ORIGINAL ARTICLE

Risk analysis applied to the sterilization process in a public health hospital center: Use of the "FMECA" method

Analyse de risques appliquée au processus de stérilisation dans un centre hospitalier de santé publique : Utilisation de la méthode « AMDEC »

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Abstract

Introduction: The sterilization of reusable medical devices in healthcare establishments is an activity of enormous importance in the quality and safety of medical procedures. The methods of risk analysis are the means that will put into exercise the critical points of this process.
Objective: To identify by brainstorming the different failure modes, to prioritize by considering the average criticality indices, each step of this process, and to lead to the proposal of preventive and corrective operational actions.
Methods: To upgrade the sterilization circuit, an a priori risk analysis according to the Failure Modes, Effects and Criticality Analysis (FMECA) method was carried out.
Results: The application of the FMECA method made it possible to identify 135 of failure modes, and to classify, in descending order, the stages of the process, according to the average criticality index. The validation/storage stage was the most critical, followed by personnel, the packaging stage.
Conclusion: Within a hospital establishment, the implementation of a risk analysis tool for the sterilization process of reusable medical devices will ensure the safety of the patient and the staff.

Key words : Sterilization, Patient Safety, Risk Management

Résumé

Introduction : La stérilisation des dispositifs médicaux réutilisables dans les établissements de santé, est une activité dotée d'une énorme importance dans la qualité et la sécurité des actes médicaux. Les méthodes d'analyse des risques sont les moyens qui mettront en exerce les points critiques de ce processus.
Objectif : Identifier par un brainstorming les différents modes de défaillances et hiérarchiser en considérant les indices de criticité moyen, chaque étape de ce processus, pour conduire à la proposition d'actions opérationnelles préventives et correctives.
Méthodes : Pour une mise à niveau du circuit de stérilisation, une analyse des risques a priori selon la méthode d'analyse des modes de défaillance, de leurs effets et de leur criticité (AMDEC) a été réalisée.
Résultats : L'application de la méthode AMDEC a permis d'identifier 135 modes de défaillances, et de classer dans l'ordre décroissant, les étapes du processus, selon l'indice de criticité moyen. L'étape de validation /stockage était la plus critique, suivi du personnel, de l'étape de conditionnement.
Conclusion : Au sein d'un établissement hospitalier, la mise en place d'un outil d'analyse de risque, au niveau du processus de stérilisation des dispositifs médicaux réutilisables, permettra d'assurer la sécurité du malade et du personnel.

Mots clés: Stérilisation, Sécurité des patients, Gestion des risques

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Introduction

Preventing nosocomial infections is a major objective for healthcare systems [1]. Sterilization of medical devices (MD) is a central process in reducing the risk of using heat-sensitive reusable MDs. This risk is estimated at 7% for hospitalized patients in developed countries and 10% in developing countries [2]. Requirements for sterilization of MDs in health establishments have intensified in recent years, as nosocomial infections are the leading cause of avoidable deaths among hospitalized patients [3]. Risk management is now integral and essential to quality management in hospitals. Risk analysis enables a dual approach: reducing potential risks and establishing safety barriers that allow sterilization units to perform their functions safely [4]. In Tunisia, most hospitals treat their reusable medical devices in the operating room. Nowadays, the centralization of processing operations for medical-surgical devices is standard on an international scale, ensuring expense control and quality of sterilized MDs [5]. However, the hospital-university Charles Nicolle follows a pavilion model of construction, making centralization of sterilization challenging. Due to several factors, the sterilization process may be insufficient. This work aims to analyze the risks associated with sterilization activity at Charles Nicolle Hospital using the Failure Modes, Effects, and Criticality Analysis (FMECA) method.

Methods

Study period and location

This study was conducted at the Charles Nicolle Teaching Hospital of Tunis at the end of March 2019 in the context of the PACS project (Health Competitiveness Assistance Project) based on the reports of the audits carried out by the National Agency for Sanitary and Environmental Control of Products (ANCSEP).

Study execution

Project initiation

The initiation of the FMECA method aims to define the relevant research questions and to assess the knowledge of the participants on the analysis portal.

Steps

The FMECA method included six steps: composition of the working group, cartography of the analyzed process, identification of potential failure modes (FM), their causes and effects, rating of FMs, after prioritization, and finally implementation of preventive/ corrective actions to minimize the risk of process failure.

