

Risk mapping of the management of a hemodialysis patient with Covid-19 in the hemodialysis department of a Moroccan hospital

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Abstract

Objective: To map the infectious risk of the management of a hemodialysis patient with Covid-19 during a hemodialysis session in the hemodialysis department of a hospital in Morocco.

Methods: Our study focuses on the analysis of a priori risks during the management of a hemodialysis patient with Covid-19 during a hemodialysis session, carried out from September to November 2020, by applying the Failure Modes and Effects and Criticality Analysis (FMECA) method in the hemodialysis department of the Provincial Hospital Centre (PHC) El Jadida in Morocco.

Results: 18 failure modes were detected during the analysis of infectious risks in a hemodialysis patient with Covid-19 during a hemodialysis session, including 8 failure modes of criticality class C1, 2 failure modes of criticality class C2 and 8 failure modes of criticality class C3. Corrective actions were proposed to deal with the failure modes of criticality class C3.

Discussion: The FMECA method allowed us to identify the most critical failure modes, to prioritize them and to determine corrective actions in order to improve the management of a hemodialysis patient with Covid-19 and consequently to develop the quality and safety of this management.

Conclusion: Risk mapping is an essential tool for continuous quality improvement, the aim of which is to maximize the safety of the patient care process and finally satisfy the population.

Introduction

Chronic kidney disease (CKD) is a major public health problem in the world [1,2] leading to a heavy burden of excessive morbidity [3,4] and health care expenses [5]. Hemodialysis is a recent palliative therapeutic management allowing the continuation of life in patients with chronic renal failure [6]. It is a budgetary treatment procedure [7,8] destabilizing the budgetary balances of health systems precisely in developing countries [9].

Hemodialysis is a technique predisposed to infectious risks [10], which constitute the second most common complication after cardiovascular complications [11] and are the second most common cause of mortality in hemodialysis patients [12]. Infectious transmission in hemodialysis goes beyond intra-individual transmission to direct or indirect cross-transmission and manuported transmission [13]. Caregiver-to-caregiver infectious transmission through accidental exposure to blood is a major concern in hemodialysis departments [14] and therefore safety of care in hemodialysis is an essential priority [15].

Among hemodialysis patients, there are patients with increased vital risks who require special care and medical prescriptions in

order to maintain their tolerance to hemodialysis sessions [16]. These hemodialysis patients at risk are cardiac, vascular, diabetic, malnourished and elderly patients [16] and therefore the establishment of specific protocols for certain associated pathologies is indispensable [15]. Following the rapid worldwide spread of Covid-19 and its declaration as a pandemic on March 11, 2020, by the WHO [17], its impact on hemodialysis patients in Africa is unknown [18]. In the context of life-threatening hemodialysis patients, caregivers must think about personalizing treatment protocols for these different types of patients [15]. The infectious risk in hemodialysis constitutes a daily constraint that prevents the transmission of the usual pathogenic microorganisms (HB, HC, HIV) and nowadays extends to other poorly

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known contaminating agents [15] such as the new Covid-19 virus. Hemodialysis patients are a vulnerable population to Covid-19 due to their immunosuppression associated with CKD [18], and therefore the risk of these patients developing a severe form of Covid-19 is estimated to be 9 to 12 times higher [19]. Hemodialysis patients have been shown to be at high risk of developing COVID-19 with a high mortality rate [20]. COVID-19 has a significant impact on patients with chronic renal failure, especially those receiving hemodialysis treatment [21], so urgent adaptation of hemodialysis care is essential [22]. Early detection is crucial for possible control of the spread of the Covid-19 pandemic in the hemodialysis center [23]. Hence the importance of establishing a quality assurance system in hemodialysis centers [10] in this crisis context, which is operationally manifested by several methods, the main one being the analysis of failure modes, their effects and their criticality (FMECA) [10].

The hemodialysis department of the Provincial Hospital Centre of El Jadida has received hemodialysis patients with Covid-19. This had an impact on its internal organization by ensuring, on the one hand, the continuity of hemodialysis services for patients not affected by Covid-19 and, on the other hand, the management of patients affected by Covid-19 by respecting the application of specific protocols in this management with the aim of preventing and minimizing the risks related to the spread of this pandemic in the hemodialysis service.

