The Implementation of a Hazard Analysis and Critical Control Points (HACCP) within a Hospital System Case: Hemodialysis Department, Central Hospital in Algeria

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Summary - **Hospital hygiene encompasses a set of protective measures to be implemented to combat the risks and nuisances to which patients, staff and visitors are exposed in a hospital environment and in particular those linked to nosocomial infections or other related infections. care (parasites, bacteria and viruses). Among the hospital services that interest us, the hemodialysis department which includes all the extrarenal purification modalities which use extracorporeal circulation. These modalities can be classified according to their techniques or according to the structures in which they are implemented. This service takes care of patients with chronic kidney failure. People with kidney failure have many risk factors predisposing to infections, including immune deficiency and multiple cutaneous portals of entry. (bacterial and viral infections) and the means implemented to avoid contamination of hemodialysis patients and hospital staff.**

Keywords- **Hemodialysis; renal failure, management of infectious risk; Hospital hygiene ; Hepatitis B.**

Abstract:

1. Introduction:

Chronic kidney failure patients (CKD) treated by hemodialysis (HD) have a life expectancy which increases regularly with the improvement of techniques; it can currently be estimated at more than 30 years. The duration and especially the quality of this survival are directly influenced by different factors (duration of sessions, correction of associated disorders, etc.) among which the

chemical and bacteriological purity of dialysis solutes plays a large role due to the importance of exchanges between these solutes and the patient's blood through a dialysis membrane a few microns thick. During a 4-hour session, 120 liters of solute are thus indirectly in contact with the blood. This purification process is largely carried out by diffusion of metabolic waste and electrolytes from the blood into the dialysis fluid.

Any hemodialysis session carries the risk of transmission of a pathogenic microorganism at each level of the purification process: dialysis water, concentrated solutions, generator, lines and vascular access.

Within the hemodialysis department of EPH central, many hemodialysis patients are exposed to the risk of infections linked to the care procedures performed. The question that arises is: how to minimize nosocomial infections in these patients? To resolve this problem, we will try to apply the HACCP approach which consists of identifying dangers and analyzing infectious risks (bacterial and viral infections) and the means implemented to avoid contamination of hemodialysis patients and hospital staff.

This study consists of identifying and listing the dangers and risks linked to the hemodialysis service in order to remedy and eliminate them to ensure maximum care and healthy and effective management of hemodialysis patients.

2. **Hospital Hygiene**

Hospital hygiene is a series of functions and activities encompassing actions that ensure better adaptation of the environment in order to achieve the satisfaction of patients and the healthcare team, essentially in the prevention of nosocomial infectious complications.

Hospital hygiene is a set of protective measures to be implemented to combat the risks and nuisances to which patients, staff, and visitors are exposed in a hospital environment and in particular against the risk of infection. [1,2]

2.1. ***Nosocomial Infections:***

The term nosocomial is Greek nosos (disease), komein : to treat.

According to circular n° 263 of October 13, 1988 of decree 88-657

of May 6, 1988 Relating to the institution of committees to combat nosocomial infections, these are :

- Any disease caused by micro-organisms

- Contracted by a healthcare establishment by any patient after their admission, either for hospitalization or to receive outpatient care

- Whether the symptoms appear during the hospital stay or afterwards

- Whether the infection is recognizable clinically or microbiologically, including serological data, or both at the same time.

These characteristics also concern hospital staff because of their activities.

"An infection is said to be associated with healthcare (HAI), if it occurs during or after treatment (diagnostic, therapeutic, palliative, preventive or deductive) of a patient if this infection was not present or during incubation or at the start of treatment," according to the WHO.

The hospital currently plays a considerable role, thanks to two factors whose development is irreversible: the progress of medical sciences which requires the concentration of qualified personnel and specialized equipment of high-tech institutions on the one hand, the ease of communications which goes hand in hand with urbanization on the other hand.

The hospital system must therefore be made accessible to all social classes and cover the geographical extent where the population lives.

On the other hand, the presence and passage of patients carrying numerous pathologies, and the chronic use of drugs and biocides exposes them to a risk of nosocomial infection.

3. Description of the HACCP system:

HACCP is the abbreviation of " Hazard Analysis Critical Control Point" which means in French: Risk Analysis – Critical Points for their Control.

