

Towards a better control of the infectious risks associated with health care activities

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Abstract

The infection associated with health care is a major cause of morbidity and mortality in health establishment. For a dialyzed renal failure, it would be responsible of about 15 % of the deaths. To answer this issue, health establishments use a classical approach, which rests essentially on risk management practices, which enters within the scope of a global analysis of risk management. These practices are built on the anticipation principle; they are based on the identification and the control of the possible risks, of which it is practically impossible to guarantee the exhaustiveness of the risky situations, so it is not possible to leave these anticipation practices at the present time. This is why, for better a control of the infectious risks associated with health care, it is necessary to consolidate more and more this preventive approach and thus to minimize the residual risks. For that purpose an approach is proposed, it is based on a continuous primary prevention strategy, which constitutes a first layer of the protection and is supported by some control and monitoring mechanisms of the critical risks. This approach is illustrated via a real case of study. It is carried out at the hemodialysis center at the teaching hospital, CHU-Batna Algeria.

Keywords: *infectious risk, hemodialysis, VHB, VHC, VIH Bacteremia.*

1. Introduction

The control of the infectious risks, particularly those associated with health care is a major and permanent concern in the health establishments. Indeed the infections associated with health care can have more or less great consequences, going from of a simple pain of the patient and/or the personnel of the establishment, making him faded temporarily the quality of life, until a serious pathology, which leads to an extension in the stay duration, in a long-term disability, and even in a death. Furthermore, additional financial expenses for the patient and the health system are to be taken into account.

In order to answer the caused issue, health establishments use a traditional approach, which rests primarily on the practices of risk management coming from industrial context. This practice enters within the framework of a total analysis of risk management. It is based on the principle of anticipation, which consists of the a priori identification of all the situations with possible risk. For the situation control, some solutions are required like by the design of prevention and protection barriers and by practicing risk analysis. The question is about the control of technological failures, and of the human and organizational errors [1]. However, the literature generally imputes more than 80% of the leading causes to the organization especially when the encountered problems are in the interfaces between the actors or the processes [2].

It is thus practically impossible to guarantee the exhaustiveness of the risky situations, and to admit the assumption that no technical, human, circumstantial or environmental failure will come to disturb the activity progression [3]. In addition to that, the methods of risk analysis do not take into account the following problems: the common mode failures and the non-coherent systems operation [4].

So this traditional approach does not always guarantee the quality of the health care and much less the safety of the patients and the personnel of the health establishment.

Then, the control of the infectious risks requires the implementation of an approach, which stresses upon mechanisms that consolidate more and more the preventive approach and thus minimize the residual risks omitted by the traditional approach. The suggested approach is inspired by the model [5], which is synthesized in figure.1, is articulated around a set of actions allowing a permanent improving of the health care quality, and so minimizing the infectious risks inherent to any health care activity.

This approach rests on a strategy of continuous primary prevention, which represents a first layer of protection continuously consolidated by some mechanisms of identification, control and monitoring of the critical risks.

