UCLouvain

Faculté de pharmacie
et des sciences biomédicales

Evaluation of the cross-contamination risk inside a production unit

A prospective observational study

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Je tiens tout d'abord à remercier mes deux promotrices Brigitte Geubelle et Pauline Anrys pour le temps qu'elles ont accordé à l'accompagnement de mon mémoire. Grace à leurs conseils précieux et leur accompagnement, la réalisation de ce travail a été un plaisir.

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C'était 3 belles années dont je me souviendrai toujours.

Abstract:

Background:
In hospital pharmacy settings, cytotoxic drugs and monoclonal antibodies (MABs) are often prepared within the same isolator, raising concerns about potential cross-contamination. The hazardous nature of cytotoxic drugs necessitates strict handling procedures. Recent guidelines, such as the PIC/S 2014 directive to be enforced in Belgium by 2026, emphasize the segregation of hazardous drug preparation activities. However, resource constraints may limit implementation in many hospitals.

Objective:
This study aimed to assess internal and external cross-contamination risks when preparing monoclonal antibodies and cytotoxic drugs inside the same isolator. We also aimed to assess current production practices inside hospital pharmacies in Belgium.

Methods:
An online survey was distributed to Francophone hospital pharmacies to evaluate current practices and identify the most commonly used CSTDs (Chemfort®, Phaseal®, Equashield®). Laboratory testing was conducted on 97 samples (43 IV bags and 43 glove swabs) for the presence of 5-Fluorouracil (5-FU), platinum-based drugs, and cyclophosphamide. Liquid samples assessed internal contamination, while glove swabs assessed external contamination.

Results:
No internal contamination was detected in any of the IV bags. However, 60% of glove swabs tested positive for external contamination: 100% for platin-based drugs, 46% for 5-FU, and 0% for cyclophosphamide. External contamination levels varied by operator and CSTD, with higher contamination observed when operators used unfamiliar devices.

Conclusion:
Under standard working conditions and with appropriate procedural controls, internal cytotoxic contamination of IV bags is unlikely even when Monoclonal Antibodies are prepared within the same isolator. However, external contamination remains a concern, highlighting the importance of regular staff training, proper CSTD usage, environmental monitoring, and adherence to cleaning protocols. These findings suggest that effective risk mitigation strategies may reduce the need for infrastructure modifications mandated by upcoming PIC/S guidelines.

Je déclare sur l'honneur que ce mémoire a été écrit de ma plume, sans avoir sollicité d'aide extérieure illicite, qu'il n'est pas la reprise d'un travail présenté dans une autre institution pour évaluation, et qu'il n'a jamais été publié, en tout ou en partie. Toutes les informations (idées, phrases, graphes, cartes, tableaux,...) empruntées ou faisant référence à des sources primaires ou secondaires sont référencées adéquatement selon la méthode universitaire en vigueur. Je déclare avoir pris connaissance et adhérer au Code de déontologie pour les étudiants en matière d'emprunts, de citations et d'exploitation de sources diverses et savoir que le plagiat constitue une faute grave sanctionnée par l'Université catholique de Louvain

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Abbreviations:

CSTD: Closed System Transfer Device

NIOSH: National Institute for Occupational Safety and Health

PIC/S: Pharmaceutical Inspection Co-operation Scheme

GMP: Good Manufacturing Practice

LFC: Laminar Flow Cabinets

IV: Intravenous

AFPHB : Association Francophone des Pharmaciens Hospitaliers Belges (Francophone association of belgian hospital pharmacists)

5-FU : 5-Fluorouracile

MAB : Monoclonal Antibody

CHU : Centre Hospitalier Universitaire (University hospital)

LOQ : Limit of Quantification

LOD : Limit of Detection

1) Introduction:

Cytotoxic drugs have been in use since the 1940s, with Methotrexate being the first chemotherapy agent approved in 1949 (1). Since then, numerous treatments have been authorized, resulting in the preservation of countless lives. These agents primarily target rapidly proliferating cells. Given that cancer is characterized by the uncontrolled proliferation of abnormal cells, cytotoxic drugs target malignant cells. However, they also impact other normal rapidly dividing cells, including those in the gastrointestinal tract, bone marrow, and hair follicles. Consequently, administration of these drugs is associated with significant adverse effects.

Recent scientific advancements have led to the development of targeted therapies and immunotherapies. Targeted therapies are drugs that selectively bind to specific biomarkers expressed by cancer cells. This class includes monoclonal antibodies, small molecule inhibitors, and antibody-drug conjugates. Nevertheless, the designation "targeted" does not imply an absence of adverse effects, particularly in the case of small molecule inhibitors and antibody-drug conjugates. Monoclonal antibodies are generally associated with fewer side effects.

The latest innovation in cancer treatment involves immunotherapies, which function by stimulating the immune system via monoclonal antibodies, directing immune responses against neoplastic cells.

