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Risk management in the sterilization process for reusable medical devices: Moroccan Hospital experience

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ABSTRACT: In the hospital environment, risk mapping aims to identify and assess the criticality of potential risks associated with each stage in the sterilization process for reusable medical devices (RMDs). Our approach aims to develop preventive and corrective measures to better control these risks. From September to December 2023, an a priori risk analysis was carried out in the central sterilization unit of Rabat's specialized hospital. The methodology used will be based on the FMEA method (Failure Modes, Effects and Criticality Analysis), enabling a qualitative and quantitative analysis of risks. A total of 37 failure modes were identified during the sterilization process, including 20 minor criticality risks, 13 medium criticality risks and 4 major criticality risks. The highest number of failures occurred in the cleaning/disinfection and packaging stages, while the riskiest process was recomposition, with two unacceptable risks identified. Once the criticality had been assessed, corrective measures were proposed for all unacceptable risks likely to have a significant impact on the safety of patients and hospital staff. In light of the results, the working group was able to implement a number of preventive and curative measures, and communication remains a crucial element in ensuring compliance with the DMR and the safety of patients and medical staff.

KEYWORDS: Risk management; Sterilization; FMEA; Reusable medical device; Quality assurance system.

1. INTRODUCTION

In hospitals, the use of reusable medical devices (DMR) exposes patients to infectious risks and generates significant hospital costs linked to nosocomial infections. The frequency and severity of nosocomial infections pose a real challenge to public health in Morocco, affecting not only patients but all healthcare professionals [1,2].

Sterilization is an essential link in the reprocessing of reusable medical devices (RMDs). It aims to prevent healthcare-associated infections by eliminating all micro-organisms while maintaining the sterility assurance level (SAL) recommended by good hospital pharmacy practice [3,4]. The Sterilization Department of the Specialist Hospital (SAL) is responsible for the production and supply of sterile medical devices intended for operating theatres and care services, under the supervision of the pharmacist. In view of this risk, the sterile processing regulations recommend the establishment of a quality assurance system that guarantees a high level of safety for patients, healthcare professionals and third parties. This system must be in conformity with the standards of quality and safety laid down in the regulations in force [5,6].

Since the publication of the NF EN ISO 14385 standard, risk management has been integrated as an essential component of the sterilization Quality Management System [7–9]. This integration is part of a process of continuous improvement of quality and performance, aimed at increasing customer satisfaction. This approach is based on the use of methodological tools such as risk mapping, which makes it possible to identify significant hazards related to care, in order to prevent the risk of their occurrence and to guarantee the control of the compliance of sterile medical devices [10,11]. This is a constantly evolving process that aims to ensure optimal use of reusable medical

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devices (RMD) for patients, to minimize legal and financial risks by making the risk acceptable after the management of adverse events [7,12,13].

With the goal to prepare for ISO 9001 certification, a risk mapping was conducted for the sterilizing department of the specialized hospital as part of the implementation of a quality assurance system. The FMEA is utilized to identify potential failure modes at each stage of the sterilizing process for reusable medical devices (RMD) [10,14,15]. The aim is to develop suggestions for preventive and corrective actions to ensure the compliance of sterile medical devices, while also protecting the safety of patients, medical staff, and the environment.

2. RESULTS

The qualitative analysis by brainstorming made it possible to identify 7 elementary processes, 18 tasks and 37 potential failure modes that can occur at different stages of the RDM reprocessing process. The failure modes that have been identified are classified according to the different stages of the part of the process concerned by the analysis (Table 1).