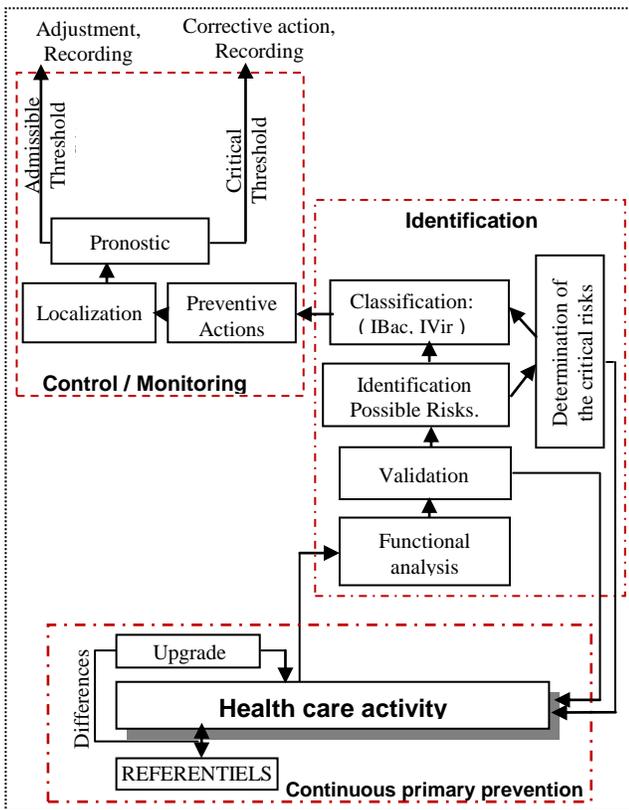


Fig 1. Synoptic diagram of the suggested approach.

The suggested approach is illustrated by a real case of study, representing infectious risks associated to health care. The activity of the chronic renal failure treatment by extra-renal purification (ERP) "Hemodialysis" is an interesting model. The site of action is the Hemodialysis center at the teaching hospital, CHU-Batna Algeria, where several studies in infectious risks are successfully carried out [6, 7, 8, 9].

The topic of the infectious risk in hemodialysis is retained because of the greatest fragility of these patients in final chronic renal failure, regularly exposed to invasive procedures that can put them in contact with various bacterial and viral infectious agents.

2. Field of activity

The hemodialysis is a blood purification technique; it requires the installation of an extra-corporal circulation:

the blood, taken at the arterial level, passes through a membrane (dialysis machine) in order to be filtered by exchange between blood and dialysate. Once purified, it turns over in the patient via the venous circuit. Dialysate circulates and is continuously renewed [10]. This method allows, therefore, to replace the defective renal function, either permanently (chronic hemodialysis, object of our study), or transiently, in waiting for recovering the renal function (grave hemodialysis).

The hemodialysis is an invasive act and requires a repetitive vascular access, on either native arteriovenous prothetic fistula, or temporary or permanent central catheters venous. Any hemodialysis session involves the risk of transmission of a pathogenic micro-organism on each level of the purification process: dialysis water, concentrated solutions, generator, lines and vascular accesses [11], and also at each stage of the intervention chains, since the arrival of the patient in the dialysis center until his exit.

In hemodialysis, the infectious risk is omnipresent, because of the complexity and the technicality of the health care. This risk concerns the patients, often immunocompromised, but also the health professionals themselves because of the many circumstances of exposure to the biological fluids met during their activity. The infectious risks related to the accidents of exposure to blood (AEB) of the health professionals are not discussed in this paper.

The patients reached of chronic renal failure are abnormally prone to the infections. These infections represent a major cause of morbidity and mortality at the dialyzed renal failure person would be responsible of about 15% for the deaths [12].

The principal infections observed among the hemodialyzed are: 1) The bacterial infections (IBac) which can be of any type but two of them are of prevalent importance in terms of morbidity and mortality and are subject to firstly epidemiologic monitoring. They are vascular access infections (IAV) whose principal micro-organisms in question are in majority Cocci with positive Gram and the bacilli with negative Gram and the bacteremia (BAC) whose principal germs in question are Cocci with positive Gram and enterobacteriaceae. (IAV) and (BAC) are regarded as indicators of the quality of the care [13]. 2) The viral infections (IVir) which are clinically represented by three hematogen viruses that are the virus of hepatitis B (VHB), hepatitis C (VHC) and the virus of the human immunodeficiency (VIH) [14,15,16]. 3) Infections related to the accidents of blood exposure (AEB) altering the health professionals and the infections related to AEB are not approached in this paper.

Like any patient, the hemodialyzed is exposed, on the one hand, with the common infection risks related to any health care activity [17] and on the other hand with the infectious risks specific to the extra-renal purification techniques as well as the working in all the stages of activity like: Contamination of the generator, of the extra-corporal circuit, of the vascular access and the environment. The infectious risks related to the water treatments before the generator are not approached in this paper.

Thus the principal transmission mechanisms of the infections associated with health care in hemodialysis were described namely: endogenous and exogenous mechanisms of contamination, mainly invasive acts, foreign materials, manual contacts and contamination by air.