Cytotoxic drugs, small molecule inhibitors and antibody-drug conjugates are all on the NIOSH (National Institute for Occupational Safety and Health) list (2) of Hazardous drugs in healthcare settings. NIOSH's primary mission is to issue recommendations aimed at preventing occupational injuries. In the 2016 hazardous drugs list, only one monoclonal antibody, Pertuzumab, was included. However, the 2024 update removed Pertuzumab because they ''determined it unlikely that Pertuzumab poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting'' and as such they, no longer consider it a hazardous drug. This difference in classification highlights the relative safety of monoclonal antibodies in comparison to cytotoxic drugs.

Cross-contamination represents a significant risk across multiple industries, mainly food and pharmaceuticals, with potential adverse effects for consumers and patients. Hospital pharmacies, which manufacture diverse drug products, are likewise susceptible to this risk. Accordingly, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines (11) emphasize the necessity of segregating different production activities within manufacturing

units. They state that ‘’In order to minimise the risk of cross-contamination, facilities should be dedicated. Rooms should be provided for hazardous products e.g. cytostatics, penicillins, biologicals, radiopharmaceuticals and blood products. In exceptional cases the principle of campaign working may be acceptable, provided that specific precautions are taken and the necessary risk assessments have been performed (Section 2, point 22)’’. PIC/S is a non-binding, informal cooperative arrangement between regulatory authorities responsible for Good Manufacturing Practice (GMP) of medicinal products (3). These guidelines have recently gained additional relevance due to a royal decree in Belgium mandating their implementation in all hospitals by 2026. Although the guidelines do not explicitly prescribe measures to mitigate cross-contamination risk, they can be interpreted as requiring distinct zones for the preparation of hazardous agents like cytotoxic drugs. Limited space and budgetary constraints, however, complicate the procurement of additional isolators/LFCs (Laminar flow cabinets) and the establishment of separate production zones.

In pharmaceutical production units, contamination may be classified as either external or internal. External contamination refers to the presence of a compound on surfaces, gloves, isolators, or air-flow cabinets. Internal contamination refers to the presence of an unintended compound within an intravenous (IV) bag (or pump/ syringe). Regarding internal contamination, the limited number of studies is most likely attributable to the prevailing assumption that risk is minimal in the absence of preparation errors. Existing investigations have employed tracer molecules to simulate cytotoxic compounds. We consider that the highest risk cross-contamination scenario, in terms of potential impact on patient safety, would be the contamination of a monoclonal antibody (used in oncology) preparation with a cytotoxic drug. Cross-contamination can of course happen with any other drug that is prepared inside the production zone, even between different cytotoxic drugs.

To mitigate contamination and reduce personnel exposure to chemotherapy drugs, many hospitals employ Closed System Transfer Devices (CSTDs). NIOSH defines CSTDs as “drug transfer devices that mechanically prohibit the transfer of environmental contaminants into the system and prevent the escape of hazardous drugs or vapor concentrations outside the system.” These devices primarily serve to protect healthcare workers from exposure to hazardous drugs and have been demonstrated to reduce, though not eliminate, surface contamination (4,5). Various CSTDs are commercially available, with additional devices under development. They can be broadly categorized into two types: those that ensure airtight containment (e.g., Phaseal®/ Equashield®) and those employing air filtration technology (e.g., Chemfort®).

This study aims to evaluate the risk of internal and external cytotoxic cross-contamination during the preparation of a monoclonal antibody (used in oncology) within an isolator concurrently used for cytotoxic drug preparation, thereby assessing the potential impact on product safety.

Prior to the experimental phase of this study, an online survey was distributed to Francophone hospitals to enhance its relevance and inform the selection of CSTDs to be included. This survey also gathered information regarding the general working conditions within the various production units.

2) Study objectives:

2.1) Primary Objective:

The primary aim of this study is to assess the presence of internal cross-contamination during the preparation of cytostatic agents and monoclonal antibodies within the same isolator. And using different Closed System Transfer Devices (CSTDs).

The primary outcome measure is the number of IV bags containing monoclonal antibodies that are found to be contaminated by cytotoxic drugs.

2.2) Secondary Objectives:

1) Assess current production practices in French speaking Belgian hospitals.
2) To identify environmental contamination within the isolator and determine its impact on the internal contamination.

3) Methodology:

The survey was an online Google Forms distributed on the French-speaking Belgian pharmacist association (AFPHB) forum on the 22nd of October 2024. The survey can be found in Annex 2, it included 11 questions relating to infrastructure, CSTD device used and PIC/S adherence.

The survey will determine the three most used CSTDs for chemotherapy preparation. These CSTDs will then be included in our study. This will guarantee that the study is relevant for multiple establishments.

