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Research Article

FAILURE MODES, EFFECTS AND CRITICALITY ANALYSIS (FMECA): APPLICATION TO PHARMACY MANAGEMENT PROCESS

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A R T I C L E I N F O

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A B S T R A C T

Pharmacy represents the last link in the drug chain and errors are still an embarrassing reality. Therefore, everything must be organized to minimize this risk and its seriousness. In this context, Failure Modes, Effects and Criticality Analysis (FMECA), applied to pharmacy activities, allows controlling risks of non-conformity which can negatively affect pharmaceutical services quality.

Our study aimed to apply FMECA tool in practice at a pharmacy store involved in the implementation of a quality management system, in order to propose for each identified risk a matrix of preventive and corrective actions. This was done through three main stages:

- Identification and description of the elementary processes forming the management macro-process of the pharmacy store;
- Drafting procedures describing main activities of identified elementary process;
- Application of FMECA tool to the described activities.

The FMECA results allowed identifying possible risks, reconsidering certain procedures and proposing measures matrix for the management of the most critical risks in the studied pharmacy. These results can also serve as a model for pharmacy stores wishing to raise their staff awareness about "risk culture" and to improve the quality of their services, which would enhance pharmacy profession value.

INTRODUCTION

Failure Modes, Effects and Criticality Analysis (FMECA) is a tool for operational safety and quality management. It allows, as a preventive measure, to control the risks of non-conformity that can negatively affect the quality of pharmaceutical acts withing the following steps (AFNOR, 2000; Landy, 2007)

- Determine the functions performed by a product;
- Determine the stages of product realization (process);
- Identify potential failures;
- Evaluate the criticality of identified failures and their seriousness for the customer;
- Propose and implement preventive actions to reduce the risk of these failures occurrence.

The objective of this work is to apply in practice the FMECA tool for pharmacy management, which would allow controlling risks, improving pharmaceutical services and sensitizing pharmacy staff about "risk culture".

MATERIALS AND METHODS

Our study aimed to apply the FMECA tool to pharmacy management process at a pharmacy store located in Rabat (Morocco).

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This pharmaceutical structure is organized in two easily identifiable sectors:

- A public area, intended for the parapharmacy which mainly includes cosmetic products;
- A professional sector, strictly regulated, including a preparations laboratory. This area is behind the dispensing counter, visible to the patient, but not directly accessible by the public.

The organizational chart of the studied pharmacy is shown in Fig 1.

The FMECA tool was applied to the pharmacy store based on data from the literature (ANAES, 2003; SQS, 2006) describing taken steps for risk analysis in pharmacy (Fig 2).

Criticality assessment

The principle of this analysis is to identify all the potential causes of each failure mode and to evaluate its criticality (C). The latter results from a triple quantified rating:

- Grade "S": Severity of the defect or failure effect;
- Grade "F": Frequency of cause occurrence;
- Grade "D": Detectability (probability of non-detection of the cause).

The criticality index is obtained by multiplying the three scores: C = S x F x D

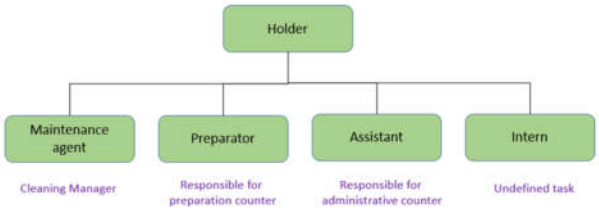

Fig 1 Organization chart of the studied pharmacy

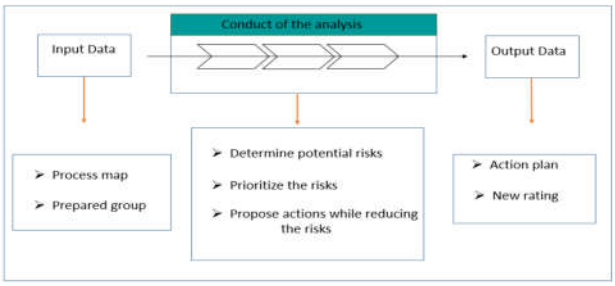

Fig 2 Schematic summary of the FMECA Process

The higher is the C score, the more critical is the failure mode. To apply this method in our study, we chose our own scale and our own risk assessment criteria taking into account the pharmacist's profession requirements (Table 1).

To be practical and to simplify the technique, we did without detectability using the combination of the two most significant factors of the failure mode, which are the Frequency (F) and the Severity (S). That allowed determining the criticality (C = S x F) of each identified risk and carrying out a digressive failures classification according to the Risk Priority Level (RPL). The resulting criticality values are assigned to three levels of risk acceptability as shown on Fig 4 and Fig 5 (Falconi and Certain, 2008).