The objective of our study is to establish a mapping of the infectious risk in a patient suffering from Covid-19 during a hemodialysis session in order to set up preventive and corrective actions, by applying the FMECA method.

Methods

This study took place from September to November 2020 at the hemodialysis service of the PHC El Jadida and opted for the methodology of risk analysis a priori. The method applied was the Analysis of Methods of Failure Effects and Criticality (FMECA). The FMECA method is a quality tool based on the inductive approach, it allows to determine the failure modes of a process and to evaluate its importance or criticality [24] even before the problems appear. It therefore aims to classify the risks in order to design an effective prevention plan [24]. The use of the FMECA method in our study was done from a qualitative and quantitative perspective that allowed us to assess the risks and prioritize preventive actions [24].

The operationalization of the FMECA method in our study went through the following steps:

Description of the process

The FMECA method began with the delimitation of the process of taking care of a patient with the Covid-19 virus during a session of hemodialysis by enumerating all the steps taken by any hemodialysis patient with the Covid-19 virus from the moment of his arrival at the hemodialysis department of the PHC El Jadida until his departure (Figure 1).

Process analysis

The analysis of the process was based on the analysis of the failures detected for each step of the process of taking care of these patients, using the Ishikawa Diagram and Brainstorming for a possible determination of the causes of the failures and their effects. This second step was initiated according to the following logic:

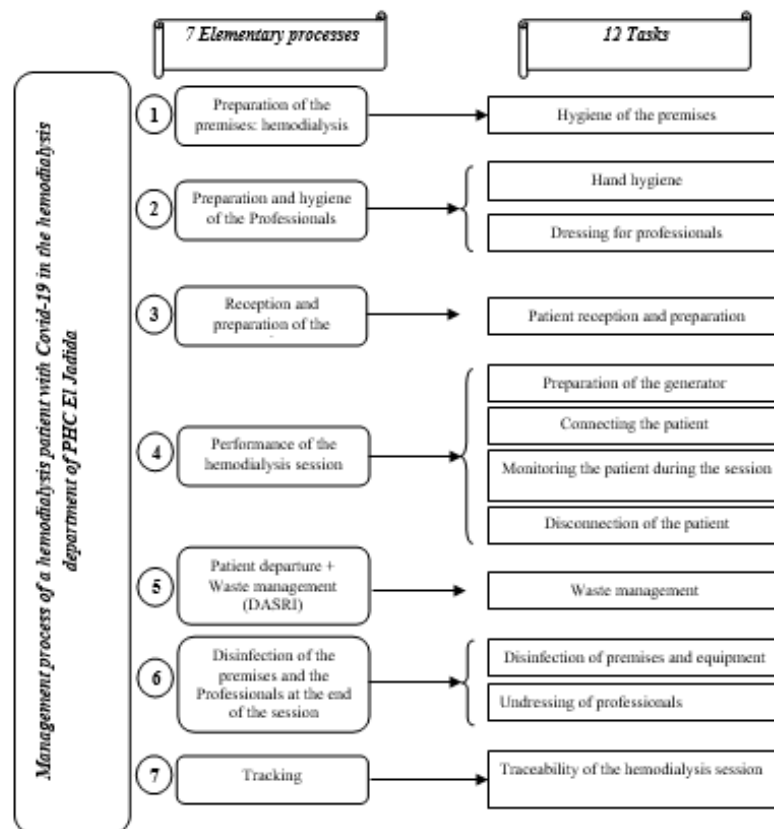


Figure 1. Management process of a hemodialysis patient with Covid-19.

Determination of failures

The identification of the risks named failure modes is based on the identification of all the inappropriate actions or errors that may have occurred for each step of the process through Brainstorming.

Identification of causes

The identification of the causes is done through the Ishikawa Diagram for the process of managing a hemodialysis patient with Covid-19 (Figure 2).

Definition of the possible effects

Then the projection of the consequences and impact of these failures on the management process of hemodialysis patients with Covid-19 virus.

Risk assessment and prioritization

The risks were rated according to three dimensions (Table 1):

- Frequency (F): How often does this risk occur?
- Severity (S): What is the magnitude of the risk to the patient?
- Detectability (D): How easy or difficult is it to detect the risk?