Testing for all cytotoxic drugs potentially present inside our isolator is not feasible; therefore, we selected three molecules with distinct properties for analysis. 5-Fluorouracil (5-FU) is the most frequently prepared compound in our pharmacy. It has been shown to evaporate at room temperature (6), although it is not the most volatile. Cyclophosphamide is a highly volatile compound; however, it is infrequently used in our hospital. As such, only a limited number of samples will be analyzed. There have been different studies measuring contamination rates of cytotoxic drugs, in one study they found that the most persistent contaminants were Platin based molecules (2). The laboratory's detection method allows for very low detection limits, concentrations as low as 15 pg (10^{-12}) can be identified. For both cyclophosphamide and 5-FU, the detection limit is 1 ng (10^{-9}).

TABLE 1: VAPOUR PRESSURE, EQUILIBRIUM CONCENTRATION AND EVAPORATION TIME FOR DRUG PARTICLES

Substance	Measured vapour pressure (Pa)		Calculated equilibrium concentration (mg/m^3)		Calculated evaporation time (s)	
	T=20C	T=40C	T=20C	T=40C	d_p=1µm	d_p=100µm
Carmustine	0.019	0.530	1.7	44	12	1.2×10^5
Cisplatin	0.0018	0.0031	0.22	0.36	110	11.0×10^5
Cyclophosphamide	0.0033	0.0090*	0.36	0.90	44	4.4×10^5
Etoposide	0.0026	0.0038	0.63	0.86	51	5.1×10^5
Fluorouracil	0.0014	0.0039	0.08	0.20	210	21.0×10^5
Fosfomycin (antibiotic)	0.0027	0.0043	0.20	0.30	90	3.0×10^5

Key: T= temperature; dp = particle diameter

** Extrapolated*

***Figure 1**: Vapor pressure, Equilibrium concentration and evaporation time for drug particles* (6)

This study was conducted in the pharmacy of the Saint-Luc Bouge hospital in Namur, Belgium. The controlled atmosphere in which chemotherapies are prepared is a Class D environment containing a Class A isolator. We have four different operating pharmacy technicians. The number of preparations per year is of approximately 10.000. In routine, cytotoxic drugs are prepared with a CSTD while Monoclonal Antibodies are prepared with a needle. Sterile gloves

worn by technicians are changed every two hours. The work surface of the isolator is cleaned daily, while a full cleaning of the entire isolator is performed once a week.

The three molecules analyzed in this study are 5-FU, platins, and cyclophosphamide. Surface and liquid samples were collected immediately after preparing the relevant cytotoxic agent. For example, when analyzing 5-FU, we selected regimens containing both 5-FU and a monoclonal antibody. The cytotoxic drug was prepared first, followed by the monoclonal antibody from which a sample is taken. This maximizes the likelihood of the sample being contaminated. Each sample was identified by the Drugcam® preparation number and the date. DrugCam® is a system designed to provide computerized double verification during the drug preparation process. This system films and records each preparation as well as identifies barcodes and volumes. To ensure the integrity of the preparation process and to identify any errors, DrugCam® video recordings will be systematically archived and reviewed when necessary.

For the purpose of this study, the brand of CSTD used was changed after 5 consecutive days (a full week). After every CSTD change, the isolator was thoroughly cleaned (once per week in routine).

Sampling frequency was as follows (Internal and external):

- 5-FU: Twice daily
- Platins: Once daily
- Cyclophosphamide: Due to low production, any regimen containing it was tested; we expect three to four samples over the whole duration of the study

The sample collection lasted for two consecutive weeks from 8/01/2025 to 22/01/2025 and for one week from 31/03/2025 to 04/04/2025.

All samples were stored in the refrigerator between 2°C and 8°C before being sent to the Toxicology Laboratory of the University Hospital of Liège (CHU) for analysis.

3.1) Liquid Sample Collection (Internal Cross-contamination):

After finishing preparing the Monoclonal antibody, the liquid samples were collected using a 3 mL syringe and a needle. The liquid was then transferred to a test tube:

- Platins: Plastic tube
- 5-FU and cyclophosphamide: Glass tube

The tubes were chosen to ensure the highest molecular stability for the samples.

Although the analysis laboratory can work with 1 mL samples, we collected 2 mL to compensate for potential loss due to spillage or processing issues. To ensure the sample contained less than 1% of the patient's intended dose, monoclonal antibodies (MABs) were diluted when possible (e.g., from 100 mL to 250 mL). If the MAB was unstable at a higher dilution, no sample was taken.

3.2) Wipe Sample Procedure (External Cross-contamination):

Gloves were swabbed immediately after the preparation of the monoclonal antibody which is part of the protocol involving the cytotoxic drug under investigation

- Platins: Samples were taken using a standard paper tissue (cut in half) moistened with 0.5 mL of water. Both gloves were completely swabbed with the tissue, which was then placed in a small tube (see Annex 1).
- Cyclophosphamide and 5-FU: The procedure was identical, except a Whatman filter moistened with 0.5 mL of methanol was used instead of a paper tissue. Methanol was chosen because both molecules are soluble in organic solvents.

