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Full Length Research Paper

Risk management in the Hospital: Application of the method FMECA in a university laboratory of Pathological anatomy and cytology (PAC)

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Our study represents a first approach in Morocco, it meets a regulatory requirement relating to the Order of the Moroccan Minister of Health No. 2598-10 of 27 Ramadan 1431 (7 September 2010) concerning GBEA (Guide to Good Execution of Analyzes): Setting preventive measures to be put in place in analytical laboratories, where workers are likely to be exposed to pathogenic chemical or biological agents. The FMECA method allowed us to identify the criticalities of all possible risk situations at the PAC laboratory. This approach complements work established on the same site in relation to chemical risk management. The purpose of the first work was to outline the need for a comprehensive process to risk management. The work performed has, on the one hand, made it possible to identify risk situations, their effect and their criticality. And on the other hands the risk hierarchy as well as the analysis of the potential causes for each mode of failure, and in the same way we identified the consequences of each failure. The results obtained highlighted the impact of risk situations on the health and safety of professionals. The identified risks relate respectively to: - Architecture and general organization, - Disinfection and maintenance, - Elimination of DASRI, - The routing of biological samples, - The treatment of samples in technical room, - Respiratory transmission in the technical room, - Transmission through the digestive tract in a technical room, - Transmission through muco-cutaneous tract in the technical room, - Information, Training and medical follow-up, - Chemical and physico-chemical risks. It was found that the FMECA is a simple process, our experience allows us to say that it is a tool adapted to the hospitable organization, the thing that incites to use it on another site in a perspective of developing a general risk mapping of the hospital environment concerned. And at the same time to make some recommendations that are in accordance with the advances of BERWICK and in particular: to make simple, to do it as a team, to measure with objectivism, to start as soon as possible, to simplify the methodology, especially to stop complaining.

Keywords: Risk management, FMECA, Risk management in the Hospital

INTRODUCTION

The mission of a hospital has evolved over time; it's becoming more and more characterized by an expanded environment of activities where zero risk doesn't exist. The hospital system must appropriately master, manage and prevent the risk. However, hospital risks are very various by nature, thus, risk management is registered

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today to be an essential component of the hospital system's strategy.

In more industrial sectors, methods and practices have evolved faster, some of them have already proven themselves. Therefore, it seems quite interesting to assess their transportation in the area of health.

Several pieces of legislation were created by the Ministry of health in Morocco, in order to strengthen the prevention of risks that are likely to result consequences on health and security of health care field workers which are exposed to potential hazards in the course of their professional activity.

The CHIS of Rabat integrated this notion of risk management in committing to an approach quality-security-environment for many years. This approach is guided by an institutional policy as well as a scalable program of actions established according to the specific risk of the establishment and retained priorities. (Revue du centre Hospitalier Ibn Sina, 2011).

Three major risk categories can be identified:

- The first one is directly associated to care (organization and coordinating caregiving, medical procedures, hygiene, the use of a health product, information management etc...)
- The second is related to activities which are said to be of support and without which care can't be correctly implemented (number of staff, competency management, equipment and their maintenance, purchase and logistics, information system, etc..)
- The third category is linked to the hospital life and environment (safety of persons and property,.)

Within this framework and in the perspective of implementing a global and coordinated approach in risk management within CHIS, our study has the aim of elaborating an internal repository of risks with prior, along with their associated criticality within an anatomic laboratory (PAC) according to the FMECA method .

For each stage of the circuitry,potential failures have been identified, and a criticality has been assigned accordingly with the equation: **occurrence frequency x gravity x detectability.**

The more the criticality is high, the more the risk level is considered to be inacceptable.The determination first, and then hierarchy of these criticalities is a decision's support of the acceptance of residual risks or the implementation of risk reduction actions.

This work made it possible to highlight the risks inherent in the process of an PAC structure (reception, macroscopy, technical treatment, microscopy and report writing) and, on the other hand, to engage a corrective and preventive action plan.

METHODOLOGY

1. Types of study:

This is about a semi-quantitative study by the appraisal of risk levels in terms of exposure conditions.

