FAILURE MODE AND EFFECT ANALYSIS APPLIED TO THE PARENTERAL NUTRITION PREPARATION PROCESS IN A MATERNITY AND NEONATAL HOSPITAL

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Background and Importance

Parenteral nutrition (PN) is an intravenous nutrition technique. It is an important part of neonatal care when enteral intake is proven to be impossible, insufficient or contraindicated. Considering the lack of marketed mixtures for the neonatal population, the preparation of PN is an essential hospital activity with a high risk of errors.

Aim and Objectives

We aim to analyze the risks associated with the process of preparing PN bags using the Failure Mode and Effect Analysis method (FMEA) in the Maternity and Neonatology Center of Tunis, Tunisia.

Materials and Methods

Our analysis was performed at the sterile preparation unit over 4 months. A multidisciplinary team carried out the FMEA. We identified the failure modes, their causes and effects using Ishikawa diagram and brainstorming sessions. Failure modes were prioritized according to the Risk Priority Number (RPN) -the product of the scores of indices: occurrence, severity and detection probability-. For each failure mode, the three indices were determined by vote. Finally, an action plan to control the risk of priority failure modes was developed.

Results

We identified a total of 90 Failure modes (**Figure 1**). The RPN goes from 3 to 630. The rounded mean (±SD) of 108±60 is used to establish thresholds (**Table I**) in order to distribute the failure modes according to their criticallity (**Figure 2**).
The absence of pharmaceutical validation and the absence of agitation after the addition of each component have an RPN of 630.
The steps with the highest cumulative criticality and number of Failure modes are production and quality control (**Table II**). The most critical sub-step is the aseptic filling in a closed system. A list of possible and achievable actions (n=46) was developed for the “critical” and “to control” Failure modes with an appointed pilot for each action.

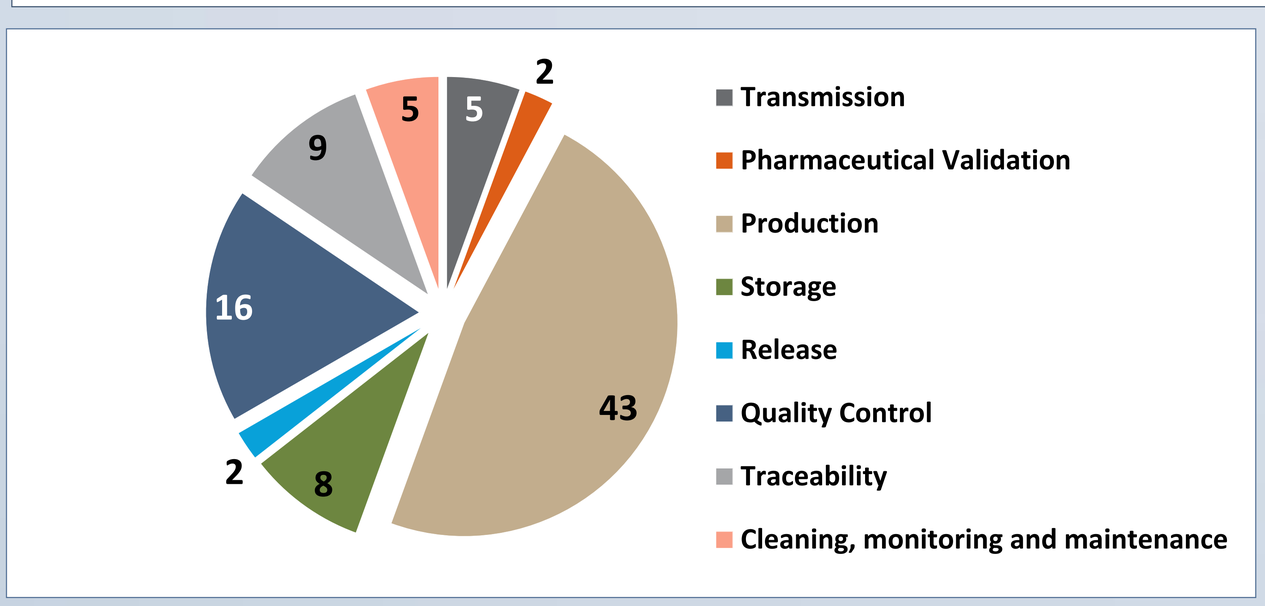

Figure 1. Distribution of the Failure modes according to the steps of the process