Working groups

The first step is the composition of the working group. It is a question of making a diversified multidisciplinary team of professionals involved in the sterilization process. One person in the group will act as a facilitator. Its role is to lead and guide discussions, plan meetings and ensure the proper application of the methodology [6]. The multidisciplinary working group was based on the MD processing committee, composed of 16 members and a few other guests. These were subdivided into 9 subgroups. The composition is diverse to target the essential departments for the proper functioning of sterilization, which are: the pharmacy, the maintenance department, the hygiene department, the care management department, the auxiliary services, the store, and the surgery centers (operating theaters).

Process cartography

The second step, the cartography of the process: Is a graphic representation of the cartography of the pre-disinfection, the packaging, and the sterilization itself, was made using the PowerPoint software to trace all the stages, themselves divided into actions.

Failure modes assessment

The third step, identification of potential FMs, their causes and effects: It is a qualitative study that consists of identifying all the potential failures by specifying how the planned operations could be badly or not carried out [7], it also boils down to identifying the effects relating to each mode of failure, and the most probable causes. An FMECA matrix will be used as a discussion support for the working group to gather all their ideas.

From the defined stages of the process, we directly looked for the FMs, by collective brainstorming, to generate the maximum number of possible ideas, by answering the question: "What could go wrong during each stage of the sterilization process?" [8]. A participant does not have to witness the occurrence of an FM to include it. For each FM, there can be one or more causes.

Failure modes criticality scoring

The fourth step, rating of FMs: Criticality assessment (quantitative study), consists of calculating the criticality index (CI) of the potential failures studied, to target the priority actions to reduce or eliminate the risk, or to plan actions to react to the non-eliminable risk [9]. The risk quantification is done using a rating scale with three parameters: severity, occurrence, and detectability [10]. A consensual rating based on voting, of the occurrence, the severity, and the detectability of each FM, is done according to the already pre-established rating scale (Table 1)[11]. The voting methodology considered the justification or even a re-rating in case of divergence of opinions of the various members of the committee.

These three rating indices have been defined for each of the identified risks, allowing its CI to be calculated (CI = severity × occurrence × detectability) [8]. This index, ranging from 1 to 81, makes it possible to draw histograms and cumulative diagrams of the risk, identify a limit criticality threshold, prioritize the various failures, and plan corrective actions. and preventive, starting with those with the highest criticality [12,13].

Table 1. Failure mode rating grid

Detectability	
Note	**Criteria**
1	The system automatically detects the anomaly (continued) (10/10)
2	The system automatically detects the anomaly (discontinuous) (9/10)
3	The system still detects the (human) anomaly (8/10)
4	The system often detects the anomaly (7/10)
5	The system sometimes detects the anomaly (6/10)
6	The system can detect the anomaly (5/10)
7	Difficult detection before reaching the patient/medical device/personnel (2-3/10)
8	Difficult detection before reaching the patient/ medical device/ personnel (1/10)
9	Impossible to detect before reaching the patient/ medical device/ personnel (0/10)
Severity	
Note	**Criteria**
1	Benign event
2	May slightly affect the system
3	May moderately affect the system
4	May affect the patient
5	Major system problem
6	Can seriously affect the patient
7	Minor patient impairment
8	Major impairment of the patient
9	Fatal patient injury
Occurrence	
Note	**Criteria**
1	Occurrence unlikely (1/10000 occurrences)
2	Occurrence unknown (1/7000)
3	Occurrence unknown (1/5000)
4	Occurrence unknown (1/1000)
5	Possible occurrence but data not available (1/500)
6	Very possible occurrence but data not available (1/200)
7	Infrequent but documented occurrence (1/100)
8	Frequent and documented occurrence (1/50)
9	Very frequent and documented occurrence (1/20)
10	Almost certain (1/10) and documented occurrence

Failure modes prioritization

After analyzing all the FMs and their respective ratings, particular attention was given to the extreme ratings obtained within the process. The risks are ranked according to the criticality scale, into three categories in descending order: critical risks (to be dealt with as a priority), risks to be controlled, and acceptable risks [14]. The hypothetic-deductive method was applied to prioritize the FMs of the sterilization process from the most critical to the least critical, using two tools: Pareto's law if the CI is found to be normally distributed, and the mean-mode indices, if not. The SPSS software was used to determine criticality thresholds.

Preventive and corrective actions

For the final step, step 6, implementation of preventive/corrective actions: After the classification of the different potential FMs, the members of the working group were called upon to formulate the corrective measures, which will be achievable within a given period, taking into account their technical, financial and human feasibility. Only the actions to be controlled or critical will be subject to corrective actions. The nine working sub-groups will propose preventive/corrective actions by mentioning the following terms and deadlines: short (1 year), medium (5 years), and long (10 years). Once the actions are applied, a follow-up program and a reassessment according to the FMECA method will be renewed to evaluate the effectiveness of these actions, to identify new FMs, and to determine the residual risk (comparison before – after).