HACCP is a systematic and rational method or approach to controlling hazards to guarantee the safety of a product. It is based

on a simple principle: “Prevention is better than cure... >>

HACCP is closely linked to safety. However, its application is not limited to the agri-food sector only; it is also used in other fields of activity such as the aeronautical industry, the chemical industry or even the nuclear industry, health sector as the case of our study.

A hazard, according to the HACCP system, is defined as a “biological, biochemical or physical agent or condition of the food which potentially has an adverse effect on health”. A critical control point (CCP) is the "stage at which monitoring can be exercised and is essential to prevent or eliminate a hazard threatening the proper functioning of the hemodialysis system or reduce it to an acceptable level".

The HACCP plan is a method which makes it possible to identify hazards and calculate potential risks in order to establish measures to control them. It is intended to control risks and avoid contamination.

In addition, the application of the HACCP system can help regulatory services in their inspection task. [3, 4, 5, 6]

3.*1 The Principles of HACCP:*

The HACCP system includes seven principles, which make it possible to establish, implement and conduct a HACCP plan while respecting the principles of the Deeming Wheel , according to the following diagram:

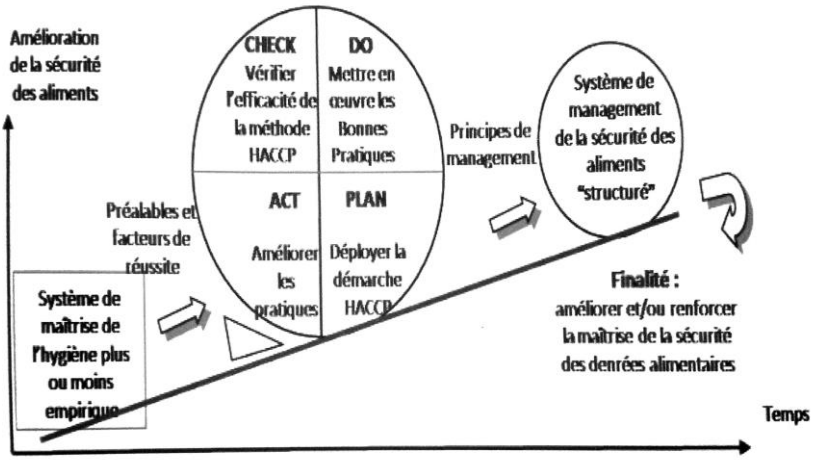

Figure 1 : Les Principes de HACCP (Roue de Deeming) [7,8]

Principle 1: Perform a risk analysis

Identify potential hazards associated with all stages of processing, using a process step flow chart.

Principle 2 : **Identify critical control points (CCP)**

Determine what operational points, procedures or steps can be controlled to eliminate the hazards, or minimize the possibility of them occurring, or reduce the hazards to an acceptable level.

Principle 3: Establish critical thresholds

Ideal levels and tolerances to respect so that CCPs are controlled. They must involve a measurable parameter and can be considered as the absolute safety threshold or limit for CCPs.

Principle 4: Establish a monitoring system to control CCPs through planned testing or observation.

Principle 5: Establish corrective actions to be taken when monitoring indicates that a given CCP is not under control.

Procedures and responsibilities for corrective action should be specified.

Principle 6: Establish procedures for verification, including including additional testing and procedures to confirm that the HACCP system is operating effectively.

Principle 7: Develop documentation of all procedures and reports relating to the application of these principles [9, 10]

Reports will be kept to prove that the HACCP system is in control and that appropriate corrective measures have been taken at the slightest deviation from the Critical Limits.

3.2 *Implementation of HACCP:*

The Hazard Analysis Critical Control Point (HACCP) system is a system that helps organizations identify possible hazards to ensure the proper operation of the hemodialysis system and eliminate the danger of contamination and infection . HACCP focuses on hazard prevention rather than control. A series of 12 measures is proposed below; it covers the essential points for the application of the HACCP method:

1- Build the HACCP team
2- Describe the product and its distribution
3- Identify the intended use of the product
4- Build the process diagram
5- Confirm diagram on site

6- Identify the hazards associated with each step
7- Determine critical control points (CCP)
8- Define critical limits for each CCP
9- Establish a monitoring system
10- Define corrective actions
11- Establish verification procedures
12- Establish documentation and archiving

A. Example of premises assessment:

The layout of the premises, the construction and the quality of the materials must be such as to prevent any condition likely to result in damage and/or contamination of patients, staff and facilities.

