A SYSTEMATIC RISK ANALYSIS METHOD APPLIED TO THE MEDICAL DEVICES MANAGEMENT PROCESS IN A HOSPITAL PHARMACY

A. Ben Cheikh Brahim[1], A. Ben Salem[1], F. Sallem[1], N. Dammek[1], A. Abbassi[2].
[1]Charles Nicolle Hospital Of Tunis, Pharmacy, Tunis, Tunisia.

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Background and Importance

During the COVID-19 pandemic, the management of medical devices was foreseen by repetitive and unforeseen breaks. To optimize management, a risk analysis is necessary.

Aim and Objectives

The present study aimed to determine risks related to the medical devices management processes in our teaching hospital according to a failure mode and effects analysis (FMEA) method.

Materials and Methods

Skilled health care professionals were recruited to form a multidisciplinary study team (pharmacists, nurses, administrative agent, and pharmacy technician). They proceeded to draft the process **cartography**. They defined all related **failure modes** that could occur indicating causes and consequences through **brainstorming** meetings. These failure modes were classified considering the **criticality index** (CI) calculated according to the indices: severity of the potential effect, detection probability, and likelihood of occurrence. **Prioritization** was carried considering the mean and the median values of CI as limits. Corrective and preventive **actions** were then proposed.

Results

We identified a total of 44 Failure modes accumulating 4176 points of criticality (**Figure 1**). The RPN goes from 12 to 336. The rounded mean (±SD) of 95±80 and the median were used to establish thresholds (**Table I**) in order to distribute the failure modes according to their criticallity (**Figure 2**).

The purchasing framework definition step has the highest mean criticality index of 161±87 points. The steps with the highest cumulative criticality and number of Failure modes are interdepot ordering and service order's processing (783, 606 respectively). The most critical sub-steps are « need estimate » and « placement in delivery area ». A list of achievable actions (n=29) was developed for the "critical" and "to control" Failure modes with an appointed pilot for each action (**Table II**).

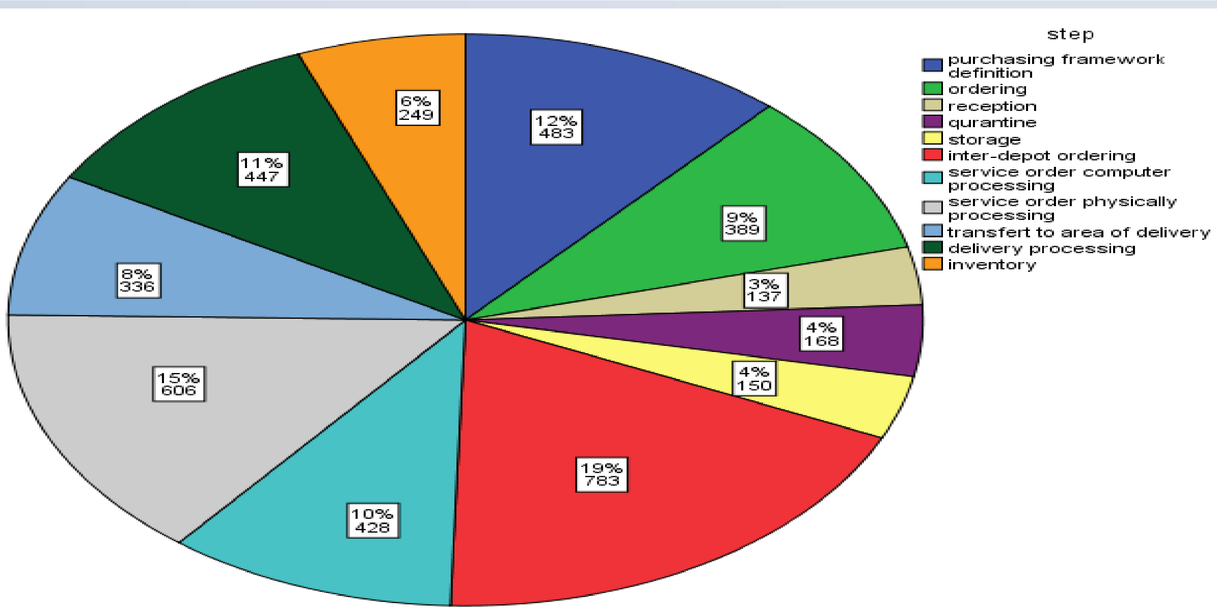

Figure 1. Distribution of the Failure modes according to the steps of the process (%, criticality)

