ORIGINAL ARTICLE

Infectious Risk in the Sterilization Process for Reusable Medical Devices: Preliminary Risk Analysis

Zoubida Khomsi, Safaa El Marnissi, Jaouad El Harti

Laboratory of Central Sterilization, Ibn Sina Hospital, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco

Abstract

Background: Patient safety is an area of health care that has emerged with the increasing complexity of health-care systems. Indeed, there are several arguments for a comprehensive and coordinated approach to risk management. This study determines all probable hazards, which may generate an infectious risk during the different steps of the sterilization process. **Materials and Methods:** The study was conducted from November to December 2019 in the central sterilization department of the IBN Sina Hospital in Rabat. The method adopted was the preliminary risk analysis (PRA) applied to reusable medical devices (DM) circuits. **Results:** A total of 38 dangerous situations generating an infectious accident were revealed, which will make 38 scenarios. The mapping of hazardous situations relating to the different phases of the sterilization process showed 5 types of generic hazards. Among these 38 scenarios, 9 are in criticality class 3, 21 situations are in criticality class 2, and 8 scenarios are in criticality class 1. After the implementation of risk reduction actions, 31 scenarios remain in criticality 1, 7 in criticality 2, and no scenario in criticality 3. **Conclusion:** The PRA method has enabled all phases of the sterilization process to be analyzed and all the probable hazards that could lead to an infectious accident to be identified. The proposed risk reduction measures are organizational and educational. After the implementation of these measures, all the maximum risks are reduced to a tolerable zone under control, and the average risks are reduced.

Key words: Infectious risk, medical device, preliminary risk analysis, sterilization

INTRODUCTION

Patient safety is an area of health care that has emerged with the increasing complexity of health-care systems and the rise in patient harm within health-care organizations. It is based primarily on continuous improvement, learning from errors and adverse events. In this way, health-care establishments are tasked with regulating the quality of care and protecting users. This involves preventing and reducing risks, errors, and harm to patients in health care.[1]

Indeed, there are several arguments in favor of a comprehensive and coordinated approach to risk management. In particular, in-depth analyses have shown that a serious event associated with health care is systematically linked to a combination of different causes within the health-care setting and in its immediate or more distant environment.[2]

This study demonstrates the commitment of Moroccan hospitals to ensuring patient safety by strengthening surveillance, risk assessment, and infection control capacities, including antimicrobial resistance, disease, and trauma, as set out in the WHO-Morocco Cooperation Strategy 2017–2021.[3]

The study is based on the preliminary risk analysis (PRA) method, which is a risk identification and assessment method. The principles and methods of PRA are used to map hazardous situations, draw up risk maps, assess benefit/risk ratios, and make preliminary safety allocations.[4]

This study concerns the sterilization process in its entirety and aims to identify all the likely hazards that could generate

Address for correspondence:
Zoubida Khomsi, Laboratory of Central Sterilization, Ibn Sina Hospital, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco.
Phone: +212655672817.
E-mail: zoubida_khomsi@yahoo.fr

Received: 16-06-2023
Revised: 19-09-2023
Accepted: 29-09-2023

an infectious risk for patients. As a part of assessing and improving professional practices within our establishment, the corrective and preventive actions to be put in place will then be defined.

MATERIALS AND METHODS

This is a cross-sectional study conducted in the central sterilization department of the IBN Sina Hospital in Rabat during the period from November to December 2019. It mainly concerned the infectious risk related to the circuit of reusable medical devices (DM), requiring sterilization.

We opted for the PRA method as described by Desroches *et al*.[4,5] PRA is one of the classical methods of a priori risk analysis that are applied in the health field.[4,6] It was chosen by our working group because its objective is to identify the scenarios, leading to a feared event in the presence of a hazard or dangerous situation. Then, to deduce the solutions to control and manage the main risks, through a global vision of the process. Moreover, it can also be used for profit during the whole life of a system.[5]

PRA is carried out in several steps:

- The constitution of the multidisciplinary working group
- The identification of the "system" studied, in our case, the sterilization: "process", from pre-disinfection to the distribution of sterile medical devices
- Drawing up a map of hazardous situations for each stage of the process; Analysis of hazardous situations with identification of scenarios for each situation
- Drawing up the initial risk map after analyzing the scenarios associated with each hazardous situation
- Proposing and implementing corrective or preventive actions
- Assessing the residual risks after correction.

In general, the study consists of making what exists more reliable and proposing organizational changes according to an analysis of the infectious risk of the sterilization system (process).

Observations in the department, a summary of reported undesirable events, and a review of the literature enabled the construction of the process, the definition of generic hazards, and the mapping of dangerous situations.