Practical application of the FMECA tool to the studied pharmacy

The process was carried out in four phases (Nimanberg and Lemarquis, 2011):

- Process identification;
- Procedures development;
- Malfunctions identification;
- Development of a matrix of measures for unacceptable criticality risks management.

Table 1 Severity and Frequency Rating Scale

Severity factor		Frequency Factor	
Severity (S)	**Factor**	**Frequency (F)**	**Factor**
Minimal: Very little disruption of activity, no impact on the customer (or very little)	1	**Extremely rare:** Almost impossible for a failure to occur	1
Significant: Significant business disruptions, event with a moderate impact on the customer	2	**Very rare:** Almost no failures. Less than one per year	2
Severe: Impact on patient comfort	3	**Rare:** Failures are few. Maximum one per quarter	3
Major: Impact on patient's health	4	**Possible:** Failures are occasional, at most one failure per week	4
		Frequent: Failures are numerous. This corresponds to a maximum of one failure per day	5
		Very frequent: failures are range from frequent to very numerous. This corresponds to several failures per day	6

Table 2 Summary of procedures performed at the studied pharmacy

Title of the elementary processes	Title of the written procedures	Coding
Acquisition	Purchase of pharmaceutical products	PHA003.01.00
	Reception of pharmaceutical products	PHA003.02.00
	Preparations in the pharmacy	PHA003.03.00
Inventory Management	Management of locations	PHA004.01.00
	Management of stock shortage	PHA004.02.00
	Management of expiries	PHA004.03.00
	Management of outdated products	PHA004.04.00
Dispensing	Dispensing of common products in the pharmacy	PHA005.01.00
	Dispensing special-status drugs in the pharmacy	PHA005.02.00

Table 3 Summary of the main risks identified for special-status drug dispensing procedure in pharmacy, in decreasing order of criticality

Steps	Risks	F	S	C
Execute the prescription	Dosage error	3	4	**12**
Deliver prescribed drugs	Dispensing error with inadequate advice	3	3	**9**
Taking charge of the prescription of psychotropic drugs	Renewal error (delivering a non-renewable prescription already delivered before)	3	3	**9**
Execute the prescription	Frequency of administration error	3	2	6
Execute the prescription	Recording omission or error in the order form and/or in the narcotics accounting record	2	2	4
Take charge of the special prescription	Misinterpretation of the special prescription	1	4	4
Take charge of the special prescription	Non-compliance with drug regulations	1	4	4
Take charge of the special prescription	Non-compliance with regulatory treatment duration (narcotics)	1	4	4

Fig 4 Definition of "risk acceptability" domains

	Frequency score					
Severity score	**1**	**2**	**3**	**4**	**5**	**6**
4	4	8	12	16	20	24
3	3	6	9	12	15	18
2	2	4	6	8	10	12
1	1	2	3	4	5	6

Fig 5 Criticality levels

Level 1	Unacceptable. Risk Reduction Measures are to be implemented
Level 2	Conditionally acceptable (or controlled)
Level 3	Acceptable. Residual risk management only

RESULTS

1. Identification and description of the elementary processes forming the management macro-process of the studied pharmacy is shown on Fig 3.
2. Procedures describing the main activities forming the identified elementary processes are listed on Table 2.

While drafting the aforementioned procedures, we noticed that the one relating to pharmaceutical products dispensation included several steps subject to non-compliance, with a particular attention for special-status drugs. Therefore, we chose it as a risk analysis model to be presented. Indeed dispensing involves competence and responsibility of the

holder pharmacist who must understand, analyze and explain the prescription. If there is any doubt about the latter or about the patient himself, the pharmacist should not hesitate to call the physician to obtain necessary clarifications within the framework of a constructive dialogue (Pitet, 2008; Thibaut, 2007).

Table 6 Matrix of measures for the dispensing process of special-status drugs in pharmacy

Score	Risks	Measure(s)
12	Dosage error	• Vigilance and attention must be particularly increased, because of the high toxicity of these products with integration of an additional double control step.
9	Dispensing error with inadequate advice	• Dispensing special-status products must be carried out under the effective control of the pharmacist who must also ensure the continuous training of his staff.
9	Renewal error (delivering a non-renewable prescription already delivered before)	• Respecting the regulation of special-status drugs in pharmacy; • Dispensing special-status products must be carried out under the effective control of the pharmacist who must also ensure the continuous training of his staff.