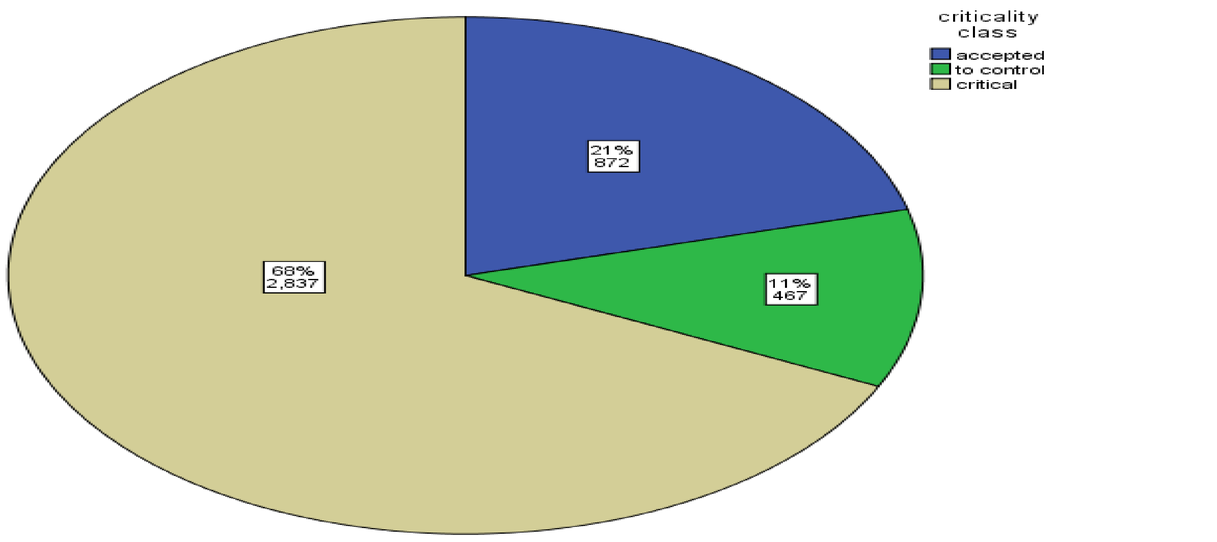

Figure 2. Distribution of the Failure modes according to their criticality (%, cumulative criticality)

Table I. Risk criticality thresholds established for the FMEA study

RPN	Interpretation	Action
RPN ≥ 95	Critical failure	Priority failure modes
68 < RPN <95	Failure to be controlled	Failure modes to be controlled
RPN ≤ 68	Acceptable failure	Failure modes to be monitored

Table II. Summary table of the main actions proposed to reduce cumulative criticality

Steps	Proposed actions
purchasing framework definition	ensure a second reading before transfer of the need ensure training of pharmacists on charge dedicate an administrative agent for pharmacy records
ordering	add to the software the display of data (average consumption, in progress orders, actual stock)
reception	acquisition of bar code readers
quarantine	-
storage	build a suitable storage room
inter-depot ordering	add constraints on the creation of articles require control visa before delivery
service order computer processing	provide a plan B with paper procedure in case of trouble on the network
service order physically processing	acquisition of transfer carts
transfer to area of delivery	dedicate a delivery area with defined locations
delivery processing	require the signature and stamp of the receiving service on the delivery note
inventory	schedule monthly inventories on the list of moved items

Conclusion and Relevance

The FMEA method was a consensual tool that permits proposal actions reducing risks related to the medical devices management process. Optimizing the prediction of needs, strengthening communication with user services, and securing access are essential to guarantee the availability of medical devices for the ultimate benefit of the patient.

References / acknowledgements

we thank all members of the work team for their involvement.
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