These different elements were then discussed and validated by the multiprofessional working group including a sector referral pharmacist, a health-care manager, a resident pharmacist, and stakeholders in the sterilization process within the central sterilization department.

A criticality was assigned to each feared event based on the hazardous situations using the institutional rating scales, to isolate the priority risks and consider improvement actions.

The non-conformities observed are recorded, analyzed, and integrated into the scenarios estimated during the RPA. An update of the initial infection risk reduction plan is then drawn up taking account of these non-conformities. Finally, for the initially high criticality scenarios, a reassessment of their residual criticality is measured using a 4-level severity and likelihood scale and a 3-level criticality scale. Criticality is a function of severity and likelihood, which measures the impact of the risk [Table 1]. It is based on the consequences of a dreaded event:

- Acceptable (C1)
- Tolerable under control (C2)
- Unacceptable (C3).

The decision matrix constructed from the severity and likelihood scales is drawn up by the working group, taking into account feedback from experience but also based on the knowledge of each member of the group. This matrix shows the three levels of criticality for the initial risks and the residual risks after the implementation of preventive actions. For each of the hazardous situations identified, a risk analysis is carried out. The consequences of the feared events are directly associated with one of the four defined severity and likelihood classes.

For the graphical representation of the initial and residual risks, Kiviat diagrams were drawn up using Excel version 2019.

RESULTS

The PRA revealed 38 hazardous situations that could lead to an infectious accident and which will make 38 scenarios. Table 2 represents the mapping of the hazardous situations related to the different phases of the sterilization process and shows the 5 types of generic hazards resulting from the analysis, which are:

- Operator human factor at 34%,
- Physical-chemical (PHYS) at 16%
- Infrastructure-environment (INFRA) at 18%,
- Material and equipment (MAT) at 3%,
- Management (MAN) at 29%.

In addition, the scale of interactions between the hazards and the system studied allowed the working group to identify

Table 1: Criticality matrix

Plausibility scale	Gravity scale			
	1	2	3	4
4	C1	C2	C3	C3
3	C1	C2	C3	C3
2	C1	C1	C2	C2
1	C1	C1	C1	C1

Table 2: Cartography of dangerous situations of system studied

System			Pre-sterilization				Steriliz-ation	Post-sterilization			
Sub-system			Pre-disinfection	Washing	Drying	Packaging	Autoclaving	Discharge	Storage	Distribution	Traceability
Generic hazard	**Specific hazard**	**Hazardous event**									
FH operator	Operational	Contamination due to non-compliance with cleaning procedures and hygiene rules	1	1	10				1	1	
		Contamination due to negligence of the task	1	1	1	1	1	1			10
	Professional	Blood exposure accident	1	1							
Physico-chemical	Product	Expired	1	10							2
		Poor quality	10	10		1					2
		Inappropriate	1	10		1					2
Infrastructure -environment	Microbiological	Microbiological contamination of water systems		1			1				1
	Ambiance	Device contaminated by untreated air			10	10		10	1		10
		Contaminated ceiling difficult to treat		2	10	10		2	1		10
	Premises	Contaminated surfaces: inappropriate floor		10	1	1			1		10
		Contaminated shelves							1		10
Material and equipment	Dysfunction	Failure of autoscrubber	10	10							10

(*Contd...*)

Table 2: (*Continued*)

System			Pre-sterilization				Steriliz-ation	Post-sterilization			
Sub-system			Pre-disinfection	Washing	Drying	Packaging	Autoclaving	Discharge	Storage	Distribution	Traceability
Generic hazard	Specific hazard	Hazardous event									
		Failure of air treatment unit			10	10		10	10		10
		Insufficient compressed air pressure			1						10
		Ultrasonic device not functional		2							10
		Failure of autoclave					1				10
Management	Human resources	Unqualified personnel	2	10	10	1	10	1	2		1
	Training	Needs in good practice not identified	10	1	1	10	1	10	1		2
	management	Supervision not regular	10	1	1	10	1	2	2	2	2

three categories of hazardous situations by assigning a priority index (PI) of 0, 1, 2, or 10 [Table 3].

- The first category rated IP 0, which means that there is no hazard/system interaction and therefore no analysis is required
- The category rated IP 1, has 38 strong-to-very strong interactions requiring risk assessment and immediate action
- The category of PI 10, with 36 strong-to-very strong interactions, for this category, the analysis can be postponed voluntarily, and the action is later because it requires other actors outside the sterilization service
- The category of PI 2, which has 15 low-to-medium interactions, for this category, the risk analysis is not a priority

The working group carried out the analysis of the process according to a criticality matrix ranging from 1 to 4 for likelihood and also for severity.

