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UNIT PACKAGING CONTROL OF REUSABLE MEDICAL DEVICES: EXPERIENCE OF MOHAMED V MILITARY TEACHING HOSPITAL – RABAT

M. R. Sefrioui*[1], M. Lamrabet[2], J. El Harti[3], A. Laatiriss[4], Y. Cherrah[5] and S. Derraji[5]

[1]Central Sterilization Service, Mohamed V Military Teaching Hospital, Rabat Morocco.
[2]Faculty of Medicine and Pharmacy, Mohamed V University, Rabat Morocco.
[3]Laboratory of Therapeutic Chemistry, Faculty of Medicine and Pharmacy, Mohamed V University, Rabat Morocco.
[4]Laboratory of Galenic Pharmacy, Faculty of Medicine and Pharmacy, Mohamed V University, Rabat Morocco.
[5]Laboratory of Pharmacology-Toxicology, Faculty of Medicine and Pharmacy, Mohamed V University, Rabat Morocco.

***Corresponding Author: M. R. Sefrioui**

Central Sterilization Service, Mohamed V Military Teaching Hospital, Rabat Morocco.

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ABSTRACT

Background: Patient safety has become a priority in Public Health. The quality assurance applied to hospital sterilization is based on several standards, including the Good Hospital Pharmacy Practices (GHPP). Packaging operations is a fundamental step in the process of sterilizing reusable medical devices. From the quality provided at this level also flows the quality and safety of the sterilization step. Our study has a twofold objective: To highlight the main packaging errors and to highlight the impact of the quality of the packaging on the sterilization. **Materials and Methods:** This is a prospective study, spread over a period of one week, from October 16 to 21, 2017. This study is carried out at the Central Sterilization Service of the Mohamed V Military Teaching Hospital, Rabat - Morocco. The control of packaging is focused on unit packaging, paper / plastic bag by methylene blue method and container packaging by the method of leakage of water. The processing and the statistical analysis of the data are carried out thanks to Excel software. **Results and Discussion:** Of 1824 tested packets, 96% are compliant and 4% are non-compliant. The main nonconformities noted are: the opening of the solder by bursting of bag, fusion of the plastic material in direct contact with the basket-carrier. The control of the containers concerned 132 units of which 77% are compliant and 23% are non-compliant. Of these, 20% is due to the non-compliance of the cover and 2% is the non-compliance due to filter problems. The results of our investigation are satisfactory compared to those of a French study by J. Molina and All, whose container non-conformity is always linked to the presence of leaks in the water tests. **Conclusion:** It is essential or even mandatory, to make all agents aware of the need to ensure correct controls on all sterilization processes. The establishment of quality indicators (control, validation ...) remains mandatory. This involves preventive and corrective actions: continuous training and regular reassessment of agents' practices.

KEYWORDS: Sterilization - Packaging - Reusable Medical Devices - Control.

BACKGROUND

The sterile state of a medical device is an ephemeral state. Therefore, it must be preserved through a suitable packaging and compatible with the sterilization process. The objectives of this step of packaging are described in the French standard NF EN ISO 11607-1.[1] The packaging must fulfill the main objectives: the maintenance after conditioning and before sterilization the level of contamination obtained by washing; the penetration of the sterilizing agent and its contact with the medical device; maintaining sterility until the use of the sterile object and aseptic extraction of the medical device. Packaging, while permitting sterilization, should withstand sterilization, transport, storage and allow for easy manipulation and opening to ensure aseptic conditions.[2] The Good Hospital Pharmacy Practice (GHPP) reminds us that the time between cleaning and packaging should be as short as possible.[3] The packaging may consist of two successive: the primary packaging which constitutes a impermeable barrier to microorganisms, then a secondary packaging which ensures the protection of the sterile medical device in its primary packaging. Each package, whose closure must be checked before sterilization, must include a passage indicator simply attesting to a passage in an autoclave. The packaging can be for multi-use or single-use and must meet the requirements of the EN 868 series of standards.[4] Multi-use packaging refers to sterilization containers consisting of a bowl and a lid. Single-use packages can be simple (paper-only) or complex