Table 1. Failure modes identified during the sterilization process

Tasks	Failure modes	Possible cause(s) of failure	Effect(s)
		1-Receiving/sorting	
Taking up a position	**D1:** Non-compliance with protective measures	Non-compliance with the hygiene procedure Non-sensitized staff	Health of sterilization personnel compromised
Verification	**D2:** The Sterilization Block link sheet (Instrument shuttle sheet) is not filled in by the operating room teams	Lack of coordination and collaboration Bloc - Sterilization	Standard handling of equipment at high risk of infection, such as prion risk equipment Wrong choice of the sterilization cycle and damage to the autoclaves
	D3: No inactivation procedure for prion risk	Pre-disinfection procedure not applied Lack of traceability of the pre-disinfection step Non-sensitized staff	Increased risk of staff contamination
	D4: Dirty, defective, poorly dried MDs	Lack of adequate tools and materials for prion risk management at the Operating theatre level	Bad influence on the quality of sterilization
Storting	**D5:** Confusion about the material	Non-compliance with the reception verification procedure Ignorance of MDs Work overload	Non -compliant operating tray at the time of the operation Organizational impact
		2- Cleaning / disinfection	
Taking up a position	**D6**: Non-compliance with regulatory requirements and protective measures	Non-compliance with the hygiene procedure Non-sensitized staff	Health of sterilization personnel compromised
Manual washing	**D7**: Non-compliance with the recommended dilutions for the use of detergents - disinfectants	Non-compliance with the manufacturer's instructions mentioned on the packaging of the detergent-disinfectant Non-compliance with the safety data sheets of the chemicals used	Poorly washed instrument Persistence of biological residues, traces of blood

Journal of Research in Pharmacy
Research Article

	D8: Non-compliance with the recommended immersion time (15min)	Non-compliance with the procedure for taking care of washing Non-sensitized staff Urgent need for the material	and dirt on the equipment Bad influence on the quality of sterilization
	D9: Poorly applied or ineffective manual brushing	Absence of brushes suitable for any type of material	
	D10: Complicated washing of reusable piping	Non-sensitized staff Lack of adequate equipment	
	D11: Forgetting to disinfect the workstation	Non-compliance with the rules of hygiene of the premises	Health of sterilization personnel compromised
Manual rinsing	**D12**: The final rinsing is carried out without resorting to osmosed or demineralized water	Maintenance problem	Instrument damage Bad influence on the quality of sterilization
		3- <u>Recomposition</u>	
Taking up a position	**D13**: Contamination of the clean area by the staff	Non-compliance with basic hygiene and clothing required when passing through a controlled atmosphere zone "CAC zone" (Improper hand washing, wearing jewelry ...)	Potential contamination of the clean area and clean equipment Bad influence on the sterilization quality
Identification of the boxes (lid, tank, basket)	**D14**: Mixing of boxes (content - container error)	Forgetfulness Non-sensitized staff Non-compliance with recomposition procedure	Operating tray not compliant at the time of the operation
	D15: Overload of the Containers	Insufficient number of containers	Staff injury Organizational impact
Windin g in Functio n of	**D16**: No recomposition listings	Non-compliance with the recommendations of the container weight limit	Organizational impact
		4- <u>Packaging</u>	
Taking up a position	**D17**: Non-compliance with regulatory outfits	Forgetfulness Non-sensitized staff Non-compliance with the hygiene procedure	Potential contamination of the clean area and clean equipment Bad influence on the quality of sterilization Health of sterilization personnel compromised
	D18: Absence of overpressure, Absence of SAS systems	Maintenance problem	
	D19: Delay in the packaging of MDs (risk of recontamination)	Non-sensitized staff Work overload	
	D20: Presence of sewers inside the area that emits odors	Poor design of the premises	
Folding	**D21**: Unsuitable folding (risk of perforation,	Non-compliance with the packaging procedure	Permeable packaging, non-compliant

	tears or other anomalies of the packaging device	Non-sensitized staff Work overload	
Thermo welding	**D22**: No control of the sealing (risk of an unsuitable closure) of the packaging device	Non-sensitized staff Non-compliance with the packaging procedure	Deterioration of the packaging (which will no longer play its protective role of sterility) Delay in the release of sterile fillers
	D23: Forgetting to affix a traceability label for packaged instruments	Forgetfulness Defective printer Labels out of stock	Hardware confusion Organizational impact
		5- Sterilization	
Taking up a position	**D24**: Non-compliance with the regulatory outfits **D25**: Absence of overpressure, Absence of SAS Systems	Non-sensitized staff Out of stock of Personal Protective Equipment (PPE) Maintenance problems	Potential contamination of the clean area and clean equipment Bad influence on the quality of sterilization
	D26: Poorly installed low temperature sterilizer	Unused due to the absence of consumables (cartridges)	
	D27: Inappropriate choice of the sterilization cycle (risk of damage to surgical instruments)	Poorly trained staff	Damage to instruments requiring passage through the sterilizer at low temperature
	D28: Forgot to set up the physico-chemical indicators (integrators) simultaneously with the load to be sterilized	Forgetfulness Non-sensitized staff	Delay in the release of sterile fillers
Unloading of autoclaves	**D29**: Non-compliance with hygiene rules	Non-compliance with the autoclave unloading procedure Non-sensitized staff	Bad influence on the quality of sterilization
		6- Storage /distribution	
Storage of Sterile MDS	**D30**: Technical installation inside the storage area	Lack of design of the premises	Bad influence on the quality sterilization Potential contamination of the sterile area and the RMDs