Results

Composition of the working group

This working group is made up of a pharmacist, a representative of General Manager, a manager of the Management Care Department, a manager of the Biomedical Maintenance Service, a manager of the Building and Equipment Maintenance Service, a hygienist, a dentist, a gastroenterologist, a pulmonologist, a representative of the ear, nose, and throat (ENT) endoscopy unit, a gynecologist, a surgeon, a representative of the operating room supervisors, two managers of the reusable MD processing unit, a store representative, and a few guests (a pharmacy intern, 2 pharmacy externs, 3 members of the maintenance department, a member of the hygiene department, a member of the maxillofacial department, and finally another guest from the ENT department).

Since the process of sterilization of reusable MDs is complex and includes several steps and sub-steps, the breakdown of this working group into several sub-groups, one group per domain, proved necessary.

Nine groups have been created, one group per area of the sterilization process, which are: pre-disinfection, cleaning, packaging, validation/storage, premises, equipment, hygiene, staff, and documentary system. A total of five 90 minutes-meetings were concluded per group.

Failure modes analysis: identification of potential failure modes, their causes and effects

A total of 135 failure modes were determined by this analysis. They were distributed as follows: pre-disinfection (15), cleaning (13), packaging (16), validation/storage (21), Premises (12), equipment (9), hygiene (33), staff (6), and documentary system (10).

Rating of failure modes according to their criticality

The overall criticality index of our process was 17790 with an average CI of 132 (Table 2).

Table 2. Representation of the final results of the FMECA study

	N	C	%	ACI
Pre disinfection	15	1891	11	127
Cleaning	13	1492	8	115
Packaging	16	2339	13	147
Validation/Storage	21	3555	20	170
Documentary system	10	1296	7	130
Hygiene	33	3688	21	112
Staff	6	910	5	152
Equipment	9	966	5	108
Premises	12	1653	9	138
Sterilization (total)	135	17790	100	BMI: 132

N: number of failures, **C**: sum of criticalities per stage, **%**: percentage of total criticality, **ACI**: average criticality index

Prioritization

To prioritize the FMs, and given that the ratings are close, Pareto's law, which consists of finding 20% of the failures that are responsible for 80% of the total criticality, is not applicable. Thus, the average index method was chosen. From all the results, a histogram and an IPR accumulation curve were constructed to help determine criticality thresholds to set priority actions. But in our case, we adopted the two-threshold approach because the distribution of the criticality indices has two peaks, the median was 135 and the mode was 90. Thus, the failures of the stages of the sterilization process having CI values greater than or equal to 135 will be considered critical failures, the values between 90 and 135, are failures to be controlled, and the values less than 90, are acceptable failures.

A total of 68 FMs are critical, accumulating 67% of the overall criticality, 39 to control accumulating (22%) and 28 acceptable presenting (11%).

There is a majority of critical failures followed by the one to be controlled and finally the acceptable errors.

Sixty-eight risks were identified as a priority, critical (CI≥ 135) of which sixteen concerned the validation/storage stage, eleven related to hygiene, ten related to the packaging stage, eight related to hygiene, six related to the documentary system, and six other staff, five related to the cleaning stage, four related to the pre-disinfection, and the last two concerned equipment. These FMs require immediate correction (table 3).

To analyze these results in more detail, table 3 makes it possible to note the various failures of the stages of the sterilization circuit by classifying them into critical errors, to be checked and acceptable.

The following histogram will make it possible to distribute the failures (acceptable, to be checked, and critical) for each stage of the sterilization process (Figure 1).

Table 3. Prioritization of failures by stage of the sterilization process

	Acceptable	To be controlled	Critical	**Total**
Pre disinfection	3	8	4	15
Cleaning	3	5	5	13
Packaging	3	3	10	16
Validation/Storage	2	3	16	21
Documentary system	1	3	6	10
Hygiene	14	8	11	33
Staff	0	0	6	6
Equipment	2	5	2	9
Premises	0	4	8	12
Total	28	39	68	135

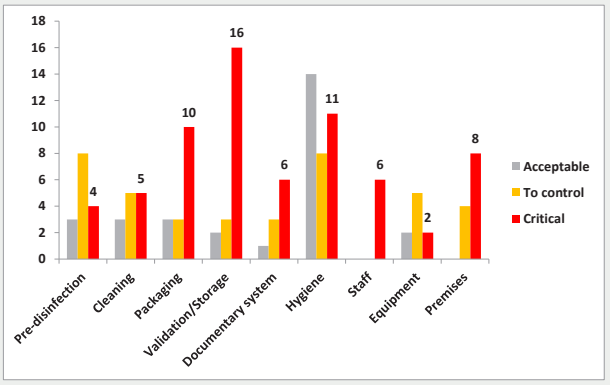

Figure 1. Histogram of the distribution of failures by circuit stages

Following the application of the analysis of failures and their effects on the sterilization process, the twenty most critical failures, having the highest criticality indices will be identified in this table 4 in descending order (table 4).