The 38 scenarios are divided by criticality class as follows:

- Criticality class 1 (C1): 8 scenarios (21%)
  - 2 scenarios are related to the generic operator hazard (FH)
  - 4 to the generic hazard (PHYS)
  - 1 to the generic hazard (MAN)
  - 1 to the generic hazard (INFRA)

- Criticality class 2 (C2): 21 scenarios (55%)
  - 8 scenarios are related to the generic hazard (FH)
  - 6 scenarios related to the generic hazard (INFRA)
  - 5 scenarios related to the generic hazard (MAN)
  - 1 scenario related to the generic hazard (MAT)
  - 1 generic hazard scenario (PHYS)

- Criticality class 3 (C3): 9 scenarios (24%)
  - 3 scenarios related to the generic hazard (FH)
  - 5 scenarios related to the generic hazard (MAN)
  - 1 scenario related to the generic hazard (PHYS)

After implementation of the proposed risk reduction actions, the distribution of residual criticalities would be as follows:

- 31 scenarios (or 81.5%) of criticality 1 (C1)
- 7 scenarios (or 18.5%) of criticality 2 (C2)
- No criticality 3 scenarios (C3).

Table 3: Scale of hazard/system interactions

Priority index	Hazard/system interaction	Analysis decision	Nbr
	No interaction	**No action**	
1	Strong to very strong	Immediately	38
10	High to very high	Later	36
2	Low to medium	Later	15

The proposed actions make it possible to eliminate the scenarios of unacceptable criticality.

The mapping of initial and residual risks is represented by the Kiviat diagram: mapping of risks (initial or residual) according to the hazards or subphases of the system. This diagram is a projection of the risk according to the criticality matrix. This diagram has 3 colored zones corresponding to the 3 levels of the criticality matrix: a green zone for criticality 1, a yellow zone for criticality 2, and a red zone for criticality 3.

- For generic hazards

The initial maximum risk distribution in the Kiviat diagram [Figure 1] is in the unacceptable zone (criticality 3) for the hazard "Management," "Physical-chemical," and "Human factor". The hazards of "Infrastructure and premises" and "Material and equipment" are in the tolerable zone under control (criticality 2).

- For the process

The initial maximum risk distribution in the Kiviat diagram [Figure 2] is in the unacceptable zone (criticality 3) "pre-disinfection," "washing," "drying," "storage," and "distribution." The process phases "packaging," "autoclaving," "discharge," and "traceability" are in the tolerable zone under control (criticality 2).

After the implementation of risk reduction actions, all maximum risks are reduced to the tolerable zone under control and the average risks are reduced. It should be noted that the same phase of the sterilization process or subsystem can have