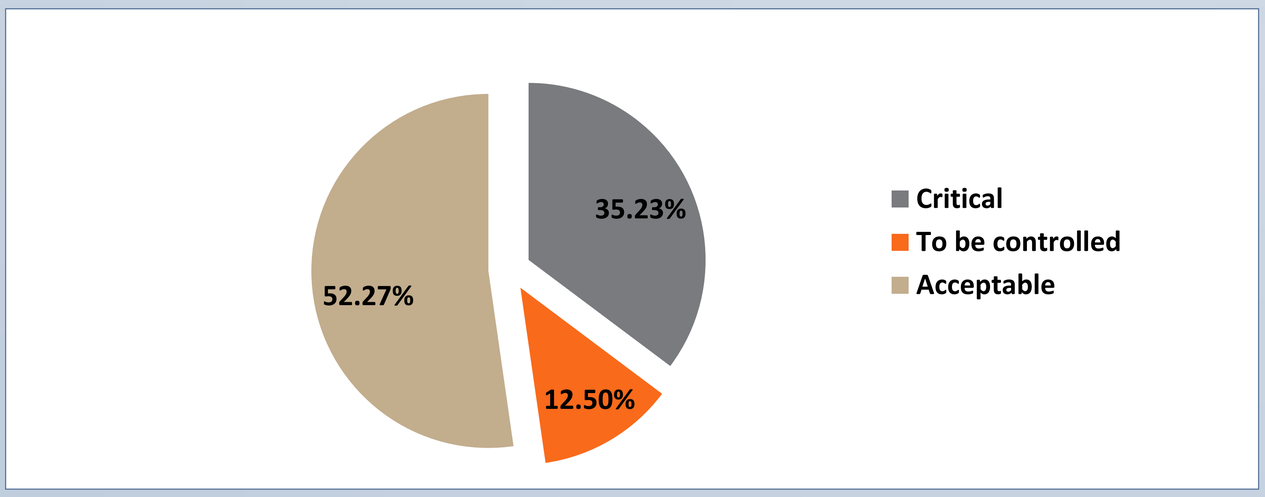

Figure 2. Distribution of the Failure modes according to their criticallity

Table I. Risk criticality thresholds established for the AMDEC study

RPN	Interpretation	Action
RPN ≥ 108	Critical failure	Priority failure modes
60 < RPN < 108	Failure to be controlled	Failure modes to be controlled
RPN ≤ 60	Acceptable failure	Failure modes to be monitored

Table II. Summary table of the global criticality index according to the steps of the process

Step	Sub-step		Global Criticality Index	
Transmission			533	
Pharmaceutical Validation			945	
Production	Preparation of documents and labels	541		
	Preparation of the material necessary for the daily activity	300		
	Equipment decontamination	287		4334
	Aseptic filling in a closed system	2974		
	Labeling	232		
				9502
Storage			527	
Release			195	
Quality Control	Visual, gravimetric and volumetric	585		
	Physico-chemical	480		2458
	Microbiological	1150		
	Environmental	243		
Traceability			1150	
Cleaning, monitoring and maintenance			132	

Conclusion and Relevance

The pharmaceutical validation is one of the most critical steps in our study. The optimal solution would be to invest in integrated commercial computerized physician order entry system. The production needs the most of the improvements. The acquisition of an automated compounding device would minimize the risk. Our study also highlighted quality control gaps. This work is part of a quality assurance perspective. A second FMEA is needed to assess the impact of the undertaken changes. It will allow us to detect residual and new risks and to compare the criticalities of the two analyzes.

References / acknowledgements

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