To avoid introducing non-sterile materials into the isolator, gloves were removed and swabbed outside the isolator.

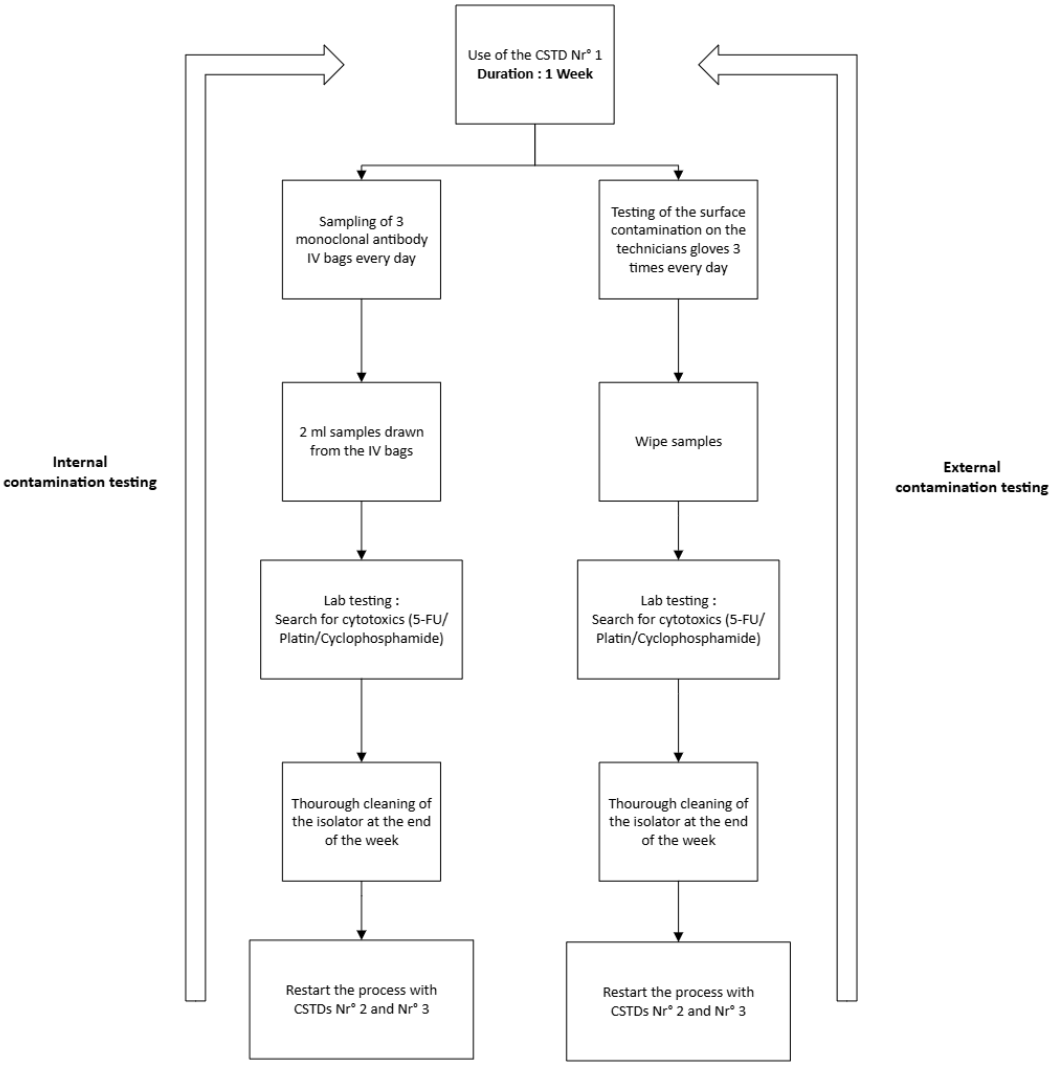

***Figure 2**: Sample collection methodology*

4) Results:

Thirty-four French-speaking Belgian hospital pharmacists participated in the survey. The results showed that 88% (30/34) of hospitals currently prepare monoclonal antibodies and cytotoxic drugs within the same isolator/cabinet. Additionally, 94% (32/34) of hospitals (all but two) prepare both types of drugs within the same controlled atmosphere zone. When asked about future changes, 53% (18/34) indicated that they would not be altering their practices to comply with the new PIC/S guidelines.

Regarding the use of Closed System Transfer Devices (CSTDs), 71% (24/34) of hospital pharmacies utilize CSTDs for the preparation of cytotoxic drugs. Among these, twenty-three respondents use Chemfort®, six use Phaseal® and two use Equashield®. Some institutions employ multiple CSTDs depending on the specific cytotoxic drug being prepared. Based on their prevalence in Belgium, Chemfort®, Phaseal®, and Equashield® were selected for the test.

