3PC-019

RISK MANAGEMENT OF CROSS CONTAMINATION OF PEDIATRIC ANTICANCER PREPARATION USING FAILURE MODE AND EFFECTS CRITICALITY ANALYSIS (FEMECA)

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Background

❑ Cross-contamination of hospital preparations is one of most frequent problem in hospital . It is responsible for quality defects of the drug, the consequences can be very serious. The failure mode effects and critically analysis is a simple and effective tool of minimizing a high-risk related to cross-contamination of preparation.

❑ **Purpose:**

Realize a risk analysis using the FEMEC Analysis, focused on preparation process of anticancer drugs in a pediatric hospital

Minimize the risk by corrective and preventive actions (CAPA).

Materials and methods

1. Identification possible causes of cross-contamination by a **cause-effect diagram (Ishikawa diagram).**
2. Identification all failure modes and possible risks for each step of preparation process
3. Listing all each failure mode, and assigned a score for likelihood occurrence (1 to 4), severity (1 to 4), and detection (1 to 4)
4. Calculating the risk priority number (RPN) / **RPN = Severity ×Occurrence ×Detectability**

Risk priority number	Evaluation of criticity
1< RPN< 18	Low risk
24< RPN< 32	Medium risk
36< RPN< 48	Hight risk
RPN= 64	Critical risk

Results

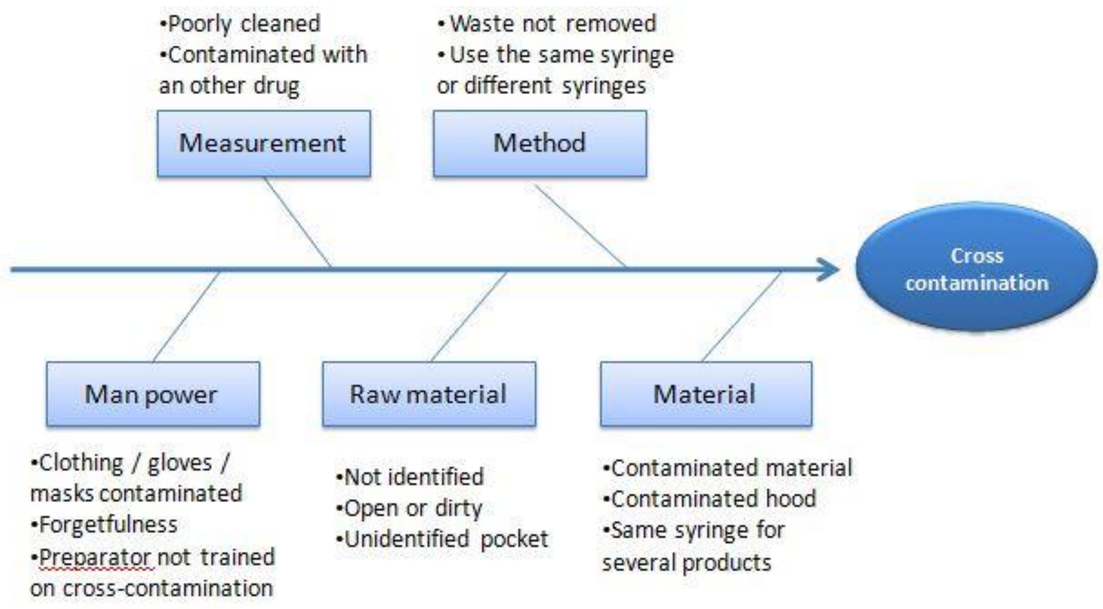

Figure 1: Ishikawa Diagram

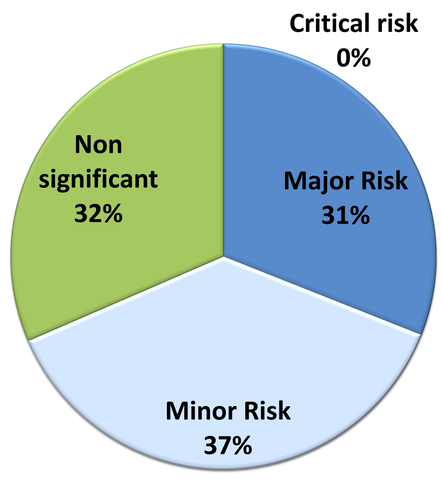

Figure 2: Distribution of risk types by frequency

Table 1: FEMEC Analysis and score of RPN

	Failure mode	Occurrence	Severity	Detectability	RPN
Measurement	**Contaminated hood**	**4**	**3**	**2**	**24**
	Contaminated clean room	2	2	2	8
	Bad organization of preparations in the airlock	3	2	1	6
Raw material	previous cross-contamination	1	4	3	12
	Wrong identification / labeling	2	4	1	8
	Use of the wrong component or diluant	3	4	1	12
Material	Contaminated equipment	2	4	2	16
	Bad identification	2	4	2	16
	Non-adapted component control tool	1	3	3	9
Method	Manual contamination between 2 preparators	1	3	2	6
	Flow not respected	2	2	1	4
	Error in the implementation of the materials	**2**	**4**	**3**	**24**
Man power	Bad hood vacuum	3	4	1	12
	Bad cleaning	2	3	3	18
	Faulty verification	1	4	1	4
	Double check of implementation of the components not respected	1	4	1	4

Table 2: CAPA of cross contamination

Corrective and preventive actions CAPA
•Training preparers on : •Respect of good manufacturing practices; •Crosscontamination, •Cleaning, •Biodecontamination of materials before preparation. •Development and validation of a cleaning procedure.

Conclusion

In conclusion: Satisfactory results

- **No critical risk and**
- **Only 30% of the major risks that decreased after the implementation of CAPA**

The continuous training of the staff, the traceability of each stage of the process and the good organization of the circuit makes it possible to reduce the risk of cross-contamination and to guarantee good quality preparations which can be administered safely to the patient.