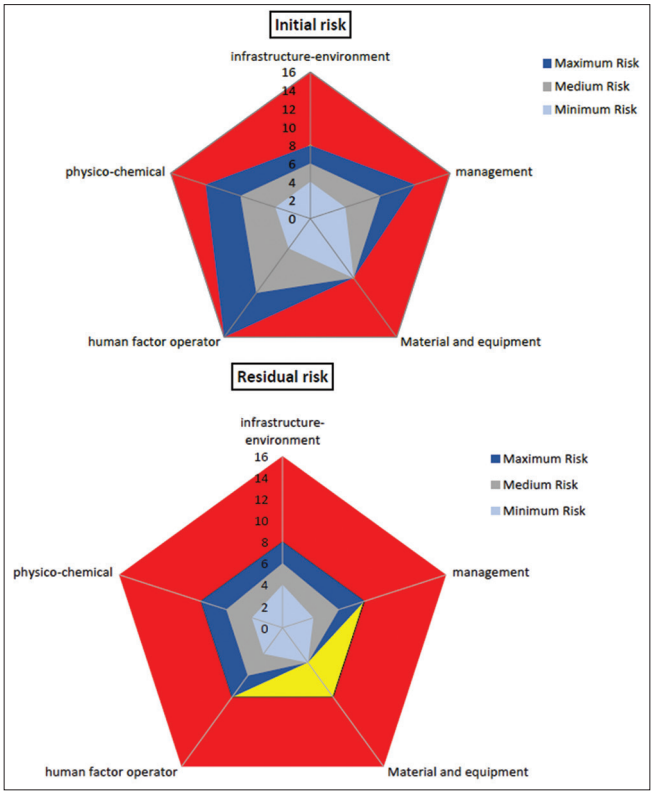

Figure 1: Kiviat diagram of initial and residual risk mapping by hazard

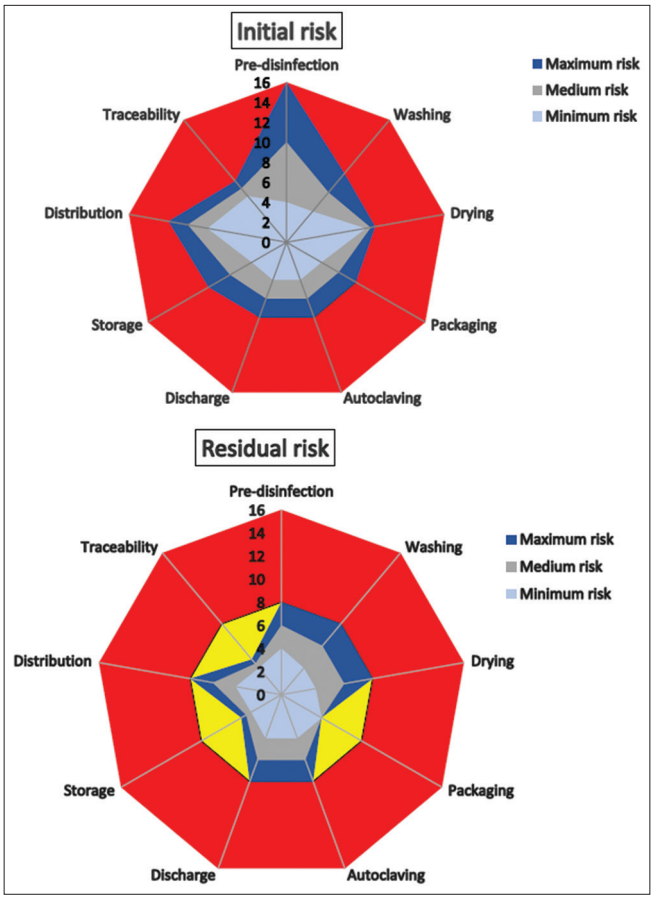

Figure 2: Kiviat diagram of initial and residual risk mapping by process

different types of generic hazards. It should also be noted that the pre-disinfection phase presents the most critical scenarios which are 3 with two types of generic hazards, one linked to the human factor (FH) and the other to management (MAN).

DISCUSSION

PRA was developed in the early 1960s in the aeronautical and military fields. According to IEC-300-3-9 (IEC 300-3-9, 1995), "PRA is a hazard identification and frequency analysis technique that can be used in the early design phases to identify hazards and assess their criticality."[7] The analyst is assisted by the checklists of hazardous entities, hazardous situations, and feared events. These checklists are specific to the field of the study and the process being studied. As the name implies, this method is not intended to deal in detail with the materialization of accident scenarios, but rather to quickly highlight the major problems likely to be encountered during the operation of the system under study.

For our study, this system is hospital sterilization, which is an indispensable process in the medical field, but it is threatened by a multitude of risks, notably the risk of infection. This type of risk is very serious and can have serious consequences, as it affects not only the health of patients but also that of staff. It includes the "transmission of infectious diseases" such as human immunodeficiency virus, hepatitis C and hepatitis B, and Creutzfeldt-Jakob disease.[8] This transmission is due to contamination of medical devices during surgery and poor sterilization of these devices. In this context, a study dealing with the analysis of the infectious risk in a sterilization department of a clinic specialized in dental care showed real contamination of medical devices, a batch of DM was not correctly sterilized and due to inattention in the control department, this incorrect sterilization was not detected, and the MDs were stored and used in the surgical procedures.[9] Other studies[10,11] have used risk analysis data to improve the safety and availability of the service. One of these studies identified the different hazardous situations, the feared events, the causes that led to these hazardous situations, and their consequences. For each situation, severity, probability, criticality, and solutions were assigned. The study led to the identification of 348 hazardous situations, of which 230 were highly vulnerable to the hazard. These 348 hazardous situations led to 364 risk scenarios.[11]

In our study, the RPA analysis method applied to the sterilization process revealed as many hazardous situations as scenarios that could lead to an infectious accident, given that the only type of risk under study was the infectious risk.

Indeed, the highest initial average risk is attributed to the generic "human factor operator" hazard. Concerning the analysis by process, the initial average risk is higher for the pre-disinfection, drying, and distribution phases. This last result confirms the first one by the fact that these phases strongly require the human factor in their realization.

Following these results, the working group drew up a risk prevention action plan which was articulated in four stages:

- The identification of preventive actions, which is the most important planning stage
- Approval and validation of these actions
- Implementation of the preventive actions
- Evaluation of the effectiveness of the measures adopted and applied.