A total of eighty-six samples were tested during this campaign, comprising forty-three liquid samples (internal) and forty-three surface swabs (external). As described in the methodology, the most frequently tested for compound was 5-fluorouracil (5-FU), followed by platinum-based drugs, and finally cyclophosphamide, with only three samples. The number of samples taken for each CSTD, per molecule, is similar. (See table 1).

***Table 1**: Total number of CSTD used per molecule*

Molecule	CSTD	# external samples	# internal samples
5-FU		26	26
	Chemfort®	11	11
	Equashield®	7	7
	Phaseal®	8	8
Platins		14	14
	Chemfort®	4	4
	Equashield®	5	5
	Phaseal®	5	5
Cyclophosphamide		3	3
	Chemfort®	1	1
	Equashield®	1	1
	Phaseal®	1	1

None of the liquid samples tested positive for any of the targeted cytotoxic agents, regardless of the CSTD used. No internal cross-contamination was detected during the testing.

As for the external swab samples, 60% (26/43) were positive with 100 % of the platin swabs being positive (14/14), no positive cyclophosphamide samples (0/3) and 46 % (12/ 26) positive 5-FU samples.

***Table 2**: Contamination rates for internal and external samples per molecule*

Molecule	Type of test	# samples	# positive samples
5-FU			
	Internal	26	0
	External	26	12 (46%)
Platins			
	Internal	14	0
	External	14	14 (100%)
Cyclophosphamide			
	Internal	3	0
	External	3	0 (0%)

We also accounted for the potential confounding factor of different operators handling the samples. Table 3 details which CSTDs were in use by each operator during the preparation of 5-FU and, their total contamination rates.

***Table 3**: 5-FU contamination rates per CSTD used and per operator*

Operator		Phaseal®	Chemfort®	Equashield®	Total 5-FU Contamination rate
A	# CSTDs used	5	3	5	8/13 (61%)
	% Contamination	2/5 (40%)	1/3 (33%)	5/5 (100%)	
B	# CSTDs used	1	5	1	1/7 (14%)
	% Contamination	0/1 (0%)	0/5 (0%)	1/1 (100%)	
C	# CSTDs used	1	3	0	1/4 (25%)
	% Contamination	1/1 (100%)	0/3 (0%)	/	
D	# CSTDs used	1	0	1	2/2 (100%)
	% Contamination	1/1 (100%)	/	1/1 (100%)	

5) Discussion:

The survey we conducted showed the reality of the field. A large majority (88%) of the hospitals that responded prepare both cytotoxic drugs and monoclonal antibodies (used in oncology) inside the same isolator or laminar flow cabinet. Regarding the area in which they are prepared, all but two hospitals (94%) reported preparing both inside the same zone. The PIC/S guidelines will come into effect in 2026 but the majority of hospitals are not currently in compliance, and many will likely be unable to make the necessary infrastructural changes. In fact, 53% have no plans for changing their infrastructure or preparation processes due to the implementation of the PIC/S guidelines. This highlights the importance of conducting this study and evaluating the actual risk of cross-contamination.

The main purpose of this study was to identify cytotoxic internal contamination of the prepared perfusions. While conducting this study, we started with the hypothesis that, if no errors were made in the process of preparing the IV bags, there was no internal contamination risk. This hypothesis proved to be true: the principal observation was that there was no internal contamination for any of the tested liquids. This study also showed that, even if external contamination is present, the contents of the IV bags are not contaminated. This is reassuring for small production units who do not possess the space or means to have multiple workstations.

In the literature search done prior to the different tests, we found that most studies are focused on external contamination and its potential impact on Healthcare workers who are regularly exposed to it (5,7,8). As for internal cross-contamination, there were mainly two studies focusing on this topic. The first study (9) focused on cross-contamination risk in a robotized preparation unit. This study used two tracer molecules, Quinine and Fluoresceine. The advantage of these molecules is their low limit of detection (LODs): Fluoresceine at 0.013 ng/mL and Quinine at 0.83 ng/mL. It is true that the LODs are lower than those of 5-FU and Cyclophosphamide (1 ng/mL), but they are higher than those for Platins (1 pg/mL). Our conclusion is that the molecules we chose to analyze have acceptable LODs while also being routinely used in production units. That study also concluded that there was no cross-contamination between IV bags.

The second study (10) simulated different handling errors and quantified the contamination risk. They also used tracer molecules (Thiamine and Retinol). The researchers determined that "external surface contamination seems to have little impact on the risk of cross-contamination", unlike handling errors (like reuse of contaminated syringes), which provoked significant cross-contamination. This coincides with our findings that suggest that, unless an error is made, there is no risk of cross-contaminating IV bags, even if outside surfaces are contaminated.

