Applying MAC-F Method for Causes Analysis of the Proven Medication Error in a Moroccan Hospital

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ABSTRACT

Medication error (ME) is a serious problem of public health. Difficulties related to the management of this error are numerous. Each stage of this process suffers from several flaws: identification, root causes analysis and improvement

This paper focuses on root cause analysis of medication error. We developed an original semiquantitative method named "MAC-F (Méthode d'Analyse des Causes basée sur la Fiabilité globale, in French). It's specific to the hospital context and constitutes a decision-making tool for professional of care. It based on a rigorous theoretical and conceptual framework (human reliability theory and high reliability organization theory).

We used our method MAC F to analyze serious proven medication errors. They have been collected over the past six months (from January to June 2020) in Moroccan hospital. The reliability matrix shows that the overall reliability index is very low ($\Omega = 0,07$). Moroccan hospital is therefore unreliable. The failure of the organizational system ($\Omega CF = 0,03$) and the absence of preventive strategies ($\Omega IF = 0$) don't help practitioners to recover the medication errors ($\Omega SF = 0,23$).

Root cause analysis is the most critical step in managing medication errors. Our aim is to provide healthcare professionals with a decision support tool "MAC-F" that we believe will help them to prevent Medication Errors and to achieve overall reliability (reliable organization and practitioner).

Our method was tested in a Belgian hospital before and Moroccan hospital recently.

KEYWORDS: analysis method, medication error, overall reliability, risk management.

JEL CLASSIFICATION: 118; 119

1.INTRODUCTION

Medication Error is an interesting topic and it's one of the main concepts in hospitals (Kiran et al., 2020).

According to the French National Agency for the Safety of Medicines and health products "Medication error (ME) is the unintentional omission or performance of an unintentional act involving a medication during the process of care. It may result in a risk or adverse event for the patient" (ANSM, 2019).

These errors are marked by the characteristics of severity, frequency and a preventability and weigh heavily on the state budget.

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The annual cost of medication errors around the world is estimated at \$42 billion (US \$), which represents almost 1% of all global health spending (WHO, 2017).

In Morocco; multicenter hospital-based studies have shown that 30.3% to 47.0% of the adverse drug events detected are preventable and turn out to be the consequence of medication errors (Soulaymani et al., 2019).

To ensure patient safety and meet the WHO's ambition to reduce serious events related to ME worldwide to 50% by 2022, the National Center for Pharmacovigilance (NCPV) set up a unit dedicated to the epidemiological surveillance of medication errors in 2006.

Despite efforts by health authorities and providers to intercept these errors, the rate of proven errors reaching the patient is still too high. It exceeds 90%. This shows that ME is not yet controllable and that more rigorous work needs to be done to achieve the desired results.

The management of ME as a process consisting of three phases: identification, cause analysis and improvement suffer from several flaws.

Beyond the problems related to the terminology used and the multitude of definitions adopted, the medication error management process has been reversed by health practitioners. The adoption of medication error improvement and reduction strategies from other settings has produced conflicting results. Moving from one hospital to another, the same solution can have both positive and negative consequences for the patient. This is because the most important step in managing ME, which is the *cause analysis*, has been neglected or skipped.

This is due in our view, to the lack of a method of *root cause analysis* easy to use and enabling decision making by creating a collective awareness of patient safety.

The objective of our work is to contribute to the cause analysis stage of ME. In this paper we present our method "MAC-F": The reasons behind the development of a new method, basics and steps of our method, we focused on the cause analysis step and finally we compared our method to those already existing.

2. WHY DEVELOPINGA NEW METHOD "MAC F"?

Medication errors are one of the most frequent hospital risks (La Prévention Médicale, 2020). Few treated patients escape medication errors, whether they are hospitalized, resident, or ambulatory, whether they are in the public or private sector, in the health or social sector (SFPC,2006).

The prevalence of medication errors is 32,1% (Sutherland *et al.*, 2020) to 94% (Assiri et al., 2018). From 52% (HAS, 2015) to 70% of these errors are preventable (Wilson et al., 1995).

In the United States, medication errors are the fourth leading cause of reported serious adverse events (SAEs). 1,3 million people are injured each year (WHO, 2017). These Errors kill at least one death a day and are responsible for approximately 7000 preventable deaths annually (WHO, 2017).

In France, the same result was confirmed. Among the 820 analyzed Serious Adverse Events (SAE) for 2018, by 111 are related to medication errors (HAS, 2019). They cause one SAE

every 2000 days of hospitalization (ENEIS 2 survey conducted in 2009^2), i.e. about 50,000 SAEs per year (1 SAE out of 2). They generate 1.5% of hospitalizations. It is important to specify that more than half of these SAEs are avoidable (Michel et al., 2010, 2011).

In Morocco, between 2006 and 2016, 1620 medication errors were reported to the NCPV, 96.42% of these errors were proven, 25.18% were serious, including 11 deaths (Alj et al., 2019b).

This brief overview of the literature shows some weaknesses in the management process of ME and inadequacy of existing methods

2.1 Some weakness in the risk management process

Managing Medication errors (ME) is a difficult issue. When we refer to the publications available in this field, we realize that this process is suffering from several weaknesses from identification to improvement phases (Filali EL Ghorfi, 2013).

In the *identification stage*, we noted the absence of a "golden rule" relating to the definition of medication error, the method of its identification and its measurement.

Indeed, the definitions given to medication error are numerous and inconsistent (Lisby et al., 2010). Barker et al. (2002) define medication error as the difference between the prescribed dose and the received dose. Kaushal et al. (2001) included errors related to the three steps in the hospital medication circuit (prescribing, dispensing, and administration). Other authors distinguish adverse drug reactions (ADRs) from adverse drug events (Otero & Schmitt, 2005).