Each measurement dimension has a rating from 1 to 4 (Table 1) which was used to calculate the criticality (C) from the product of the frequency, severity and detectability $C = F \times S \times D$ of each failure mode and was illustrated by a criticality decision matrix (Table 2).

The prioritization of risks is always based on the calculation of criticality (C), which allows us to categorize the levels of risk (Table 3):

- Low criticality: Acceptable under control;

- Moderate criticality: Tolerable under supervision and must be corrected;

- High criticality: Unacceptable and should be treated as a priority.

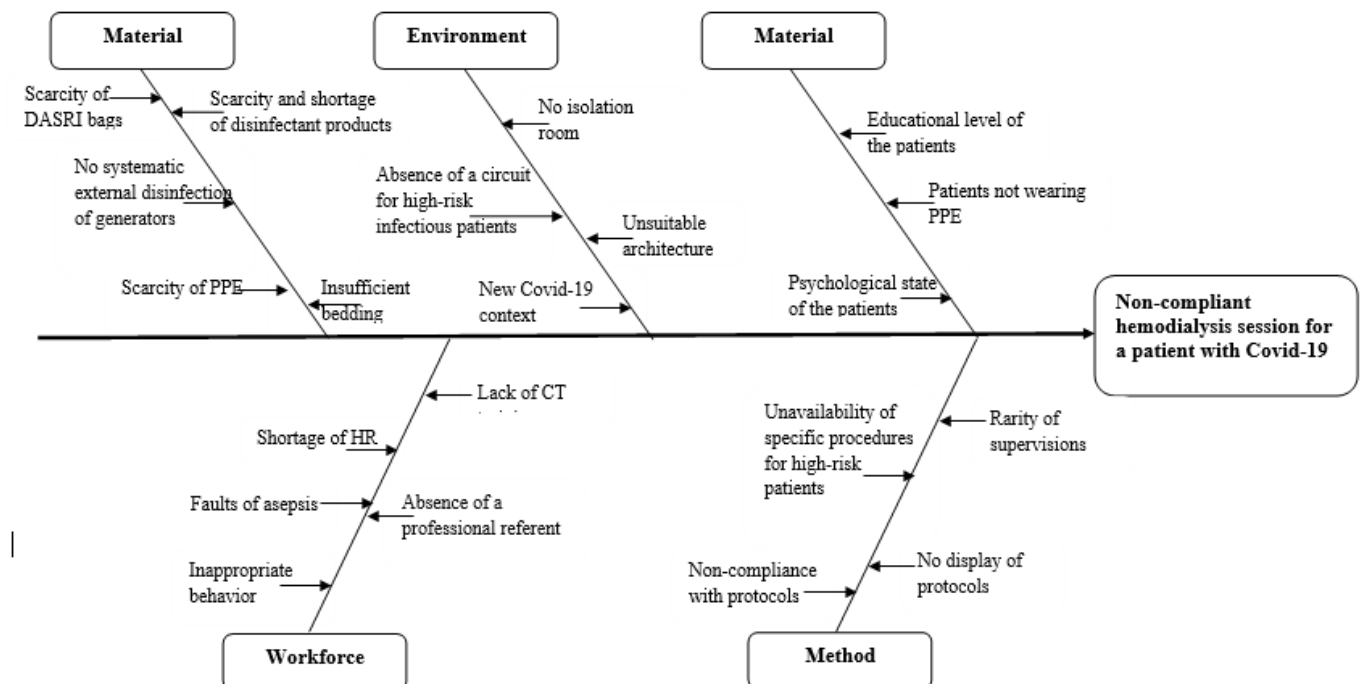
Finally, the determination of the criticality levels of the different failure modes allowed the elaboration of the risk control plan by prioritizing the implementation of the proposed corrective actions in order to reduce the failures whose criticality is high first, followed by the failures whose criticality is moderate.

Result

The mapping of the infectious risk in a patient with Covid-19 during a hemodialysis session from arrival to departure by applying the FMECA method allowed us to deconstruct the process of managing

Table 1. Risk rating scale.