(paper/plastic). All these packages are either welded or folded. The welding is carried out using a heat sealer which must be maintained (temperature control and crushing force). An optimal weld must be perfectly sealed while remaining easily peelable to allow easy aseptic extraction of material.[5][6]

Among the tests carried out for the control of the paper / plastic bags, we find: the resistance test of the packaging system Ultra® with absorbent paper in the transport basket, the resistance test of the packaging system Ultra® with carpet of silicone in the transport basket, the visual test of the weld and the methylene blue test. The methylene blue test is the most widely used method for routine bag testing. The bags are filled with blue dye for several minutes. The penetration of the dye indicates the non-compliance of the bag. The conformity check of the crepe paper is done according to the standards of the series NF EN 868.[7] The main tests are: the visual examination, the mass per square meter, the regularity of the thickness, the resistance to the burst, tears strength, tensile elongation and tensile strength, air permeability or methylene blue, bubble point (average pore diameter), absence of optical brighteners and the control of the coating. When used daily, containers must undergo the following routine inspections and checks:[8] lid seal inspection, fixed-filter seal inspection, filter inspection, closures inspection. Routine controls include silicone gasket, filter port seals, vessel integrity, lid integrity, rivets or nuts, locks and flatness control. Water-tightness test is most commonly used for container control. Our study has a twofold objective: to bring out the main packaging errors and the impact of the quality of the packaging on the sterilization.

MATERIALS AND METHODS

This is a prospective study, spread over a period of one week, from October 16 to 21, 2017. This study is carried out at the Central Sterilization Service of the Mohamed V Military Teaching Hospital in Rabat, Morocco. The control was carried out on the unit packs, paper / plastic bag by the methylene blue method and on container packaging by the water leak method. This study aimed to measure the daily number of non-conformity of packaging and in which one observes the occurrence of sterilization defects. The processing and the statistical analysis of the data are carried using the Excel software.

RESULTS

Our study aims to evaluate, on the one hand, the conformity of the packaging before sterilization and, on the other hand, the conformity of the packaging after sterilization of the material.

The check of the conformity of the packaging of the bags before the sterilization concerned 25 baskets of autoclave or 1824 bags. The control is based on the conformity of the weld by a methylene blue test. Of a total of 1824 paper / plastic bags tested, 35% have sealing errors (*Figure 1*). The quality of the crepe paper packaging is about a tight fold; a corner of the leaf protrudes to open without fault of asepsis; the end of the indicator ribbon is folded back on itself for easy opening; the stereoliths are of different colors and the presence or absence of tears on the paper. Our survey involved 130 crepe paper envelopes, of which 14 (11%) are not conform (*Figure 2*). Container control is based on a visual check (seal check, filter door check and tank integrity check) and a leak test (water test). Out of a total of 132 containers checked before sterilization, our survey found that the compliance rate is 78%. Nonconformities (22%) are due to cover (20%) or filter problems (2%) (*Figure 3*).

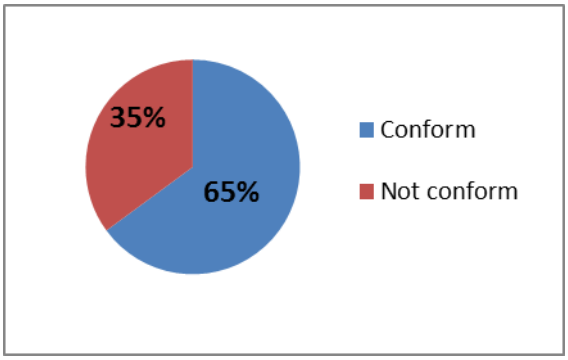

Figure 1: Percentage Compliance Paper / Plastic Bag.