Implementation of preventive/ corrective actions

The working subgroups will propose, considering the classification of failures, preventive and corrective actions, mentioning the terms and deadlines. These corrective actions will affect the following three axes by considering the feasibility parameter:

- The documentary system which includes the quality manual, procedures, operating modes, job descriptions, posters, instructions, and the sterilization file.
- The training cycles for staff including the training material which has been validated at the level of the CHU Bizerte.
- The estimate needs for the different sterilization units in reusable accessories (trays, brushes, swabs…), and consumables (integrator, adhesive tape, Bowie & Dick test...). After this estimate, a call for tenders is launched to supply these needs.

Table 4. Top 20 most critical failure modes

Sterilization area	Stages / sub-components	Failure modes	Causes	Effects	Means of detection	D	G	F	VS
Validation/ Storage	Check the sterilizer	**1/**Inefficient autoclave	Unqualified autoclave	Sterility is not assured	Consultation of the qualification document	6	8	6	288
	Unload the autoclave	**2/**Damaged packaging	Untrained staff	Sterility is not assured	Checking the integrity of the packaging on unloading	5	8	7	280
Packaging	Close the packaging	**3/**Damaged containers not ensuring closure	Lack of means	Faulty sterilization	Regular container checks	5	7	7	245
Pre-disinfection	Prepare the pre-disinfection tray	**4/**Inadequate solution concentration	Absence of graduated containers Faulty pumping system	If the concentration in the tank is low: sterilization will be defective high: the material will be damaged and the consumption of the disinfectant (enzymax®) will be doubled	Regular control	6	5	8	240
Validation/ Storage	Check the sterilizer	**5/**Bowie-Dick test not done	Bowie-Dick test not available Unaware / trained staff/negligence	Unverified steam penetration quality	traceability register (document consultation)	4	6	10	240
Validation/ Storage	Store Units	**6/**Non-compliant storage duration	Storage time not determined No expiry date tracking Untrained staff	Sterility not assured	Label consultation	5	6	8	240
Hygiene	Bio-cleaning	**7/**frequency not appropriate	Negligence and lack of staff training	Sterility of MDs is not assured	Observation and control of personnel	6	4	10	240
Pre-disinfection	Inject and aspirate the pre-disinfectant solution into the tubing of the hollow MDs	**8/**Not treating hollow MDs properly	The number of staff is reduced Staff rush	Sterilization is unreliable	Observation and regular monitoring of staff	7	4	8	224
Validation/ Storage	Unload the autoclave	**9/**Wet packaging	Untrained staff	Sterility not assured	Examination of the dryness of the load and recording on the sterilization file	4	8	7	224
	Start the sterilizer	**10/** Inappropriate cycle		MD alteration Ineffective treatment	MD damage sterilization record	5	6	7	210
Hygiene	Microbiological sampling/ surfaces	**11/**sample not taken	Untrained staff	Sterility of MDs is not assured	Traceability of each microbiological sample	4	5	10	200
		12/Incorrect rhythm	Untrained staff	Sterility of MDs is not assured	Traceability of each microbiological sample	4	5	10	200
Packaging	Close the packaging	**13/**Unsealed container	Negligence and lack of knowledge of staff	faulty sterilization	Regular container checks	4	7	7	196
	Group the MDs and proceed to the composition	**14/**Quantitatively / qualitatively incorrect composition	The staff is not trained enough	waste of time gene for medical and surgical activity	Observation and control of personnel	4	6	8	192
Packaging	Put into sterile packaging system	**15/**Filter not changed	Lack of means Lack of staff knowledge	faulty sterilization	Regular control of packaging systems	4	6	8	192
		16/Unsuitable folding	lack of staff knowledge			4	6	8	192
		17/Unclean containers				4	6	8	192
Validation/ storage	Load the autoclave	**18/**Damaged packaging	Non-compliant packaging Improper packaging technique Aggressive MD handling	Sterile status will no longer be guaranteed	Visual inspection of the packaging during loading	4	8	6	192
	Unload the autoclave	**19/**Unverified integrators	Lack of integrators Untrained staff	Unverified sterility	Traceability register (document consultation)	4	6	8	192
	Position integrators	**20/**Integrators not set	Unavailability of passage indicator Untrained staff	Sterility not guaranteed	Sterilization file (document consultation)	3	6	10	180

Discussion

Using the FMECA method, the working group identified the most critical failures in the sterilization process and ranked them in descending order according to the average CI. Understanding the causes and effects of these failures also enabled the proposal of corrective measures to better control the associated risks.

