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### RESEARCH ARTICLE

#### AUDIT OF THE THERMO-SENSITIVE DRUGS CIRCUIT AT UNIVERSITY HOSPITAL CENTER OF BRAZZAVILLE (CHUB).

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#### Abstract

The hospital pharmacist manages drugs and must ensure that the drug storage conditions including thermo-sensitive drugs which are under his responsibility, are respected. The repeated power outages make the drug security control difficult at CHUB. This exposes the CHUB to many risks: drug alteration, financial and regulatory risks. Our objective was to verify cold chain management's maintaining, at all stages of the thermo-sensitive drug circuit using a clinical audit that assessed the compliance of practices of pharmacy staff and care units with international recommendations. From March 1st to March 31st, 2017, a hospital pharmacist and one pharmacy technician carried out a clinical audit of the reception, storage of thermo-sensitive drugs at the pharmacy, their dispensing and storage in five care units and two operating theaters. No step has been revealed to be 100% compliant. 70.8% compliance for immediate drug storage; 60.3% compliance for dispensing priority and 50% immediate storage in thermostatic chambers of 2 operating theaters. This audit showed that the cold chain is not maintained throughout the drug circuit at CHUB. Improvement actions such as the appointment of referential storekeepers responsible for the management of thermo-sensitive drugs at the pharmacy and in the care units and operating theaters will raise awareness and will empower healthcare staff at CHUB.

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#### Introduction:-

Many factors can damage medications, including heat, air, light, and moisture. Exposure of medication to inappropriate conditions may render them ineffective, or even harmful if ingested. Temperature is one of the most important parameters to control. Drugs must be stored according to predetermined conditions as supported by stability data. Thus, in health centers, drug storage conditions must be permanently controlled. The hospital pharmacists are responsible for monitoring the supply of all medicines used in the hospital and are in charge of purchasing, manufacturing, dispensing and quality testing their medication stock along with help from pharmacy assistants and pharmacy technicians. In University Hospital Center of Brazzaville (CHUB), every day, heat-sensitive medicines are received at the hospital pharmacy and then dispensed in the different care units.

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According to the recommendations governing the management of health products subject to the cold chain (AFF, 2008; MTES, 2011; Bulletin de l'ordre n°391, 2006), heat-sensitive medicines must be transported and stored at +2°C to +8°C. The hospital pharmacist must ensure the maintenance of the cold chain and the respect of conservation conditions of these products. When cold chain products are received at a pharmacy, it is important that they are promptly checked in and placed in a refrigerator. The person responsible for receiving the delivery must also satisfy themselves that the goods have been transported under appropriate conditions. In the pharmacy department of CHUB, the conservation conditions of pharmaceutical products are sometimes called into question because of the repeated power cuts. These power cuts are nevertheless reduced thanks to the power generator which provides enough level of electricity in the storage places of the thermosensitive drugs of the pharmacy. However, it happens that during a period of fuel shortage, the power generator is not functional; which leads to temperature rises in the thermostatic enclosures of the hospital pharmacy and the refrigerators of the care services with as a main consequence the deterioration of drug quality. In addition, CHUB is exposed to financial and drug regulatory risks (Saint-Lorant et al., 2014). The main objective of this study was to check the maintenance of the cold chain, at all stages of the thermosensitive drug circuit in CHUB, from its receipt to storage. This study was realized in using the clinical audit tool, recommended and largely employed by experts in quality. This tool allowed us to evaluate the compliance of the practices of storekeepers, pharmacy technicians and caregivers with international recommendations (AFF, 2008; MTES, 2011; Bulletin de l'ordre n°391, 2006). Also, alternative solutions were proposed to improve the system in CHUB.