SFPC (2006) emphasize the preventability of the error and integrate the therapeutic follow-up stage and also the organizational factors related to the patient's drug management process. NCCMERP (2020) gives the most complete definition. It integrates the preventability and direct and indirect causes related to this error such as professional practices, product, procedure and System including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Moreover, these errors have been collected using heterogeneous methods: spontaneous error reporting (Alj et al.,2019 a; Etchegaray & Thorckmorton, 2010; Pfeiffer et al., 2010), patient record review (Stheneur et al., 2006), observation (Dean and Barber, 2001), interventions by pharmacists (Baudrant et al.,2008), the trigger tool (Matlow et al., 2011, Agarwal et al., 2010), computerized monitoring (Rozich et al., 2003), and the use of a variety and classic collection methods such as the Mortality and Morbidity Review, audits, and complaints and incident reports(Baudrant et al., 2008, Brisseau & Bussières, 2010). Each of these methods has limitations. For this reason, some authors have combined two or three methods to ascertain the data collected (Lisby et al., 2005).

The literature review shows that the authors do not use the same approach neither the same method of calculating the drug error rate (Miller et al., 2007; Wilmer et al., 2010). The adoption of a transversal, retrospective or prospective approach (Michel et al., 2004) contributes to overor under-estimating the rate of drug error detected. In the calculation rate some authors include opportunities for error; others include intercepted errors, and timing errors. The result is that error rates are scattered (Lisby et al., 2010) and cannot be used as a criterion for comparison

² A new national survey (ENEIS 3) was launched in April 2019; the results are not published yet.

between the institutions in which they are collected. We cannot conclude that one hospital is more or less safe than the other.

The root *cause analysis* step is the most critical. It is descriptive and exploratory. Studies focusing on this stage are not numerous. They classify the causes in two categories: direct and indirect causes. Direct causes related to the individual: actors in the drug circuit, doctors, pharmacists and nurses (Duthie et al. 2005; Pham et al. 2011) and the types of human errors committed at the time of the patient's drug management: misuse and slips, negligence, lack of knowledge and skill, deviation from procedures (Fahimi et al. 2008; Westbrook et al. 2010; Salar et al., 2020).). Indirect system-related causes focused on workload, interruption of professional work, patient transfer, training, organization of the hospital drug circuit, etc.(Pham et al., 2011; Dahan & Sauret, 2010).

The analysis of indirect causes requires the use of some methods (Table 1). There are two types of methods: risk analysis methods (FEMEA, HACCP, etc.) and human reliability methods (FRAM, SHERPA, etc.). (We will discuss these methods in the § 2.2)

However, cause analysis is not linked to feedback and error learning systems. The occasional nature of the analysis does not allow assessing its effects on the behavior of the actors and cannot create a culture of safety and transparency.

Some factors are not sufficiently studied such as the human error; the nature of communication between the actors (inter/intra department, formal/informal, synchronous/

asynchronous); the analysis of procedures (normal or abnormal deviation/lack of coherence, acceptability, standardisation); the centralisation/ decentralisation of pharmacy and drug preparation, the social dimension and the role of the existing culture; policies for the management of human, material and information resources (information and communication technologies) and the hospital's financing policy. These elements deserve to be included in the causal analysis(Filali El Ghorfi et al., 2016).

In the *third* stage, several *improvement actions* were proposed in the literature to reduce medication errors. Two approaches are mainly addressed in the different works:

The "individual" approach, is based on the human factor and emphasizes the knowledge, creativity and competence of health care providers (Wetterneck, 2012), the presence of clinical pharmacists in the health care units (Hicks et al., 2004), and the "individual" approach, which is based on the human factor and emphasizes the knowledge, creativity and competence of health care providers (Wetterneck, 2012).

The "system" approach is based on investments and changes made at the organizational level to reduce medication errors, such as the implementation of computerized prescribing and decision support systems (HAS, 2005; Eslami et al., 2008, Pedersen, 2010), automated dispensing machines (AD) (Paparella, 2006; Kheniene et al. 2008), bar codes (Pedersen et al., 2012; Hassink et al., 2012), etc.

However, we found that these improvements have had mixed results. They can reduce the error as well as worsen the consequences for the patient. This can be explained by the fact that hospital organizations have imported solutions proposed by large institutions (NCCMERP, ISMP, JCAHO, AHRQ, etc.) without taking into account the limited resources and social context of each organization. These solutions were not justified and proven by reporting a real

need for the service. Root cause analysis, which alone is capable of determining the needs of each service and proposing appropriate strategies, is often neglected.

The risk management process has therefore been reversed. It begins with the implementation of strategies (phase three) without going through identification (phase one) and analysis of causes (phase two, which is essential for any improvement).

We have noted the *absence of a method based on human and organizational reliability* and which aims at analyzing the causes of medication errors.

2.2 Some remarks about risk analysis Methods used in the ME

We felt it was essential to develop a new method for Root Cause Analysis for many reasons:

1. The risk management methods that we find in the literature (FMEA, HACCP, REMED, etc.) (Table 1), don't integrate the human factor in their components and the social dimension is almost absent. Other methods, even if they integrate the human factor, such as HAZOP, ALARM (based on Reason's model), remain descriptive and don't show the existing interactions between the different factors.

| Method | Authors and year | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|
| of analysis | Authors and year | | | | | | | |
| Reason Model | Leape et al., 1995; Monsel et al., 2010 | | | | | | | |
| RCA | Hicks et al., 2007; Hicks et al., 2004; Cowely et al., 2001; Pham et al., 2011; Duthie et | | | | | | | |
| | al., 2005 | | | | | | | |
| ALARM | Stheneur et al, 2006; Collomp, 2008 | | | | | | | |
| FMEA | Lethuillier et al., 2005; Bonnabry et al., 2006; Paparella, 2007; Lenclen, 2007; Koppel et | | | | | | | |
| | al., 2008; Chiozza and Ponzetti, 2009; Côté et al., 2011; Goubella et al., 2012; Jeannin et | | | | | | | |
| | al., 2015; Jouhanneau et al., 2016; Djermoune et al., 2016; | | | | | | | |
| HFMEA | Knight and Caudill, 2010; Cheng et al., 2012 | | | | | | | |
| HACCP | Bonan et al., 2009 | | | | | | | |
| The simulated | Kazaoka et al., 2007; Sfez et al., 2008 | | | | | | | |
| case | | | | | | | | |
| Human HAZOP | Trucco and Cavalin, 2006 | | | | | | | |
| REMED | SFPC, 2013; Dufay et al., 2009; Rhalimi et al, 2010; Guillaudin et al., 2013 | | | | | | | |
| | | | | | | | | |
| PRISMA | Van Den Berge and El Hiki, 2012 | | | | | | | |
| FRAM | Cridelich et al., 2012 | | | | | | | |
| SHERPA | Lane et al., 2006; Filali et al., 2010; Bligard and Osvalder, 2014. | | | | | | | |
| HFCF | Mitchel et al., 2015 | | | | | | | |
| | Course control control on | | | | | | | |

