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Evaluation of the Safe Handling of Anticancer Medicines in a National Oncology Center in Côte d'Ivoire by FMECA / Cyto-SAT

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Abstract

The increasing incidence of cancer in sub-Saharan Africa, particularly in Côte d'Ivoire with 17,300 new cases reported in 2020, has motived improvements in patient care, marked by the establishment of a National Centre for Medical Oncology and Radiotherapy. This study aimed to evaluate compliance with international standards regarding the safe handling of cytotoxic drugs, which pose risks to healthcare personnel, patients, and the environment. The methodology encompassed all stages of the anticancer drug management circuit. Failure modes in management that could lead to risks, particularly during the handling of anticancer drugs, were analyzed using the Failure Mode, Effects, and Criticality Analysis (FMECA) method. These failure modes or non-compliant practices were previously identified using the Cyto-SAT tool, which is adapted for evaluating anticancer drug handling practices in low- and middle-income countries. The median compliance rate with good practices was 69%. Among all identified or potential failures, 61 risks were identified. Regarding processes directly involving pharmaceutical activities, specifically logistics and preparation, 21 risks were prioritized. Twenty-seven actions were defined to control them. During the study, the rate of safe practices at the CNRAO was higher than the average rate in low-income countries and that of middle-income countries. For a new centre, the CNRAO shows promising results. It is essential to continue and improve the implementation of safe handling practices to protect both patients and healthcare staff.

Keywords: Anticancer Drugs, Safety Standards, Cyto-SAT, FMECA, Côte d'Ivoire.

INTRODUCTION

Long considered a disease of Western countries, cancer has become a major health issue in low- and middle-income countries (LMICs) (Sung *et al*., 2021). In 2020, GLOBOCAN estimated nearly 250,000 new cases in West Africa alone (Sung *et al*., 2021). Côte d'Ivoire, a country in this sub-Saharan African region, recorded an increasing incidence of all cancer types that same year, with approximately 17,300 new cases reported *(Sung et al*., 2021). This rising cancer incidence poses an economic threat due to treatment costs for LMICs like Côte d'Ivoire. To address this economic burden, the WHO has listed over 60 anticancer drugs on the Essential Medicines List to improve accessibility (Jenei *et al*., 2022). Anticancer drugs are considered high-risk medications due to their narrow therapeutic index, potential for iatrogenic harm, and the severity of errors associated with this drug category (Drapeau *et al*., 2023). Beyond patient safety concerns, health risks for personnel handling cytotoxic drugs are a major issue due to their genotoxic, carcinogenic, or reprotoxic properties (Drapeau *et al*., 2023). Additionally, improper management of cytotoxic waste can have serious long-term ecological consequences with public health impacts (Ndaw *et al*., 2018). To ensure the safe handling of cytotoxic drugs, many countries have adopted or are developing guidelines or recommendations from professional societies (Power & Coyne, 2018). These good practice standards help implement preventive measures to limit the risks of incidents and contamination during transport, receipt, storage,

preparation, or administration (Mathias *et al*., 2019). Based on these principles, assessment tools have been designed to improve hospital staff practices, such as the Cyto-SAT tool, a self-assessment tool adapted for resource-limited settings (Von Grünigen *et al*., 2021).

In Côte d'Ivoire, the government has improved the availability of anticancer drugs and established a public institution dedicated to cancer care, the CNRAO. Opened in 2018, the CNRAO includes a radiotherapy unit, a day hospital, and a centralized chemotherapy preparation unit. Given the extensive use of cytotoxic drugs in this facility, it is imperative that they are handled appropriately to avoid compromising health objectives. Therefore, it was important to assess the compliance level with safe handling practices for cytotoxic drugs in this reference center, which is also committed to quality improvement.

The objective of this work was to evaluate safe handling practices of anticancer drugs by staff at the CNRAO to contribute to their improvement.

MATERIAL AND METHODS

A descriptive cross-sectional study was conducted over seven months, from September 2022 to March 2023, at the CNRAO.

The safety evaluation in handling anticancer drugs involved identifying and analyzing potential failure modes using the Cyto-SAT tool and the FMECA method.

FMECA was used to analyze cytotoxic drug handling practices. This a priori risk analysis method was employed to:

- Identify potential failure modes listed using the Cyto-SAT tool;
- Rate the frequency (F, from 1 to 4) and severity (G, from 1 to 4) of each failure mode based on the implementation score of Cyto-SAT grid items. Detectability (D) was not rated because, unlike technical failures (e.g., equipment malfunction), deviations from recommendations are often only identified a posteriori;
- Calculate the criticality index (CI): CI = F × G (from 1 to 16) for each failure mode (Table 1).

