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Original article

Analysis of Infectious Risk in the Hemodialysis Unit at the University Hospital Center

Sonia Kamoun[1*], Héla Ghali[2,3], Raja Boukadida[3,4], Asma Ben Cheikh[2,3], Asma Fradi[4], Dorsaf Zellama[3,4], Houyem Latiri Said[2,3]

[1] Regional Health Directorate of Sousse, Tunisia
[2] Prevention and Care Safety Department, Sahloul University Hospital Center, Sousse, Tunisia
[3] Faculty of Medicine of Sousse, University of Sousse, Sousse, Tunisia
[4] Nephrology Department, Sahloul University Hospital Center, Sousse, Tunisia

Abstract

Hemodialysis, as an extra-renal purification technique, carries an inherent infectious risk. This study aimed to assess the infection risk associated with hygiene practices around hemodialysis patients in a hospital setting. This study employed Failure Modes and Effects Analysis (FMEA) to evaluate risks. A comprehensive visit was conducted at the hemodialysis unit of the nephrology department at Sahloul University Hospital of Sousse on a single day. The visit comprised a documentary inventory, premises observation, professional and patient interviews, and observation of professional practices to comprehensively understand infectious risk during patient care. The study identified seventeen failure modes during a hemodialysis session, categorized into six of level 1 criticality, four of level 2, and seven of level 3. The most critical failure modes included the improper handling and distribution of multi-dose heparin into single-dose injections in an unspecific area, as well as the absence of a 4-stage skin preparation for the puncture site. Proposed corrective measures to mitigate infectious risk were outlined. The FMEA approach effectively identified potential risks, necessitated a review of certain procedures, and proposed matrices to manage the most critical risks. This analysis, when conducted periodically, facilitates a genuine quality-focused approach, enhancing patient satisfaction and bolstering all stakeholders' confidence within the hemodialysis center.

Keywords: FMEA - Hemodialysis - Infectious risk - Quality

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1. Introduction

Hemodialysis is an extra-renal purification technique associated with infectious risks, posing a significant public health problem due to its frequency and its human and economic impact [1]. Hence, it is important to implement a quality assurance system within hemodialysis centers. Several methods are available, among the most effective being Failure Modes and Effects Analysis (FMEA). This is a method of a priori risk analysis. Properly used, this approach would enable optimal management of hemodialysis and improvement in the quality of care for hemodialysis patients. It integrates perfectly with the concept of adequate or effective hemodialysis, which remains the cornerstone of the survival quality of hemodialysis patients [2].

In Tunisia, hemodialysis activity is subject to general regulations, including the Decree No. 98-795 of April 4, 1998, establishing the conditions for the creation and operation of hemodialysis centers; the Decree No. 2010-318 of February 22, 2010, listing complementary examinations and other services that hemodialysis centers must provide to patients, and the Circular No. 3/2000 of January 17, concerning preventive measures to combat the transmission of infections associated with care in hemodialysis centers aiming to improve service quality and safety of use within the centers [3-5].

In Tunisia, contributing to improving the conditions for managing patients with end-stage renal disease treated with hemodialysis techniques holds a crucial place in public health. The Sahloul University Hospital of Sousse, a university hospital center, positions itself as a reference establishment in healthcare. The hemodialysis unit of this hospital plays a crucial role in providing hemodialysis to patients with end-stage renal disease. The average number of new patients benefiting from hemodialysis within this unit is 87.7 patients per year [6]. However, this unit faces potential infectious risks that could harm the health of patients and healthcare personnel.

To prevent and effectively control these risks, it is essential to conduct an in-depth analysis of the specific infectious risk in this unit. Therefore, our work aimed to identify and classify infectious risks for patients during a hemodialysis session in the Nephrology Unit of Sahloul University Hospital in Sousse. The objective was to recommend preventive and corrective actions by applying the FMEA method.