2 scope for action:

The study is carried out in the PAC laboratory of the CHU Ibn Sina in Rabat, the largest PAC laboratory in Morocco. It is characterized by:

- **Surface**

Differentrooms	Area en m²
Sample	10.23
Head nurse office	10.23
Reception	10.23
Archives room	6.35
Macroscopy room	21.9
Technical room	60
Course and blade's playing room	49
Department head office	12.54
Office of doctor 1	8.91
Office of doctor 2	8.91
Office of doctor 3	8.91
Secretariat	9.86
Break room	13.2
Product deposit	7.60
Area of liquids	8.60
Sanitations	9.72
Corridor	21.84
Sas	3.29
Total	281.32

- **Human ressources:**

The laboratory presents multiple human resources intervening in the different phases; there are six categories distinguished "At the date of December 2014":

Human ressources	Number
Doctors	5
Engineers	2
Technicians	7
Nurses	3
Secretaries	2
Service officers	2

Other human resources may intervene periodically: maintenance officers, cleaning and trainees.

• **Main phases of an ANAPATH review:**

The progress of an ANAPATH examination can be summarized in the following table:

Table 1. steps of examination realisation in PAC

Phases	Steps
Pre-Analytics	Reception, sorting and recording
Analytics	- Macroscopy - Technic: Impregnation, coating, microtomy, cytology, colouring, mounting. - Microscopie
Post-Analytics	Examination report of pathological anatomy

3. Method: FMECA

• **The choice of the method:**

FMECA is the acronym for Failure Mode, Effects and Criticality Analysis (FMECA). It is a rigorous methodology to identify and transact potential failures before they occur, with the intention of eliminating them or minimizing the associated risks. "Failures" can be those of an object, machine, service or process.

The method always goes through a qualitative analysis that begins with the analysis of the causes of failure, then the failure modes and finally the effects of these failures.

Subsequently, a quantitative analysis is performed to assess the frequency of occurrence of these failures, the severity of these failures and the likelihood that these failures will go undetected.

Each detected fault is then analyzed to determine its frequency (F), its severity (G) and its detectability (D). The multiplication of these three values makes it possible to calculate the criticality index. This corresponds to a numerical value and is used to carry out a classification of the observed failures, thus defining the corrective actions to be undertaken as a priority (high criticality index) and the failures that can be considered acceptable.

The FMECA is well-suited to health processes, simple to implement. It enables the quantification of risks and quantifies the impact of improvement measures as well (Bonnabry P, 2005). Especially since it is recommended by the High Authority of Health (Marie Castagné HDJ BAUDIN, 2009).

• **Principal of FMECA:**

Never lose sight of the FMEA principle.

The FMEA is an inductive method which starts from the elementary failures of the components to deduce what results and therefore to what situations, due to these failures, we must expect.

The FMECA adds an evaluation dimension to the gravity of these situations.

FMECA consists of identifying and assessing the impact of failures of elements of the system on the latter, its functions, and its environment (Yves MORTUREUX, 2005).

III.4. Progress of FMECA

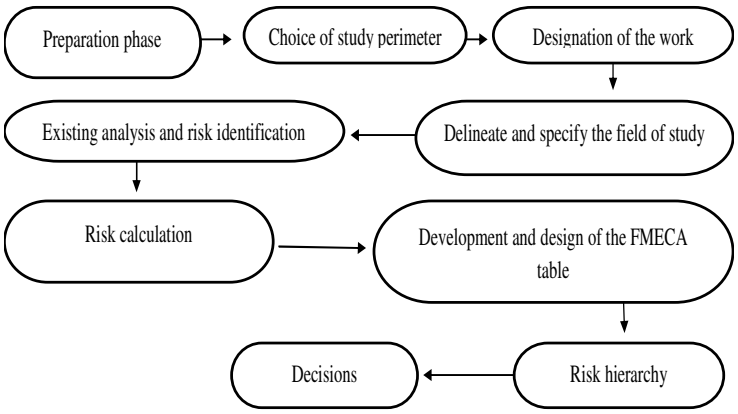


Figure 1. Realisation steps of FMECA in the laboratory of PAC

• **Implementation of risks analysis:**

- Designation and conditioning of group of work

Risks analysis in a group of work resemble to a brainstorming exercise. It is about considering all the risks generated relying on the method of analysis FMECA in the most exhaustive way (Rapport d'étude N° INERIS-DRA-2006-P46055-CL47569, 2006).

The people in the group of work were selected for their skills (knowledge and experience).

The work team is represented by the Quality Management Unit, Operational Committee of Risk Management, and certain members of the service selected for their technical competence in the field of study.