Regarding external contamination, all glove swabs sent to the laboratory for platinum detection tested positive. This is likely due to the higher sensitivity of the platinum assay, which can detect concentrations in the picogram range (10^{-12}), compared to nanogram sensitivity (10^{-9}) for cyclophosphamide and 5-fluorouracil (5-FU). No cyclophosphamide glove swabs were positive; however, the sample size was limited (only three samples). For 5-FU, nearly half of the glove swabs (46%) tested positive despite the assay's higher limit of detection. It is important to note that the exterior of cytotoxic drug vials have been shown to be contaminated (15), making it impossible to determine whether the detected contamination originated from the preparation of the IV bags or from the outside of the vials.

A potential source of bias is also the length of time the samples remained refrigerated before being analyzed by the laboratory. For instance, samples collected during the first two weeks were sent the following week, meaning some samples remained refrigerated for over two weeks, in addition to the lab's processing time. At such low concentrations, stability data is not available.

One confounding factor in our study is the involvement of multiple pharmacy technicians in this study, as variations in glove contamination could potentially stem from differences in technique. While contamination rates differed across operators, it is hard to precisely determine the reason. We believe the most likely reason for this difference in contamination rates is related to the operators' familiarity with the different CSTDs. This is highlighted by the results with Equashield®, which was the device operators were least familiar with and, for most, it was their first time using it. This device showed the highest contamination rate (100% 5-FU contamination). This is one of the reasons why we believe operator A showed such a high contamination rate. These findings emphasize the importance of comprehensive training, particularly when introducing a new CSTD. This variability, while a potential confounding factor, can also be considered a strength of the study, as all liquid samples remained negative for internal contamination despite multiple technicians and CSTDs being involved.

One weakness is the number of samples taken, which was mainly limited by budgetary constraints as well as time. Additional studies with a higher number of samples are necessary to corroborate our findings.

As for the strengths, to our knowledge, this is the first study of its kind to evaluate cross-contamination of actual cytotoxic molecules in a routine hospital production unit. By testing under real working conditions rather than simulated environments, this research provides real insights into the risks faced by healthcare professionals and patients.

It also provides an evaluation of both internal and external contamination. This approach allows for a broader understanding on the subject of cross-contamination. The finding that external contamination does not necessarily lead to internal contamination, provided protocols are followed, is a highly reassuring and significant discovery.

Another strong suit of this study is the fact that it is tailored to reflect current practices and challenges in Belgian hospital pharmacies. This ensures that the findings are highly relevant and directly applicable to numerous establishments, especially in light of the PIC/S guidelines enforcement in 2026.

As explained in the introduction, one of the motivations for this study was the context of the new PIC/S measures, where a strong emphasis is placed on separating different activities to avoid cross-contamination. Our results indicate that producing different drugs inside the same isolator can be safe provided that procedures are respected and surveillance is put in place.

There seems to be a very limited risk for the patient to receive a cytotoxic drug they were not prescribed, provided the process is correctly followed. A complementary, broader, risk analysis is currently being prepared by a group of hospital pharmacists to corroborate our findings.

Considering the results of our study, we believe it is necessary to:

- Remind pharmacy technicians of the importance of protocol adherence. Protocols and procedures are only effective when followed by the entirety of the staff.
- Ensure sufficient training (especially when using a new CSTD) and continued education (as mentioned in the PIC/S guidelines, point 2.3)
- Reinforce cleaning procedures
- Consider more frequent glove changes
- Organize yearly surface testing at a minimum and compare future results to the current ones
- Emphasize process surveillance, as the absence of internal contamination is only guaranteed in the absence of human error (Drugcam®, Druglog®)

Additionally, developing analysis protocols with higher sensitivity for volatile molecules like cyclophosphamide would be valuable for better qualifying both internal and external contamination risks. The Platin test method, while very sensitive, is limited by the fact that platins are not volatile molecules.

6) Conclusion:

This study demonstrates that, under proper procedural adherence, internal contamination of cytotoxic preparations is unlikely, even when different drugs are prepared in the same isolator or zone. Although external contamination on operator gloves was detected, it did not translate into contamination of the IV bags. These findings suggest that, in our working conditions and despite cytotoxic drugs and monoclonal antibodies being prepared inside the same isolator, strict cleaning protocols, operator training, CSTD usage, and process monitoring are effective in preventing cross-contamination. Regular environmental surveillance and ongoing staff education remain essential to maintain safety.

Conflict of interest :

All CSTDs used in this study were provided free of charge by Becton Dickinson (Phaseal®), Arega (Chemfort®) and Equashield®.

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AI was used to reformulate sentences as well as to help browse literature.