Through the listed transmission mechanisms, a diagram of as a basis flows is used to identify the various situations at the risk; taking into account on the one hand the conditions and specificities of the hemodialysis center of the CHU of Batna and on the other hand the interactions between the various processes of the hemodialysis activity as well as the various actors.

3. Methods and results

The activity of the chronic renal failure (CRF) treatment by the ERP practice 'our case study' is essentially characterized by a heavy center of hemodialysis, established within the CHU of Batna town, thus allowing the full-time hospitalization of the patient in other service beds. The center comprises 19 stations of the CRF treatment with the trademark "fresenius 4008B and 4008C", of which a rescue station. With a personnel made up of two nephrologists (a head of center and a medical supervisor), the center functions uninterruptedly (except Friday) in 03 sessions per day. For each session, the team is composed of a doctor nephrologist and 7 to 8 nursing graduate status (NGS) including a man of maintenance.

The study was carried out by a multidisciplinary group of the establishment which is sometimes organized in two subgroups working separately on the basis of the same stand, leading to a single result, and this after rapprochement. This is so, with the aim of setting up the maximum reliability to the results.

3.1 Continuous primary prevention

The environment can play a significant role to indirectly facilitate the micro-organisms transmission and to increase the risk of infections.

This phase thus consists in obtaining a favourable environment to the practice of a healthy care activity. It aims at reducing the design intrinsic measurements or upgrade the contamination sources generated by the infrastructure, the logistics and the technical operating conditions of this activity. It is regarded as an essential base to the development of the suggested approach. This measurement allows reducing the primary risk and is regarded as the first layer of protection [18].

Carried out according to lawful referential requirements which specify the existing dialysis methods [19] and detail the logistic characteristics of realization and operation of each one of them [20, 21] as well as the referential of normative requirements, translated by the standards of the good practices of hospital hygiene [22, 23, 24]. The five aiming aspects, likely to generate an environmental infectious risk during the CRF treatment by the extra-renal practice [20] are: establishment of the hemodialysis center, the buildings, the equipment, personnel, and technical conditions of operation.

This phase is presented in the form of synthesis grid, which states the criteria to be satisfied (referential) in each aimed aspect. Stay closer with the existing, emphasizing variations which are estimated on the basis of following criteria of evaluation: major gap (LMa); minor gap (LMi) and acceptable (Acc). For each slack, necessary measurements for a upgrade are taken. These measurements can be engineering changes, working instructions, procedures, recommendations, without affecting as much the aspects "and monitoring controls" in the strict sense.

It should be noted, that to minimize the risk of evaluation error, this stage is carried out by two groups of experts of the establishment, working distinctly on the basis of a single document, emphasizing after rapprochement, a common evaluation grid (table 1).

The analysis of the situation of the studied hemodialysis center, shows that the establishment under study, presents considerable deficiencies, primarily related: to an infrastructure not much adapted to this activity, no standardization of the practices, a total weakness of the provisions governing the institutions as well as the technical installations, the absence of a program of human resource valorization (sensitizing, formation, and motivation).

That is summarized primarily by not taking into account the human and organizational aspects. On the other hand the center is equipped with trademark machines "fresenius 4008B and 4008C", whose device of measurement, of

control are reliable as well as an installation of trademark water treatment " CAMRO " in good operating condition.

Table 1: Summary of the case study evaluation

Aspects	LMa		LMi		Acc	
	Criterion	%	Criterion	%	critetion	%
Location	0	0	0	0	2	100
Buildings	2	9	7	32	13	59
Equipement	1	7	4	29	9	64
Personnel	2	22	3	33	4	45
Operation	10	40	6	24	9	36
Total	15	22	20	29	35	50

3.2 Functional analysis.

The control of a system thus supposes that we have the required knowledge to suitably understand it and that we have defined and implemented the technical and organizational provisions allowing to control and supervise the operation and to react to any event.

Given that our system is regarded as sociotechnical complex [25] its modeling then requires the use of the systemic approaches which are mainly focused on the interaction of sub systems and more particularly on the flow analysis.

