlorinated product. In addition, after discharge of any patient who received antineoplastic drugs during the hospital stay, more intensive cleaning of the room was done. These changes may have been associated with the decrease in contamination between the two sampling dates. However, we did not collect daily data to confirm the change in cleaning practice and the number of high-touch cleaning sessions realized. In the adult hospital, the first round of sampling was conducted within the first few months after opening of a new hospital building, when the building's infrastructure was not yet very contaminated (given the small number of hospitalized patients who had received antineoplastic drugs by the sampling date). This may partly explain the difference observed in the adult hospital in Period 2. In the study by Ramphal et al. [11], sampling was conducted in an outpatient oncology clinic one month after opening, and all six samples were negative. These authors believed that the absence of traces of cyclophosphamide was associated with the limited use of the building.

In the current study, we targeted treatment days and rooms with exposure to antineoplastic drugs, and the traces found aligned with the drugs administered, although traces of other drugs were also detected. Soubieux et al. [17] showed that it may take up to five successive cleanings to completely remove all traces of cyclophosphamide on a deliberately contaminated surface. Koller et al. [14] took six samples from targeted sampling sites over five consecutive days to measure the evolution of contamination; their results did not show large differences from one day to the next. Thus, it is difficult to completely eliminate traces of hazardous drugs, and the traces measured in any particular analysis will come from multiple doses of hazardous drugs administered over time.

In the current study, the quantities detected ranged from the LOD to 62 ng/cm^2; however, the 75th and 90th percentiles were both below the LOD. Koller et al. [14] measured on the floor in the patient's toilet room (from 16.3 to 500 pg/cm^2 for 5-fluorouracil and from 7.5 to 100 pg/cm^2 for platinium) and on the floor under the infusion stands (47.8 and 262.5 pg/cm^2 for 5-fluorouracil and 1.3 and 70 pg/cm^2 for platinum). Ramphal et al. [11] measured cyclophosphamide levels of 0.82 ng/cm^2 on the floor of the patient's room before cleaning, 0.79 ng/cm^2 on the floor of the patient's room after cleaning, and 22.17 ng/cm^2 on the floor of the patient's bathroom. Page et al. [18] measured traces of antineoplastic drugs in a dedicated room for patients' families (e. g. cyclophosphamide 2.1 ng/100 cm^2 and ifosfamide 3.7 ng/100cm^2 on a chair; cyclophosphamide 3.0 ng/100 cm^2 on an exercise bicycle; and cyclophosphamide 1.7 ng/100 cm^2 on a table).

In the Environmental Monitoring Program described earlier, the same 12 sampling sites have been monitored since the program began, to allow longitudinal monitoring and trend analysis. However, none of these sampling sites are in inpatient care areas. The current study, which was conducted in two inpatient care units, showed the potential value of targeting sampling sites in the inpatient setting. The results showed that traces of antineoplastic drugs can be found everywhere; future studies should try to characterize the sources of contamination by sampling site (e. g. bag or syringe containing antineoplastic drugs, patient's sweat, saliva, or excreta). Measurement of trace contamination is an intermediate measure of the risk of professionals' exposure to antineoplastic drugs, and a better understanding of the source of trace contamination can help to better protect workers. In all cases, the use of personal protective equipment is an essential measure to be respected at all times.

There are many maintenance strategies and many factors affect the effectiveness of these strategies. If the introduction of high-touch seems a relevant measure to target traces of contamination during the administration of chemotherapy, more work is needed to confirm these results.

There are limitations to this study. A convenience sample was used, and the adult hospital administers four times as many doses of Group 1 hazardous drugs as does the pediatric centre. Only 24 of the 36 targeted sites were considered equivalent between the two hospitals. Each sampling site had a variable level of probability of contamination (e. g. the intravenous pole in the targeted patient

room is more likely to be contaminated than a randomly selected pencil at the caregivers' workstation). The variable proportion of sampling sites with a positive result for at least one antineoplastic drug was probably related to the heterogeneity of selected sites and partial pairing between hospitals. The presence of trace contamination is dynamic and varies over time depending on clinical activity and facility maintenance. Measurements at other times may thus yield different results. Nonetheless, this study did involve a sample of 36 sites per sampling day.

Conclusion

The surfaces of inpatient care units tested in this study were contaminated with antineoplastic drugs, and the contamination was present throughout the oncology care unit (structures, furniture, medical equipment, office equipment). Environmental surveillance programs should encompass inpatient care units.

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