### Materials and methods:-

The CHUB is a health center composed of 37 services. We conducted a prospective and observational survey based on the clinical audit method which is about measuring the quality of care we provide such as drug delivery against relevant standards. The audit ran from March 1, 2017 to March 31, 2017 all days. The pharmacist and its assistants observed the reception, storage and drugs dispensation in 5 units of care: cardiology, surgical resuscitation, nephrology, emergency and pediatric. But also, in obstetrical and visceral operating theaters. Two thermostatic enclosures equip the hospital pharmacy. The 5 care units and the operating theaters are equipped with refrigerators. Firstly, we studied the thermosensitive drugs circuit and highlighted five essential steps: ordering, receiving, stockage, dispensation and prescription. In a second step, we carried out a bibliographical research to elaborate the collection grids, supports of the audit of the circuit of the thermosensitive drugs (1, 2, 3) using pubmed and others research motors such as Google. Keywords used were "thermosensitive drug", "cold chain" and "security". Also, regulatory texts relating to the securing of the cold chain were studied, and four stages of drug circuit (reception, storage, dispensation and conservation in care units) were audit (AFF, 2008; MTES, 2011; Bulletin de l'ordre n°391, 2006).

Thirteen criteria were evaluated in this study as shown in the Table 1. For each criterion, we marked the following endorsements: "compliant", "non-compliant" or "not applicable". The number of compliant or non-compliant criteria was compiled at each step and for each "medical department". The recorded insufficiencies have led to proposals to improve the reception, dispensation and storage system of thermosensitive drugs at CHUB. The dispensation of thermosensitive drugs directly to families was excluded from this study because the use of the drug is immediate, it is not stored in a thermostatic chamber.

Data are expressed as mean  $\pm$  S.D. Analysis of statistical significance was performed according to STUDENT t test. Differences were considered significant when  $p < 0.001$ .

### Results:-

This study was conducted at CHUB and involved units 7 out of 37, representing 18.9% of all units. Concerning the drug reception and storage, on 100 receptions, 48% represented thermosensitive drugs. A total ten storekeepers received drug over the audited period an average of  $4.8 \pm 1.03$  receptions per storekeeper.

The results obtained show that at each thermosensitive drug reception, the date and time of receipt were recorded on the delivery voucher for 29 receptions representing 60.4% of compliance. The date and time of storage in the thermostatic chamber were recorded for 25 receptions representing 52% of compliance. The Cardboard packaging were withdrawn at 30 receptions, representing 62.5% of compliance. Drugs were immediately stored for 34 receptions representing 70.8% of compliance. Temperature monitoring was carried out for 15 days, this represents 20 receptions, a compliance rate of 41.7 % (Figure 1).

On ten storekeepers audited, four responded in accordance with all criteria, three responded in accordance with three criteria: the recording of the date and time of storage in a thermostatic chamber, the removal of cardboard packaging and immediate storage in a thermostatic chamber. Three other storekeepers responded to two criteria only: the recording of the date and time of receipt and storage in a thermostatic chamber.

Concerning the thermosensitive drugs dispensation to care units and operating theaters, 78 dispensations by fifteen pharmaceutical preparators were observed in about one hundred dispensations for the five units of care and the two operating theaters audited with a dispensation rate of 78%. The average drugs dispensation per pharmaceutical preparator was of  $5.2 \pm 0.77$ . On all observed dispensations, 47 were for the 2 operating theaters representing 60.3% of total dispensations and 31 were for the 5 care units, representing 39.7% of total dispensations (Table 2).

Drugs were put in an isotherm box with cold accumulators during the 31 dispensations to the 5 care units representing 100 % compliance. No pharmaceutical preparer has labeled the medications dispensed to the care units and operating theaters with the term "thermosensitive". Drugs were managed in priority in 47 dispensations is a rate of 60.3% and this for the obstetric and visceral blocks by all preparers. No dispensing voucher containing the drug's name, quantity and nature was given during the 78 dispensations (Figure 2).

Table 3 shows the distribution of the storage of thermosensitive drugs by caregivers. Overall, 50 drugs were storage by the six caregivers representing  $8.3 \pm 4.1$  storage drugs by caregiver. These stocks are distributed as follows: 25 for the five health-care assistants in the audited care units (50%) and 25 for only caregiver-help caring for 2 blocks (10 for the visceral block and 15 for the obstetric block).

No record of the date and time of storage in the thermostatic chamber was observed. No temperature monitoring was performed or traced. The thermostatic chamber of the five care units contained only medications while those in the two operating theaters also contained blood bags. 50% of drugs were immediately storage in the thermostatic chambers after dispensation in the two operating theaters while no immediate storage was observed in the 5 care units.