Delimitation of the field of study:

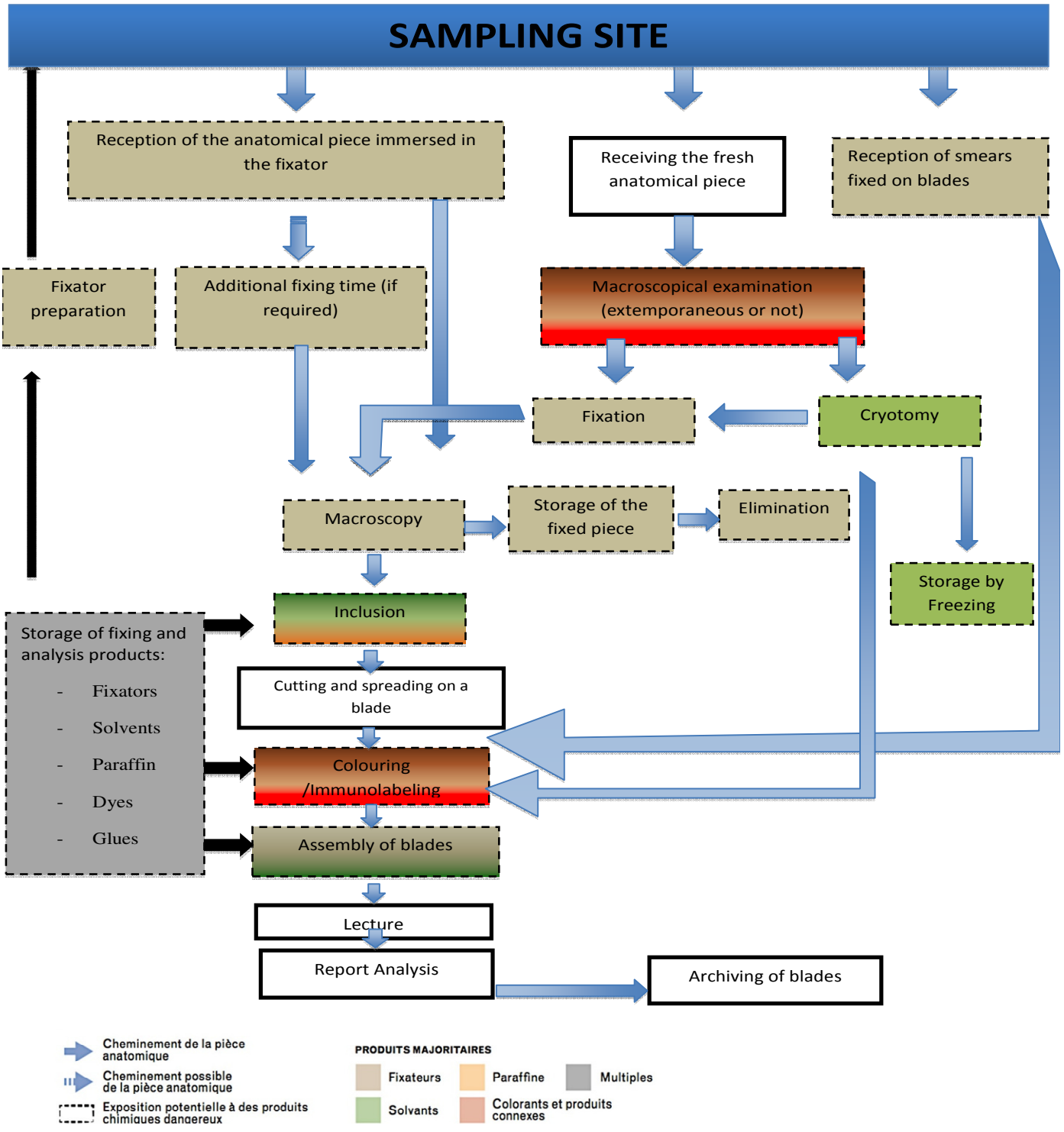
The scope of the study must be limited very precisely. In the laboratory process there are three main distinguished phases in PAC (Laboratoires d'anatomie et de cytologie pathologiques, 2014):

✓ **Pre-Analytics :** Support for sampling, sorting and recording

✓ **Analytics**: Treatment of the samples (macroscopy, cytology, histology, extemporaneous), lastly comes the microscopic phase.