Evaluation criteria	State of play	Adequate	Action to take
Layout			
Has premises allowing easy movement of patients with reduced mobility or wheelchairs	It has premises allowing easy movement of patients with reduced mobility.	acceptable	/
Has a specific room for training in self-dialysis or home dialysis	Absence	Major gap	Appropriate premises must be provided
Has technical premises including:			
A room reserved for the storage of clean linen and consumables	Yes	Acceptable	/
A room reserved for the storage of dirty linen and waste without communication with the preceding one	Yes	acceptable	/
A pharmacy room with a lockable medicine cabinet that can be used for preparing medications	adapted	Acceptable	/
Evaluation criteria	State of play	Adequate	Action to take
A water treatment room	Adapted	Acceptable	/
A technical room allowing the storage of emergency generators and which can be used as a workshop	Adapted to needs	Acceptable	/
Has a consultation room including:			
Access to a medical consultation office	Access to the office is easy	Acceptable	/
Access to a room used for interviews with the social worker, psychologist or dietician	Absence of the psychologist, social worker and dietitian	Major gap	Consider the presence of these practitioners
Has technical premises including:			
A room reserved for the storage of clean linen and consumables	Yes	Acceptable	/
Has other premises			

3.3. *Risk analysis in hemodialysis*

A. Healthcare-associated infectious risks (AIS)

***Endogenous infections (microorganisms from the patient)**

-Increasingly complex explorations and interventions.

-Patients increasingly fragile.

-Nosocomial infections >>

-Infections transmitted from one patient to another by the hands of medical and paramedical personnel, or from a caregiver to a patient.

-Role of the hospital environment, a reservoir of microorganisms likely to contaminate patients. [11, 12]

A.1 *Dialysate contaminated with sodium:*

* Thirsty

interdialytic weight gain

* hypertension (acute hypertension)

One of the causes of dialysate contamination is the development of a biofilm in the osmosis water distribution loop and/or in the hydraulic circuit of the generator.

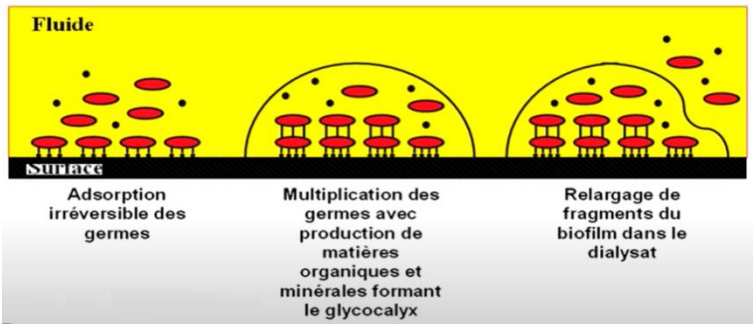

Figure 2 : Schéma pour le développement de bio-film [13,14]

B. Risks linked to health products:

Contamination of medicinal solutions is contamination of antiseptic solutions and/or medications administered during or after hemodialysis. These are most often germs rarely isolated in microbiology.

*Multi-dose vials

*EPO, insulin , heparin.

* Injector pens: individual use, by the patient (AES risk for caregivers)

*Medical devices shared without sufficient maintenance between two patients (blood glucose meter). [15]

C. HBV viral risk:

* Highly transmissible virus.

*Relatively resistant virus in the environment possible stability of 7 days on an inert surface.

* Transmission from a source patient.

* Contamination of the generator, contacting the vascular access via gloves or other contaminated supports.

* Possible risk linked to unsuitable vaccination strategies.

* Residual risk associated with poor immune response of patients.