Frequency	Score	Frequency level	Criteria
F1	1	Infrequent	Failure noted at least once a month
F2	2	Somewhat frequent	Failure noted at least once a week
F3	3	Common	Failure noted once a day
F4	4	Very common	Failure noted more than once a day
Severity	Score	Severity level	Criteria
S1	1	Minor	Minor incident with no impact
S2	2	Moderate	Incident with temporary injury
S3	3	Major	Incident with impact
S4	4	Review	Serious incident
Detectability	Score	Detectability level	Criteria
D1	1	Very detectable	Always detectable by observation
D2	2	Detectable	Easily detectable
D3	3	Not very detectable	Difficult to detect
D4	4	Not detectable	Never detectable



PPE: Personal Protective Equipment; HR: Human Resources; CT: Continuous Training

Figure 2: Ishikawa diagram.

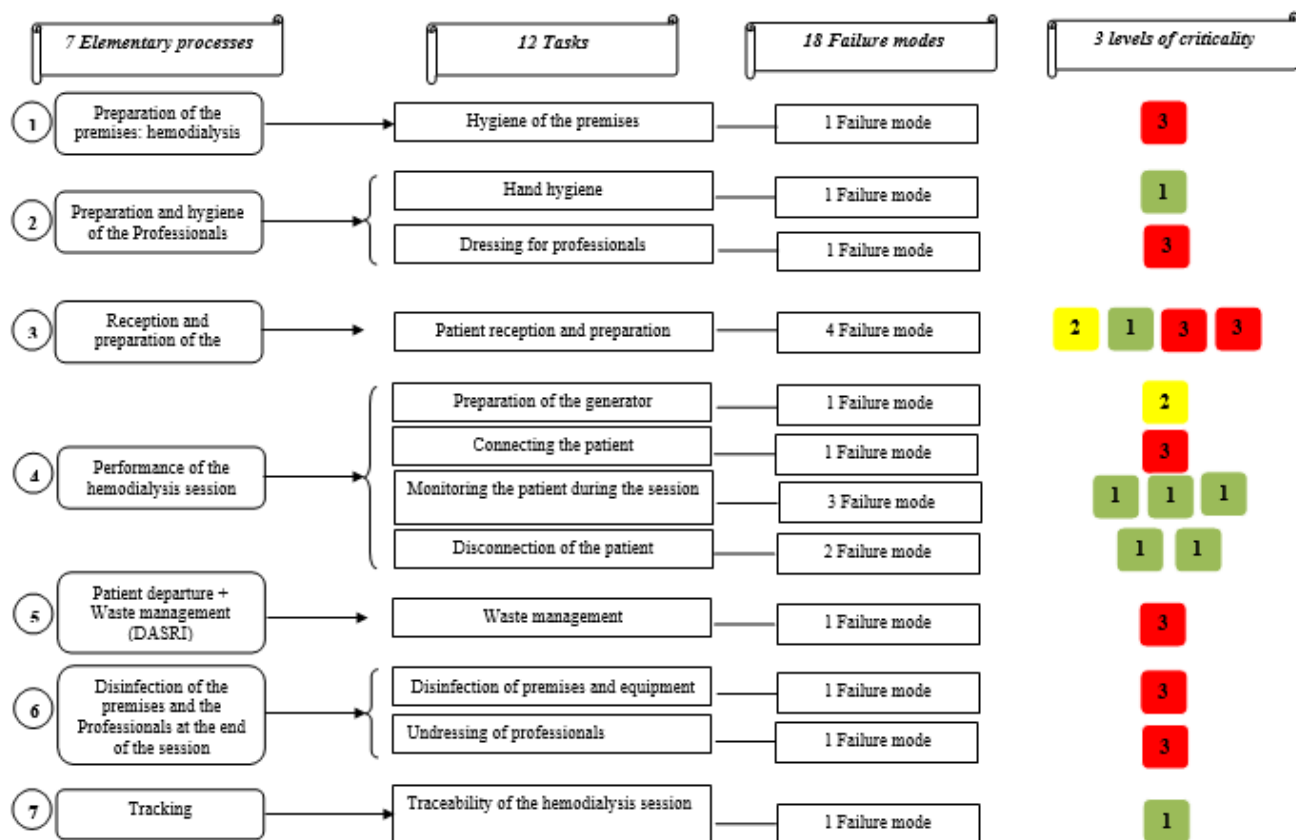


Figure 3: Représentation de la cartographie des risques du processus complet.

the hemodialysis patient with Covid-19 into 7 elementary processes containing 12 tasks (Figure 1).