Table 1. Methods used for the analysis of the causes of ME from the literature

Source:our contribution

- 2. Human reliability analysis methods (FRAM, SHERPA etc) (table 1), focus on task analysis and use measurement tools based on data from the industrial environment. These methods are unsuitable for the hospital environment. They use jargon that is very specific to the field under study (aeronautics, nuclear, etc.), which calls into question their suitability for the hospital context.
- 3. Furthermore, risk management methods and human reliability methods are based on the duality of causes (direct and indirect) and don't take into account the interaction between the two. In fact, this interaction between direct and indirect causes is always implicit in these methods.
- 4. Most methods require the expertise of a risk management specialist or human reliability for their use. We consider that if this analytical work is in the hands of specialists, it will not

contribute to the creation of a "collective consciousness" within the organization. The method must be simple enough to guarantee its appropriation by the actors concerned, its reliability and its reproducibility.

Hospitals therefore need a tool that can be used by all personnel involved in patient safety. A method that integrates human and system component for the Root Cause Analysis. A method that allows practice and organizational improvement and provides automatic feedback.

3. "MAC-F" BASICS, STEPS AND ADDED VALUE

3.1 Basics and steps

Our contribution is based on a hybrid approach combining the individual and the system approach using the theory of human reliability and that of highly reliable organizations. It consists in developing a conceptual framework and proposing a method for analyzing the causes of ME based on global (human and organizational) reliability.

Our conceptual framework suggests that ME can be the consequence of human unreliability (direct causes that we named *Specific factors*), organizational unreliability (indirect causes/ *Common Factors*) and also a conjunction of both (*intermediate Factors*). Error can occur even in a safety-conscious organization when risk management tools are not appropriate or when corrective plans are not adequate. Thus, our contribution consists in highlighting the existence of a third category never dealt with in the literature: the existence of intermediate factors which show the influence exerted by the system on the individual (i.e. the correlation relationship between the two factors). The *intermediate* factors (IFs) are related to the set of preventive and/or corrective actions implemented within a hospital to prevent medication errors from occurring (Filali El Ghorfi et al.,2016).

According to this conceptual framework we proposed a new method of cause analysis based on reliability which we named MAC-F. Our proposal is thus intended to be a tool to help health professionals to develop the most adapted and effective risk management and improvement strategies.

MAC-F combines the characteristics of risk management methods and human reliability analysis methods. However, it differs from the former by integrating the concepts of human and organizational reliability theory and from the latter by analyzing the entire process and not just an isolated task. Our method of analysis focuses on the three factors of ME causes and aims to help healthcare professionals develop the most appropriate and effective improvement strategies.

MAC-F is a method based on the theory of human reliability and that of highly reliable organizations. It takes into account the multidimensional nature of man (the cognitive/subjective dimension and the intersubjective/social dimension) and the complex nature of the hospital drug circuit (static/structural and dynamic/interaction between actors).

MAC-F is a process-oriented method. It follows the logic of the problem-solving approach cycle. It therefore has a structure that resembles several methods that aim at continuous improvement (such as DMAICS - Define, Measure, Analyze, Improve, Control and Standardize).

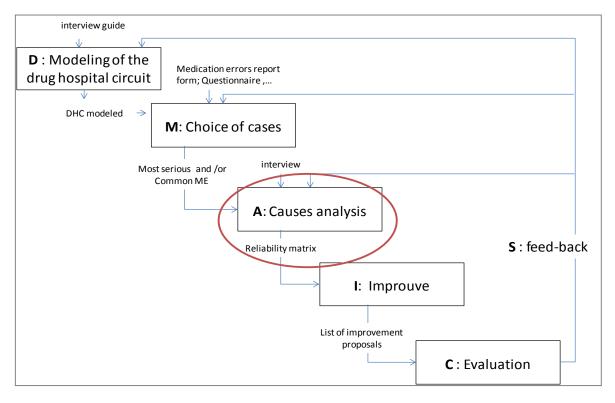


Figure 2.The steps of the MAC-F method according to DMAICS *Source:* our contribution

Our method consists of six steps: modeling, case selection, cause analysis, improvement, evaluation and feedback.

In the modeling step we use a flowchart to model the process. Among the collected errors we select only serious and / or common Medication errors. We analyze these selected errors by using a reliability matrix (table 2) and then we can improve our process by making suggestions. We assess the proposals based on cost and urgency criteria. Finally, we provide feedback to all interested parties by disseminating the results of the previous steps of the method (matrix, reliability index, figures from both vertical and horizontal analyzes, and the assessment of improvements)

However, the main contribution of our method lies in the *analysis phase*. This uses a *reliability matrix*.

3.2The added value: Reliability Matrix for Causes analysis

The reliability matrix is based on the multidimensional taxonomy that distinguishes the three factors of reliability: specific factors, common factors and intermediate factors (table 2). It is a simple and easy tool to be appropriated by health care providers.