A Flow diagram (figure 2) it indicates the principal stages of the process used for the patient treatment by ERP. This treatment requires a chain of interventions with, at each stage, the risk of human error, and/or a material failure [26], can lead to infectious risks. Thus, the field of analysis defined by the working group goes from the patient arrival in the hemodialysis center to its exit, it includes the reception and the session preparation, the care of the patient carrying a transmissible germ, the preparation of the generator, the connection of dialyzed the dialysis progress, the end of meeting and disconnection of the dialyzed, the evacuation of the linen and waste, and finally the departure of the dialyzed.

For the examined hemodialysis process '12 'steps were obtained. Thus, each step can induce the risk of bacterial and / or viral infection that will be identified within a dysfunctional analysis. In addition, a mapping identifying all risky situations of transmission by the different actors (categories of personnel) to the patient is carried out effectively.

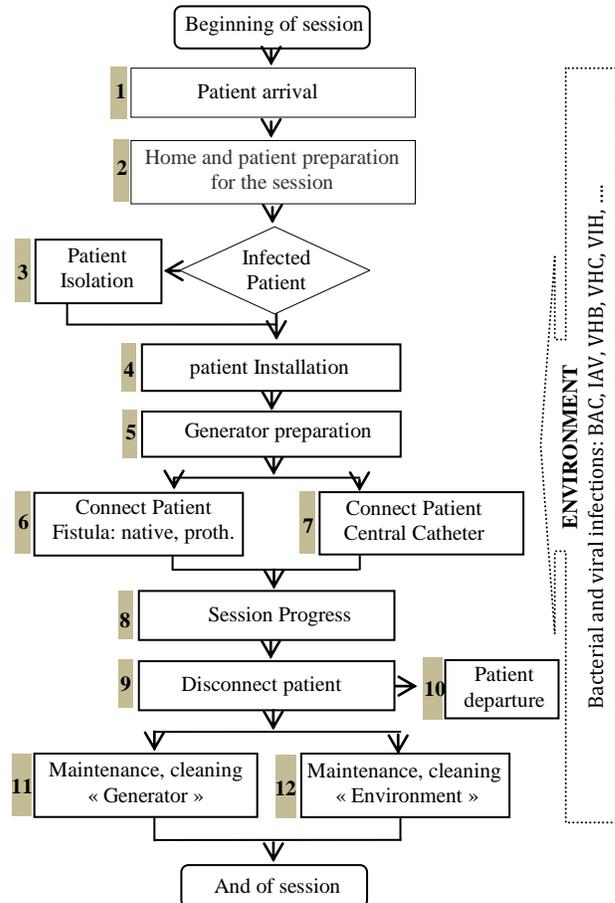


Fig.2. Flow diagram of 'Hemodialysis session'

3.3. Dysfunction analysis

3.3.1. Identification of the potential risks

The five determining elements in the control of the infectious risk (figure.3) for any hemodialysis activity are: the personnel (Labour), the air (Medium), the equipment (Material), and the products (Material) to which we add the organization and implementation methods.

So, the identification of the probable potential risks associated with the activity of care during all the chain of intervention for all its tasks rests on the situation analysis by taking into account all the intervening parameters.

For the activity of the hemodialysis center of the CHU Batna, 59 risky situations were identified and controlled; table.3 summarizes the main identified risks.

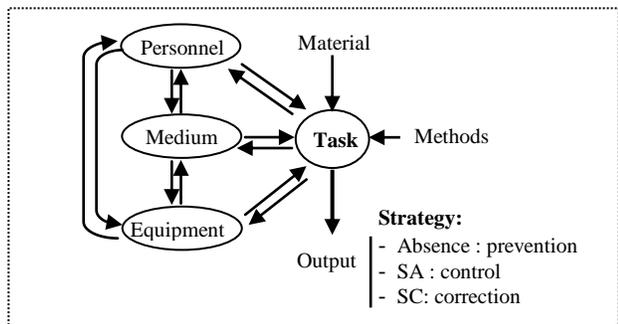


Fig 3. Infectious phenomena is occurred at the time of a care task

3.3.2. Estimate of the risk importance

It is an estimate carried out by a group of expert, qualifying the importance of the risks identified by ' Mi: Minor, Ma: Major, Cr: Critical (figure 4), in order to decide about the probable places where the critical points are situated, and about the required monitoring level to decrease the magnitude of the considered risk.

