Failure Mode and Effect Analysis: A Technique to Prevent the Risk of SARS-COV-2 Infectionin A Retrocession Unit

Esso Eric Valery Latt[1], Youssef Moutaouakkil[2], ZidaneQriouet[3], YassineAtbib[1], YasminaTadlaoui[4], Jamal Lamsaouri[5], YassirBousliman[6]

[1]Resident in Clinical Pharmacy, Laboratory of Pharmacology and Toxicology, Faculty of Medicine and Pharmacy, Mohammed V University in Rabat, Rabat Institute, Rabat, Morocco, [2]Specialist in ClinicalPharmacy, Laboratory of Pharmacology and Toxicology, Faculty of Medicine and Pharmacy, Mohammed V University in Rabat, Rabat Institute, Rabat, Morocco, [3]PhD Student, Laboratory of Pharmacology and Toxicology, Faculty of Medicine and Pharmacy, Mohammed V University in Rabat, Rabat Institute, Rabat, Morocco - Medical Biotechnology Center, Moroccan Foundation for Science, Innovation & Research (MAScIR), Rabat, Morocco, [4]Professor of Clinical Pharmacy, Pharmacy Department, Mohamed V Military Training Hospital, Rabat, Morocco, [5]Professor of Therapeutic Chemistry, Laboratory of Medicinal Chemistry, Faculty of Medicine and Pharmacy, Rabat Institute, University Mohamed V, Rabat-Morocco, [6]Professor of Toxicology, Laboratory of Pharmacology-Toxicology, Faculty of Medicine and Pharmacy, Rabat Institute, University Mohamed V, Rabat Morocco.

Abstract

Securing healthcare workers and patients against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection/transmission, require the development of new tools and methods. Several laboratories have started recently clinical trials to develop vaccines and drugs, however these solutions require more time to evaluate and validate them.

As an alternative and in order to stop the spread of SARS-CoV-2 infection, our objective is to implement preventive and corrective actions to reduce the infectious/transmission risk of SARS-COV-2 during hospital retrocession, using the failure mode effect analysis (FMEA) method. The criticality of each failure mode was assessed by calculating the criticality index (CI). The obtained data showed 12 fault modes with a total criticality index (CI) of 480, two acceptable risks, four significant risks and six critical risks. Ten risks were identified as priorities (CI > 15): four related to patient reception, two related to personnel, two during dispensation, one related to the end of dispensation and the last related to traceability. These risks were corrected by improvement actions proposed by FMEA and then re-evaluated effectively.

This study assessed the feasibility and relevance of the use ofFMEA in the hospital retrocession dispensing process related to the infectious/transmission risk of SARS-CoV-2.

Finally, FMEA seems to be an effective method to reduce the infectious/transmission risk of SARS-COV-2 during hospital retrocession**.**

Key words: *FMEA, hospital retrocession, risk of infection, SARS-CoV-2, COVID-19, quality, security*

Introduction

The coronavirus pandemic (COVID-19) has been spreading rapidly across the planet since January 2020. The World Health Organization (WHO) designated COVID-19 as a public health emergency of international concern on 30 January 2020 and considered it a pandemic on March 11,2020.[1-3]

After infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), incubation time varies from 5 to 14 days, and can be up to 22 days,

Corresponding author:
Y. Moutaouakkil
e-mail : youssefmoutaouakkil@yahoo.fr

while the duration for doubling the number of cases is 6.4 days.[4,5]Although more than 80% of patients have a mild form of the disease, with an estimated mortality rate between 2 and 3 %, elderly people or those suffering from associated diseases are particularly at risk of developing severe forms.[6,7]The same thing is applied to cancer patients who have a 39% risk of requiring invasive ventilation or death.[8,9]

In this context, the functional unit for the retrocession of products with special status of the pharmacy cluster of the military hospital Mohamed V of Rabat, actively participate in the provision of drugs to patients (with cancer, hepatitis, certain rheumatoid diseases and staturo-weight growth retardation), and the care-delivery delays and continuity of treatment that have a prognostic impact.[10]The number of patients admitted each day in this unit makes it a place with high risk of transmission of the virus. It is therefore necessary to be vigilant during the epidemic period to ensure continuity of hospital retrocession and to limit the transmission risk of SARS-CoV-2 in the unit. Hence the importance of applying a quality and safety assurance system within our unit.

