University Hospital of Bizerte

5PSQ-156

RISK ASSESSMENT AND MANAGEMENT TO IMPROVE THERMO-SENSITIVE DRUGS SAFETY

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Background

Thermo-sensitive drugs must be stored overall the circuit, from manufacture to administration for the patient, at 2-8 ° C. Hospital mission is to insure patient safety and quality of care. Evaluation and improvement of thermo-sensitive drug management process are essential to prevent and limit iatrogenic events.

Purpose

The present study aims to assess risk of thermo-sensitive drug management process according to a proactive analysis: Failure mode and effects analysis method (FMEA).

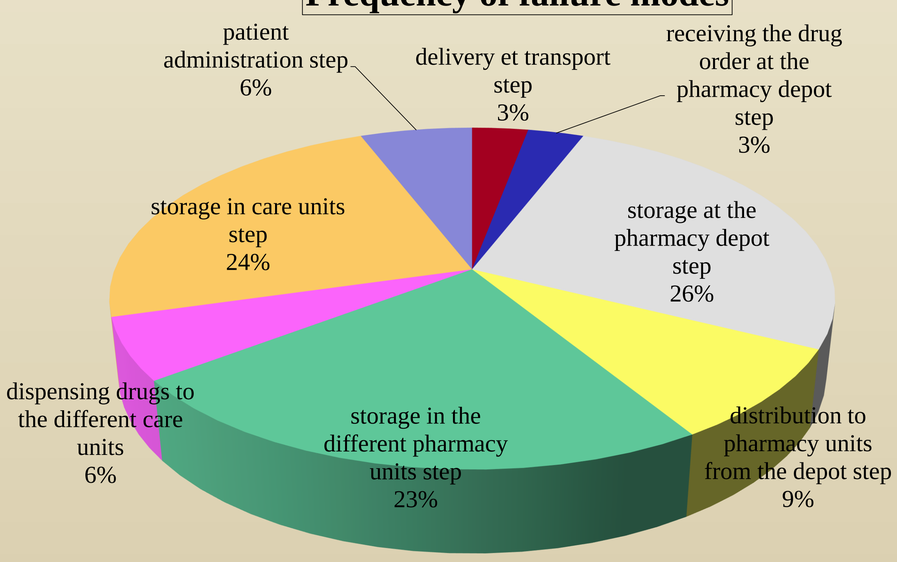
Material and methods

- A multidisciplinary study group was assembled and a process diagram was drafted, illustrating all steps of cold chain.
- Failure modes that could occur were identified and classified according to their risk priority score (RPS) determined on the basis of the likelihood of occurrence, the severity of the potential effect, and the detection probability.
- The most critical failures were selected by applying the Pareto principle which states that roughly 80% of the effects come from 20% of the causes.
- The failures causes were closely examined by establishing Ishikawa diagrams.

RESULTATS

The evaluation process detected 34 potential failures.