4. Risk Management

Compliance with general hygiene precautions or “Standard” precautions when caring for all patients:

- hand hygiene
- Wearing gloves
- treatment of soiled materials
- management of linen and waste in waterproof packaging, closed at the end of the treatment
- descaling
- cleaning
- the use of bactericide, fungicide, virucide, mycobactericide during the disinfection of hydraulic circuits.
- Sterilization using the autoclave [16]

5. Application of the HACCP Method in the Hemodialysis Department at EPH Central

5.1 *Presentation of the Team*

The care of dialysis patients is provided by:

- A nephrologist
- 04 general practitioners
- 11 IDE nurses.
- 04 ATS
- 04 technicians
- A medical supervisor.
- A psychologist.
- A social worker

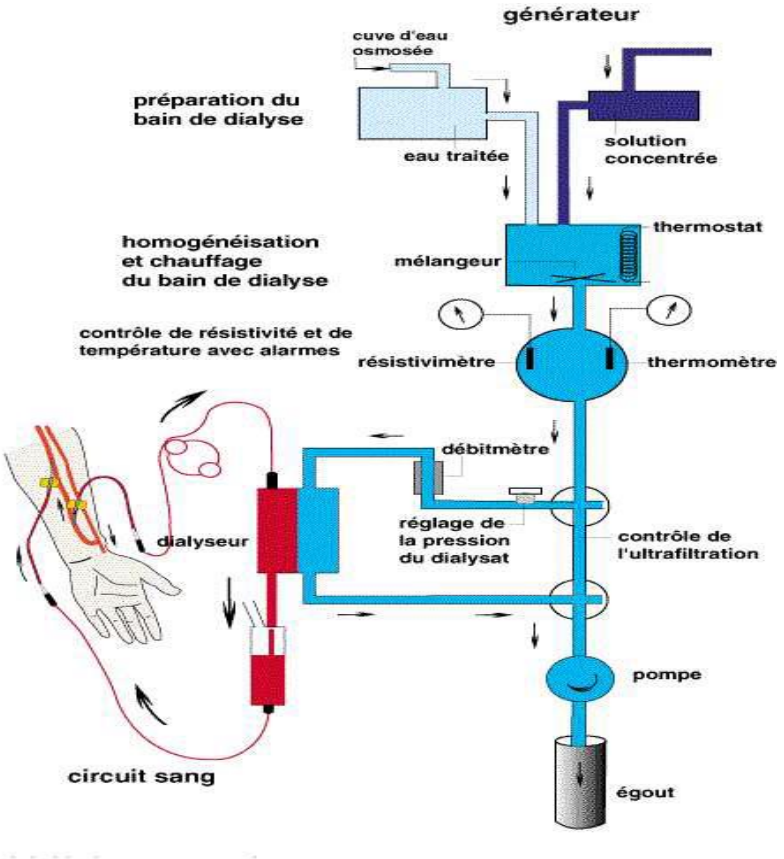

Figure 3: Dialysis generator with blood and dialysate circuits Diagram for hemodialysis [17]

5.2 *Determination of CCPs:*

Generally there are two methods used for determining a CCP

5.1. The decision tree below is generally intended for the food industry, as part of the implementation of a HACCP plan. It consists of a systematic series of four questions designed to objectively estimate whether a CCP is necessary for control the danger identified at a given stage

The application of this tool for identifying risks in healthcare activity cannot be adapted for all stages of healthcare activity. Work has been carried out in this direction except that it has not been satisfactory in terms of reliability of the results. However, this tool allowed us to validate the critical points identified by the weighting method.