***Correspondence:** Dr. Sonia Kamoun. Regional Health Directorate of Sousse, Tunisia. Email: kamounsony@hotmail.com

2. Material and methods

2.1 Study Conception

We conducted as a cross-sectional study at the hemodialysis unit of Sahloul University Hospital of Sousse in April 2023. To analyze infectious risk, we opted for the FMEA method, a preventive, qualitative, and quantitative process analysis technique. This analysis requires the application of the Ishikawa diagram, a brainstorming method used to search for and represent the different causes of a problem, an effect in the case of FMEA. Starting from the identified effect, brainstorming is conducted around five categories of causes (manpower, method, environment, material, matter), also known as the rule of 5 Ms. The failure mode is defined by a defective or malfunctioning system. The criticality of the failure is quantified by triple rating (Table 1): Note "G": severity of the failure, evaluated on a multi-level scale; Note "F": frequency of the failure occurrence, an evaluation of the number of cases per unit of time; Note "D": detection of the failure, represented by a coefficient on a multi-level scale, reflecting the attenuation of the severity of consequences in case of detection weighted by the probability of detection. The criticality index is obtained by the product of the three notes (C = G × F × D). The higher the criticality, the more the considered failure mode is concerning. FMEA allows for the preventive control of non-compliance risks that could negatively affect the quality of a hemodialysis session before they occur. For data collection, we applied the method in the following steps:

1) Definition of the scope's objective to be studied: management during the connection and disconnection of patients on Arteriovenous Fistula (AVF);

2) Formation of a multidisciplinary working group: the medical and paramedical team. It is noteworthy that one of the group members is a quality specialist;

3) Determination and analysis of the stages of the process to monitor a hemodialysis session. At this stage, the working group drew inspiration from the literature [7-11] and adapted it to Tunisian regulatory texts [3-5] for the process breakdown, which was later adjusted to the study's context after several brainstorming sessions;

4) highlighting potential failures, causes, and effects, according to the Ishikawa diagram.

2.2 Data Analysis

The Ishikawa diagram identifies causes that can lead to an inadequate hemodialysis session with a high infectious risk. Causes are identified and classified by categories: 1) Organizational causes: inadequate and/or insufficient materials, malfunctioning work organization, and malfunctioning supply; 2) Pedagogical causes: lack of knowledge about procedures and/or risks, lack of training; 3) Professional causes: lack of qualification, inattention, and lack of professional experience.

Evaluation of the criticality of these failures and severity for the patient and personnel. For criticality calculation, the working group chose to work with four levels for frequency, severity, and detectability. A decision matrix was developed by the working group to define risk levels based on the criticality class (Fig. 2).