This matrix is completed using data collected by interviewing healthcare providers. It provides a cross-referenced view of the medication process, the organization and the behavior of individuals. Using these data, we were able to analyze the contribution of each factor to ME.

| | | Table 2 | . The reliabilit | y matrix | | | | | | | |
|--|------------------------------|------------------------------|---------------------------|---|----------------------------------|--|--|--|--|--|--|
| Reliability Factors | Circuit Steps /Actors | | | | | | | | | | |
| | Prescription (Physician) | Dispensation (Pharmacist) | Administration (Nurse) | Renability index By yomichlo | Suggestions for mprovement | | | | | | |
| Specific Factors (SF) | - + 0 | 0 - + | + 0 - | | - | | | | | | |
| Reliability index of Specific Factors | | | | $\Omega SF = \left(\frac{\Sigma +}{(\Sigma -) + (\Sigma 0) + (\Sigma \emptyset)}\right)$ | | | | | | | |
| Intermediate Factors (IF) | Ø - + 0 | - 0 Ø + | - Ø + 0 | | | | | | | | |
| Reliability Index of Intermediate Factors | | | | $\Omega IF = \left(\frac{\Sigma +}{(\Sigma -) + (\Sigma 0) + (\Sigma \emptyset)}\right)$ | | | | | | | |
| Common Factors (CF) | + - 0 | - 0 + | - + 0 | | | | | | | | |
| Reliability Index of Common Factors | | | | $\Omega CF = \left(\frac{\Sigma +}{(\Sigma -) + (\Sigma 0) + (\Sigma \emptyset)}\right)$ | | | | | | | |
| Overall reliability index | | ~ | urce: our contribu | $\Omega = \left(\frac{\Sigma +}{(\Sigma -) + (\Sigma 0) + (\Sigma \emptyset)}\right)$ | | | | | | | |

Table 2. The reliability matrix

Source: our contribution

The evaluation of this contribution is carried out using a scale of signs (negative, nil, non-existent or positive):

- Sign (-) when the Reliability Factor is not functioning optimally and therefore contributes to the medication error (it does not prevent the error from occurring).
- Sign (0) when the factor is neutral as to the occurrence of the error (it is not directly related to it or has no effect)
- Sign (Ø) when the factor is non-existent (this sign is especially relevant for Intermediate Factors (IFs)
- Sign (+) when the factor helps to recover and correct the error.

We then calculate per row and column the corresponding reliability index.

Per line, we obtain **reliability index by variable** (Σ -; Σ +; Σ 0; Σ Ø). They reflect the contribution of each variable in the ME along the clinical pathway of the drug. That is, at all stages of the process.

Reliability index are calculated by column **by factor**. This index gives us, for each of the 5 cases, the contribution of each type of factor in the appearance of ME ($\Sigma^{(SF)}$; $\Sigma^{(IF)}$; $\Sigma^{(CF)}$).

The matrix thus makes it possible to see the positive, negative, neutral or non-existent contribution of each factor and to see whether this index is specific to a single type of ME or

whether they have a repetitive character, common to all the actors and whether they are involved in all the MEs in the medicinal product circuit.

It distinguishes between factors that hinder reliability and contribute to the error (those with the signs (-; 0; \emptyset)) and reliable factors that recover the error (those with the sign (+)). We will therefore calculate the **overall reliability index** for each factor (SF, IF and CF) using the following formula: $\Omega = (\frac{\Sigma +}{(\Sigma -) + (\Sigma 0) + (\Sigma 0)})$.

Given the paucity of studies in the area of reliability in the hospital setting, there is no threshold that allows us to separate reliability from unreliability. We wish to contribute to this field by sharing our thinking.

We consider that this index (Ω) must be between 1 and ∞ $(1 \le \Omega \le \infty)$ to have a reliable and secure clinical circuit. In this case, the level of reliability is said to be **acceptable** when Ω of each factor is ≥ 1 . However, this level of reliability **performs well** (competitive), when Ω tends towards infinity (∞) . That is, when the denominator tends towards 0. This means that the positive effect is predominant and that the factors are reliable and cover the failure of the other factors (fallible, neutral or non-existent).

However, if $0 \le \Omega < 1$ the unreliability of the factors is predominant and ME will become more and more frequent (or even severe). Serious improvement actions are needed to reduce the error.

The reliability matrix allows us to conduct a vertical analysis (by actor/circuit step), a horizontal analysis (by reliability factor) and cross analysis which shows the contribution of all the factors in the Medication Error through the overall reliability index (Ω) which is necessary for decision-making and prioritizing improvement actions.

The reliability matrix contributes to the creation of collective awareness of reliability and patient safety.

4. APPLICATION OF THE MAC-F METHOD

In order to prove the validity of our method, we decided to test it in different contexts and for different types of errors. First, in a previous study we tested this method for intercepted medication error in Belgian hospital (Filali El Ghorfi et al., 2016). In this article we analyzed proven medication errors. The study took place in a provincial public hospital in the northen region of Morocco. We will focus on the "analysis step" of our method: i.e'the reliability Matrix".

4.1 Data collection

We collected proven medication errors that appears in the last six month from January to June 2020. All patients contaminated by COVID 19 were excluded. The proven errors we collected are rare but serious. The level of severity ranging from extended stay with increased surveillance to permanent injury (limb amputation, etc.) (Box 1).

Case 1 prescription error and case 3 administration error (women's medicine department).

This is the case of a prescription error that induces an administration error. Patient aged 26 years old hospitalized in the women's medicine department for hysterical crisis. Upon medical prescription of ATARAX (hydroxyzine 100mg/2ml injectable), the nurse on duty (not yet a nurse, recruited six months ago) injected the product directly intravenously without respecting the recommended dilution (dilution in at least 20ml of physiologicalsaline) and the recommended injection time (5min). The prescription produced by the Prescribing Physician (25 years of experience) does not include complete information regarding the dilution of the product and the flow rate and route of administration. Consequences: excruciating pain and inflammation at the injection site. Prolonged stay and increased surveillance.

Case 4 of administration (operating theatre)

31-year-old patient admitted to the operating room to remove a foreign body in the forearm. Surgery was performed under general anesthesia. Faced with a sudden bradycardia, the nurse anesthetist, present in the department for two months, injected 1mg of adrenaline instead of 1mg of atropine (resemblance of a light bulb and small writing).