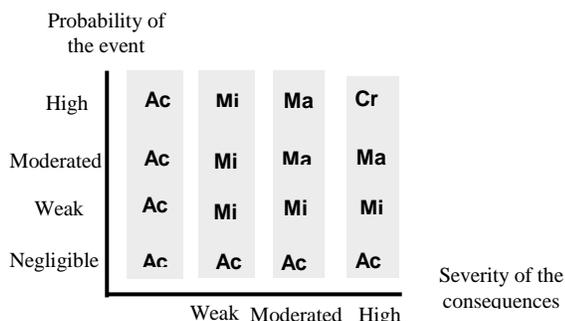


Fig 4. Estimation method of the danger importance [27]

Table 3. Principal identified risks

Identified risks	Summary of the principal identified risks
Risks of bacterial infections	<p>1. Infections related to vascular access:</p> <ul style="list-style-type: none"> The chronic hemodialysis generally implies a permanent vascular access generally an arteriovenous fistula, sometimes a catheter. These vascular accesses are exposed to risks related to their nature and their condition of use Contamination carried manually from environmental tanks (surfaces, objects.) or from infected patients, at the time of a hygiene rules breaking during the vascular access handling.

	<p>2. Infections not related to vascular access::</p> <ul style="list-style-type: none"> Dialysate contamination by its components (water, concentrated acid and bicarbonate). Contamination of the medicamentous solutions (nonspecific to the ERP practice) Contamination of the hydraulic system of the generator (bad disinfection..etc. Contamination system of the sewer drainage.
Risks of viral infections	<p>1. Contamination by virus VHB / VHC :</p> <ul style="list-style-type: none"> Internal contamination of dialysis generator by the blood of a previous dialyzed patient (flooding of the arterial or venous pressure sensor, dialysate hydraulic system). Injection of drugs or aqueous solutions that are contaminated by the patient blood carrying the virus from multi-purpose bottles. Virus presence on the vascular access or the site of injection of the extra corporal circuit of the receiving patient. This virus penetrates in the blood at the time of the vascular access puncture, of an injection or a time of taking. <p>Virus transmission by multiple ways: hands of the health care personnel, hands of infected patients, shared objects and medical devices, contamination of the generator surfaces and external components as well as the environment of the patient.</p> <p>2. Contamination by virus VIH.</p>
Risks of infections AEB	Not approached in this paper

3.3.3. Measure of control.

For each identified potential risk, measurements of control have been carried out in order to prevent or eliminate any risk for the patient to reduce it to an acceptable level. These measurements are referred primarily on the good operational practices and the good hygiene practices [28].

3.3.4. Determination of critical points.

A critical point must be at the same time controllable so that a specific action can be undertaken in order to reduce to an acceptable level and/or to eliminate the risk in this point and directed to take measurements in order to ensure itself of its controllability.

The question is to identify the risks which are not completely controlled by the hemodialysis center within

the framework of the good hygiene practices, and the good operational practices identified with a stage to which the application of a measurement for the control is essential. For that, the quotation method is used. To minimize the risk of error, the determination of the critical points by weighting, is carried out by two subgroups of experts, working distinctly on the basis of same criteria, emphasizing after rapprochement, a single result. It should be noted that the working group has exploited the existing literature, by taking into account the specificities and the proper conditions at the hemodialysis center of the CHU Batna.

The analysis made on 74 stages of the intervention chain in the hemodialysis center of the CHU Batna enabled us to determine 03 critical points to be controlled (table 4).

Table4. Critical control point.

Stage n°	Designation	CCP n°	Type
06	Connection of the patient.	CCP.1	Bacterial Viral
07	Disconnection of the patient.	CCP.2	
11	Disinfection of the hydraulic circuit.	CCP.3	

3.4. System of control.

The permanent control of the quality of the health care and in particular the patient safety and/or the health personnel pass by the implementation of a monitoring system of the hemodialysis activity in all its chain of intervention, thanks to observations or regular measuring. This system aims at being ensured of the implementation conditions of each identified preventive measure, by comparison to a target reference frame, and to set up pre-established corrective actions in the case of drift event. This system of control is exerted in controlled critical points, i.e. the tasks of the hemodialysis activity, which one must control in order to eliminate the risks or to reduce their probability of occurrence.