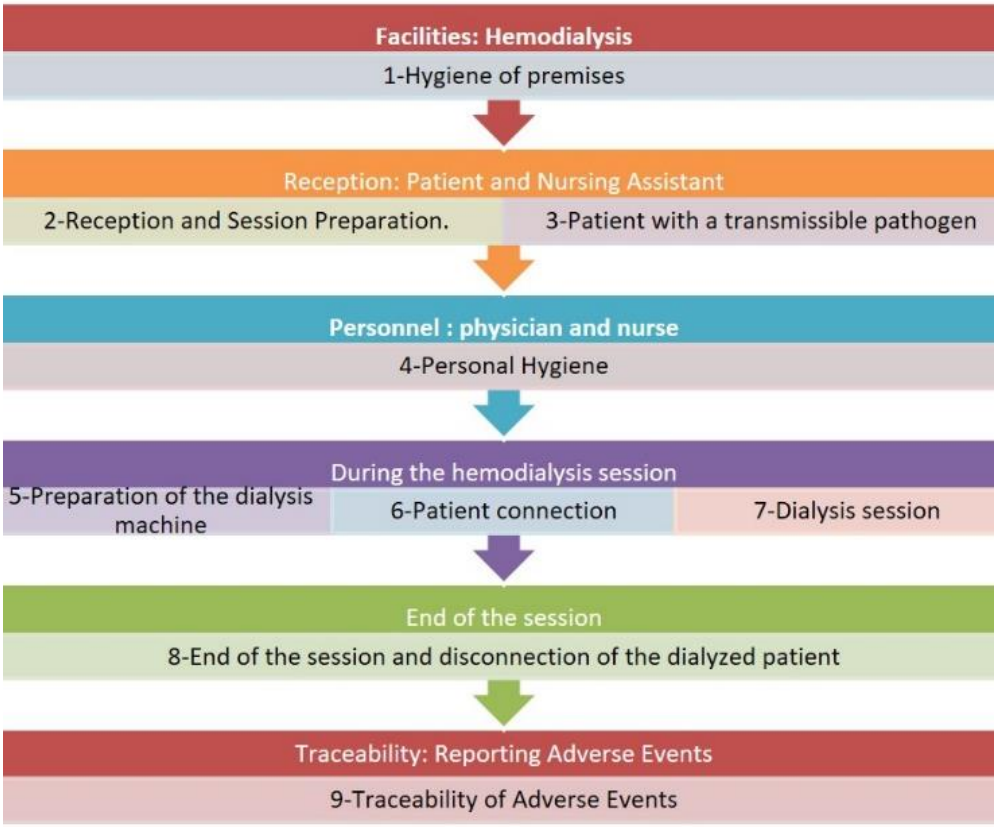

Fig.1. The steps of a hemodialysis session [14]

Table 1. Risk assessment grid [14]

Frequency			
Frequency	**Score**	**Frequency Level**	**Criteria**
F1	1	Infrequent	Failure observed less than once a month
F2	2	Moderately Frequent	Frequently observed at least once a week
F3	3	Common	Failure observed once a day
F4	4	Very frequent	Failure observed more than once a day
Severity			
Severity	**Score**	**Severity Level**	**Criteria**
G1	1	Minor	Minor consequences with no impact Reversible injury or damage not requiring medical intervention
G2	2	Moderate	Incident with temporary harm Injury with reversible damage requiring medical treatment
G3	3	Major	Incident with impact Injuries or irreversible damage
GS	4	Critical	Serious consequences Fatal or severe consequences in the short term (<24h)
Detectability			
Detectability	**Score**	**Detectability Level**	**Criteria**
D1	1	Very detectable	Observable defect : It cannot escape visual detection
D2	2	Detectable	Detection is easy to implement
D3	3	Slightly detectable	Sampling is required to detect the defect
D4	4	Non detectable	Failure is not detectable

Table 2. Risk Acceptability Level [12]

Criticality			
Class	**Score**	**Risk Level**	**Actions**
C1	**1 to 8**	Acceptable	No action to be taken
C2	**9 to 16**	Tolerable under control	Organize residual risk management follow-up
C3	**17 to 64**	Tolerable under control	Organize residual risk management follow-up

Finally, concerning the treatment of failures, at the end of the study, corrective and/or preventive actions are proposed at the different stages of the hemodialysis session process to reduce the risk of these failures occurring. Solutions are provided based on the criticality levels obtained after identification and analysis of failures. After evaluating criticality levels, all stages in criticality class 3 will require an immediate corrective measure. After correction, the process stage can be submitted to analysis to reevaluate its criticality, and thus its acceptance.

2.3 *Ethical considerations and conflicts of interest*

The professional secrecy and anonymity of patients have been preserved throughout our study. We declare that we have no conflicts of interest or financial ties.

3. Results

In the hemodialysis unit, there are 21 generators and two reserves, operated by three doctors, fourteen nurses, and one worker. Our approach to presenting results involves organizing information into concise paragraphs, each dedicated to articulating the study's findings for a clearer and more coherent presentation.

3.1 Description of hemodialysis session steps

The hemodialysis session comprises 6 elementary processes and involves 9 tasks, from the patients' arrival to their exit with traceability (Fig.1).

3.2 Identification of failures using the 5M method (Ishikawa)

Our study uncovered 17 failures in the hemodialysis unit, categorized through the Ishikawa diagram, as illustrated in Fig.2.