✓ **Post-analytics:** Delivery of the examination report to the prescribing doctor

Figure 2. Summary of the circuit of a sampling within the PAC structure



The scope of analysis defined by the group of work resumes all the phases in order to measure the influence of the safety barriers put in place and to judge the relevance of considering new barriers with regard to the identified risk.

The approach chosen in this work is the functional approach. Our field of study assures the functions from the reception of the samples until the report writing.

The functional approach consists in subdividing the phases into activities in order to extract as much potential information related to these processes.

- **Risk identification:**

According to ISO 31000 Risk Management - Principles and Guidelines (Norme internationale ISO /FDIS 31000, 2009): "It is appropriate that the organization identifies sources of risk, areas of impact, events (including changes in circumstances), as well as their causes and potential consequences. The purpose of this step is to provide an exhaustive list of risks based on events that may cause, stimulate, prevent, hamper, accelerate or delay achievement of objectives. It is important to identify the risks associated with not seizing an opportunity. A thorough identification is essential, as an unidentified risk at this stage will not be included in a subsequent analysis".

In this context ,several visits were made, we identified 50 dangerous situations.

- **Risk analysis and assessement:**

Risk analysis provides data to assess risks and decide whether to treat them and to choose the most appropriate strategies and treatment methods (Norme internationale ISO /FDIS 31000, 2009).
The (a priori or predictive) analysis of the process was carried out following the FMECA methodology.
This step was to determine the criticality of each risk situation. For this, a scale of measurement has been defined by the group of work (see the tables below).
Risk ratings have been calculated from the scale, the scorings used are as follows:

- Effects Gravity related to each mode of failure (G)
- The Frequency of occurrence of each mode of failure (F)
- Failure Mode Detectability (D)

Criticality is the product of the three factors: C= F x G x D

Table 2. frequencyscale

Gravity (G)	**1**	**2**	**3**	**4**
	Discomfort everything at most	Injury; physical or moral damage	Hospitalization or extension of hospitalization	Death, Life threatening; Permanent disability
	Minor	low	serious	Veryserious (major)

Table 3. Gravityscale

Detectability (D)	**1**	**2**	**3**	**4**
	Easy	Littleeasy	Difficult	Impossible

- **Hierarchy:**

This phase is performed according to the value of the criticality index (C = G x F x D) in order to distinguish the most serious risks in the laboratory of PAC (Marie Castagné HDJ BAUDIN, 2009).
This prioritization has helped us to plan corrective or preventive actions and to prioritize the action plan.
A failure is considered a priority if: G = 4 and / or if 48 ≤ C ≤ 64
A failure is to be treated if: 13 ≤ C ≤ 47 and G <4
A failure is to be monitored if: 1 ≤ C ≤ 12 and G <4

RESULTS

Risk identification:

In order to identify potential risks at the CHIS laboratory, several visits were carried out. This step allowed us to establish a table containing the number of hazardous situations by function according to the FMEA analysis logic. The results of this step indicate the presence of 59 dangerous situations, see table below (Laboratoires d'analyse médicales, 2009):

Table 6 below represents the number of risk situations identified by risk area, the chemical risk is the most important in the field of study, followed by the risks related to disinfection and maintenance, then the risks associated with the treatment of the samples of the technical room ,architecture and general organization. Mucocutaneous transmission in the technical room comes in 4th place, the respiratory transmission in the technical room and the elimination of the DASRI in 5th place, transmission through the digestive tract in the technical room comes last.

Table 4. Detectabilityscale

	Risks	Reception & recording	Macroscopy	Technical room	Liquids zone	Dépôt des produitschimiques	Microscopy	Archives	Break room	Sanitary	Courses rooms and demonstration
AOG	Architecture and General Organization	7									
AEB	Routing of biological samples	3									
TPST	Treatment of samples in technical room		7								
TVRST	Respiratory transmission in the technical room		4								
TVDST	Transmission by digestive tract in a technical room		2								
TVCMST	mucocutaneous transmission in the technical		5								
C	Chimicals	14									
DEM	Desinfection et maintenance		8								
DASRI	Elimination of DASRI	4									
IFSM	Information, continuing education and medical follow-up	5									