Distribution of sterile MDS	**D31**: Absence of a documented storage procedure (classification, location, handling conditions, staff safety)	Quality management system being implemented	Ignorance of the stock Bad influence on the quality of sterilization
	D32: Risk of release of an expired MD	Lack of a traceability label Non-compliance with storage deadlines (absence of dating of sterile MD)	Issuance of expired medical devices Bad influence on the quality of sterilization
	D33: Distribution of the sterilized charge by the sterilization agent	Lack of staff Work overload Non-professional staff	
	D34: Improper arrangement of the bags in the baskets	Inattention of the staff Work overload Poorly trained staff	Risk of crushing the packages Delay in delivery of sterile RMDs
	D35 : Freight Elevator cleanliness	Absence of a lift cleaning and maintenance procedure	Bad influence on the quality of sterilization
		7- Traceability	
Taking up a position process	**D36:** Lack of traceability by Instrument	Poor transmission of information between the Blocks and Sterilization	Organizational impact
	D37 : Input error	Inattention of the staff Non-sensitized staff	

The quantitative analysis made it possible to evaluate 3 criticality levels divided into 20 failure modes of minor criticality order (acceptable), 13 failure modes of medium criticality order (tolerable under control) and 4 failure modes are considered major (unacceptable). The distribution of risks in the sterilization circuit according to the sum of criticalities can be seen in Figure 1 (Table 2).

Table 2. Percentage of failure modes identified by process

RDM reprocessing process	Number of failure modes
Reception / Sorting	5 (13,6 %)
Cleaning / Disinfection	7 (18,9 %)
Recomposition	4 (10,8 %)
Packaging	7 (18,9 %)
Sterilization	6 (16,2 %)
Storage / Distribution	6 (16,2 %)
Traceability	2 (5,4 %)

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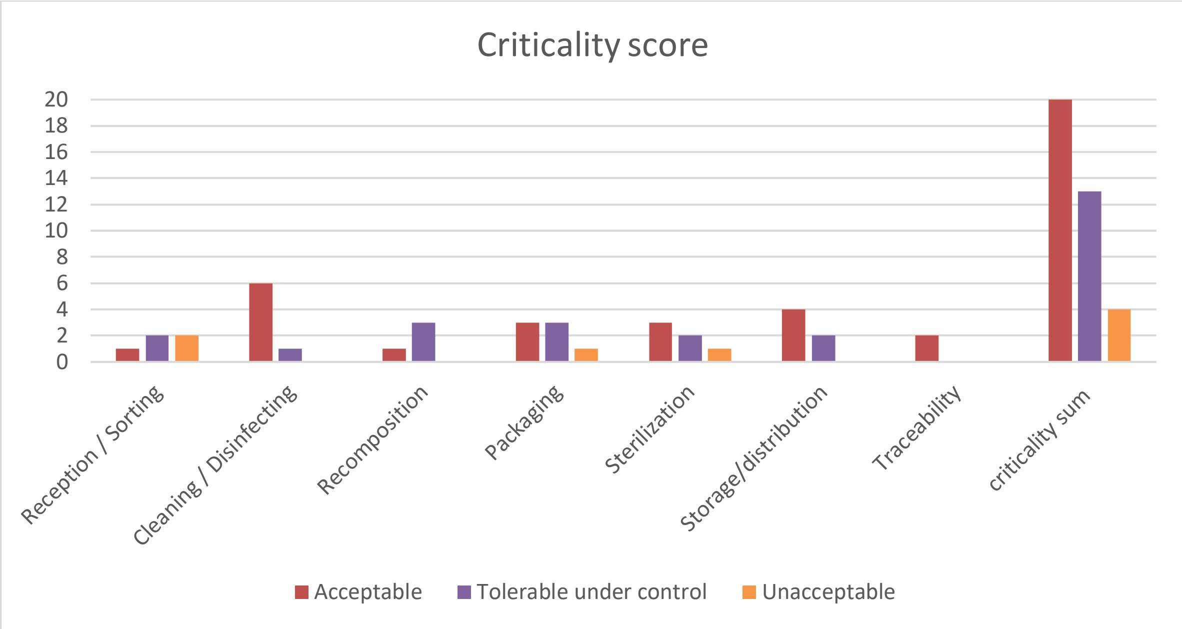