Table 1: Severity, Frequency, and Criticality rating

Severity rating of effects	
G1	Minor disruptions with no health impact
G2	Impact on patient or staff comfort
G3	Impact on patient or staff health
G4	Irreversible impact on patient or staff health
Frequency rating based on Cyto-SAT implementation score	
F1	Fully implemented
F2	Partially implemented
F3	Considered and discussed
F4	No activity
Criticality rating	
High criticality ≥ 9 :	
Moderate criticality [4-8] :	
Low criticality < 4 :	

Cyto-SAT, used for identifying failure modes in cytotoxic agent management, is a free online tool comprising 134 items organized into 10 domains and 28 subdomains (Table 2), covering all stages of chemotherapy drug management (e.g., receipt, storage, transport, prescription, preparation, administration, waste management, cleaning, and patient counseling). It was validated using a two-round Delphi process involving a panel of 27 pharmaceutical experts in oncology practice from 13 low- and middle-income countries and high-income countries (Von Grünigen *et al*., 2021).

Table 2 : Classification of Cyto-SAT domains and subdomains and their number of items (Von Grünigen *et al*., 2021)

Domains	Sub-domains	Number of Items accepted
Management		**11**
Personnel	Education and training Medical surveillance	4 3
Logistics	Receipt Storage Transport	5 6 5

Domains	Sub-domains	Number of Items accepted
Prescription		**5**
Preparation	Management and organization	4
	Parenteral medicine preparation areas	10
	Hygiene and personal protective equipment	6
	Preparation process set-up	4
	Preparation technique	9
	Packaging and labeling	3
	Checking procedure	2
	Documentation	3
	Maintenance	2
	Non-sterile preparation	1
Administration	Management Hygiene and safety measures Documentation Work practices	2 5 3 4
Incident management	Surface contamination Staff contamination Extravasation Quality assurance	6 3 3 1
Waste management	Waste disposal Patients' excreta	7 3
Cleaning	Management and organization Cleaning practices Laundry	2 6 2
Patient counseling		4
	Total	134

For the study, two working groups led by the head pharmacist of the center were established with key stakeholders directly involved in the processes under evaluation to incorporate diverse perspectives.

The failure mode analysis covered the 10 domains identified by the Cyto-SAT tool. Each tool element was evaluated using a scoring system ranging from 1 (no activity) to 4 (full implementation). The scoring system (Table 3**)** was based on that of the Institute for Safe Medication Practices (Von Grünigen *et al.*, 2022).

Table 3 : Scoring system (Von Grünigen *et al*., 2021)

Scoring system	
1	No activity
2	Considered and discussed but not implemented. A document may exist but has not yet been implemented, and only limited staff awareness actions have been conducted.
3	Partially implemented in the facility or only implemented in certain areas, or for certain patients and/or staff members.
4	Fully implemented throughout the facility for all patients, medications, and/or staff.

N.A.: Not applicable. This item cannot be considered in the local context. Note: Scores 3 and 4 can only be selected if there has been real implementation. Unapplied procedures or guidelines are not enough.

However, the criticality index calculation focused on domains with safe practice scores below 80% and where pharmacists were the primary actors, namely logistics and preparation of cytotoxic drugs. Improvement measures targeted high-criticality risks.

An authorization request to conduct the study was submitted to the center's managers. Prior to obtaining consent, the staff who participated in the self-assessment were given explanations on the objectives, expected results and scope of this study.

RESULTS

- Identification of Non-Compliances

Overall, the median level of safe practice at the CNRAO was 69%. Prescription, administration, and waste management represented the organization's strong domains, with a safe practice implementation percentage greater than or equal to 80%. Safe handling practices in logistics and preparation had a low implementation percentage, as shown in Table 4.

Table 4: Identification of non-compliances

Domains	Sub-domains	Points	Max points	Percentage Achieved
Management		**26**	**44**	**59.1%**
Personnel		**18**	**28**	**64.3%**
	Education and training	9	16	56.2%
	Medical surveillance	9	12	75%
Logistics		**41**	**64**	**64.1%**
	Receipt	12	20	60%
	Storage	19	24	79.17%
	Transport	10	20	50%
Prescription		**19**	**20**	**95%**
Preparation		**123**	**176**	**69.9%**
	Management and organization	15	16	93.7%
	Parenteral medicine preparation areas	23	40	57.5%
	Hygiene and personal protective equipment	21	24	87.5%
	Preparation process set-up	8	16	50%
	Preparation technique	31	36	86.1%
	Packaging and labeling	8	12	66.7%
	Checking procedure	5	8	62.5%
	Documentation	12	12	100%
	Maintenance	0	8	0%
	Non-sterile preparation	0	4	0%
Administration		**46**	**56**	**82.1%**
	Management	8	8	100%
	Hygiene and safety measures	18	20	90%
	Documentation	12	12	100%
	Work practices	8	16	50%
Incident management		**29**	**52**	**55.8%**
	Surface contamination	8	24	33%
	Staff contamination	8	12	66.7%
	Extravasation	9	12	75%
	Quality assurance	4	4	100%
Waste management		**32**	**40**	**80%**
	Waste disposal	22	28	78.6%
	Patients' excreta	10	12	83.3%
Cleaning		**26**	**40**	**65%**
	Management and organization	4	8	50%
	Cleaning practices	20	24	83.33%
	Laundry	2	8	25%
Patient counseling		**11**	**16**	**68.8%**
Total		**371**	**536**	**69 %**

- **Risk Analysis of Logistics and Preparation Domains**

In logistics, nine risks were identified. 22% of risks at this level showed high criticality (Figure 1).