Consequence: ventricular tachycardia which required a cardioversion. Heartbeat 180 per minute which required electroshock stimulation.

Case 5: Administration error (operating theatre)

Parturient, 25 years old, admitted to the operating room for emergency Caesarean section. Caesarean section under spinal anesthesia. After the extraction of the baby, the resuscitation doctor (20 years of experience) accompanying the nurse in the block injected 6 mg of ephedrine (5ml syringe with 30 mg of ephedrine) following a drop in blood pressure. The woman quickly lost consciousness and stopped breathing.

The syringe prepared during a previous operation contained Esmeron (rocuronium 50 mg: curare =myorelaxant), and was labelled ephedrine.

Consequence: awakening after respiratory assistance (parturient intubated ventilated).

Case 6: Administration error (women's medicine)

Patient aged 15 years old hospitalized for a febrile syndrome, on medical prescription, put under antibiotics (maxiclave (amoxicillin 1g + clavulanic acid 200mg) an intravenous injection three times a day by the nurse (6 choices in the unit). After eight days of treatment, the patient developed an important inflammation at the injection site, which after a few days became complicated (ischemia (gangrene)) and amputation of the limb.

Box 1: Description of proven medication errors

We selected five medication errors from those that occurred in the hospital medication circuit. One prescription error and four administration errors. The dispensation errors are non-existent (None). Pharmacists at the provincial hospital don't prepare the medications. Their role is limited to stock management.

We decided to analyze the causes of these serious proven medication errors. The result of analysis appears in the reliability Matrix below (table 3 - reliability matrix).

4.2 Causes analysis using the reliability matrix

For each drug error (prescription or administration error), we selected the appropriate sign $(-, +, 0, \emptyset)$ for each cause/factor of the error (Table 3).

For Intermediate Factors (IF) we selected the preventive or corrective actions that should be implemented in the hospital to reduce errors (based on the literature review) such as: Computerized Physician Order Entry (CPOE), Automated Distribution system (AD), Issuance with Daily Nominal Dispensation (IDND), Centralized medication Preparation (Centr. Prepar), Resources Management (RM); Emergency provisioning (EP); Clinical Pharmacist (clinical Phar.) and Check list, training, report, ... etc.

This matrix allows us to conduct three levels of analysis: vertical, horizontal and a crossanalysis.

| | | | Circuit Steps /Actors | | | | | | | | | | |
|------------------------------|---------------------------|---------------------------------------|---------------------------|------------------------------|----|----|----|----|------------------------------|----------------|------|-----------------------------------|----------|
| | Reliability | Factors | Prescription Physician | Dispensation (Pharmacist) | | | | | | iabil oy va | | Suggestions for improvement | |
| | N° de o | cas | 1 | NEANT | 3 | 4 | 5 | 6 | Σ- | Σ + | Σ0 | ΣØ | |
| | Perception | Auditive | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | |
| | reiception | Visual | 0 | | 0 | - | 0 | 0 | 1 | 0 | 4 | 0 | |
| | | Content | + | | + | + | + | + | 0 | 5 | 0 | 0 | |
| | Knowledge | Process | + | | - | - | + | I | 3 | 2 | 0 | 0 | |
| Specific factors (SP) | | Conditionnal | + | | - | - | + | - | 3 | 2 | 0 | 0 | |
| act | | Routine | + | | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 0 | |
| ïc f£ (SP) | | Urgent | + | | 0 | - | - | 0 | 2 | 1 | 2 | 0 | |
| cifi (| Decision | Complex | - | | 0 | 0 | 0 | 0 | 1 | 0 | 4 | 0 | |
| ipe | | On Time | + | | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 0 | |
| 9 1 | | Adequate | 0 | | - | - | 0 | - | 3 | 0 | 2 | 0 | |
| | | Action | - | | - | - | - | - | 5 | 0 | 0 | 0 | |
| | Vigilance | Control | - | | - | - | - | - | 5 | 0 | 0 | 0 | |
| | - C | Communication | - | | - | - | - | - | 5 | 0 | 0 | 0 | |
| | • | Σ- (FS) | 4 | | 6 | 8 | 4 | 6 | 28 | | | | |
| D 11 1 | | Σ + (FS) | 6 | | 1 | 1 | 3 | 1 | | 12 | | | |
| | oility index of | Σ0 (FS) | 3 | | 6 | 4 | 6 | 6 | | | 25 | | |
| - | cific Factors | ΣØ (FS) | 0 | | 0 | 0 | 0 | 0 | | | | 0 | |
| | (ΩFS) | ΩFS | | | | | | | $\Omega FS = 12 / 53 = 0,23$ | | | | |
| | | CPOE | Ø | | Ø | Ø | Ø | Ø | 0 | 0 | 0 | 5 | |
| | Information Technology | Barre code | ø | | ø | Ø | ø | ø | 0 | 0 | 0 | 5 | |
| | | AD | Ø | | ø | Ø | Ø | ø | 0 | 0 | 0 | 5 | |
| IS | Organization | IDND | ø | | ø | ø | ø | ø | 0 | 0 | 0 | 5 | |
| cto | | Centr. prepar. | Ø | | ø | Ø | Ø | ø | 0 | 0 | 0 | 5 | |
| Intermediate factors (IF) | of the circuit | EP | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | |
| diate (IF) | or the encut | Secure cabinet | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | |
| edi (] | | Clinical Phar. | ø | | ø | ø | ø | ø | 0 | 0 | 0 | 5 | |
| rm | | Check list, cont | - | | 0 | - | - | - | 4 | 0 | 1 | 0 | |
| nte | Human | Training | 0 | | Ø | Ø | Ø | Ø | 0 | 0 | 1 | 4 | |
| I | Factor | Report | ø | | ø | Ø | Ø | ø | 0 | 0 | 0 | 5 | |
| | i dettoi | Analysis | Ø | | Ø | Ø | Ø | Ø | 0 | 0 | 0 | 5 | |
| | | Feedback | Ø | | Ø | Ø | Ø | Ø | 0 | 0 | 0 | 5 | |
| | | Σ - (FI) | 1 | | 0 | 1 | 1 | 1 | 4 | 0 | 0 | 5 | |
| Reliab | ility Index of | $\frac{\Sigma^2 (FI)}{\Sigma^+ (FI)}$ | 0 | | 0 | 0 | 0 | 0 | - | 0 | | | |
| | ediate Factors | $\Sigma 0$ (FI) | 3 | | 3 | 2 | 2 | 2 | | 0 | 12 | | |
| | (ΩFI) | $\Sigma \emptyset$ (FI) | 9 | | 10 | 10 | 10 | 10 | | | 12 | 49 | |
| (22FI) | | ΩFI | , | | 10 | 10 | 10 | 10 | 01 | | 0/65 | | |
| 0 | 1 | Consistency | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | |
| Commo | Procedure | Dissemination | + | | - | - | 0 | 0 | 2 | 1 | 2 | 0 | |
| | riocedure | Standardisation | + + | | - | - | 0 | 0 | $\frac{2}{2}$ | 1 | 2 | 0 | |
| | 1 | Stanuaruisation | Ŧ | | - | - | 0 | U | 4 | 1 | 2 | 0 | <u>i</u> |

