Background Thermo-sensitive drugs must be stored overall the circuit, from manufacture to administration for the patient, at 2°C–8°C. The hospital mission is to ensure patient safety and quality of care. Evaluation and improvement of the thermo-sensitive drug management process are essential in preventing and limiting iatrogenic events.

Purpose The present study aimed to assess the risk of the 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 the 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 probability of detection. The failures’ causes were closely examined by establishing Ishikawa diagrams in order to propose corrective and preventive actions.

Results The evaluation process detected 42 potential failures. The frequency of failure modes were as follow: 24% in drug storage at the depot step, 21.4% in drug storage in the different units of the pharmacy step. These three steps were considered the most critical. Among the most critical failure modes was the failure of the refrigerator with a RPS equal to 16, the non-compliance of the cold chain during transport with a RPS equal to 60 and the non-control of the temperature at receipt of the thermo-sensitive drug. This last mode of failure seems to be the most critical, with a RPS equal to 80. Preventive measures such as the control of temperature at the drug reception and immediate storage in a freezer box have been proposed to get rid of the most critical failures.

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

REFERENCES AND/OR ACKNOWLEDGEMENTS

Special thanks to the multidisciplinary group members.

No conflict of interest.