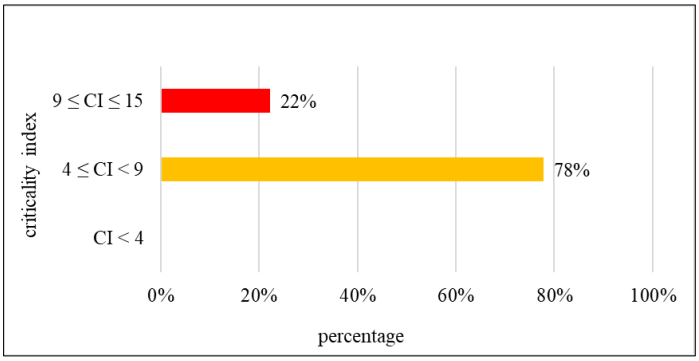

Figure 1: Proportion of criticality indices in the logistics domain

These risks primarily concerned the failure to wear gloves during the receipt and unpacking of cytotoxic drugs, as well as the absence of a procedure for managing accidental spills during receipt.

Regarding the centralized preparation unit, 12 risks were identified. Half of the risks had high criticality (Figure 2).

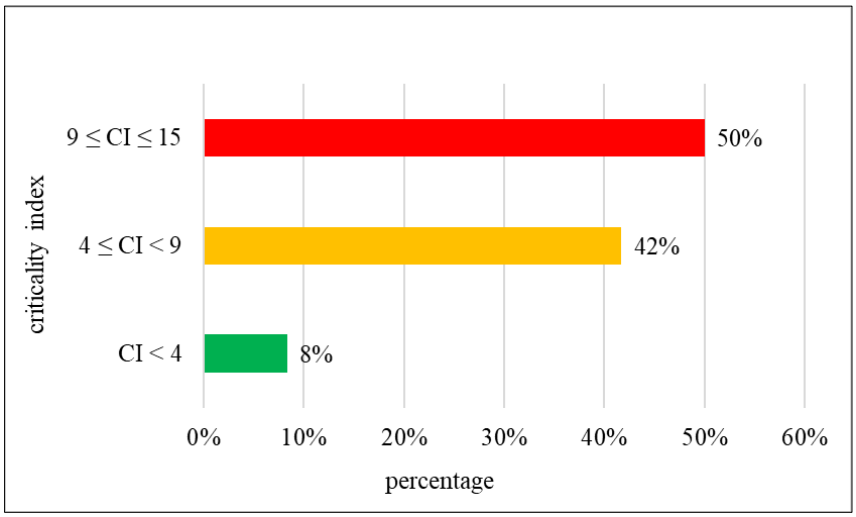

Figure 2: Proportion of criticality indices in the preparation domain

These risks concerned the absence of a Controlled Atmosphere Zone (CAZ) and specific procedures, particularly for storing and using drug remnants, or vials containing residual cytotoxic solutions.

- **Proposed Control Measures**

The criticality of risks identified in logistics and preparation necessitates the implementation of an action plan, essential elements of which are presented in Table 5.

Table 5: Description of main risks and proposed action plan

Risk description	Recommendations	Responsible parties	Timeline
Failure to wear gloves	Restrict access to chemotherapy storage area Develop a procedure for receiving cytotoxic drugs	Head Pharmacist	Short term
Absence of accidental spill management procedure during receipt	- Make a decontamination kit available - Develop a procedure describing actions to take in case of accidental contamination by a cytotoxic drug	Head Pharmacist	Short term
Absence of preparation control procedures	- Implement double verification by preparers - Supervise preparation by a pharmacist - Develop a "chemotherapy" checklist	Head Pharmacist	Short term
Non-compliant centralized preparation unit	- Upgrade the centralized chemotherapy preparation unit: • Install exhaust ventilation system in storage area • Establish a controlled atmosphere zone to create strict aseptic conditions and ensure preservation and use of leftovers beyond 24 hours • Ensure work surfaces and all preparation room surfaces are smooth and easy to clean and disinfect • Install a biological safety cabinet with continuous monitoring system verifying adequate airflow and/or cabinet performance	Management	Long term

DISCUSSION

- **Comparison to Other Resource-Limited Countries**

The Cyto-SAT tool covers the entire cytotoxic drug handling process in healthcare facilities. It enables self-assessment and aims to improve handling practices in LMICs. The median level of safe practice at the CNRAO was higher than that found in LMICs in the study by Von Grünigen *et al*., (2022), which was 63%. Despite this favorable position of the CNRAO compared to other centers operating in similar economic contexts, additional efforts are recommended, particularly in

incident management. Focusing our study on domains involving pharmacists, specifically logistics and preparation, revealed that they were among the weakest areas at the CNRAO. This corroborates the findings of Von Grünigen *et al*., (2022) that safe handling practices for cytotoxic drugs in these two domains should be strengthened in most LMICs.