Approaches such as product inspection and control as well as statistical process control are insufficient to solve, prevent and avoid problems that may subsequently appear in the different systems of our unit. Among the tools and techniques for preventing potential problems (SARS-COV-2), [11]the FMEA method is a simple and highly effective method. It consists of systematic analysis of a process by initially identifying its failure modesor at least reduce the risk of system failures risk analysis. [12-15]

This method is also proposed by the institute for safe medication practices (ISMP) in Canada.[16]The criticality of each failure mode is assessed by calculating the criticality index (CI).

This index combines notions of frequency of occurrence, detection capacity and severity of the effect generatedand should be carried out in a team, preferably multidisciplinary one. [14-17]

In this sense, our study aims to analyze and establish a mapping of the infectious/transmission risk of SARS-CoV-2 (COVID-19) during hospital retrocession in order to implement preventive and corrective actions to reduce the infectious/transmission risk of SARS-CoV-2 (COVID-19) using the FMEA method.

Materials and Methods

The FMEA was conducted in the functional unit for the retrocession of products with special statutes of the pharmacy cluster of the Mohamed V military training hospital in Rabat, during January 2020. The unit received an average of 80 patients per day.

The problematic, on which the FMEA analysis was performed, was the risk of infection and the transmission risk of SARS-CoV-2 during hospital retrocession.

A working group consisting of two pharmacists, two health professionals and two pharmacy students were formed in early January 2020. Brainstorming sessions provided a systematic description of the stages of the infectious/transmission risk of SARS-CoV-2 during hospital retrocession.

The potential failure patterns or risks of this process were identified during the brainstorming sessions of the team by answering the question: “what are the potential riskfactorsfor the transmission of of SARS-CoV-2 during hospital retrocession?”

For each risk obtained, CI was calculated taking into account the frequency (F), severity (S) and detectability (D) of the risk according to:

$$CI = F \times S \times D$$

The 3 variables: frequency, severity and detectability were rated from 0 to 4.

The maximum CI was 64 (4 × 4 × 4). The working group thus developed a criticality matrix. Three distinct levels of criticality were defined: low criticality (0 < CI < 15), high criticality (16 < CI < 32) and major criticality (33 < CI < 64).

Failure modes whose CI was strictly above the threshold of 15 were considered priorities and required the implementation of improvement actions.

Finally, with regard to the treatment failures, at the end of the study, corrective and/or preventive actions are proposed at different stages of the hospital retrocession

processes in order to reduce the risk of occurrence of these failures. Solutions are provided based on the criticality levels obtained after performing fault identification and analysis. After assessment of criticality levels, all steps are in criticality class 3 will require immediate corrective action. After correction, one can again submit the process step to a new analysis in order to reassess its criticality and therefore its acceptance.

Result

The hospital retrocession process was divided into six elementary processes and included eight tasks, from the arrival of the patient to his exit with traceability.

The FMEA, conducted, highlighted 12 failure modes.

The total CI was 480.

10 risks were identified as priority (CI > 15): four related to patient reception, two related to personnel, two during dispensation, one related to the end of dispensation, the last related to traceability.

Discussion

This is the first time to our knowledge that an FMEA method is applied to the hospital retrocession process related to the infectious/transmission risk of SARS-CoV-2 (COVID-19) in the patient.

Analysis of the results of the FMEA assessment helped us to identify certain infectious/transmission risks of SARS-CoV-2 (COVID-19) that impact patient and personnel safety during hospital retrocession.

12 failure patterns have been observed, which may lead to major consequences such as infectious/ transmission risk of SARS-CoV-2 (COVID-19).

The patient reception phase alone has four failure modes.

In our study, the effects of minor and tolerable infectious risk failure of SARS-CoV-2 contamination/ transmission (COVID-19) are only two cases. In addition, six critical failure modes have been recorded and may have negative impacts.

Indeed, we decided to focus our work on the process of hospital retrocession related to the infectious/ transmission risk of SARS-CoV-2, based on the recommendations of the French Society for Oncology Pharmacy to adapt oncological pharmacy activities during the period of a pandemic such as COVID-19[10].

The advantage of FMEA is that it can be implemented throughout the life cycle of a system. It is used as a preventive analysis technique to detect potential failures, assess risks and trigger prevention actions. Its effectiveness lies in the pooling information, and thus in the creation of a multidisciplinary and multi-functional working group.

Its application within the hospital retrocession unit has contributed to the development of the safety culture. These information exchanges facilitated communication between professionals, who were able to become aware of the overall contamination/transmission risks of SARS-CoV-2 faced by patients and personnel. This method has also increased the vigilance of personnel in the face of the emergence of failures.