Figure 1. Graphical distribution of the sum of the criticality scores by stage of the circuit

The stages of cleaning/disinfection and conditioning lead to the greatest number of failures while the riskiest process is the recomposition with 2 unacceptable risks identified. The criticality sum underlines the importance of implementing preventive measures from the first phases of the process, which will lead to a reduction in the criticality sum for the stages preceding the intervention. The FMEA table above reveals the results of the qualitative and quantitative risk analysis by assigning ratings according to the three scales: Severity, Frequency and Detectability (Table 3).

Table 3. Failure Mode, Effects and Criticality Analysis (FMEA) table of risk analysis results for each stage of the HSR sterilization unit.

Elementary process	Tasks	Description of failure modes	Risk typology	F	G	D	Criticality
Reception / Sorting	Taking up a position	D1: Non-compliance with protective measures	OHS risk	8	4	4	128
		D2: The Sterilization Block link sheet (Instrument shuttle sheet) is not filled in by the operating room teams	OHS risk	10	4	4	160
	Verification	D3: No inactivation procedure for prion risk	OHS risk	10	8	4	320
		D4: Dirty, defective, poorly dried MDs	OHS risk	10	8	4	320
	SORTING	D5: Confusion about the material	Professional risk	4	1	4	16
Cleaning / Disinfection	Taking up a position	D6: Non-compliance with regulatory requirements and protective measures	OHS risk	8	4	4	128
	Manual cleaning	D7: Non-compliance with the recommended dilutions for the use of detergents-disinfectants	Professional risk	4	1	8	32

		D8: Non-compliance with the recommended immersion time (15min)	OHS risk	4	4	4	64
		D9: Poorly applied or ineffective manual brushing	OHS risk	4	4	4	64
		D10: Complicated washing of reusable piping	OHS risk	4	4	4	64
		D11: Forgetting to disinfect the workstation	OHS risk	4	4	4	64
	Manual rinsing	D12: The final rinsing is carried out without resorting to osmosed or demineralized water	OHS risk	4	4	4	64
Recomposition	Taking up a position	D13: Contamination of the clean area by the staff	OHS risk	4	8	4	128
	Identification of the boxes (lid, tank, basket)	D14: Mixing of boxes (content - container error)	Professional risk	4	4	4	64
		D15: Overload of the containers	Professional risk	8	4	4	128
	Reassembly according to the listings	D16 : No recomposition listings	Professional risk	8	4	4	128
Packaging	Taking up a position	D17: Non-compliance with regulatory outfits	OHS risk	10	8	4	64
		D18: Absence of overpressure, Absence of SAS systems	OHS risk	10	8	4	320
		D19: Delay in the packaging of MDs (risk of recontamination)	OHS risk	8	4	4	128
		D20: Presence of sewers inside the area that emits odors	OHS risk & Professional risk	4	8	4	128
	Folding	D21: Unsuitable folding (risk of perforation, tears or other anomalies of the packaging devices)	OHS risk & Professional risk	4	4	4	64
	Heat Sealing	D22: No control of the sealing (risk of an unsuitable closure) of the packaging device	OHS risk	4	4	4	64
		D23: Forgetting to affix a traceability label for packaged instruments	Professional risk	8	4	4	128
Sterilization	Taking up a position	D24: Non-compliance with regulatory requirements	OHS risk & Professional risk	4	4	4	64
		D25: Absence of overpressure, Absence of SAS Systems	OHS risk & Professional risk	10	8	4	320
	Loading of the autoclaves (autoclaving)	D26: Poorly installed low temperature sterilizer	OHS risk & Professional risk	8	4	4	128
		D27: Inappropriate choice of the sterilization cycle (risk of damage to surgical instruments)	Professional risk	4	4	8	128