3.3 FMEA Analysis

The 17 failure modes are distributed across three classes: 6 class C1 failure modes (33%), 4 class C2 failure modes (26%), 7 class C3 failure modes (41%) (Table 3). Within class C1 failure modes, notable issues include premises (insufficient distance between beds and lack of floor cleaning), session preparation (unmaintained equipment and inadequately trained staff), personnel (some nurses wearing jewelry and nail polish), during the session (patients not wearing surgical masks during connection).

For class C2 failure modes, we find issues related to premises hygiene (lack of cleaning and disinfection), patient hygiene (absence of clean attire), nursing staff (lack of eye protection and involvement in AE analysis).

The most critical failures for class C3 modes involved the session preparation (lack of specific area for heparin injections), nursing staff (non-compliance with attire regulations), during the session (absence of external disinfection, improper skin preparation, and non-compliance with glove usage).

3.4 Prioritization of failures according to criticality level

Based on criticality levels, we prioritized identified failures, as detailed in Table 6.

3.5 Corrective and preventive Action

Our goal is to provide an action plan to reduce criticality. Proposed measures, summarized in Table V, focus on pedagogical corrective actions, theoretical and practical training, and organizational awareness workshops. The 3-month implementation period aims to renovate practices, enhance hygiene, and improve the quality management system. Protocols for premises hygiene are crucial to prevent failures at their level.

3. Discussion

To our knowledge, this is the first study in Tunisia on hygiene conditions during a hemodialysis session in a hospital center. The analysis of the Failure Mode and Effect Analysis" (FMEA) evaluation results helped us identify some infectious risks impacting the safety of patients and healthcare personnel during hemodialysis sessions.

Seventeen failures were observed, with major consequences of "infectious risk" type. The failure mode with the highest level of criticality was the preparation of multi-dose heparin into single-dose injections, not done in a specific area. According to Bernasconi et al [13], cases of infections have been linked to non-compliance with hygiene procedures in the preparation or storage of drugs and are secondary to extrinsic contamination by microorganisms from the environment or healthcare personnel, or more rarely, from another patient.

Multi-dose drug vials (heparin, insulin, etc.) also represent a source of infections due to vial contamination resulting from non-compliance with aseptic recommendations [13], which are 1) single doses dedicated to a single patient and punctured only once; 2) multi doses dedicated to a single patient whenever possible; 3) preparation of injectable in a clean area separated from equipment and potentially contaminated surfaces as well as treatment areas; 4) adherence to asepsis during the preparation and administration of injectable.

The second failure mode with the highest level of criticality was the absence of a 4-step skin preparation in the puncture site area (cleansing, rinsing, antiseptic, drying) and from the top of the arm downwards. According to the French National Audit of Hemodialysis Practices, skin preparation with an Arteriovenous Fistula was correct for only 22.4% of patients [14]. Additionally, during our audit, we noticed that some patients did not adhere to hygiene rules (hand hygiene, arm washing, vascular access management, self-monitoring of blood glucose) either because they were not sensitized or were dependent patients. This lack of hygiene was also noted in a study conducted by Bussière et al., which showed that in 40% of cases, the hygiene of the patient's arm was non-compliant [9]. Furthermore, a prospective study conducted by Hajjar et al. in five hemodialysis centers in the Rhône-Alpes region concluded that the hygiene level of patients was very poor in 3.7% and mediocre in 10.3%, with significant variations among centers [15]. Regarding the hygiene of healthcare personnel, we observed that the healthcare professionals in the hemodialysis unit did not wear the required attire, and some nurses wore jewelry and nail polish. In this context, in 2012, the Operational Hygiene Team of the Metropole Savoie Hospital Center launched a campaign to raise awareness, "zero jewelry on healthcare workers' hands," and conducted samplings on jewelry (rings, bracelets, watches) from voluntary and anonymous staff, placing them aseptically on a culture medium to visualize the presence of microorganisms after incubation. The experience showed contamination of jewelry in all departments of the facility [16]. The rate of jewelry carriage decreased from 54% in 2014 to 20.9% in 2016, attributed to the campaign's effect [17].