The Ishikawa Diagram identified the causes of the various failures leading to the non-compliant management of the hemodialysis patient with Covid-19 (Figure 2).

The FMECA analysis illustrated 18 failures in the ECP of a Covid-19 patient during a hemodialysis session, including 8 failure modes classified in criticality class C3 (44.44%), 2 failure modes classified in criticality class C2 (11.11%) and 8 failure modes classified in criticality class C1 (44.44%) (Table 4).

Figure 3 represents the risk map of the complete process of managing a patient with Covid-19 during a hemodialysis session highlighting 7 elementary processes, 12 tasks, 18 failure modes and 3 criticality levels.

The failure modes of criticality level 3 are the object of immediate corrective actions that have been reported in Table 5.

Discussion

The application of the FMECA method in the process of managing a hemodialysis patient with Covid-19 during a hemodialysis session allowed us to map the infectious risk in this patient by highlighting 18 failure modes likely to affect the quality of this management. The evaluation of the degree of risk acceptability highlighted 8 failure modes of unacceptable criticality (C3) which must be treated as a priority.

The FMECA method helped us to determine the different stages of the process of care of a patient with Covid-19 during a hemodialysis

session as well as the failures related to any stage of the process based on two components. On the one hand, the qualitative part of the FMECA elucidated the failure modes related to each task in each step of the process by deconstructing the causes through the Ishikawa diagram (Figure 2), and the consequences through brainstorming (Table 4). On the other hand, the quantitative part of this method has counted the criticality of each failure mode by adopting a scale of frequency, severity and detectability (Table 1) in order to categorize the criticality of all failures and then prioritize the corrective actions following this component (Table 5).

The detected failures and their consequences (Table 4) have been categorized into three levels of criticality:

Acceptable risks under control

The FMECA allowed us to identify 8 failure modes with acceptable risks in the different steps of the process of taking care of hemodialysis patients suffering from Covid-19 during a hemodialysis session at low frequency and easily detectable:

The lack of hand hygiene with low frequency resulting in infectious and professional risks;

Poorly stored bedding material, mainly due to the non-availability of bedding linen, leading to the non-change of this linen between two patients (Covid-19);

Accidental removal of the catheter due to inadequate fixation, which leads to hemorrhagic and infectious risks;

Table 2. Criticality Decision Matrix.

Frequency	Severity						Detectability
		1	2	3	4		
	1	1	2	3	4	1	
	2	4	8	12	16	2	
	3	9	18	27	36	3	
	4	16	32	48	64	4	

Table 3. Risk acceptability level.

Criticality class	Score	Level of risk	Actions
C 1	1 à 8	Acceptable under control	Evaluation implemented, effective follow-up
C 2	9 à 16	Tolerable under control and must be corrected	Action to be taken to reduce the risk
C 3	17 à 64	Unacceptable to be treated as a priority	Immediate action to be taken

Table 4: FMECA analysis.