Frequency of failure modes

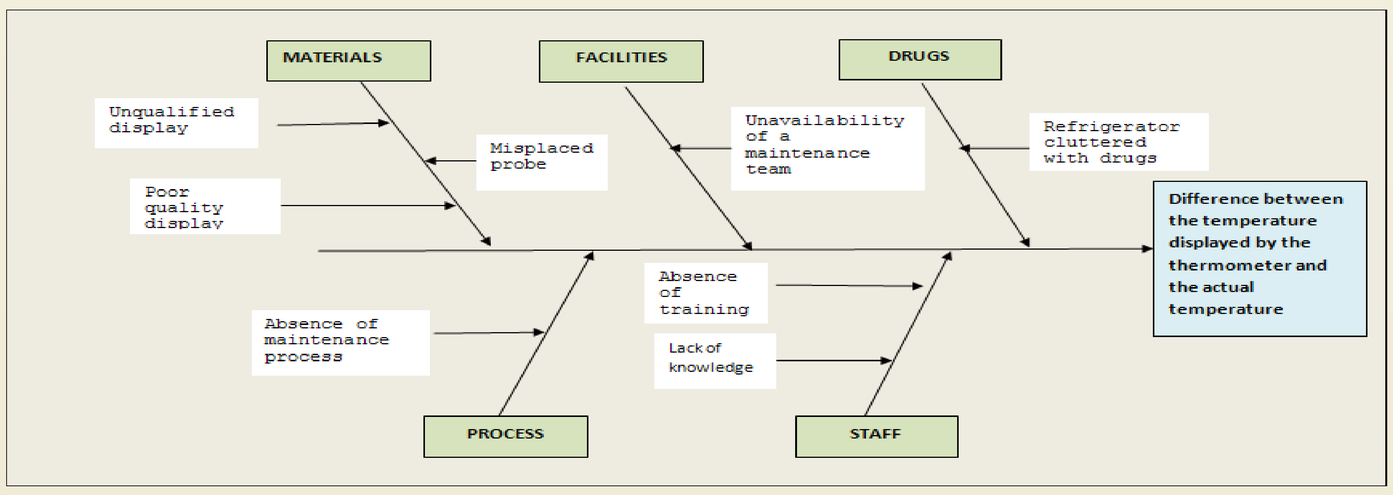


Risk priority score ranged from 4 to 60. The Pareto principle was used to select 18 failures modes that have the highest RPS (from 12 to 60). Among those potential failures, we selected **14 higher RPS** which it was essential to act.

Higher RPS failures: typology

Steps	Failure modes	IC
storage thermo-sensitive drugs in care units	difference between the temperature displayed by the thermometer and the actual temperature	60
storage thermo-sensitive drugs in care units	the refrigerator temperature required not reached	40
distribution thermo-sensitive drugs to pharmacy units from the depot	Non-respect of the cold chain during transportation to the external pharmacy and the maternity site	36
receiving the thermo-sensitive drug order at the depot	non-control of the temperature at receipt of thermo-sensitive drug	30
storage thermo-sensitivedrugs at the pharmacy depot	difference between the temperature displayed by the thermometer and the actual temperature	30
storage thermo-sensitive drugs in pharmacy units	difference between the temperature displayed by the thermometer and the actual temperature	30
storage thermo-sensitive drugs in care units	Drug left on standby outside the refrigerator before storage	30

Ishikawa Diagram for the Failure mode with the Highest RPS: storage step in the care units



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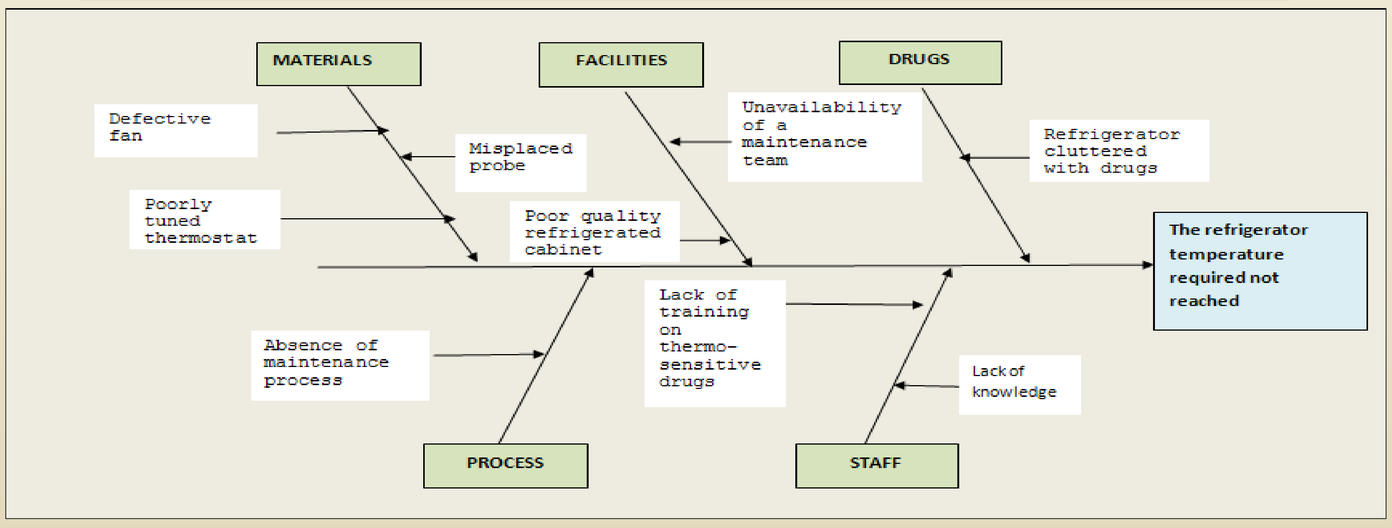

Preventive measures such as setting up a preventive maintenance, the control of temperature at the drug reception and immediate storage in freezer box have been proposed to get ride of the most critical failures.

CONCLUSION

FMEA was useful to help understanding the cold chain process, detecting possible failures and prioritizing remedial interventions. Systematic use of proactive risk analysis is needed for continuous safety improvement of thermo-sensitive drug management process.

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