	Unloading of autoclaves	D28: Forgot to set up the physico-chemical indicators (integrators) simultaneously with the load to be sterilized	OHS risk	1	8	8	64
		D29: Non-compliance with hygiene rules	OHS risk	4	4	4	64
Storage / Distribution	Storage of sterile medical devices	D30: Technical installation inside the storage area	OHS risk	4	4	4	64
		D31: Absence of a documented storage procedure (classification, location, handling conditions, staff safety)	OHS risk	8	1	4	32
	Distribution of sterile medical devices	D32: Risk of release of an expired MD	Professional risk	1	4	4	16
		D33: Distribution of the sterilized charge by the sterilization agent	Professional risk	4	4	4	64
		D34: Incorrect arrangement of the bags in the baskets	OHS risk	4	4	8	128
		D35: Freight Elevator cleanliness	Professional risk	8	4	4	128
Traceability	Taking up a position	D36: Lack of traceability by instrument	Professional risk	8	1	4	32
		D37: Input error	Professional risk	4	1	8	32

After criticality assessment, corrective measures were suggested for all unacceptable risks that could have a significant impact on patient safety and hospital staff. These improvement proposals will be reviewed and approved in the coming months by the pharmacist in charge and the members of the sterilization team (Table 4).

Table 4. Proposals for risk reduction actions with a corrective aim for all unacceptable risks

Elementary process	Tasks	Description of failure modes	Causes	Effects	Criticality	Propositions des mesures correctives
Reception / Sorting	Vérification	D3: No inactivation procedure for prion risk	Predisinfection procedure not applied Lack of traceability of the pre-disinfection step Non-sensitized staff	Standard handling of equipment at high risk of infection, such as prion risk equipment Wrong choice of the sterilization cycle and damage to the autoclaves	320	Make block management aware of the importance of the pre-disinfection stage, particularly regarding prion risk, in order to release budgets to carry out the necessary actions in the blocks Raise awareness and provide continuing education for the bloc's teams

				Increased risk of staff contamination		
		D4: Dirty, defective, poorly dried MDs	Lack of adequate tools and materials for prion risk management at the Operating theatre level	Bad influence on the quality of sterilization	320	Invite the person in charge to request the installation and commissioning of the materials and equipment necessary for prion risk management at the operating theatre level
Sterilization Packaging	Taking up a position	D18: Absence of overpressure , Absence of SAS systems	Maintenance problem	Potential contamination of the clean area and clean equipment	320	Installation and qualification of the appropriate overpressure equipment and airlock systems according to the regulations and good practices in force
		D25: Absence of overpressure , Absence of SAS Systems		Bad influence on the quality of sterilization	320	Acquisition of a system capable of integrating and recording pressure and temperature data and relative humidity

3. DISCUSSION

Following the identification of the risks by the application of the FMEA method, various risk reduction measures have been put in place. Corrective actions aimed at unacceptable risks are currently being processed and are being thoroughly analyzed due to their complexity. Among the unacceptable risks identified in our study, the Reception/Sorting sub-process highlighted two unacceptable risks of high criticality, in particular with regard to pre-disinfection in the operating theatres and the prion risk. The high criticality is attributed to insufficient pre-disinfection, resulting in the direct transfer of the material to sterilization without prior pre-disinfection. Improvement actions have been suggested, such as the implementation of continuous training for the block's teams and raising management's awareness of the importance of pre-disinfection to unlock the necessary budgets. In addition, discussions are underway on how collaboration and the communication of information between the operating theatre and the sterilization department could be optimized, in particular by considering the use of a shuttle card to check. Regarding the prion risk, the personnel in the washing area are exposed to a risk of injury when handling contaminated equipment, with a possibility of transmission of viruses. A reminder was made regarding the procedure to be followed in case of accidents of exposure to blood, highlighting the importance of interrupting tasks, disinfection, and medical consultation. In addition, the possibility of establishing a computer traceability of the pre-disinfection is envisaged, including a coding of the prion risk emanating from the operating theatre.

The working group, composed of the pharmacist in charge and the members of the sterilization team, was able to implement certain preventive measures taking into account the results obtained. For example, at the level of the cleaning/disinfection and conditioning sub-process phases, which have the greatest number of failure modes, a significant effort has been made to revise the operational procedures and instructions, with particular emphasis on the manual washing steps. These initiatives have resulted in an improvement in the quality of the sterilization of equipment, while strengthening compliance with regulatory standards. In addition, the risk associated with a hand hygiene defect, although difficult to detect, can lead to serious consequences for the patient. In order to minimize this type of human error, staff awareness-raising has been initiated to encourage them to respect the clothing standards and protective equipment imposed by the service. Communication remains an essential element in this process, constituting a key point to guarantee the compliance of the DMR and ensure the safety of the personnel [16,17].