Elementary process	Tasks	Failures	Causes	Consequences	F	S	D	C
1	Hygiene of the premises	Inappropriate state of disinfection	-Scarcity and shortage of disinfecting products; -Absence of protocols for disinfecting the premises.	Infectious risks	3	3	2	18
2	Hand hygiene	Lack of hand hygiene	-Non-compliance with handwashing protocols; -Failure to post handwashing protocols.	Infectious risks Professional risks	1	3	2	6
	Dressing for professionals	Dressing techniques	- Lack of ongoing training; -No specific protocol developed	Infectious risks Professional risks	3	4	2	24
3	Patient reception and preparation	Poor patient hygiene	Non-application of hygiene rules by the patient; Non-use of PPE by patients (surgical mask; -Dependent patient.	Infectious risks Professional risks	2	4	2	16
		Poorly maintained bedding material	-Insufficient Bedding; -Lack of linen change between two patients Covid-19;	Infectious risk; Organizational risk.	2	3	1	6
		Lack of knowledge of the modes of transmission of Covid-19	-New context of the Covid-19 pandemic - Scarcity of scientific studies	Infectious risk; Organizational risk Professional risks	3	3	3	27
		Isolation of the uninsured patient	-Absence of the isolation room -Lack of appropriate procedures		4	3	2	24
4	Preparation of the generator	External disinfection of the generator (EDG)	-Failure to develop disinfection procedures; -Failure to provide ongoing training in this area (EDG)	Infectious risks Professional risks	1	3	3	9
	Connecting the patient	Asepsis and safety rules not respected for intravenous fistula (IF) puncture or catheter placement	Non-application of management protocols ; -Aseptic errors.	Infectious risk;	2	4	3	24
	Monitoring the patient during the session	Accidental removal of the catheter	Insufficient fixation of the catheter	Risk of infection Risk of bleeding	1	3	2	6
		Improper handling of the line during the session	Lack of immediate needle removal.	Infectious risk;	1	2	1	2
		Asepsis rules not respected during the session	Faults of asepsis.	Infectious risks Professional risks	1	3	1	3
	Disconnection of the patient	Septic Compression	Non-sterile dressings	Infectious risk	1	2	1	2
5	Waste management	Inadequate Waste from Healthcare Activities with Infectious Risks (WHAIR) management	- Absence of WHAIR bags; -Absence of a central waste management room in the hemodialysis department;	Infectious risk	2	3	3	18
		Disinfection of premises and equipment	-Inappropriate disinfection of premises; -Professional not trained in disinfection of premises;	Infectious risks Professional risks	3	3	3	27
6	Undressing of professionals	- Undressing technique difficult to practice and not mastered	-Duration of the hemodialysis session; -Non-compliance with the protocol for undressing after contact with a Covid-19 positive patient	Infectious risks Professional risks	2	3	3	18
7	Traceability of the hemodialysis session	Input error	Workload	Organizational risk	1	2	2	4

Table 5: Corrective actions for criticality level 3 failure modes.

Elementary process	Tasks	Failures	Causes	Consequences	F	G	D	C	Corrective actions
1	Hygiene of the premises	Inappropriate state of disinfection	-Scarcity and shortage of disinfecting products; -Absence of protocols for disinfecting the premises.	Infectious risks	3	3	2	18	- <i>Elaboration of disinfection protocol;</i> - <i>Availability of quality disinfectant products.</i>
2	Dressing for professionals	Dressing techniques	-Lack of ongoing training; -No specific protocol developed	Infectious risks Professional risks	3	4	2	24	- <i>Continuous training for the staff of the department in the management of a Covid-19 patient;</i> - <i>Elaboration of specific protocols for this management.</i>
3	Patient reception and preparation	Lack of knowledge of the modes of transmission of Covid-19	-New context of the Covid-19 pandemic; - Scarcity of scientific studies.	Infectious risk; Organizational risk	3	3	3	27	- <i>Adaptation of management to the latest scientific developments.</i>
		Isolation of the uninsured patient	-Absence of the isolation room; -Lack of appropriate procedures.	Professional risks	4	3	2	24	- <i>Proposal to set up an isolation room in the hemodialysis department.</i>
	Connecting the patient	Asepsis and safety rules not respected for IF puncture or catheter placement	Non-application of management protocols ; -Aseptic errors.	Infectious risk;	2	4	3	24	- <i>Updating and application of management protocols;</i> - <i>Supervision of management activities.</i>
5	Waste management	Inadequate WHAIR management	- Absence of WHAIR bags; -Absence of a central waste management room in the hemodialysis department;	Infectious risk	2	3	3	18	- <i>Availability of DASRI bags.</i> - <i>Training of professionals in DASRI management in Covid-19</i>
6	Disinfection of premises and equipment	-Inappropriate disinfection of premises	-Inappropriate disinfectant quality; -Professional not trained in disinfection of premises;	Infectious risks Professional risks	3	3	3	27	- <i>Training of professionals in disinfection;</i> - <i>The supply of sufficient quantities of quality disinfectants.</i>
	Undressing of professionals	- Undressing technique difficult to practice and not mastered	-Duration of the hemodialysis session; -Non-compliance with the protocol for undressing after contact with a Covid-19 positive patient	Infectious risks Professional risks	2	3	3	18	- <i>Continuing education for department staff in the management of a Covid-19 patient.</i>

Inadequate handling of the line during the session due to the absence of immediate removal of the needle, leading to an infectious risk;

Asepsis rules not respected during the session due to asepsis faults, which can lead to infectious and professional risks;

Septic compression at very low frequency due to the use of non-sterile dressings generating an infectious risk;

Inappropriate dressing of catheters or fistulas due to non-compliance with asepsis rules resulting in the appearance of infectious risks.