- **Contribution of the Cyto-SAT Tool to the Development of Hospital Pharmacy Best Practices**

In the absence of specific regulatory frameworks, consensus standards established by peers prove essential for identifying inadequate behaviors and guiding medication circuit stakeholders in implementing better pharmaceutical practices. The Cyto-SAT tool is aligned with recommendations from professional societies, guidelines, and regulations from worker protection agencies (Ndaw *et al*., 2018; Kennedy *et al.*, 2023; NIOSH, 2023). The various items of this tool, developed by peers, allow for rigorous internal review. It can be accompanied by external technical assistance, as was the case in our study.

In terms of applicability and ease of use of the tool, few difficulties were encountered during our study at the CNRAO. The experience in this institution highlighted good acceptability by the evaluated staff, who were open to receiving observations to maintain safety and service quality. This resulted in a tendency to spontaneously seek possible sources of dysfunction and propose improvements. In terms of modalities, multidisciplinary exchanges and self-criticism conducted at each stage of the circuit complement the meticulous examination carried out during pharmaceutical practice inspections. Thus, the Cyto-SAT tool enabled the application of the same analytical rigor without the apprehension that can result from inspections. In this sense, such a tool can be to the self-assessment of safe practices what the inspection grid is to the inspection mission of pharmaceutical establishments, particularly those handling anticancer agents. Its items could therefore serve as axes for strengthening regulations in this area in resource-limited countries.

- **Benefits of Adding FMEA and involving Staff in the Change**

Identifying non-compliant practices, including high-risk ones, is not sufficient to enhance the application of good practices. It is still necessary to indicate the effective conduct to stakeholders and then evaluate its implementation.

In our study, the FMECA method was combined with the use of the Cyto-SAT tool to deepen the analysis of non-compliances in the logistics and preparation domains. It also helped map the risks incurred by users, staff, and environmental preservation to minimize them.

The logistics circuit and chemotherapy reconstitution are high-risk areas for staff. Chemotherapy preparation is one of the highest-risk steps in the cancer patient care process, as demonstrated by the study by Roche *et al*., on securing the anticancer drug manufacturing circuit (Roche *et al*., 2022). At this stage, handling staff are exposed to concentrated anticancer drugs, posing an occupational risk, and a dosing error can also be fatal for patients. Staff are also exposed during the handling of anticancer drugs during receipt, storage, and transport due to the presence of cytotoxic residues on primary packaging. A study by Hilliquin & Bussières, (2020) proved that the exterior of antineoplastic drug containers remains a significant source of contamination. The failure mode analysis of the logistics and preparation domains led to the identification of 21 risks, including eight with high criticality impacting safe handling practices. Short-term and long-term recommendations were submitted to the center to minimize these risks. The recommendations were based on those from the ANSM good preparation practice guides (Agence nationale de sécurité du médicament et des produits de santé, 2023) and the ASSTSAS prevention guide for the safe handling of hazardous drugs (Bédard, 2021).

One recurring improvement point raised by the working team was staff training. It remains a salient element of change, alongside investments such as the establishment of a CAZ. According to the WHO, it is necessary to move from "training" to "education," which encompasses, in addition to skill acquisition, a proper understanding of health issues and the adoption of a vision for better health (Nutbeam, 2000).

The key recommendation from the study is therefore to continue awareness-raising at the CNRAO to maintain the continuous engagement of staff, who are essential stakeholders in the system.

CONCLUSION

The evaluation conducted with the Cyto-SAT tool identified 61 non-compliances at the CNRAO in Abidjan, where staff adhere to good practice standards at a rate of 69%. By examining failures in domains involving pharmacists, specifically logistics and preparation, in more detail, FMECA allowed us to prioritize 21 risks to patient, staff, and environmental safety.

This study, aligned with hospital reforms in Côte d'Ivoire, is part of the hospital practice improvement approach led by CNRAO management. Implementing the suggested recommendations would significantly improve the compliance level with good practices. Staff training and follow-up of improvement measures should lead to the strengthening of safe good practices. This self-assessment showed good prospects; it should be repeated to ensure the application of good hospital practices within this national reference center.

The Authors Declare: no conflicts of interest

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