The mapping table highlights the diversity of causes and consequences associated with each failure mode. It also reveals that several failure modes can be generated by the same cause, leading to the same consequences. However, neither the FMECA method nor the a priori approach can assess the criticality of a combination of several

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Research Article

failure modes. This is why a multi-disciplinary approach is necessary. The combined use of two complementary methods is essential to capture all risks and failures. An inductive or a posteriori analysis, such as the fault tree method based on declarations of non-conformity, enriches and optimizes the a priori approach by filling in any omissions or blind spots not taken into account.

4. CONCLUSION

The implementation of a risk management policy, with a view to obtaining ISO 9001 certification, has resulted in the development of a risk mapping specifically adapted to the sterilization service. This approach has also led to the implementation of risk reduction measures, aimed at improving the understanding of the different stages of the sterilization process, thus contributing to the reduction of the risks of nosocomial infections. Moreover, the involvement of the team, combined with theoretical and practical training, is an essential factor for the success of this initiative. However, this requires an additional pharmaceutical investment, while taking into account the socio-economic context of the University Hospital.

5. MATERIALS AND METHODS

A priori risk analysis was carried out from September to December 2023 within the central sterilization unit of the Hospital of Specialties in Rabat (HSR). The methodology will be based on the FMEA method (analysis of failure modes, their effects and their criticality), following the following steps [18–20]**:**

- Modeling of the steps of the process concerned by the analysis,
- Qualitative analysis,
- Quantitative analysis,
- Proposals for risk reduction actions.

The modeling of the stages of the process of sterilization of RMDs is based on a process approach, which organizes the activities into three large groups (Figure 2) [21]:

- Operational process: it is the sterilization process describing all the operations and controls carried out from the reception of the contaminated material to the delivery of the sterile material
- Support Process: It contributes to the proper functioning of the operational process by providing the necessary resources and conditions.
- Management Process: It brings together the administration's policy and management activities.

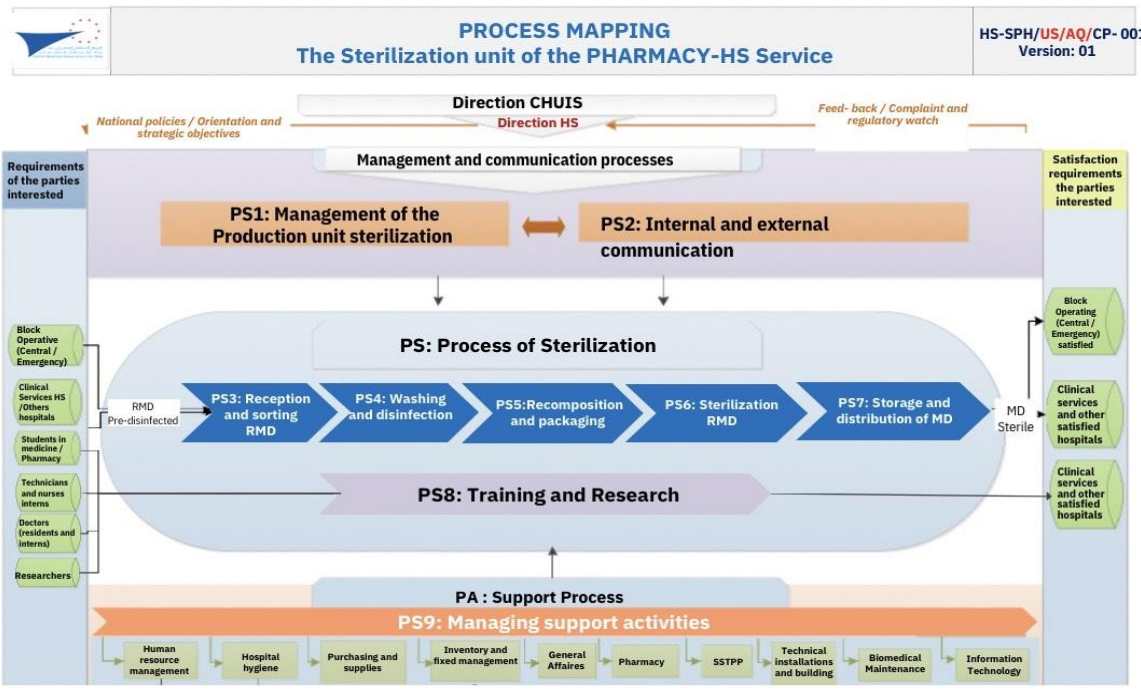

Figure 2. Process mapping of the HSR sterilization unit

Each process offers an organized and harmonized perspective of the activities within the sterilization unit, including the flows and the different relationships between products and services, allowing effective management, continuous improvement and adaptation to QMS quality standards [22].