Table 3. The reliability matrix

| | | | Circuit Steps /Actors | | | | | | | | | | | |
|--------|-------------------------------|--------------------|---------------------------------------|--|---------------------------|----|---|----|----------------------------------|------|------|---|-----------------------------------|--|
| | Reliability Factors | | Prescription Physician | Dispensation (Pharmacist) | Administration (Nurse) | | | | Reliability Index by variable | | | | Suggestions for improvement | |
| | Médication | Nature | 0 | | 0 | - | 0 | 0 | 1 | 0 | 4 | 0 | | |
| | /medicine | Management | - | | 0 | I | - | 0 | 3 | 0 | 2 | 0 | | |
| | /medicine | Flux | - | | I | - | - | - | 5 | 0 | 0 | 0 | | |
| | | inform. RM | - | | - | - | - | - | 5 | 0 | 0 | 0 | | |
| | RM | Human RM | - | | I | - | - | - | 5 | 0 | 0 | 0 | | |
| | | Material RM | - | | 0 | - | - | 0 | 3 | 0 | 2 | 0 | | |
| | | Collectivist | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | | |
| | Culture | Transparency | - | | 1 | 1 | - | - | 5 | 0 | 0 | 0 | | |
| | | Proactive | - | | I | I | - | - | 5 | 0 | 0 | 0 | | |
| | Patient | Clinical condition | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | | |
| | Patient | Communication | - | | 1 | 0 | 0 | 0 | 2 | 0 | 3 | 0 | | |
| | | Itinerary | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | Σ- (FC) | 8 | | 8 | 10 | 7 | 5 | 38 | | | | | |
| Reliab | ility Index of | Σ + (FC) | 2 | | 0 | 0 | 0 | 0 | | 2 | | | | |
| Com | mon Factors | Σ0 (FC) | 5 | | 7 | 5 | 8 | 10 | | | 30 | | | |
| | (ΩFC) | ΣØ (FC) | 0 | | 0 | 0 | 0 | 0 | | | | 0 | | |
| | | ΩFC | | | | | | | | C =2 | /68= | | | |
| REL | VERALL IABILITY DEX (Ω) | | $\Omega = (\frac{1}{(\Sigma - 1)^2})$ | $\frac{\Sigma + (\Sigma 0) + (\Sigma 0) + (\Sigma 0)}{\Sigma + (\Sigma 0) + (\Sigma 0)}$ | EØ) | | | | | 0, | 07 | | | |

Through the vertical analysis,(figure 3 only for case 3) we can understand how some factors have hindered the reliability of the main actor in the circuit (the nurse). These administration errors occurred in the women's medicine and operating theatre units. They are related to the route of administration (intravenous), the preparation (dilution not respected) and the time of administration (long or fast flow).

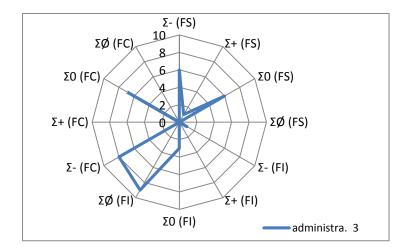


Figure 3. Vertical analysis contribution of all factors in administration error $n^{\circ}3$ (role of the nurse)

In the reliability matrix (table 3 case $n^{\circ}3$), **Specific factors** (SF) related to the individual (nurse), contributed to ME with 6 variables having a negative effect and 6 having a neutral effect. It shows a lack of procedural and conditional knowledge of the nurse. Only content (basic) Knowledge is positive but it is insufficient. The nurse makes an inadequate decision (non-dilution of the drug) and an erroneous action (administration by the wrong route) because information on prescribing was missed and the accompaniment, communication and control were lacking.

Indeed "The order did not include complete information. It's a drug that has to be diluted and administered slowly. This is a new nurse recently recruited (two months). So, she didn't prepare the medication properly. She gave the drug intravenously when it was supposed to be given intramuscularly" (Case 3)

Under these conditions the absence of **Intermediate Factors** (IF), i.e prevention policies such as: the CPOE, clinical pharmacist, favors the arrival of the error to the patient. There was no possibility to recover the error. The check list exists but has a neutral effect the nurse doesn't need to complete it.

In addition, **Common Factors** (CF) related to procedures, organizational culture, medication, resource management and patient status also contributed to the production of such errors. (Σ -(FC) = 8 for case n °3). All the organizational factors have negative or neutral effect. All ME have no chance to be recovered by the actors.

In *the horizontal analysis* (figure 4), we focus on **common factors** (**CF**) **of all administration errors**.