The overall analysis of the various results indicates that the stages leading to the most failures are the validation/storage stage, followed by hygiene. These are also the stages with the highest number of critical failures that can lead to significant consequences for patient safety.

Indeed, most failures were related to hygiene; however, the validation/storage stage showed a predominance of acceptable failures, resulting in a lower number of FMs but a higher number of critical FMs, indicating that this stage is at greater risk than hygiene.

The main dangerous situations inherent in the validation/storage stage, which was identified as the riskiest, mainly involved the loading of the autoclave (lightly loaded autoclave, single-door autoclave, uneven load, damaged packaging) and unloading (load not yet cooled, damaged packaging). There were also failures concerning the storage of the units (duration and condition of non-compliant storage).

More than half of these failures were considered critical, with a CI ≥135. Therefore, the majority of these errors were prioritized and required effective and quickly feasible improvement work to remedy the identified problems.

The analysis of the causes of these FMs revealed that most errors stemmed from negligence and poor knowledge among personnel, a lack of staff, architectural issues within the sterilization units, a lack of organization, the absence of a quality system, or the unavailability of consumables.

After identifying and prioritizing the failures, this approach led to corrective action plans that targeted three areas: the documentation system, staff training, and the needs of sterilization units.

These actions must consider feasibility in terms of the effort necessary for their implementation, as well as the human, financial, and material resources required [15]. For ideas related to staff training, we can refer to the study conducted in the sterilization units at the Valence Hospital in France, which created a card game as a teaching tool that enables sterilization workers to acquire or consolidate knowledge [16]. Generally, in our study, errors related to poorly trained personnel are FMs with a relatively high CI; however, those related to the documentary system usually involve failures that can be controlled with lower criticality indices.

The proposed risk reduction actions would eliminate critical failures while increasing the percentage of risks to be controlled and acceptable risks. Our corrective preventive action plan will target the nine stages of the sterilization process; however, the study conducted at the Valence Hospital in France will focus only on five stages: cleaning, packaging, loading the sterilizer, unloading the sterilizer, and distribution of MDs [17]. The identification and assessment of risks have shown the complexity and inter-disciplinarity of the sterilization process for reusable MDs at the Charles Nicolle Hospital, which occurs in a decentralized organizational system across nine stages. In C. Hamel's study, he opted for a different method of risk management. Indeed, nonconformities of reusable MDs, along with their consequences and the types of corrective actions to be taken, are reported by the operating room via paper material monitoring sheets. The objective of this work was to create a new communication tool between the operating room and the sterilization unit by integrating shared management of non-conformities into the sterilization business software for computerized management. This integration will allow better utilization of declarations, and for a genuine continuous improvement approach, this tool will be combined with monthly meetings between the theater and the sterilization unit to ensure that corrective actions are well-targeted [18].

Regarding the benefits and strengths provided by the FMECA method, these include continuous improvement management through action plans with regular updates, reduced loss costs, and improved communication. In effect, it fosters a multidisciplinary and dynamic collaboration among the various parties involved in the process across different services [12]. However, the main limitation of this study is the subjectivity in scoring each risk. To minimize judgment bias, we utilize explicit and clear criteria [8]. Another consideration for this approach is its implementation, which can be cumbersome due to the number of individuals involved and the time required [12].

Along with these organizational limitations, this method also presents technical and practical constraints. Indeed, the FMECA matrix revealed that a single FM can have multiple causes and effects, and multiple FMs can share the same cause and effect. However, it is impossible to evaluate the combination of several FMs in terms of criticality [2].

Conclusion

In this study, a risk analysis was conducted to review the sterilization process in a teaching hospital. Serving as a pavilion model, where the process is not centralized, the sterilization process was found to be critical. The main areas of concern regarding the process are validation, hygiene, and packaging. Urgent actions were taken, including implementing a documentary system, acquiring certain validation consumables, and providing continuous training for the team.

Following this work, further actions must be taken to implement adjustments by focusing on the new points to be controlled and critically identified, with the aim of improving the management of medical devices and thereby reducing the risks of nosocomial infection.

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