Table 5. Number of risk situations chis PAC laboratory

Risk code	Designation Risk	F	%F
C	Chimicals	14	24%
DEM	Desinfection and maintenance	8	14%
AOG	Architecture and general organisation	7	12%
TPST	Sample treatement in technical room	7	12%
TVCMST	mucocutaneous transmission in the technical	5	8%
IFSM	Information, continuing education and medical follow-up	5	8%
TVRST	the respiratory transmission in the technical	4	7%
DASRI	Elimination of DASRI	4	7%
AEB	Routing of biological samples	3	5%
TVDST	transmission through the digestive tract in the technical room	2	3%
Total		**59**	**100%**

- **Failures analysis:**

In an inductive process, a failure or combination of failures is at the origin of the analysis. It is then necessary to identify the consequences of this or these failures on the system or its environment. It is generally said that we start from causes to identify effects.

The qualitative analysis of risks is summarized in three sub-phases:

- Analysis of the causes of failures.
- Analysis of failures modes.
- Analysis of the effects of these failures.

The results obtained, see Table 6, highlight the impact of risk situations on the health and safety of professionals.

The risks identified relate respectively to:

- Architecture and general organization,
- Disinfection and maintenance,
- Elimination of DASRI,
- The routing of biological samples,
- The treatment of samples in technical room,
- Respiratory transmission in the technical room,
- Transmission through the digestive tract in a technical room,
- The Transmission muco-cutaneous way in the technical room,
- Information, Training and medical follow-up,

• Evaluation of failures and determination of their criticality: (C = G x F x D):

Table 6. Breakdown of risks by risk class identified at the PAC laboratory

FAILURE CLASS	UNDE CLASS	D	F	G	C
Architecture & general organisation	**AOG1**	1	4	2	8
	AOG2	1	4	4	16
	AOG3	2	4	3	24
	AOG4	2	4	3	24
	AOG5	1	4	4	16
	AOG6	1	4	4	16
	AOG7	1	4	4	16
Desinfection& Maintenance	**DEM1**	1	4	2	8
	DEM2	2	4	3	24
	DEM3	2	4	3	24
	DEM4	2	4	4	32
	DEM5	2	4	4	32
	DEM6	2	4	4	32
	DEM7	2	4	2	16
	DEM8	2	4	4	32
	DASR1	2	4	2	16

Table 6 continue

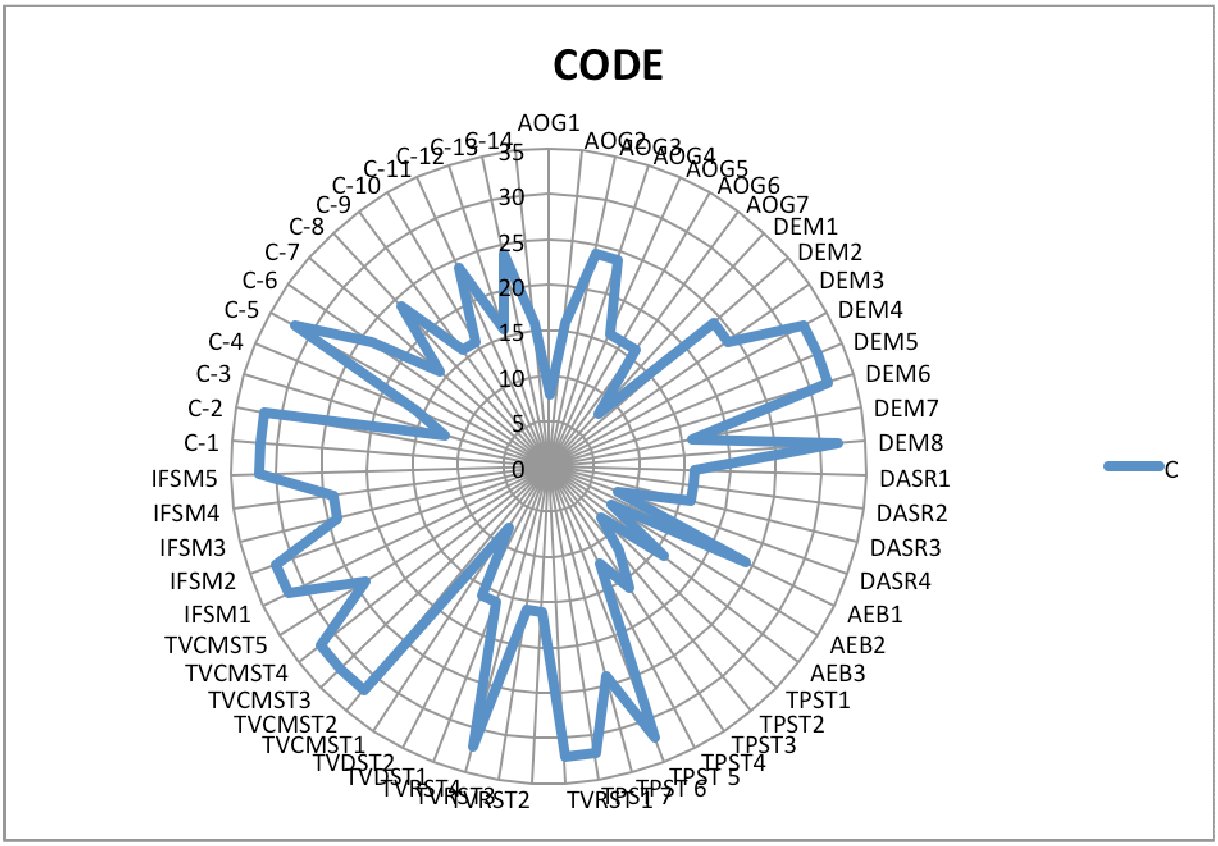
Elimination of DASRI	**DASR2**	2	4	2	16
	DASR3	2	4	2	16
	DASR4	1	4	2	8
	AEB1	2	4	3	24
Routing of biological samples	**AEB2**	1	4	2	8
	AEB3	1	4	4	16
	TPST1	1	4	2	8
Treatement of samples in a technical room	**TPST2**	1	4	3	12
	TPST3	1	4	4	16
	TPST4	1	4	3	12
	TPST 5	2	4	4	32
	TPST 6	2	3	4	24
	TPST 7	2	4	4	32
Respiratory transmission in the technical room	**TVRST 1**	2	4	4	32
	TVRST2	1	4	4	16
	TVRST3	1	4	4	16
	TVRST4	2	4	4	32
Transmission through the digestive tract in a technical room,	**TVDST1**	1	4	4	16
	TVDST2	1	4	4	16