### **Discussion:-**

This study allowed us highlighted out some problems related to the drug circuit at the CHUB. The choice of methodology used in this work was based on the good results obtained by others authors. It allows to quickly know positive and negative points of the studied system. Although the number of audited units was low (18.9%), results obtained are interesting. Receipt and storage of thermosensitive products at the pharmacy showed compliance rates above 50%. Otherwise, the difference observed between receipt criteria and storage criteria was not statistically significant ( $p > 0.05$ ). The highest and significant compliance rate was for immediate storage ( $p = 0.0009$ ). This shows that most storekeepers (7 out of 10) are aware of the breakage risks of the cold chain. In order to improve the removal of cardboard packaging and the monitoring of temperature, we propose to appoint reference storekeepers as suggested previously (Saint-Lorant et al., 2014).

1. Date and time reception recording has no impact on the cold chain break of the cold, but it permits to verify the good condition of received drugs. These data make to control especially the delay between the reception and the storage. Thus, one can measure the critical degree of cold chain break. To ensure a better monitoring of the temperature and to be warned at the earliest in the event of a breakdown, all thermostatic chambers in the pharmacy should be equipped with a continuous temperature recording system and a control system alarm. The training of storekeepers and the pharmacy staff at traceability is also essential for securing the drug circuit at CHUB.
2. For Dispensation of thermo-sensitive drugs to care units and operating theaters, it is interesting to note that the priority treatment concerned exclusively the operating theaters audited (60.4%). However, the difference between preparers giving priority and those not doing so was not statistically significant ( $p = 0.09$ ). In this study, all units of care audited benefited from an isotherm packaging with cold accumulators (39.7%). We could not determine if less distribution of this conditioning was voluntary or simply by lack of isotherm conditioning with cold accumulator. The traceability was almost non-existent since the concept of thermo-sensitive drug has never been indicated and no dispensing form indicating name, quantity and nature of the drug has been given. It is recommended that drug packaging must be labeled "product to be kept cool between  $+ 2^{\circ} \text{C}$  and  $+ 8^{\circ} \text{C}$ " to inform the caregiver of the storage conditions (MTES, 2011; Bulletin de l'ordre

n°391, 2006). A dispensing voucher permits also to insist on the drug nature and to prove that it has been dispensed (Bulletin de l'ordre n°391, 2006). The development of pre-printed cards in advance with columns to record the date, the drug name, its quantity and its nature would solve this problem.

- For the storage of thermo-sensitive drugs in care units and operating theaters, many gaps were noted: no storage record, no temperature monitoring and the presence of blood pockets within the two audited blocks. To remedy this practice training of the operating blocks staff is necessary. Indeed, drugs must be separated from blood bags to avoid contaminations (Bulletin de l'ordre n°391, 2006 ;Royer et al.,2017). However, the observation of a single caregiver did not allow us to say that all caregivers mix the thermo-sensitive drugs and the blood bags.As for the immediate storage of thermo-sensitive drugs in the thermostatic chambers of the two operating theaters, this is probably due to the fact that thermosensitive drugs are not protected by isothermal packaging. It would be interesting in another study to study the waiting time before drug storage.In order to improve the circuit of the thermosensitive drug and to allow all the care units to dispose of these drugs especially in emergency, we propose the census of all units possessing thermosensitive drugs and to centralize one or two thermostatic chambers. Centralization would save money on the purchase and maintenance of refrigerators. One of the priority actions would be the appointment of pharmacy representatives by service to empower all healthcare staff and to improve the storage by a better follow-up.

### Conclusion:-

This audit revealed that the traceability of the reception and storage of drugs at the CHUB pharmacy by the storekeepers was satisfactory (compliance greater than 50%). However, this traceability is not carried out by all storekeepers and it should be automatic. The development of a procedure and the appointment of reference storekeepers are the actions that will be implemented soon. Regarding the drug dispensing, it was highlighted a lack of labeling specifying the concept of thermosensitive drug and dispensing voucher. We propose the implementation of pre-established labels and pre-filled forms. Their realization and use will be described in the future procedure. Finally, observations of the storage in the care units and operating theaters have revealed several non-compliances in terms of traceability, temperature monitoring and immediate storage. This audit shows that improvement actions are needed from the healthcare staff at all stages of the cold chain circuit. The development of strict procedures for the thermosensitive drugs management both at the pharmacy and in the care units will ensure the drug circuit security. Actions to be done necessarily are the appointment of representatives by department and the centralization of the thermostatic chambers. A new audit will have to be carried out after the implementation of these actions in order to judge their relevance.