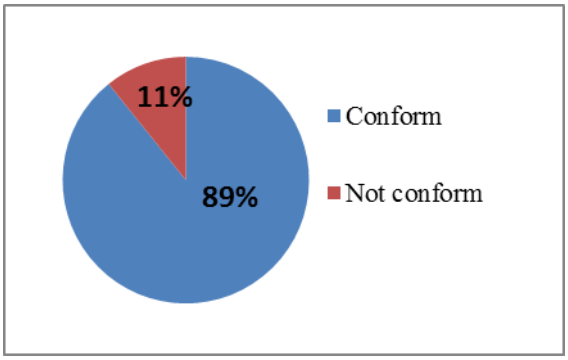

Figure 2: Percentage of Crippled Paper Compliance.

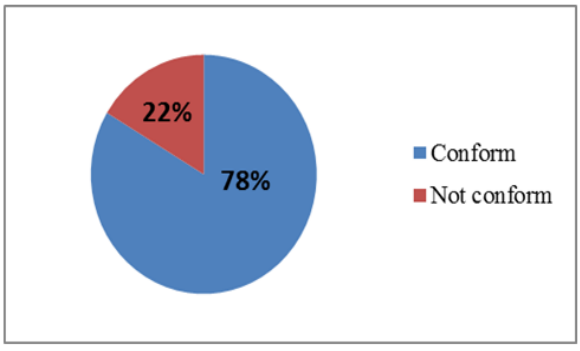

Figure 3: Percentage of Container Compliance.

After sterilization, the control of the packaging concerns a control of the tightness and a control of the humidity. The tightness is checked by visual inspection or methylene blue test. The sterilized material must be visually dry, the presence of traces of water is declared as not conform. The check is visual to check the absence of moisture on the outer packaging, filters and porous

materials. Of the 1824 sterilized bags, 261 sachets (14.30%) show traces of water after sterilization (*Figure 4*). Sealing after sterilization failed in 74 bags, ie 4.06% (*Figure 5*). The anomalies observed are the opening of the weld by bursting of the bag and the melting of the plastic material in direct contact with the basket-carrier.

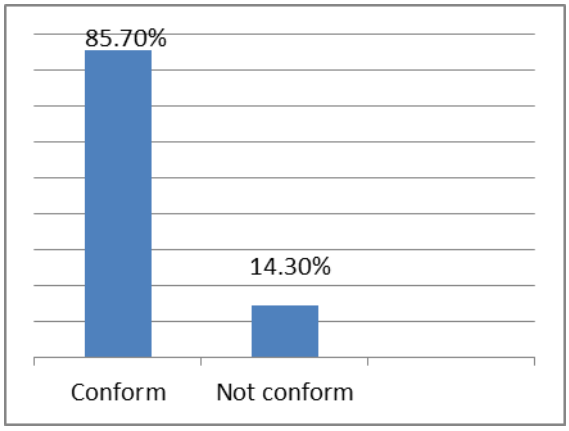

Figure 4: Percentage of moisture compliance.

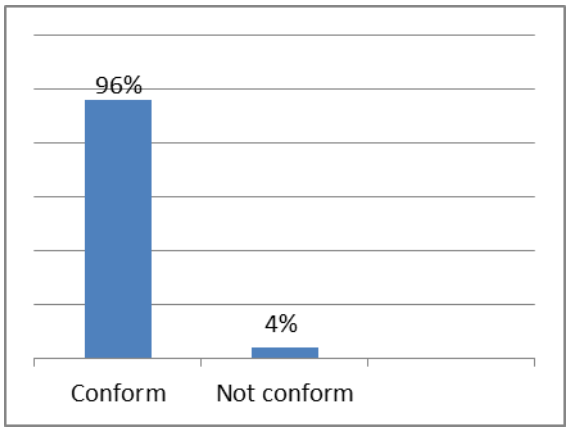

Figure 5: Percentage of compliance tightness.