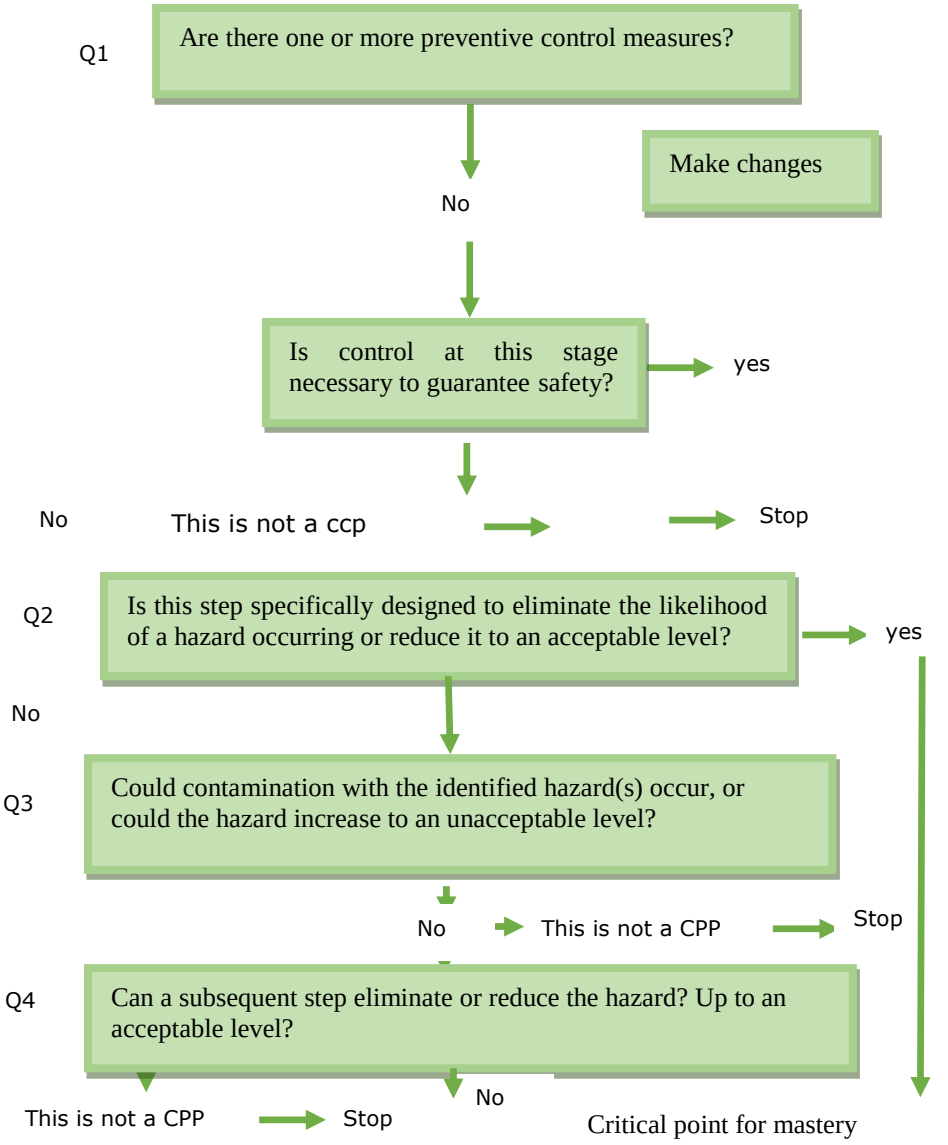

Figure 4: Decision tree

5.2. Weighting method.

Determining CCPs by weighting (rating) is a widely applied tool. It is a tool which must be applied by a multidisciplinary group, it involves weighting each identified danger taking into account three criteria: the seriousness of the danger, its frequency of appearance and its frequency of non- detection. Development rating scales (Tables 5.1; and 5.2) of the characteristics of the dysfunctions in particular the level of severity (G), the frequency of appearance (occurrence) (0) and non-detection (ND) are given by experts in the field of hemodialysis activity

Table 5.1
Severity scale (company data)

Table 5.1: Severity scale.	
Severity	Note (unit)
Discomfort, disturbance or minor incident	1
Reversible lesion or damage not requiring medical intervention	2
Absence of vital risk.	3
Incident or accident without vital risk (serious or prolonged discomfort).	4
Medium-term disruption.	5
Reversible injury or damage requiring medical treatment.	6
Non-immediate vital risk.	7
Delayed but serious consequence for the patient	8
Irreversible injury or damage.	9
Fatal or serious short-term consequence.	10

Table 5.2
Probability of occurrence scale (company data)

Probability of occurrence	Note (unit)
About once a year	1
1 time per semester	2
1 time per quarter	3
1 time per month	4
2 times a month	5
1 time per week	6
2 to 3 times a week	7
Each day	8
Several times a day	9
To each incoming patient	10

identified dangers : Example of process 1: Reception and preparation of the patient for the session.

A quantitative evaluation using the method of weighting the dangers identified at each of the processes, sub-processes and at each of the stages of the hemodialysis activity from the patient's arrival until their departure was carried out.

Estimates of the level of severity, the probability of occurrence and the probability of non-detection of the identified dangers are assessed jointly with the practitioners of the N'gaous hemodialysis service through the use of feedback.

Table 6.1 Process 1:
Reception and preparation of the patient for the session.

