Risk analysis on cytotoxic circuit in a central pharmacy

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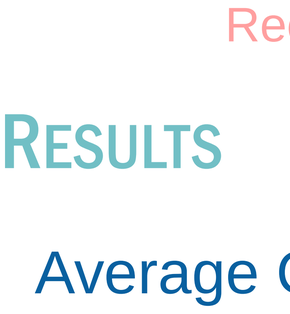
L01 - Cytostatics

Background

- **Good Distribution Practices** require labelling of the containers to **identify products with health risks** and **secure their handling**.
- Manipulation of these products is a source of concern for hospital pharmacy (HP) staff.



- Our HP ensures the supply and distribution of health products to 37 hospitals.
  ➔ Highly impacted by this risk even if cytotoxics are **stored in specific areas** and are subject to **specific procedures** in accordance with the **Good Hospital Pharmacy Practice**.
  ➔ Therefore, we wanted to assess all the risks related to the handling of cytotoxics in our HP.

Purpose

The objective is to establish a mapping of the risks associated to the cytotoxic circuit within our HP. The steps identified as most risky will be subject to action plans and corrective measures to secure the health products circuit.

Materials and Methods

① FMECA (Failure Mode, Effects, and Criticality Analysis) used to map risks.
➔ Failure modes with a criticality index (CI) greater than the average CI will be subject to a corrective action proposal.

② Scop of the study :

Reception of cytotoxics → Storage → Preparation order → Delivery to hospitals → Return circuits

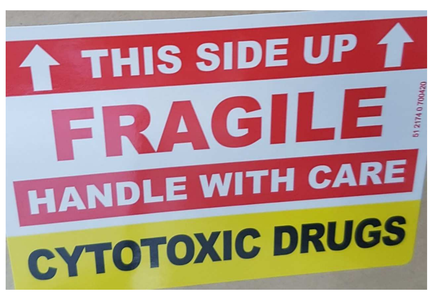
Results

	Reception of cytotoxics	Storage	Preparation order	Delivery to hospitals	Return circuits
Average CI [min;max]	**27** [6;48]	10 [3;27]	15 [3;64]	10 [3;16]	**20** [6;36]

Principal failure: No mention of “cytotoxics” or “dangerous products” on packages (n = 13)

Other failures:
- Reception, storage, shipping of damaged packages
- Product setting error
- Unsuitable cleaning

Effect: Handling without special precautions
➔ Risk of contamination with cytotoxics



Highest risk

Why these steps ? Packages coming from suppliers
- Delivery by the suppliers
- Returning from hospital

Risk: Breaks that can occur any time lead to a significant risk of contamination.

All steps

- 51 failures
- Average CI of 16 [min = 2 ; max = 48]

Ongoing corrective action

- Internal audit to identify the suppliers that don’t label their containers
- Disposal circuit processed at each step via the purchase of specific bucket carrying broken cytotoxics
- Update of trainings about cytotoxics and broken products
- Systematic verification by a pharmacy dispenser of the computer classification of new products

Conclusion

- The action plan to be set up requires working with suppliers, carriers, our logistics sectors, in such a way that everyone is aware of the risks incurred by each actor.
- The main focus of improvement concerns the identification of cytotoxics and staff training, especially in case of product breakage.
- Finally, the return circuit is to be improved. A continuous evaluation process must allow the follow-up of the corrective actions.