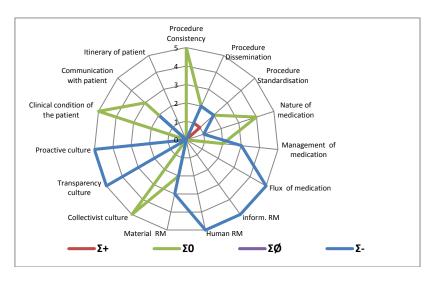


Figure 4. Horizontal Analysis: Reliability index of Common Factors (CF)

Administration errors occurred and reached the patient because procedures are poorly disseminated and not standardized (cases 3 and 4). Medications are misplaced (case 4) and mislabeled (case 5). The resemblance of the ampoule and the illegibility of the labels is a major problem (case $n^{\circ}4$).

Poor management of human, information and material resources, lack of a risk prevention culture and lack of error reporting contributed at 100% to all proven medication errors (blue line in figure 4). Nurses suffer from unbearable working conditions. The workload is high, the staff is insufficient, the team members are inconsistent, the coordination and the communication have been lacking. All of this, create opportunities for major mistakes.

Despite the existence of a collectivist culture, this had no effect since no one asked his colleague for help in case of an error. No errors were reported and no analysis of their causes or feedback is planned. In addition, lack of communication with the patient contributed negatively to the situation (cases $n^{\circ}3$ and even $n^{\circ}1$).

Regarding *cross-analysis* (figure 5), this allows us to visualize the reality of our organization and to judge the reliability of its human components (SF); its systems (CF) and the interaction between them (IF) (the three axes in Figure 5).

The green zone (positive contribution of factors $(\Sigma+)$) is very small. It concerns only the human factor (SF). The health care provider relies on his basic, procedural and conditional knowledge to recover the error and avoid its harm to the patient. However, despite this level of knowledge and the cumulative experience (20 years) of some actors (case n°5) the error occurred.

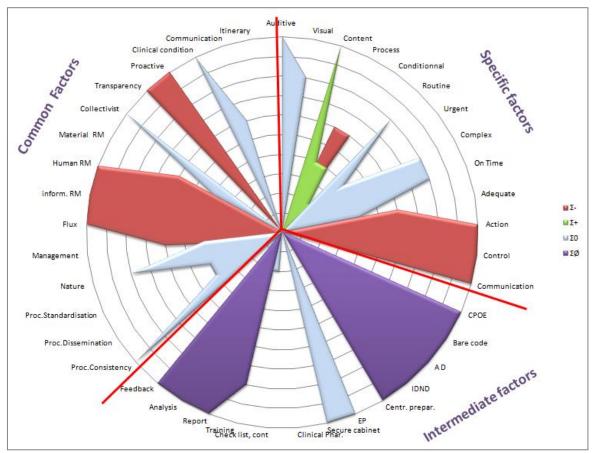


Figure 5. Cross-Analysis of Factors

The actors are not vigilant (Σ - red zones on the right SF). Workload and inconsistency among team members, poor management of materials, information and drug flow (Σ - red zones on the left CF) contributed largely to the error reaching the patient. No measures ($\Sigma \emptyset$ purple zone IF)) concerning the introduction of new information and communication technologies, training and feedback on risk management were put in place to help providers prevent and avoid error. Some factors played no role in producing the error ($\Sigma 0$).

Factor reliability indices are all less than 1 (figure 6). $\Omega FS = 0.23$, $\Omega FI = 0$ and $\Omega FC = 0.03$.

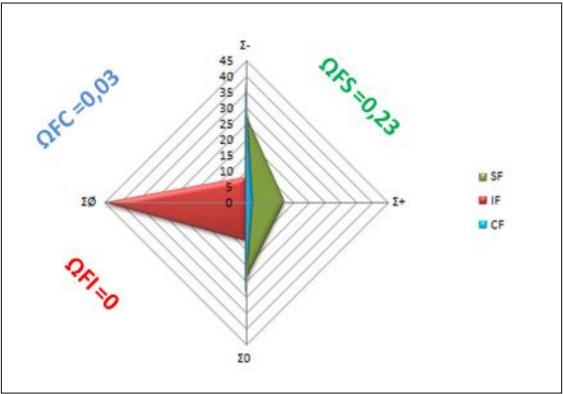


Figure6. Reliability indices

Specific Factors (SF) are "more reliable" than IF and CF which means that humans operate in a failed system and cannot be reliable enough to pick up the medication error (even with advanced knowledge and years of experience). Reliability index of intermediate Factors is 0. No preventive or corrective measures have been adopted to reduce or recover the medication error. In Morocco some of these IF are absent for all hospitals (clinical pharmacist, for exemple).

Reliability index of Common factors is too low (0,03). The work environment, organizational culture and resource management were unreliable.

The overall reliability index is 0.07. It can be concluded that the hospital in which we carried out the study is not reliable. Several actions must be taken to reduce medication error and ensure patient safety.

4.3 Comparison of two studies using MACF method in two different contexts

If we compare this study with the one we conducted in Belgium (Filali El Ghorfi et al., 2016), there are three differences between the two studies:

1- Type of error analyzed: in the Belgian hospital we analyzed the intercepted medication error, i.e. the error did not reach the patient, whereas in the Moroccan hospital we analyzed the proven error. So the decision of the seriousness of the consequences of ME is well-founded whereas in the Belgian case it was only an estimate based on the experience of the actor interviewed.

2- Analysis of the causes: In the Moroccan case, the analysis of causes focused on the negative points and weaknesses of the system and of individuals. In the first case, the analysis focused more on the positive factors that contributed to the recovery of the error, where intermediate factors played an important role.

3- Calculation of reliability indices by factor and overall reliability. From the outset, a very low level of reliability was expected in Morocco compared to the Belgian case due to the presence of certain intermediate factors (clinical pharmacist as example).

The objective of this study was not to compare the Belgian hospital and the Moroccan hospital because the financial resources; the culture of the organization and the eco-system in which the two hospitals operate are different, but our objective was to test the validity of the method. We have drawn some interesting conclusions that confirm and validate our conceptual framework: "ME is the combination of the three factors, the individual alone cannot recover from the error".

5. COMPARISON OF OUR METHOD WITH EXISTING METHODS

This comparison is made in relation to risk management methods (Table 4) and human reliability analysis methods (Table 5).