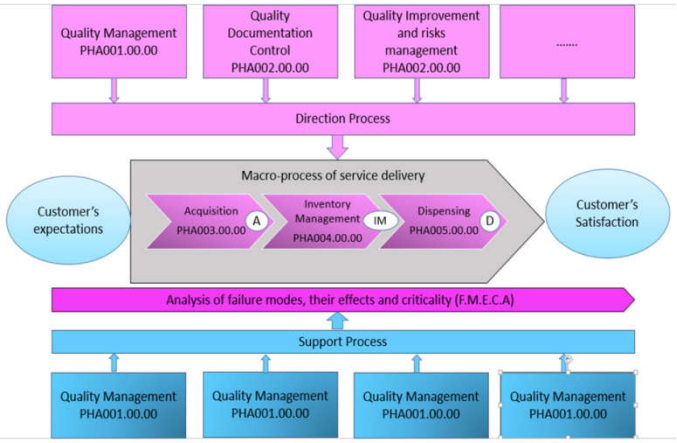

Fig 3 Process map of the studied pharmacy

The identification of medication errors during the various stages of dispensing allowed to assess the effectiveness of the dispensing system and to put in place corrective and preventive measures to improve it.

3. Application of the FMECA tool to the described activities with special-status drugs dispensation as the presented activity.

After involving all the pharmacy staff, main failures noted for the different procedures were identified (Mockly-Postal *et al*., 2007). Table 3 presents obtained results for special-status drugs dispensation procedure as a model.

DISCUSSION

The FMECA allowed us first to identify more precisely critical steps of the various pharmaceutical activities and the risks related to these activities, and also to intervene in a preventive and corrective way, particularly at the level of the most critical procedure steps.

Regarding the identified risks management, we provided solutions according to the criticality obtained levels, after carrying out failures identification and analysis. These results may vary from one pharmacy to another given the relativity of "Frequency" and "Severity" factors quantification. In order to better control non-compliance risks, we proposed a matrix of corrective and preventive measures for the most critical identified risks during the procedure analysis as shown on Table 4.

It is not easy to introduce this new concept of risk analysis into pharmacy team daily work without considering aggravating factors, such as the inexperience and limited knowledge of the staff, some environmental factors like noise and interruptions, the workload and fatigue, the poor communication between health professionals, the poor pharmaceuticals storage (improper storage, improper refrigerator temperature, etc.) and some confusing drug names compounded by illegible handwriting...

In the case of the studied pharmacy, we found that the dispensing process is the one with the highest proportion of risks. This is not due to the frequency of errors (most were rated 3: rare to 4: possible) but to their seriousness (most were rated 3: serious to 4: major) which is linked to drug effects on the patient's health.

When dispensing, the greatest caution should be accorded to fragile patients (pregnant or breastfeeding women, elderly subjects taking several medications, renal insufficiency, etc.) and to patients using medications that are most often involved in serious iatrogenic drug events (digitalis, lidocaine, potassium, theophylline, antiarrhythmics, hypoglycemics, tranquillizers, aspirin and Immunosuppressants) (Schmitt, 1999).

Incidents caused by medication errors can be fatal in some patients, and the entire pharmacy team must be aware that these incidents must be avoided. For this reason, it was decided to implement the risk analysis method (FMECA) which allows preventing incidents and oversights or to detect and correct them in time.

Finally, adverse drug reactions prevention linked to errors over the medication circuit requires a quality approach aimed at collecting cases of malfunction and their analysis and following work procedures put in place.

CONCLUSION

Risk is inseparable from any human activity. Thus, by crossing the threshold of a pharmacy, any patient is exposed to risks that may be related to the product pharmacology, but also, as we have seen in this work, to the organization of services offered at the pharmacy store.

In this logic, pharmacies should be committed to a quality approach that includes many steps resulting in the identification and description of elementary processes forming the pharmacy management macro-process, the development of their mapping, the drafting of detailed procedures describing the main activities forming the identified elementary processes and the application of the FMECA tool to the described activities.

The completion of this work showed that the implementation of risk control for customers in the pharmacy is entirely feasible.

This work is a tool for the head of the company, the pharmacist, to raise his staff awareness about the "risk culture"

by proposing a risk analysis methodology (FMECA) as well as solutions for dealing with the identified failures.

The presented quality approach is important but still considered as incomplete initial step in a quality management system (QMS). Indeed, it is necessary to take into account the whole environment of the pharmacy, the workload of the team and the available measures. This is why the implementation of a complete system (e.g. QMS certifiable ISO 9001:2008) requires time (minimum 2 to 3 years) given the complexity and the range of pharmacy activities.

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