Annex 1 :

Wipe sample Procedure

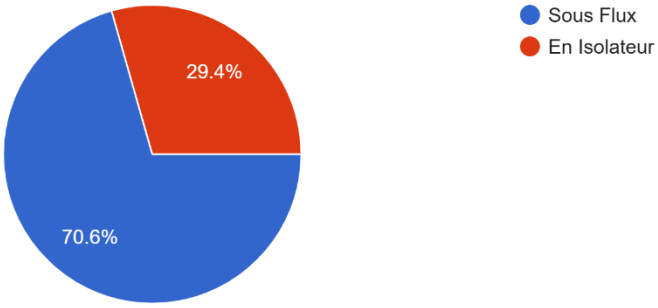
1) The technician takes his gloves off, rolls them and sends them through the Tubing.
2) Put sterile gloves on
3) Cut the plastic bag and take the gloves out
4) Lay them on a sterile surgical drape
5) Moisten the Tissue/ Whatmann filter with 0,5 mL of Sterile Water/ Methanol respectively
6) Wipe the gloves on both sides as seen in the image below.
7) Turn the gloves and do the same on the other side
8) Place the Tissue/ Filter in a plastic tube
9) Place the plastic tube in the fridge

Annex 2 :

Survey :

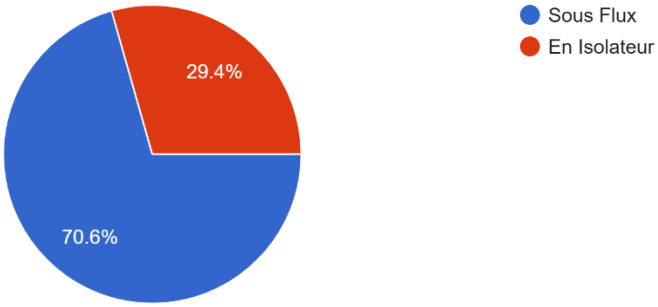
Comment préparez-vous les cytotoxiques ?

34 responses



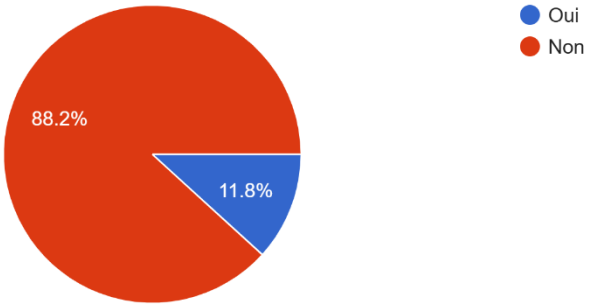
Comment preparez-vous les anticorps monoclonaux ?

34 responses



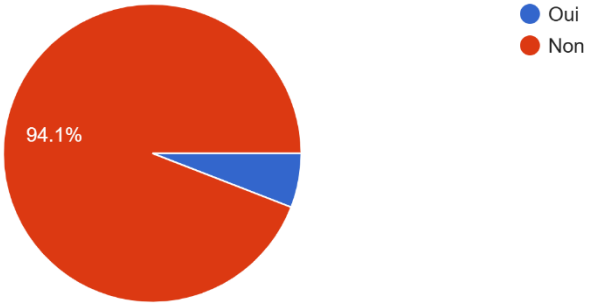
Préparez-vous les anticorps monoclonaux dans un isolateur/flux diffèrent des cytotoxiques ?

34 responses



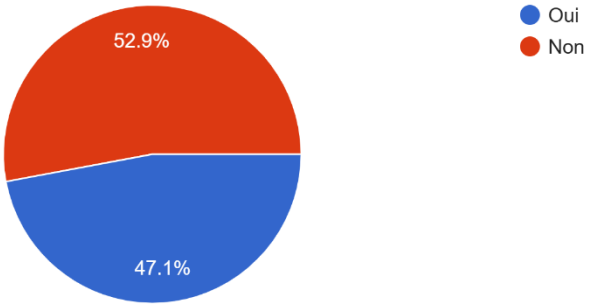
Préparez-vous les anticorps monoclonaux dans une salle différente des cytotoxiques ?

34 responses



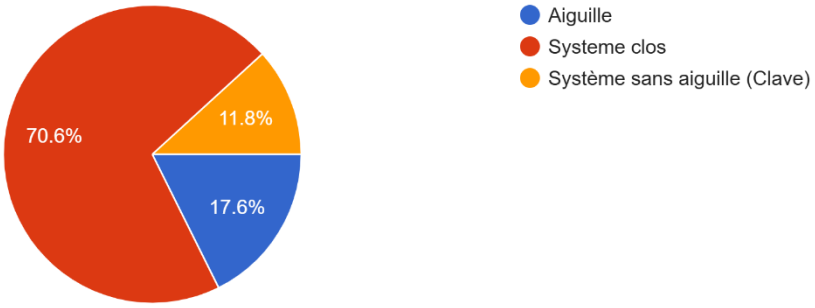
Avez-vous l'intention de pratiquer autrement dans le futur afin de respecter les normes PIC/S ?