Table 6 continue

The transmission through mucocutaneous tract in the technical room	**TVCMST1**	1	4	2	8
	TVCMST2	2	4	4	32
	TVCMST3	2	4	4	32
	TVCMST4	2	4	4	32
	TVCMST5	2	4	3	24
Information, Training and medical follow-up	**IFSM1**	2	4	4	32
	IFSM2	2	4	4	32
	IFSM3	2	4	3	24
	IFSM4	2	4	3	24
	IFSM5	2	4	4	32
Chemical and physicochemical	**C-1**	**2**	**4**	**4**	**32**
	C-2	**2**	**4**	**4**	**32**
	C-3	**1**	**4**	**3**	**12**
	C-4	**1**	**4**	**4**	**16**
	C-5	**2**	**4**	**4**	**32**
	C-6	**2**	**4**	**3**	**24**
	C-7	**1**	**4**	**4**	**16**
	C-8	**2**	**4**	**3**	**24**
	C-9	**1**	**4**	**4**	**16**
	C-10	**1**	**4**	**4**	**16**

Table 6 continue

	C-11	**2**	**4**	**3**	**24**
	C-12	**2**	**4**	**2**	**16**
	C-13	**2**	**4**	**3**	**24**
	C-14	**1**	**4**	**4**	**16**