Among the high-criticality failures in our study was the lack of an attendant. Indeed, the hemodialysis unit had only one attendant for 21 machines. However, Decree No. 98-795 of April 4, 1998, establishing the conditions for the creation and operation of hemodialysis centers, stipulates that one attendant is required for every 4 machines [3]. Our study showed the absence of disinfection and cleaning of the external surfaces of generators, beds, and other surfaces (workstations, care carts) as well as the lack of maintenance of the scale and sphygmomanometer.

During our audit, we noticed that no healthcare personnel wore eye protection. In this regard, a study conducted by the French Blood Exposure Accidents Surveillance Network showed that the repeated manipulation of vascular accesses in hemodialysis was responsible for 23.5% of Blood Exposure Accidents [18]. Another study by Tarantola et al. showed that 24.8% of Blood Exposure Accidents recorded in hemodialysis were due to splashes [19].

During this work, it was found that paramedical professionals were not involved in the analysis of Adverse Events Associated with Care. This reluctance was also observed in a study conducted in France, showing that the main barrier is the fear of sanctions. Therefore, it was recommended that the reporting system be independent of an authority with sanctioning power and that the identity of the reporter not be disclosed to a third party.

Furthermore, this study showed that involving reporters in the analysis increased the number of reports in establishments. Monitoring the implementation of these recommendations will ensure the assurance of patient care safety, improved work organization, and patient satisfaction. This rigorous group work method is highly effective, notably through the pooling of the experience and knowledge of each participant. Identifying risks through Failure Mode and Effect Criticality Analysis (FMECA) added informative value to the quality assurance and safety approach adopted. The subjectivity presents the delicate aspect of the FMECA method, both for the selection of failures and for the rating of criticality. Moreover, this approach may overlook scenarios not yet observed.

The evaluation of failure modes and their criticality depends on the knowledge and professional experience of the individuals in the working group, as well as their experience in risk management. Implementing the FMECA analysis requires training and methodological support. Its steps are crucial, even if they are time-consuming.

Table 3. FMEA Analysis

Elementary Process	Tasks	Failure Mode	Cause	Effect	F	G	D	C
Reception	**Reception and preparation for the session**	Bed arrangement	The distance between two beds is less than 1.50m	Infectious risk	**4**	**1**	**1**	**4**
		Insufficient cleanliness state	- Lack of cleaning and disinfection of beds according to the recommended frequency (Between two patients/After the patient's departure/Before use by the next patient)	Infectious risk	**3**	**2**	**2**	**12**
		Insufficient cleanliness state	- Lack of floor cleaning after clearing the station: between two patients and after each session	Infectious risk	**3**	**2**	**1**	**6**
		Poor patient hygiene	-Patient's hygiene deficiency - Patients do not wear clean attire reserved for dialysis, allowing easy access to the fistula arm for thorough cleaning.	Infectious risk	4	2	**2**	**16**
			The patient does not adhere to hygiene rules (hand hygiene, arm washing, management of vascular access, self-monitoring of blood glucose). Dependent patient or not sensitized	Infectious risk	4	3	**2**	**24**
		Dirty and contaminated scale	- Unmaintained scale Personnel not trained for cleaning this type of equipment	Infectious risk	4	1	**2**	**8**
		Dirty and contaminated sphygmomanometer	- Unmaintained sphygmomanometer Nursing staff not trained for sphygmomanometer cleaning	Infectious risk	4	1	**2**	**8**
		Contaminated cart	- Care cart is not regularly cleaned	Infectious risk	4	1	**2**	**8**
		Preparation of heparin injections	- The preparation of single-dose heparin injections is not done in a specific area; sharing of heparin dose (1 dose for 5 patients)	Infectious risk	4	4	**4**	**64**
Personnel	**Personnel hygiene**	Increase in infectious risk	due to non-compliance with regulatory attire - Unaware personnel	Infectious risk - Professional and organizational	4	3	**2**	**24**
		Lack of hand hygiene	- Some nurses wear jewelry and nail polish. Non-compliance with the service protocol	Infectious risk	1	3	**2**	**8**
		Sick caregivers	- Staff does not use eye protection (wearing safety glasses/visor) during connection and disconnection.	Infectious risk - Professional and organizational	4	2	**2**	**16**
	Number	Number of workers	- Only one worker per unit for 21 generators	Professional risk	4	2	**3**	**24**
During the hemodialysis session	**Generator preparation**	Irregular external disinfection	Lack of external maintenance of the generator after each patient. External disinfection not performed.	Infectious risk - Professional and organizational	4	3	**2**	**24**
	Connection of the dialyzed patient	Aseptic and safety rules not followed during connection.	- There is no four-step skin preparation of the puncture site area (cleansing, rinsing, antiseptic, drying) and from the top of the arm downwards	Infectious risk	3	4	**3**	**36**
			-Understanding of touching other objects (computers, phones, violet generator, glasses, notebook, pen...) while wearing their gloves.	Infectious risk	3	3	**3**	**27**
End of the session	**End of the session and disconnection of the dialyzed patient**	Septic compression	-Patients do not wear clean gloves during compression after removal. Aseptic rules not followed.	Infectious risk	2	3	**3**	**18**
Traceability	**End of the session**	Reporting	- Paramedical professional not involved in the analysis of AEIs. Unaware personnel.	Infectious risk - Professional and organizational	2	2	**3**	**12**