Preventive actions are mainly educational: training, supervision, and awareness raising of sterilization staff. These actions are a part of the continuous improvement of quality within the sterilization service. They are mainly about:

- Display of procedures relating to high-risk phases
- Reminder of possible hazards for each sterilization phase
- Updating of adverse event reporting forms
- Organization of training sessions for sterilization operators
- Frequent supervision to raise awareness among sterilization staff.

After the implementation of the actions to reduce the infectious risk, all the maximum risks go into the tolerable

zone under control and the initial average risks are reduced. As a result, for the generic "human factor" operator hazard, the average residual risk decreased from 10 to 5.5, and the average residual risks related to the pre-disinfection, drying, and distribution phases decreased from 10 to 6, from 8.5 to 5.5, and from 10 to 6, respectively.

Limitations

However, PRA is one of the classical methods of risk analysis;[12] it can also and even should be complemented by the most functional risk analyses. The main limitations of this method can be summarized in the following points.[13]

- Its implementation is time consuming
- The more general it is, the less it takes into account the specification of the system studied
- The complexity of the method requires extensive and specific training to implement it
- The method is not known by all professionals.

CONCLUSION

The hospital sterilization process is subject to reported failures requiring preventive actions to be taken. However, despite these declarations, certain undesirable events persist during this process. To this end, the method of PRA in sterilization has emerged as a means to resolve these problems within the framework of risk management, to eventually bring effective solutions to promote the reduction of the occurrence of these accidents and their consequences. These results impose continuous awareness and regular supervision, as the human and organizational factors, in our sterilization teams and structures, are the key element to consider to ensure patient safety, through an individual and collective behavioral change of the sterilization actors.

REFERENCES

1. World Health Organisation. Sécurité des Patients; 2019. Available from: https://www.who.int/fr/news-room/fact-sheets/detail/patient-safety. Last accessed on 2020 Aug 07].
2. Haute Autorité de Santé. Amélioration des Pratiques et Sécurité des Soins: La Sécurité des Patients Mettre en Œuvre la Gestion des Risques Associés Aux Soins en Établissement de Santé Des Concepts à la Pratique; 2012. p. 9.
3. Organisation Mondiale de la Santé. Stratégie de coopération OMS-Maroc 2017-2021. Egypt: Bureau régional de la Méditerranée orientale © Organisation mondiale de la Santé; 2016.
4. Desroches A, Gatecel C. Preliminary risk analysis: A tool adapted to care establishments. Rev Risques Qual 2006;3:141-50.
5. Desroches A, Baudrin D, Dadoun M. Preliminary Risk Analysis, Principles and Practices. Hermes Science Publications; 2009.
6. Asgari HD, Khorasani E, Yarmohammadian MH, Ahmadzade MS. Evaluating the application of failure mode and effects analysis technique in hospital wards: A systematic review. J Inj Violence Res 2017;9:51-60.
7. Mazouni H. Pour une Meilleure Approche du Management des Risques: De la Modélisation Ontologique du Processus Accidentel au Système Interactif D'aide à la Décision. Automatique/Robotique. France: Institut National Polytechnique de Lorraine-INPL; 2008.
8. Di Mascolo M, Flaus JM, Daadaa M. A New Integrated Approach for Risk Analysis and Performance Evaluation of a Hospital Sterilization Service. In: 9th Conférence Francophone en Gestion et Ingénierie des Systems Hospitaliers. GISEH 2018. Genève, Switzerland; 2018.
9. Cheng VC, Wong SC, Sridhar S, Chan JF, Ng ML, Lau SK. Management of an incident of failed sterilization of surgical instruments in a dental clinic in Hong Kong. J Formos Med Assoc 2013;112:666-75.
10. Bernard V, Lacroix P. Restructuration d'un service de stérilisation dans le cadre d'une démarche qualité. ITBM-RBM 2001;22:116-24.
11. Talon D. Gestion des Risques Dans une Unité de Stérilisation Centrale d'un Établissement Hospitalier: Apport de la Traçabilité à L'instrument. Phd Thesis. Ecole centrale Paris; 2011.
12. Villemeur A, Reliability, Availability, Maintainability and Safety Assessment. England: John Wiley and Sons Ltd.; 1992.
13. Tixier J, Dusserre G, Salvi O, Gaston D. Review of 62 risk analysis methodologies of industrial plants. J Loss Prev Process Ind 2002;15:291-303.

Source of Support: Nil. **Conflicts of Interest:** None declared.