An example of control of the critical points is presented through the process "treatment of the hydraulic circuits of the generators" which requires the realization of three principal stages: cleaning, descaling, disinfection associated with a rinsing phase in the case of a chemical treatment. The stage n°11 'Disinfection' represents a critical point (CCP-3) corresponds to the probable risks of infections associated to this stage.

3.4.1. Critical and acceptable threshold

It is the separation of acceptable and the non-acceptable one by the establishment of a critical threshold for each critical point. If the monitoring reveals a slip towards the loss of control before exceeding the critical threshold, this threshold activate starts the preventive action and is called acceptable threshold (Figure 5).

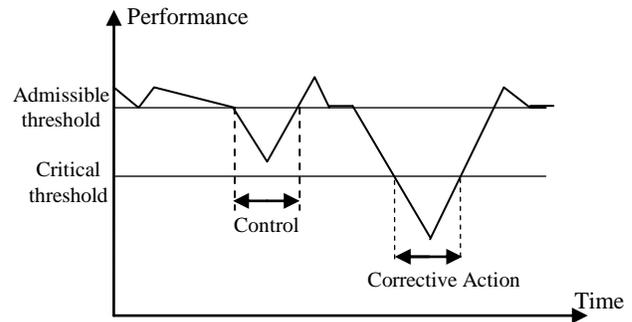


Fig 5. Critical limit and operational limit

An example of critical limit and operational limit (table 5) related to the CCP-3 'disinfection'.

Table 5. Critical threshold (CCP-3: disinfection).

Stage n°	CCP n°	Risk Description	Critical threshold
Disinfection of the hydraulic system of the generator	CCP-3	1. Temperature/time The non-respect of the scale (temperature / time) of disinfection can cause a bad treatment as well as the survival of pathogenic bacteria.	According to the type of the generators [29] According to Fresenius: - Heat: 84 °C – 15 mn to 30 mn. - chemical : 37 °C – 20 mn
		2. Concentration. The non-respect of the dose of the disinfection chemicals (chemical or thermochemical) can cause a bad treatment as well as the survival of bacteria.	According to the type of the products.

3.4.2. Monitoring system (preventive action).

The actions of monitoring allow the detection of the loss of control on the level of the CCP (table 6).

Table 6. Monitoring system (CCP-3: Disinfection).

<i>Monitoring Procedures «Preventive Action»</i> CCP-1 : Disinfection of the hydraulic system
<p>1. Control scale: temperature / time.</p> <p>Concerning the thermal disinfection, the effectiveness parameters i.e. the temperature reached in the circuit and the contact time, are measured and recorded throughout the treatment.</p> <ul style="list-style-type: none"> ▪ Monitoring 1 : The NGS must permanently supervise the real temperature displayed on the level of regulator PID. (Temperature regulation). Frequency: continuous. ▪ Monitoring 2 : The existence of a sound or visual alarm system starts in the case of anomaly of the disinfection cycle in particular the temperature and the pressure. Frequency: continuous. ▪ Monitoring 3 : The existence of a sound or visual alarm system and/or the stopping of the machine if the disinfection or the rinsing of the apparatus did not take place before a dialysis session. Frequency: continuous. ▪ Monitoring 4 : Once controlled, the dialysate passes in one to two ultra-filters. The role of these filters is the retention of bacteria or endotoxins, which can be developed within the generator, in spite of the disinfection procedures implementation [29]. <p>2. Control concentration.</p> <p>For chemical or thermochemical disinfection, the user must make sure at least, that the disinfecting quantity that allows obtaining the necessary concentration was indeed introduced into the circuits.</p> <ul style="list-style-type: none"> ▪ Monitoring 1 : For the generators equipped with automatic controller (flowmeter or level detector on the disinfecting internal vessel), the NGS must imperatively supervise these parameters. For the generators, which are not equipped with such means, the NGS must imperatively supervise by means of a visual reference mark located on the disinfecting container that the aspired volume corresponds to that required. Frequency: at each dosage operation. ▪ Monitoring 2 : The measurement of conductivity allows giving information on the concentration of the product present in hydraulic system.