All these C1 criticality risks must be controlled so that they do not develop into another criticality level (C2 or C3) and must be managed by training professionals, raising their awareness and standardizing and applying management procedures and protocols.

Tolerable risks under supervision

Two failure modes have been identified for tolerable risks in the different steps of the management process of hemodialysis patients with Covid-19 during a hemodialysis session:

Faulty hygiene of the patient due to the non-application of hygiene rules by the patient, non-use of PPE by the patients, which generates infectious and professional risks;

The external disinfection of the generator (EDG) due to the non-elaboration of disinfection procedure and non-dispensation of continuous training in EDG during the Covid-19 pandemic.

The monitoring of these two failures will be ensured on the one hand by training and information of professionals, and on the other hand by sensitizing patients to hygiene and the use of PPE during the hemodialysis session.

Unacceptable Risks to be Prioritized

Eight failure modes have been identified for unacceptable risks in the different steps of the process of taking care of hemodialysis patients with Covid-19 during a hemodialysis session and which must be treated as a priority given their criticality and their impact:

The state of disinfection of the premises is inappropriate due to the scarcity and shortage of disinfecting products, the absence of protocols for disinfection of the premises during the Covid-19 pandemic, which includes the infectious and professional risk. The corrective actions lie in the elaboration of protocols of disinfection of the premises in the context of Covid-19, in addition to the availability of disinfecting products in quality and sufficient quantity;

The inappropriate dressing and undressing techniques used by professionals during this care due to lack of training, non-development of protocols for these techniques, and finally, the difficulty in implementing these techniques, which results in the propagation of infectious and professional risks. The corrective actions are based on the practical training of the professionals in the management of a Covid-19 patient as well as the elaboration of protocols for this management;

The lack of knowledge of all the modes of transmission of Covid-19 given the new context of the Covid-19 pandemic and the scarcity of

scientific studies, which leads to the appearance of infectious risk. Nevertheless, the adaptation of the management to the scientific actuality, to the evidences and to the directives of the Ministry of Health;

The isolation of the patient suffering from Covid-19 is not ensured because of the absence of an isolation room in the hemodialysis department, which facilitates the propagation of the infectious risk. So, the installation of an isolation room remains the most appropriate way to deal with this risk, nevertheless it will take time and in order to act immediately the department has recommended two to three half-days per week dedicated to the care of only those patients with Covid-19 and requiring hemodialysis;

Risk of sepsis and safety not respected for IF puncture or catheter placement due to sepsis and non-application of management protocols, which results in the appearance of infectious risks. In order to cope with this, supervision activities must be organized to ensure rigorous application of management protocols;

Inappropriate Waste from Healthcare Activities with Infectious Risks (WHAIR) management at the end of the hemodialysis session due to the unavailability of WHAIR bags, the absence of a central waste management room in the hemodialysis department, and the absence of WHAIR management training in the Covid-19 context. However, the correction of this risk lies in the training of professionals in the management of WHAIR as well as the adequate supply of WHAIR bags;

Inappropriate disinfection of the premises and equipment at the end of the hemodialysis session of the Covid-19 patient due to the inadequate quality of the disinfectant products and the lack of expertise of the professionals in the department in the area of disinfection of the premises. However, the resolution of this risk lies in the adequate choice of the quality of the disinfectants that meet the need and the organization of practical workshops on disinfection of the premises for the benefit of the professionals of the hemodialysis service.

Conclusion

The method of risk analysis FMECA is an essential tool in the detection a priori of risks that can affect the process of taking care of a patient with Covid-19 during a session of hemodialysis by making a risk map whose goal is to improve the safety of the patient during this care and consequently to improve the quality of care and satisfy the population. Nevertheless, this method illustrates certain limitations, particularly the choice of failures and the rating of criticality, which depended on the work team.

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