Table 4. Prioritization of risks according to the level of criticality

Risk factor -	Criticality
-The preparation and reconstitution of multi-dose heparin into single doses are not done in a specific area. No use of heparin mono-dose	64
-There is no four-step skin preparation of the puncture site area (cleansing, rinsing, antiseptic, drying) and from the top of the arm downwards.	36
-There is no respect for not touching other objects (computers, phones, violet generator, glasses, notebook, pen...) with the gloves.	27
-Absence of external maintenance of the generator after each patient. External disinfection not performed.	24
-one worker per unit for 21 generators	24
-The patient does not adhere to hygiene rules (hand hygiene, arm washing, management of vascular access, self-monitoring of blood glucose). Dependent or unaware patient.	24
-Non-compliance with the regulatory attire. Unaware personnel.	24
-The staff does not use eye protection (wearing safety glasses/visor) during connection and disconnection.	16
-Patients do not wear clean attire reserved for dialysis, allowing easy access to the fistula arm for thorough cleaning.	16
-Paramedical professional not involved in the analysis of AEIs. Unaware personnel.	12
-Lack of cleaning and disinfection of beds according to the recommended frequency (Between two patients/After the departure of the patient/Before use by the next patient).	12
-Unmaintained scale. Nursing staff not trained for cleaning this type of equipment.	8
-Unmaintained sphygmomanometer. Nursing staff not trained for cleaning the sphygmomanometer	8
-Care cart not regularly cleaned	8
-Some nurses wear jewelry and nail polish. Non-compliance with the service protocol.	8
-Failure to clean the floor after clearing the station: between two patients and after each session.	6
-The distance between the two beds is less than 1m50.	4