DISCUSSION

The results obtained by this control are the result of work done at a given moment, and on a well-defined circuit. Indeed, we made the decision to restrict our work to the following factors: conditioning before sterilization, sterilization and control after sterilization. In this study, the conditioning steps and the circuit of reusable medical devices were included.

According to the results of our investigation, 22% of the containers checked are non-conform, the non-conformity is always linked to the presence of leaks in the water tests. According to a study carried out in France by J. Molina and all about 257 containers before recomposition (of different sizes and different brands) and in 7 health facilities, the results revealed that on average 30% of containers declared visually non-compliant have a water leak.[9] According to the same study, the control of 1300 sachets over a period of 5 months revealed that the non-compliance of solder pouches type "fold" is the most common (85 to 90%). On the other hand, 70% of nonconformities is due to the width of the bag which is greater than 18cm.[10] According to the results of our investigation, 35% of the bags inspected are non-conform. The fusion of the plastic material in direct contact with the basket-carrier is the most frequent anomaly. According to a French study by A. Robert and all, 100 baskets have been tested for strength of the Ultra packaging system with paper towels in the transport basket.[9] With an absorbent paper backplane, no wetting or tearing was observed on the 100 baskets. Nevertheless, 96% of the baskets had a melting point on at least one of the two packages. It is linked to a friction zone that makes the Ultra® material virtually transparent. This phenomenon makes the product unusable in the state since it is difficult, with the naked eye, to make the difference between a melting point and a tear. Only a methylene blue test can show the absence of tearing.[11] The results of our study are stackable to those performed at the sterilization department of the Nancy Hospital.

CONCLUSION

Sterilization is a special process. Thus, the mastery of each level of the sterilization process is necessary to ensure and guarantee the quality of the final product. Checking the dryness of each package is a routine check when releasing a sterilized load. The wet compositions are therefore rejected during these validation checks. However, some packaging systems, container and nonwoven folding in particular, do not always detect the presence of residual moisture at the end of the sterilization cycle. It is only when the surgeon decides to use the operating tray that the moisture is discovered. As a precautionary principle, these wet compositions are generally excluded from any use.

BIBLIOGRAPHIC REFERENCES

1. AFNOR. Norme NF EN ISO 11607-1 : Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage. La Plaine Saint-Denis; Juillet 2006.
2. AFNOR 11607-2: 2006. AFNOR 2006. Norme ISO/DIS 11607-2: 2006. Emballages de dispositifs médicaux stérilisés au stade terminal. Partie 2: exigences de validation pour les procédés de formage, scellage et assemblage.
3. Arrêté du 22 juin 2001 relatif aux Bonnes Pratiques de Pharmacie Hospitalière. JO n°152 du 03 juillet 2001.
4. AFNOR. Norme NF EN ISO 11607-1: Emballages des dispositifs médicaux stérilisés au stade terminal – Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage. La Plaine Saint-Denis; Juillet 2006.
5. Norme NF EN 868-2: Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés – Partie 2: enveloppes de stérilisation. Exigences et méthodes d'essai. Septembre 1999. Indice de classement S98-051-2.

6. Collectif. Guide FD S 98-135 pour la Maîtrise des traitements appliqués aux dispositifs médicaux réutilisables. Paris: AFNOR; 2005.
7. Collectif. Guide FD S 98-135 pour la Maîtrise des traitements appliqués aux dispositifs médicaux réutilisables. Paris: AFNOR; 2005.
8. Eliane Chassot _Neuchâtel_29.09.11: Retraitement des Dispositifs Médicaux en petites Structures: Le Conditionnement.
9. Bernadette VALENCE - Julien MOLINA - Robert DEBRE: validation des emballages en stérilisation hospitalière.
10. Julien MOLINA et Bernadette VALENCE: validation des emballages en stérilisation centrale hospitalière. 2013.
11. NBN EN 868-5:1999 Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés - Partie 5: Sachets et gaines thermo-scellables et auto-scellables en papier et en film plastique - Exigences et méthodes.