In our study, we grouped the consequences of failure patterns by effects, in order to detect and identify the most sought potential effect, which is represented by the infection/transmission risks of SARS-CoV-2 around the patient. By detailing the consequences, this helps to better understand the effect of the infection / transmission risks of SARS-CoV-2:

Among the acceptable fault modes in the context of our study, i.e. low frequency and easily detectable, we found:

- The insufficient cleanliness of the premises has as major consequencesthe contamination of the personnel and the patient.
- The lack of the hygiene of the personnel handshas as major consequences the contamination of the patient.

In our study, self-contamination and cross-contamination are the main consequences to be highlighted.

The criticality calculation guided the task force to propose preventive measures and corrective actions. The aim of these proposals is to significantly reduce the criticality rating and to continuously improve the quality

management system. They are adaptable for the hospital retrocession unit. They allow a renovation of practices facing COVID-19.

The suggested corrective actions are mainly organizational and pedagogical in nature, emphasizing the provision of resources and materials in the face of COVID-19 and the organization training to sensitize personnel to the adopt good practices, thus allowing reducing by half the criticality of these critical failures by acting on their frequency of occurrence.

For the corrective actions envisaged for failure modes at a high risk of criticality are found:

· According to the FMEA analysis carried out, non-respecting distancing between patients is a critical point to be monitored and prevented by sentencing one in two seats in the waiting room and marking the floor at the secretariats in order to respect a distance of at least 1 m between patients.

· The lack of protective equipment for the patient is also a critical failure to be prevented by the obligation to wear the surgical mask for all patients.

· The poor patient hands hygiene is also a critical point to be monitored by the provision at the reception of the service of a non-contact dispenser of hydroalcoholic solution with instructions given to all returning patients to rub their hands, moreover a poster showing the gestures to be performed is affixed in the same place, rubbing with an alcoholic solution is also requested from the patient before and after the dispensing of the drugs.

· Lack of knowledge of the infectious state of the patient is also a critical failure to be preventedby asking the patient before the retrocession, in particular regarding the symptoms (fever 38ºC, cough, aches, sore throat, diarrhea, vomiting, conjunctivitis, anosmia, agueusia) and the contact with COVID-19 patient.

· The risk of infection of the personnel is increased by wearing laboratory coats which is a critical point to monitor and prevent by the systematic wearing of a surgical mask during the entire working time, to be changed by 4 h period, for all personnel , the provision of disinfectant wipes for the surfaces (worktop, desk, computer keyboard, professional telephone), the reminder to all teams of the rules of hygiene: regular washing of hands with soap or with a hydroalcoholic solution (before and after each contact with a patient), no consumption of food or drinks at the treatment station, also the limitation of the number of personnel and the systematic wearing of pajamas under the blouse so as not to contaminate personal clothes.

· The lack of awareness of the infectious state of the personnel is a critical failure to be prevented by monitoring the symptoms: fever 38ºC, cough, aches, sore throat, diarrhea, vomiting, conjunctivitis, anosmia, agueusia.

· The rules of asepsis and safety are not observed during the medication dispensing, theyare also a critical failure to prevent through compliance with the procedures of the dispensation, training of personnel and compliance with the protocol.

· The lack of professional distancing is a critical failure to prevent by respecting a distance of at least 1 m and the systematic wearing of a surgical mask.

· Potential contaminated paper and pens requires the provision of disinfectant wipes for surfaces (worktop, desk, computer keyboard, business phone) and the provision of single-use pens.

· In order to control the risk of infection of the patient registry and computer equipment, this requires the provision of disinfectant wipes for surfaces (worktop, desk, computer keyboard, professional telephone), compliance with dispensation procedures, training of personnel and compliance with protocol.

Corrective and preventive actions are already carried out, relating to compliance with the general regulations of the hospital retrocession unit, and in particular the continuous training of personnel on hygiene, the preservation of a permanent stock of personal protective equipment, and the drafting of the protocol of hygiene of the premises.

Conclusion

This study assessed the feasibility and relevance of the use of FMEA in the hospital retrocession dispensing process related to the infectious/transmission risks of SARS-CoV-2. It highlighted the complexity of the process and the associated risk of infection.

Following the risk analysis, corrective action were taken. Monitoring and maintaining these changes in practice over time is often complex.

Ethical Clearance: Compliance with Ethical Standards

Source of Funding: Self

Conflict of Interest: We declare that we have no conflict of interest.

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