<p>The NGS must supervise the measurement of conductivity permanently, if the system is equipped with a conduct meter. Failing that, samples will be taken for measurement. Any time the measurement of conductivity is not indicative, it reveals only one error of dilution. It is necessary to be ensured of the identity, the quality and the storage conditions of the chemicals.</p> <p>Frequency: continuous.</p> <ul style="list-style-type: none"> ▪ Monitoring 2 : The existence of a sound or visual alarm system starting at the moment of anomaly of the disinfection cycle. Frequency: continuous.
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3.4.3. System of control of deviations.

Establishment of the procedures of deviation (corrective actions), for any deviation (loss of control), and for each critical point. The loss of control is regarded as a deviation compared to a critical limit for a CCP (table 7)

Table 7. System of control of deviations (CCP-3):

<i>procedures of deviation</i> <i>«corrective action »</i>
<p>1) In the case of deviation, not regulated by the automatic device, the NGS must :</p> <ul style="list-style-type: none"> a) Stop the process, and call upon the maintenance technician to carry corrections. b) Recording and reporting about the quality control and maintenance <p>2) In the case the recorded parameters show that the conditions for a given disinfection period are not met the NGS should:</p> <ul style="list-style-type: none"> a) Remake the disinfection process before any new activity of hemodialysis. b) Record: deviations and corrective actions. <p>- Responsible : NGS.</p>

3.4.4. Checking System.

It allows to confirm if the system of control is always valid and functions effectively (table 8).

Table 8. Checking System (CCP-3: disinfection).

<i>Monitoring Procedure</i> <i>« Checking »</i>
<p>1. Checking of the scale: temperature / time.</p> <ul style="list-style-type: none"> ▪ Checking 1 : Generally the generators are equipped with a system of measurement and traceability that allow recording the critical parameters of disinfection. The NGS must check that the required temperature, measured by the thermal probes, and the contact time was indeed reached during the cycle of disinfection.

Frequency: in the course and at the end of any operation of disinfection

2. Checking concentration.

▪ Checking 1 :

The NGS must check the evolution of the quantities of the consumed products per cycle. The number of cycles carried out with the same can or the order frequency of the products constitutes good indicators of operation.

Frequency: after each operation of disinfection.

3.4.5. System of traceability.

Establishment of a system (table 9) of documentation and recording of any action (preventive or corrective). Documentation and recording are essential, for the validity and the conformity of the implemented system.

Table 9. System of traceability (CCP-3: disinfection).

<i>Documentation and recording system</i>
- Report and recording of the deviations and corrective actions.
- Report and recording of the checks.

4. Conclusions

This item has no claim to be exhaustive; it is intended to be a work a more comprehensive approach to risk management. This is a field work and an experience sharing which aim at strengthening and consolidating of the current preventive approach to minimize this residual risk.

This approach usually involves an ongoing assessment of factors affecting the logistical and environmental characteristics that may affect infectious risk of the patient during the CRF treatment, as it involves checking and control for the sake of a continuous improvement. It must be constantly checked, supported and improved in order to offer a service quality of health care and safety.

The environment can play an important role to indirectly facilitate the transmission of microorganisms and to increase the risk of infections. In the hemodialysis center of Batna, space planning can be improved to ensure the quality of health care for improving patient safety: minimum separation between patients remains below the standard of a specific area, adjusting a specific area for drugs preparation and another one for the maintenance of reusable materials, sufficient water points for the equipment (one water point for four dialysis stations).

Standard precautions are far from being present in routine practice, especially for connection and disconnection of patients.

There is a need for the establishment of written protocols for the management of the dialyzed patient. There is a need to sensitize caregivers about the risk of cross-transmission.

As perspective, we can say that this approach requires a better consideration of the human factor, this by deploying the notion of variability of human performance, as is our current research work.

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