Graph 2. Critical radar cartography by failure

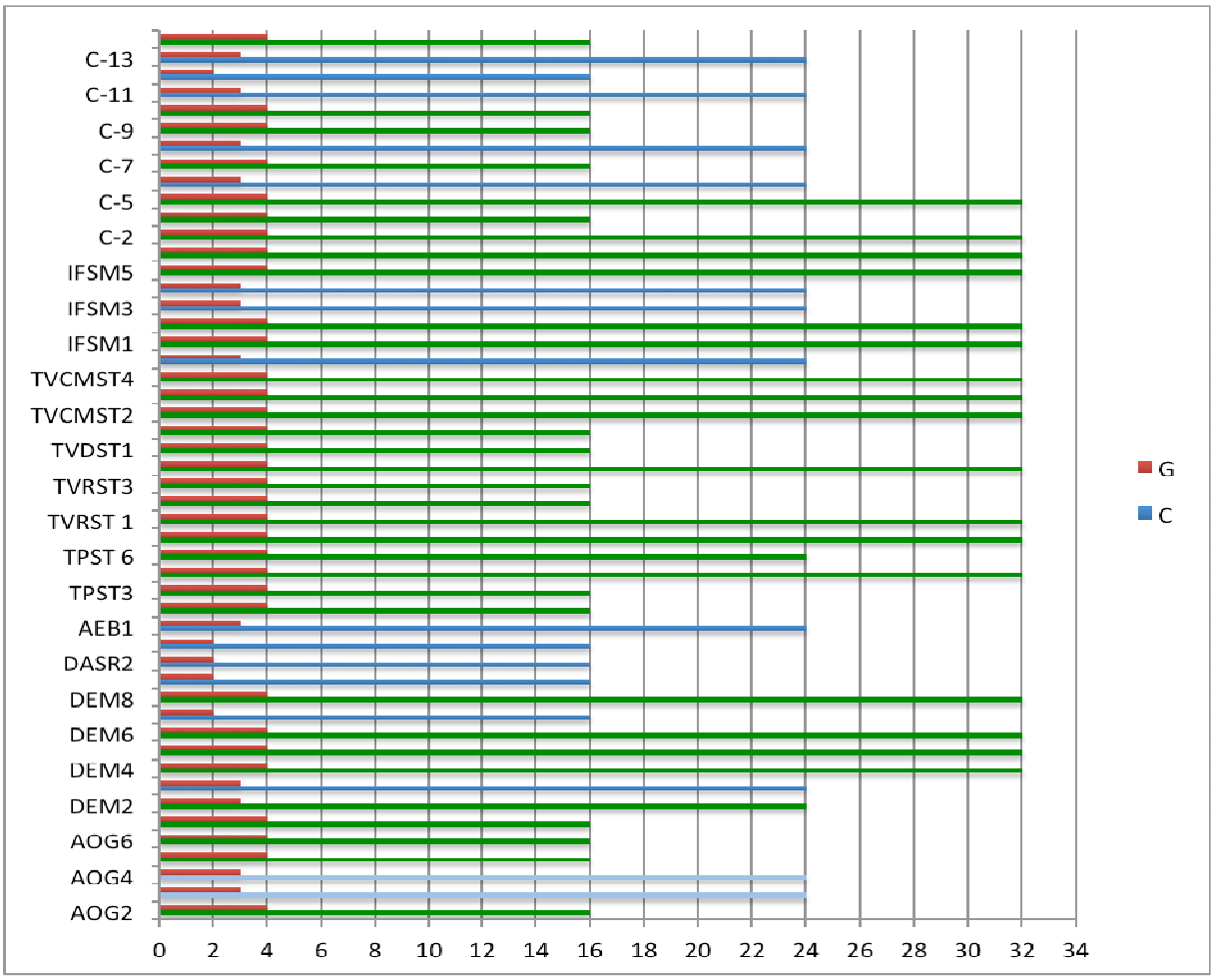
- **Hierarchy**: GRID OF CRITICALITY

The risk hierarchy allowed us to identify the most serious risks. It has contributed to the planning of prevention actions by highlighting the priorities of the action plans (Rapport d'étude N° INERIS-DRA-2006-P46055-CL47569, 2006).

Criticality analysis does not demonstrate any failure deemed to be a potential critical risk, see Figure 1. However, failures requiring emergency corrective actions, risks with a gravity of 4 and a criticality between 13 and 48, are marked in green on the graph 2 below.

The graph above reflects the importance of criticality index by subclass of failure.

After implementing the action plan, it is desirable to carry out an FMECA analysis, using the same analytical tools, in order to judge the effectiveness of the proposed actions.



Graph 2. Couple criticity and gravity of failures

DISCUSSION

Our study represents a first approach in Morocco, it meets a regulatory requirement relating to the Order of the Minister of Health No. 2598-10 of 27 Ramadan 1431 (7 September 2010) concerning GBEA (Guide to Good Execution of Analyzes): Setting preventive measures to be put in place in analytical laboratories, where workers are likely to be exposed to pathogenic chemical or biological agents. It is also part of the official bulletin - N ° 5926 12 Rabii II 1432 (17-03-2011) - Chapter VI - Safety, Hygiene and Risk Management.