The qualitative analysis enabled the identification of probable failure modes based on a brainstorming exercise designed to draw up an exhaustive list of all possible failure modes based on the process steps concerned and to find possible causes and effects. Brainstorming involves the participation of all staff, taking into account aspects related to staff safety (OHS risk: Occupational Health and Safety) and the effectiveness of the process (professional risk) [23].

The quantitative analysis is based on the calculation, for each of the probable failure modes identified previously, of a criticality score based on the severity of the resulting effects (severity), its probability of occurrence (frequency of occurrence), and its detectability [24,25].

The criticality score is calculated after having manually collected the data for each sub-process in a register, then transposed this information on an Excel® table.

The objective of FMEA is to look for all the ways a process or product can fail. Ways in which a process can fail are called failure modes. Each failure mode has a potential effect and each potential effect has a relative risk associated with it. The relative risk of failure and its effects is determined by three factors:

- Severity – The consequence of the failure.
- Frequency - The probability of the failure occurring.
- Detection – The probability of the failure being detected before the impact of the effect is realized.

Each factor is given a score of 1 – 10 (1 = low, 10 = high). A risk priority number (RPN) is determined by multiplying the rating for the three factors (severity x frequency x detection).

The determination of the rating scales and the criteria for accepting the risks related to the failure modes (FM) are detailed in the tables below (table 5, table 6, table 7 and table 8) [26,27].

Table 5. Gravity scale for a FM

Rating	Risk category
1	Minor effects
4	Significant effects
8	Critical effects
10	Catastrophic effects

Table 6. Detectability scale for a FM

Rating	Risk category
1	Systematically detectable
4	Moderate detection
8	Weak detection
10	Undetectable

Table 7. Frequency scale for a FM

Rating	Risk category
1	Unlikely
4	Quite Likely
8	Probable
10	Common

Table 8. Criticality scale for a FM

Rating	Risk category	Decision on the acceptability of risks
1 to 90	Acceptable	No action is required
90 to 160	Tolerable under control	Risk reduction actions are proposed to reduce the risk to a reasonably acceptable

170 to 600	Unacceptable	Risk reduction actions are necessary to be implemented immediately

The risk priority number is used to rank the need for corrective actions to eliminate or reduce potential failure modes. Failure modes with the highest RPNs should be attended to first. Once corrective actions have been taken, a new PRN is determined by reevaluating the severity, frequency and detection ratings. The new RPN is called the resulting RPN. Improvement and corrective actions must continue until the resulting PRN is at an acceptable level for all potential failure modes (Table 9, Table 10 and Table 11) [28].

Table 9. Detectability Criteria for FMEA

Score	Category	Criteria
10	Undetectable	Cannot be detected during the relevant process steps
8	Weak detection	Difficult to detect during the relevant process steps
4	Moderate detection	Possible but not always detected during the relevant process steps
1	Weak detection	Quite easily detected during the relevant process steps

Table 10. Frequency Criteria for FMEA

Score	Category	Criteria
10	Common	Daily
8	Probable	Once a week
4	Rare	Once a quarter
1	Unlikely	Once a year

Table 11. Severity Criteria for FMEA

Score	Category	Quality/Regulation	Personal/patient safety
10	Catastrophic	Significant impact on quality that may lead a health authority to suspend the sterilization activity Non-compliance with the quality specifications of the sterile RMD	The effects can have serious consequences on the health of the patient and medical staff
8	Criticism	The effects can lead to serious/critical regulatory observations	Effects can have a significant impact on the health of the patient and medical staff
4	Significant	The effects may give rise to minor observations or recommendations in terms of regulatory inspections, without impact on the quality of the sterile RMD	The user feels the effects, which can make it difficult to use the RMD
1	Minor	No impact on the quality of the sterile RMD	The effects will have a negligible impact, if any effect on the health of the patient and medical staff

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