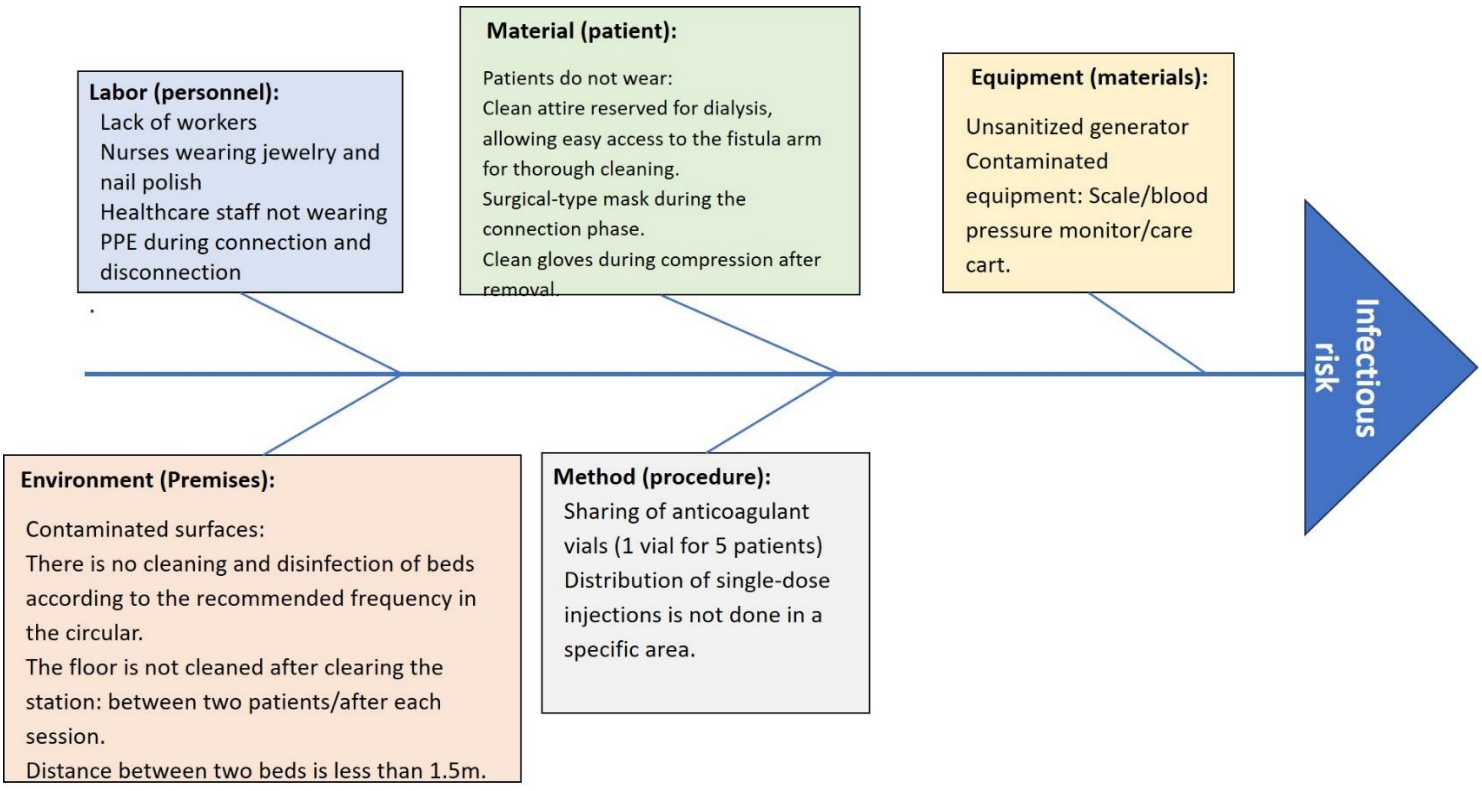

Fig.2. Ishikawa diagram

Table 5. Level of acceptability of risks

Elementary Process	Tasks	Failure Mode	Cause	Effect	F	G	D	C	Nature des actions correctives	F	G	D	C
Reception	**Reception and preparation for the session**	Heparin injections preparation	The preparation of heparin injections is not done in a specific area; sharing of heparin dose	Infectious risk	4	4	4	64	Prioritize: -Single doses dedicated to a single patient and punctured only once. -Multi-doses dedicated to a single patient whenever possible. -Preparation of injectables in a clean area separated from potentially contaminated equipment and surfaces as well as treatment areas. -Adherence to asepsis during the preparation and administration of injectables.	1	4	4	**16**
Personnel	**Personnel hygiene**	Increased risk due to infectious attire	Non-compliance with regulatory attire Unaware personnel	Infectious professional and organizational risk	4	3	2	24	Adherence to protocols and implementation of precautions. Surveillance and awareness	1	3	2	**6**
	Number	Number of workers	One worker for 21 machines.	Organizatio nal risk	4	3	2	24	Submit requests for the recruitment of another worker to the general management of the University Hospital.				**12**
During the hemodialysis session	**Connection of the dialysis patient**	Preparation of the generator	Lack of maintenance after each patient. External disinfection not performed	Infectious and professional risk	4	3	2	24	Adherence to entry procedures	1	3	2	**6**
		Aseptic and safety rules not adhered to during connection	There is no 4-step skin preparation of the puncture site area (cleansing, rinsing, antiseptic, drying) and from the upper arm downward.	Infectious risk	3	4	3	36	Training of personnel in protocol compliance	1	4	4	**16**
			Touching other objects (computers, phones, violet generator, glasses, notebook, pen, etc.) while wearing gloves.	Infectious risk	3	3	3	27	Training of personnel in protocol compliance				
Premises	**Hygiene of the premises**	Insufficient cleanliness	There is no cleaning and disinfection of beds according to the recommended frequency (Between two patients/after the departure of the patient/before the use by the next patient).	Infectious risk	3	2	2	12	-It is necessary to raise awareness through training for nurses in the importance of cleaning and disinfecting beds, blood pressure monitors, and scales according to the recommended frequency. -Paramedical staff must be aware of the importance of cleaning and disinfecting other surfaces (work surfaces, care surfaces, care carts) between two patients/after each use.	1	2	2	**6**
Reception	**Reception and preparation for the session**	Poor hygiene of the patient	Patients do not wear a clean outfit reserved for dialysis, allowing them to easily expose the fistula arm for proper cleaning	Infectious risk	4	2	2	16	-The paramedical staff must provide therapeutic education to the patient and their family about the importance of wearing a clean outfit reserved for dialysis, allowing them to easily expose the fistula arm for proper cleaning. -Training of staff in the techniques used for therapeutic education of patients	2	2	2	**8**