The FMECA method allowed us to identify the criticalities of all possible risk situations at the PAC laboratory. This approach complements work established on the same site in relation to chemical risk management. The purpose of the first work was to outline the need for a comprehensive process to risk management (El Hani et al., 2016).

The work performed has, on the one hand, made it possible to identify risk situations, their effect and their criticality. And on the other hand the risk hierarchy as well as the analysis of the potential causes for each mode of failure, and in the same way we identified the consequences of each failure.

The results obtained highlighted the impact of risk situations on the health and safety of professionals. The identified risks relate respectively to:

- Architecture and general organization,
- Disinfection and maintenance,
- Elimination of DASRI,
- The routing of biological samples,
- The treatment of samples in technical room,
- Respiratory transmission in the technical room,
- Transmission through the digestive tract in a technical room,
- Transmission through muco-cutaneous tract in the technical room,
- Information, Training and medical follow-up,
- Chemical and physico-chemical risks,

Table 1 shows the number of risk situations identified by risk area, the chemical risk is highest in the field of

study, followed by the risks related to disinfection and maintenance, then the risks associated with the treatment of samples in the technical room and architecture and general organization. Transmission through the dermal muco-cutaneous in the technical room comes in 4th place, the respiratory transmission in technical room and the elimination of the DASRI in 5th place. Digestive transmission in the technical room comes last.

The various risks are presented in graph 2 with positions or dimensions representative of the evaluation criteria, it is the mapping.

The classical representation is a two-axes graph, "frequency" (or probability, or likelihood) and "gravity" in which points will represent each of the risks retained (Desroches et al., 2006). In our case we have chosen a cartographic representation in RADAR in order to have the representativeness of the criticality (Frequency x Gravity x Detectability).

Criticality analysis does not demonstrate any potential critical risk failure. However, failures requiring emergency corrective actions relate to risks with a gravity of 4 and criticality ranging between 13 and 48 are marked in green in graph 2.

The proposed corrective and preventive actions will enable:

- Initially to reduce risks below the acceptable risk threshold;
- Secondly, to reduce still some (already acceptable) risks where corrective action will allow a reduction in risk of greater value than the cost of the action;

Implementation of all these corrective actions will make the system evolve towards a viable and secure system.

In carrying out this analysis with the FMECA, we have been able to identify some positive aspects related to the use of this method:

- simplicity of implementation with good appropriation by the actors, even those who were not trained in this method,
- Ability to classify failures according to three parameters: gravity, occurrence and non-detection. This makes it possible to classify the failures and to prioritize the actions to be undertaken [Bonnabry et al., 2006],
- The multidisciplinarity of the constituted team makes it possible to take into account all the points of view throughout the process [Bonnabry et al., 2006] and to obtain a judgment on the basis of a consensus.

However, we have also identified certain limits, namely:

- The subjectivity of the method, both for the choice of failures, but also for the criticality rating [Bonnabry et al., 2006],
- Risk of missing scenarios not yet observed,
- Does not allow cross-vision of possible failures and their consequences,
- Takes hardly into account the human aspects (fatigability, experience, etc.) and the organizational aspects (collaboration between teams, communication between teams, etc.) with only global or macro vision.

It was found that the FMECA is a simple process, our experience allows us to say that it is a tool adapted to the hospitable organization, the thing that incites to use it on another site in a Perspective of developing a general risk mapping of the hospital environment concerned. And at the same time to make some recommendations that are in accordance with the advances of BERWICK and in particular: to make simple, to do it as a team, to measure with objectivism, to start as soon as possible, to simplify the methodology, especially to stop complaining (El Hani et al., 2016).

CONCLUSION

The analysis of the failure modes, their effects with or without the analysis of their criticality is a logical and common sense approach.

Admitting that no system is infallible, it consists of identifying, describing, and evaluating the risks arising from failures. Well structured, systematic, the FMECA enables achieving this objective in confidence.

It is relevant whenever the component failure modes and internal system operations are well known or can be known. It should accompany the life of any system that is conceived and realized of man's brain and hands.

It has the limitations due to the method itself (inadequate to represent the dynamics of a system, the temporal dimension and the logical combinations) and available information (like any method of safety, it exploits knowledge, It does not create them from nothing).

Beyond the method itself, the form of reasoning that it supports and the formalism proposed to present the information is a very natural and effective way to ask good questions and to store in a structured and accessible way all kinds of Information about any system.

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