Table 6.1 : Reception and preparation of the patient for the session

ID number	Stage	Danger "*I ,AES,DT *" identifies	*G	*O	*ND	G
1	Patient reception	- the arrangement of a common locker room, - Insufficient maintenance of the locker room, - Cleanliness of clothes. May lead to cross-contamination between patients	6 5 7	4 4 5	1 1 1	24 20 35
		Cross contamination. I-(1, 2): The introduction of sock shoes into the dialysis room increases the risk of infection and environmental contamination	4	6	2	48
2	Preparation and access to the approach	**Cross contamination. I-(2, 1):** Clothing that is difficult to remove and long sleeves in contact with the puncture site lead to: - Difficulty of access to the approach, - Self-contamination by contact, - Difficulty disinfecting the puncture area, - Dysfunction of the fistula by placing the tourniquet on clothing. Which leads to contamination of the approach	 5 6 7 5	 5 5 5 5	 2 3 2 2	 50 90 70 50
3	Assessment of patient cleanliness	**Cross contamination I-(3, 1):** **Poor patient hygiene :** - Lack of cleanliness of arms and hands, -Non-quantitative adequacy of staff for patient care, - Loss of patient autonomy, - Absence of sanitary means in the patient May induce an infectious risk, contamination of the patient's approach	 2 4 4 7	 2 2 6 4	 2 2 2 2	 8 16 48 56

(G) *: the severity level; (o)* the frequency of appearance (occurrence) and (ND)*: non-detection; (I)*: Infectious; (DT)*: Technical Defection.

7.Discussions : see table below:

Among the dangers identified at all stages of hemodialysis activity, we can distinguish those which are controlled within the framework of good care and hygiene practices and those which represent critical points and require particular attention from professionals. who must treat them as a priority (See table 7).

Table 7

Summary of critical point descriptions, example of some steps

Steps No.	CCP No.	Description of the critical point	Mastered at
Generator disinfection	CCP-I1	- The volume of the disinfection solution insufficient; disinfectant chemicals ; - An insufficiency of the disinfection scale (temperature cycle time); Can lead to an absence or insufficient disinfection hence the hydraulic circuit (dialysis) -Poor quality of the rinsing operation which results in: -Insufficient rinsing time, leads to insufficient disinfection, resulting in contamination of the generator	1. Systematic cleaning and disinfection after each dialysis session of the external surfaces of the generator. 2. Compliance with maintenance and cleaning procedures for the exterior of the generator. 3. Renewal of disinfection operations after a storage time of more than 12 hours. 4. Disinfection protocol regular backup generators. 5. Recording of disinfection operations.

Dialysis conductivity monitoring	CCP-DT.1	Excessive values of dialysate manufacturing parameters could lead to hemolysis	-Reduce the values of manufacturing parameters dialysate
Blood pressure monitoring	CCP-DT.2	Too low blood pressure indicates occlusion of the arterial line upstream of the pump. Which induces a collapsed fistula.	1. Frequently monitor the arterial pressure, 2. control means : if the fistula flow is too low compared to the requested flow it can collab. In this case, the pump blood is stopped
Venous pressure monitoring	CCP-DT.3	An abnormally high value (greater than 150 mm Hg) of the blood pressure downstream of the dialyzer (venous pressure), in dual puncture circuits, indicates an obstacle to blood restitution; If the venous pressure increases gradually, especially at the end of the session, it is usually a case of progressive thrombosis of the distal tubing and/or the needle or catheter and/or the fistula itself	1. Find a seam in the tubing located downstream, 2. Suspect an obstacle at the level fistula ; 3. Extracting clots from the fistula which adhere to the needle at the moment the withdrawal of the latter; 4. More heparinization intense must then be ensured during purification sessions later

8. Conclusion :

Hospital hygiene encompasses a set of protective measures to be implemented to combat the risks and nuisances to which patients, staff and visitors

are exposed in a hospital environment and in particular those linked to nosocomial infections or other related infections. care (parasites, bacteria, viruses). The hemodialysis department presents our favorite area, it includes all the extrarenal purification modalities which use extracorporeal circulation.

This service takes care of patients with chronic kidney failure. People with kidney failure have many risk factors predisposing to infections, including immune deficiency and multiple cutaneous portals of entry.

The pathogens are viruses such as hepatitis B, hepatitis C, AIDS, staphylococcal bacteria and Gram-negative bacilli.

Our study allowed us, through HACCP, to determine all excesses: identification of dangers, analysis of infectious risks (bacterial and viral infections) and to propose barriers in order to avoid contamination of hemodialysis patients and hospital staff (Table 7 : Summary of descriptions of critical points).

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