Personnel	**Personnel hygiene**	Sick caregiver	The staff does not use eye protection (wearing safety glasses/visor) during connection and disconnection.	Infectious and professional risk	4	2	2	16	Adherence to protocols and implementation of precautions, monitoring, and awareness.				**4**
			The staff does not wear a surgical mask during the puncture, connection, and disconnection	Infectious risk	4	2	2	16		1	2	2	**4**
Traceability	**End of the session**	Reporting	Paramedical professional not involved in the analysis of AEIs Unsensitized personnel	Infectious and organizational risk	2	2	3	12	Training of personnel on the importance of reporting	1	2	2	**4**

Furthermore, a last essential point, which constitutes a limitation of this method, is that it does not take into account the evolution of a system over time. However, to apply it to a process related to the healthcare system, it needs to be executed periodically, as the latter often undergoes many changes. In our study, this limitation is confirmed, as the FMECA analysis did not consider the context of the hemodialysis unit except at the time of the study.

Additionally, there is the possible influence of observation on the behavior of healthcare personnel (staff is aware of being observed), known classically as the "Hawthorne effect", as well as the impact of the observer's interpretation of definitions and the situation on the reliability of the collected data. Furthermore, the implementation of the proposed corrective actions will ensure the assurance of patient care safety, improved work organization, and patient satisfaction.

In conclusion, this study highlighted the infectious risks present in the hemodialysis unit of Sahloul University Hospital Center of Sousse, demonstrating the importance of implementing a quality assurance system within hemodialysis centers. The application of the FMECA method identified 17 failures distributed into three criticality classes, highlighting the main points of vulnerability. The most critical shortcomings concerned the preparation of multidose heparin injections and the lack of adequate skin preparation before connection. These results emphasize the need for increased awareness and regular training for healthcare personnel and patients to improve hygiene practices and reduce infectious risks. The corrective and preventive actions proposed in this study aim to reduce the criticality of identified defects, emphasizing continuous training, awareness, and the adoption of best practices. These measures required strong commitment from the institution, including the establishment of clear protocols and the allocation of necessary resources to ensure effective implementation. Regular monitoring of these actions is crucial to ensure continuity in the quality and safety of care within the Hemodialysis Unit of Sahloul University Hospital Center of Sousse.

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Declaration of Competing Interest

The authors declare that they do not have a conflict of interest.

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