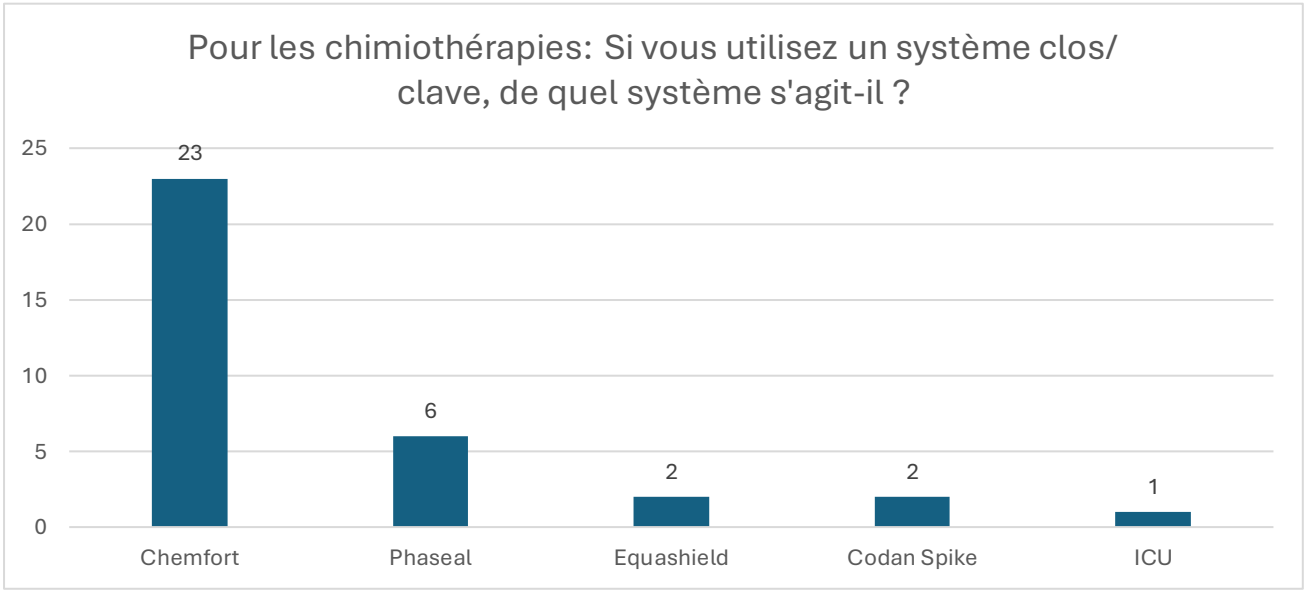
34 responses



Pour les chimiothérapies: Travaillez-vous à l'aiguille ou avec un système clos/ Clave ?

34 responses





Annex 3 :

ENTRETIEN ISOLATEUR

Clinique Saint-Luc Bouge

FREQUENCE	ACTION	PRODUITS	REMARQUES
TOUS LES JOURS			
	Nettoyage des flacons	DESINFECTANT**	
	Nettoyage plan de travail de l'isolateur	DETERGENT* + 2x DESINFECTANT**	
	Vérification visuelle des gants et manchettes		
TOUTES LES SEMAINES			
LUNDI	TESTO vérification		Vérifier Température, pression et humidité
MERCREDI	Test d'étanchéité		Cliquer sur étanchéité puis départ test
VENDREDI	Intérieur enceinte ISOLATEUR (plan de travail + vitre + gants + manchette)	DETERGENT* + 2x DESINFECTANT** + DESINFECTANT ***	
	Extérieur ISOLATEUR	Produit d'entretien pour matière plastique (PAS D'ALCOOL)	
TOUTES LES 1-3MOIS			
	Changement de gants (et si défectueux)		Conserver une paire stérile à l'intérieur de l'isolateur + veiller à avoir en stock 1 paire stérile et 1 paire non stérile
	Nettoyage complet de l'Isolateur : • Enceinte isolateur • Bac reliquat frigo (vide) • Boites de stockage de l'enceinte • Tuyau tubing	DETERGENT* + 2x DESINFECTANT** + **décontamination H2O2 (grand cycle)** • Fermer portes : déchets – tubing • Ouvrir porte reliquat frigo avec le reliquat dont la date de décontamination est la plus éloignée • Laisser porte SAS ouverte	Prévoir de **vider totalement l'isolateur et le SAS** : • Transférer le stock T°amb et frigo (+ désinfectant et détergent) dans le tubing, • Laisser les boites de stockage (boites bleues et en acier) et le tuyau tubing • Prévoir de vider un bac reliquat frigo • Après décontamination, indiquer la date de décontamination sur le bac reliquat frigo
TOUS LES ANS			
	Changement de manchettes (et si défectueuses)		Veiller à avoir en stock 1 paire
	Maintenance TCPS (filtre, préfiltre...)		

VAPORISER SUR LA COMPRESSE plutôt que directement sur surface

Detergent * Klercide™ Neutral ; Désinfectant** Klercide™ Alcool isopropylique 70/30, Désinfectant ***Klercide™ Sporicidal Low Residu Peroxide

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