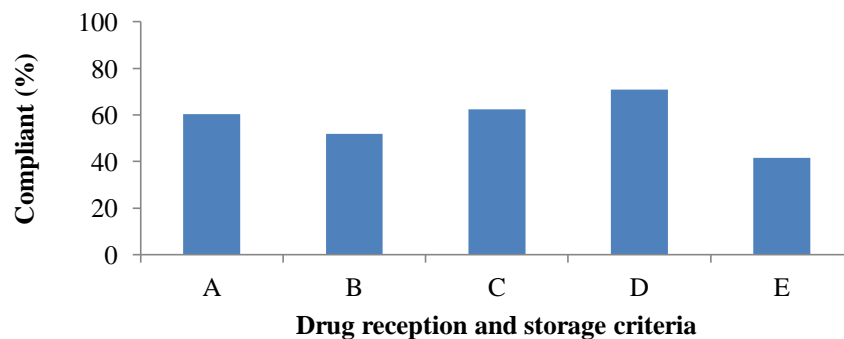
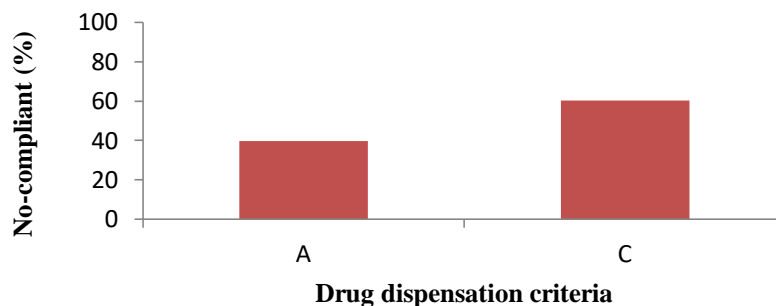


Figure 1:-Drug reception and storagecriteria

A = date and time of drugreception ; B = date and time drugstorage; C = Cardboardremoval and immediatestorage in a thermostaticchamber ; D = Drugimmediatestorage in a thermostaticchamber ; E = Temperature dailyoversight



**Figure 2:-Drug dispensation criteria**

A = Drugs protection in isotherm packaging with cold accumulator

C = drugs management priority

**Table 1:-Evaluated criteria**

Drug reception and storage(5 criteria)	Drug dispensation (4 criteria)	Drug storage(4 criteria)
Recording date and time of drug reception	Drugs protection in isotherm packaging with cold accumulator	Recording date and time drug storage in a thermostatic chamber
Recording date and time drug storage in a thermostatic chamber	Thermosensitive drug notion on the labeling	Temperature daily oversight and traceability
Cardboard removal and immediate storage in a thermostatic chamber	Priority management of these drugs	Exclusively presence of drugs in thermostatic chamber
Temperature daily oversight	Drug dispensation voucher with name, quantity and nature of drug	Immediate storage of thermosensitive drugs
Temperature daily recording		

**Table 2:-Thermosensitive drugs dispensation on units of care**

Units of care	obstetrica l operating theaters	visceral operatin g theaters	cardiolog y	nephrolog y	pediatri c	surgicalresuscitatio n	emergenc y	Tota l
Dispensatio n number	22	25	6	4	6	10	5	78
Dispensatio n rate(%)	28.20	32.05	7.69	5.13	7.69	12.83	6.41	100

**Table 3:-Storage of thermosensitive drugs by caregivers**

Units of care	obstetrical operating theaters	visceral operating theaters	cardiology	nephrology	pediatric	surgicalresuscitation	emergency	Total
Nombre de mises en stock	15	10	5	5	3	7	5	50
Taux de mises en stock (%)	30	20	10	10	6	14	10	100
Nombre d'AS	1	1	5	5	5	5	5	6

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