Compared to risk analysis methods, our method MAC-F has been developed for the hospital environment and is based on both a process and an indicator approach.

Our method MAC-F provides a cross view of the different causes of error and is based on taxonomy of human error.

The reliability matrix and the representation of its results in a spider diagram allow a clear visualization of the situation and the factors that contributed to the error.

| | | | - | | | | 0 | | | |
|---|----------------------|-------------------------|-------------------------|-------------------------|----------------------|----------------------|-------------------|-------------------|-------------------|--|
| Risk Management Methods Assessment criteria | НАССР | HAZOP | FMEA (AMDEC) | HFMEA | Récupérare- Santé | ALARM | RCA | REMED | RM&M | MAC-F |
| Origin field | Industry | Industry | Industry | Hospital- adapted | Hospital- adapted | Hospital- adapted | Hospital | Hospital | Hospital | Hospital |
| Theortical framework | Operational security | Operational security | Operational security | Operational security | Human error | Human error | Human error | Human error | Human error | Overall reliability |
| Approach | Problem- based | Problem- based | Process based | Process based | Indicator based | Problem- based | Problem- based | Problem- based | Problem- based | Process+ problem+indicator |
| Analysis | A posteriori | A priori | A priori | A priori | A posteriori | A posteriori | A posteriori | A posteriori | A posteriori | A posteriori |
| Process Modelig | No | No | Yes | Yes | No | No | No | No | No | Yes |
| Human error taxonomy | No | No | No | No | No | No | No | No | No | Yes |
| Crossover vision | No | No | No | No | No | No | No | No | No | Yes |
| Results Representation | Table | Table | Matrix | Tree | Table | Table | Table | Ishikawa | Rapport | Reliability Matrix+ spider Diagram |
| Monitoring indicators | No | No | No | No | Yes | No | No | Yes | No | Yes |

Table 4. Comparison of MAC-F to risk management methods

Compared to human reliability methods (table 5), our method MAC-F is semi-quantitative. It analyzes the whole process, not just the task. It allows the representation and identification of actors involved in the error. It allows for cross-analysis and doesn't require expert advice. It is a decision support tool aimed at creating a collective awareness of reliability.

| | - | | | | | | | - | |
|---|--------------------|--------------------|--------------------|-------------|--------------------|--------------------|--------------------|-------------|--|
| Human reliability methods Assessement criteria | SHERPA | HEART | HCR | Tripod | CREAM | GEMS | FRAM | PRISMA | MAC-F |
| Type of method | Qualitative | Quantitative | Quantitative | Qualitative | Quantitative | Qualitative | Qualitative | Qualitative | Semi quantitative |
| Data source | Expert judgment | Expert judgment | Expert judgment | Data base | Expert judgment | Expert judgment | Expert judgment | Interview | Questionnaire + interview |
| Scope of analysis | Task | Task | Task | Task | Task | Task | Task | Task | Process |
| Actor representation &identification | No | No | No | No | No | No | No | No | Yes |
| Internal error mode | Yes | Yes | Yes | No | Yes | No | No | Yes | Yes |
| External error mode | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| Influencig factors | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Decision criteria | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes |
| Reliability calculation | Yes | Yes | Yes | Yes | Yes | No | No | Yes | Yes |
| Cross analysis | No | No | No | No | No | No | No | No | Yes (reliability matrix and (Ω) |
| Improvement Cycle | No | No | No | No | No | No | No | No | Yes |
| validation according to the Kirwan criteria, 1992 | Yes | Yes | Yes | No | Yes | Yes | No | No | No |

Table 5. Comparison of our method MAC-F with human reliability methods

6. CONCLUSION

In this paper we present our method "MAC-F": The reasons behind the development of a new method, basics and steps of our method, we focused on the cause analysis step and finally we compared our method to those already existing.

We have therefore proposed a new method for analyzing the causes of ME (MAC-F) based on overall reliability. Our contribution is based on a hybrid approach combining the individual and the system approach using the theory of human reliability and that of highly reliable organizations. It consists in developing a conceptual framework and proposing a method for analyzing the causes of ME based on global (human and organizational) reliability.

This method is a contribution to ME management. It follows the same sequence of continuous improvement methods such as DMAICS but differs from these methods by adopting a specific theoretical and conceptual framework.

MAC-F could be used to analyze the causes of all types of adverse events related to care. This method can be generalized due to its particular structure. It takes into account both "fixed" and "variable" reliability factors. The "fixed" factors are the *common* and *specific* factors and the "variable" factors are the *intermediate factors*. The latter can be adapted and modified according to the type of event to be analyzed.

MAC-F provides an overall and cross-referenced view of all reliability factors and their interactions throughout the process under study.

Its added value lies in the combination of a vertical and horizontal analysis of the reliability matrix and by the calculation of an index that provides a vision of the overall reliability of the process

Its added value lies in the reliability matrix allowing a vertical and horizontal analysis of the reliability matrix and by the calculation of an index that provides a vision of the overall reliability of the process which is essential for defining appropriate improvement strategies.

The method we have proposed is an original contribution in the field of medication error management. It has been tested in two different contexts and in different hospitals,

Based on the MACF method, the result of the study related to proven medication errors conducted in a Moroccan hospital shows that the human factor reliability index (SF) is 0.23. The reliability index for common factors is 0.03, while the reliability index for intermediate factors is zero (0), meaning that the human factor alone cannot recover the error. The reliability of the CF and IF is essential to have an acceptable level of overall reliability (\geq 1). Otherwise, patient safety cannot be ensured. The Moroccan hospital in which we conducted the study is therefore unreliable. The overall reliability index is 0.07 (very far from 1).

The managerial implications are therefore numerous:

- The need to set up a structure (a working group) responsible for patient safety and the reduction of ME
- The establishment of collecting and analyzing the ME
- The integration of the three dimensions (structure, process and result) in the evaluation of improvement strategies.
- The effects of such an approach will have a significant impact on the change in the culture of actors (safety culture, admitting errors, analysis of the causes)

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