

INTRODUCTION

Risk refers to the probability that an action or lack of action will result in an unfavourable situation or an undesired, non-beneficial loss.^[1] Medicine stability is at risk of deterioration if not stored within the correct upper and lower limits of the prescribed temperature by the appropriate pharmacopoeia.^[2]

AIM AND SETTING

The purpose of this study is to outline the temperature control system to be able to identify any possible risks that may endanger the reliability of the system and in turn, pose a risk to the stability of medicinal products. The study took place at the Central Procurement and Supply Unit (CPSU), an entity responsible for the procurement of all pharmaceutical products required within the public healthcare system in Malta.

METHOD

- 1) A risk assessment plan consisting of the identification, analysis and evaluation of risks was developed (Figure 1).
- 2) A temperature logging exercise was undertaken over a period of six days and temperatures were taken hourly for each probe. Probes were placed in both high and low areas of the warehouse, allowing the monitoring of top shelves. Data collected was evaluated and compared using the Kruskal-Wallis test. The null hypothesis was tested at 0.05(95%) confidence interval.

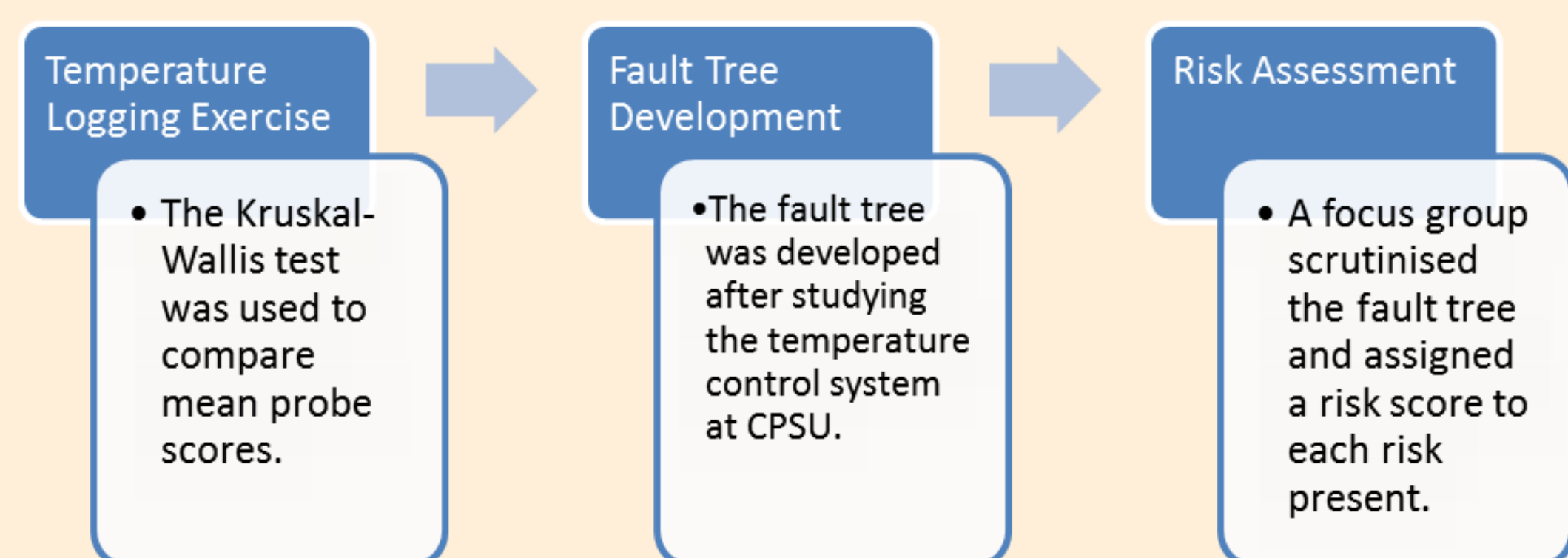


Figure 1. Illustration of steps involved in the study.

- 3) A fault tree was developed; composed of event symbols which describe the event taking place and gate symbols which connect and create relationships between different events. The gates used in the development of the fault tree were the “and”, “or” and the “combination” gate.
- 4) During a focus group with stakeholders of CPSU, the risks identified in the fault tree were assessed using a risk matrix (Figure 2). Probability and severity criteria were defined and each risk was assigned a risk-priority number (RPN).

| Risk Matrix | | Probability | | | | |
|--------------------------|----------------|-------------|------------|------------|----------|------------|
| | | 1 Rare | 2 Unlikely | 3 Possible | 4 Likely | 5 Frequent |
| Severity of Consequences | 5 Catastrophic | 5 | 10 | 15 | 20 | 25 |
| | 4 Major | 4 | 8 | 12 | 16 | 20 |
| | 3 Moderate | 3 | 6 | 9 | 12 | 15 |
| | 2 Minor | 2 | 4 | 6 | 8 | 10 |
| | 1 Negligible | 1 | 2 | 3 | 4 | 5 |

Figure 2. Risk-Probability Matrix

If risk falls within the green area, it is acceptable and operation is permissible. If risk falls within the orange area, the risk is provisionally acceptable and requires a time waiver in which actions need to be discussed and implemented. If risk falls within the red area, immediate action needs to take place.

RESULT

Results indicated that out of the 14 probes examined, only 6 obtained a p-value above 0.05 whilst 8 probes obtained a p-value lower than 0.05, suggesting that there is significant fluctuation in temperature throughout the days. The fault tree (Figure 3) identified 11 risks that might affect temperature control. The RPN scores obtained from the risk-probability matrix were: 1 fell within the green area, and 10 risks fell within the orange area. No risks were placed in the red area (Table 1). The top event scored an RPN of 10 and was given a 24 hour time waiver were corrective action needs to be discussed and implemented.

| Risk | RPN Score |
|---|-----------|
| Failure to maintain all sectors at prescribed temperature | 10 |
| Failure to maintain individual sectors of the warehouse at the required temperature | 8 |
| Failure to obtain reliable sensory information from either a probe fault or a base unit fault | 12 |
| Risk of inadequate out-door unit performance due to a combination of faults in a number of external units | 10 |
| Risk of inadequate indoor unit performance due to failure in multiple indoor air-condition units | 12 |

Table 1. Risk priority numbers obtained for five of the risks present.

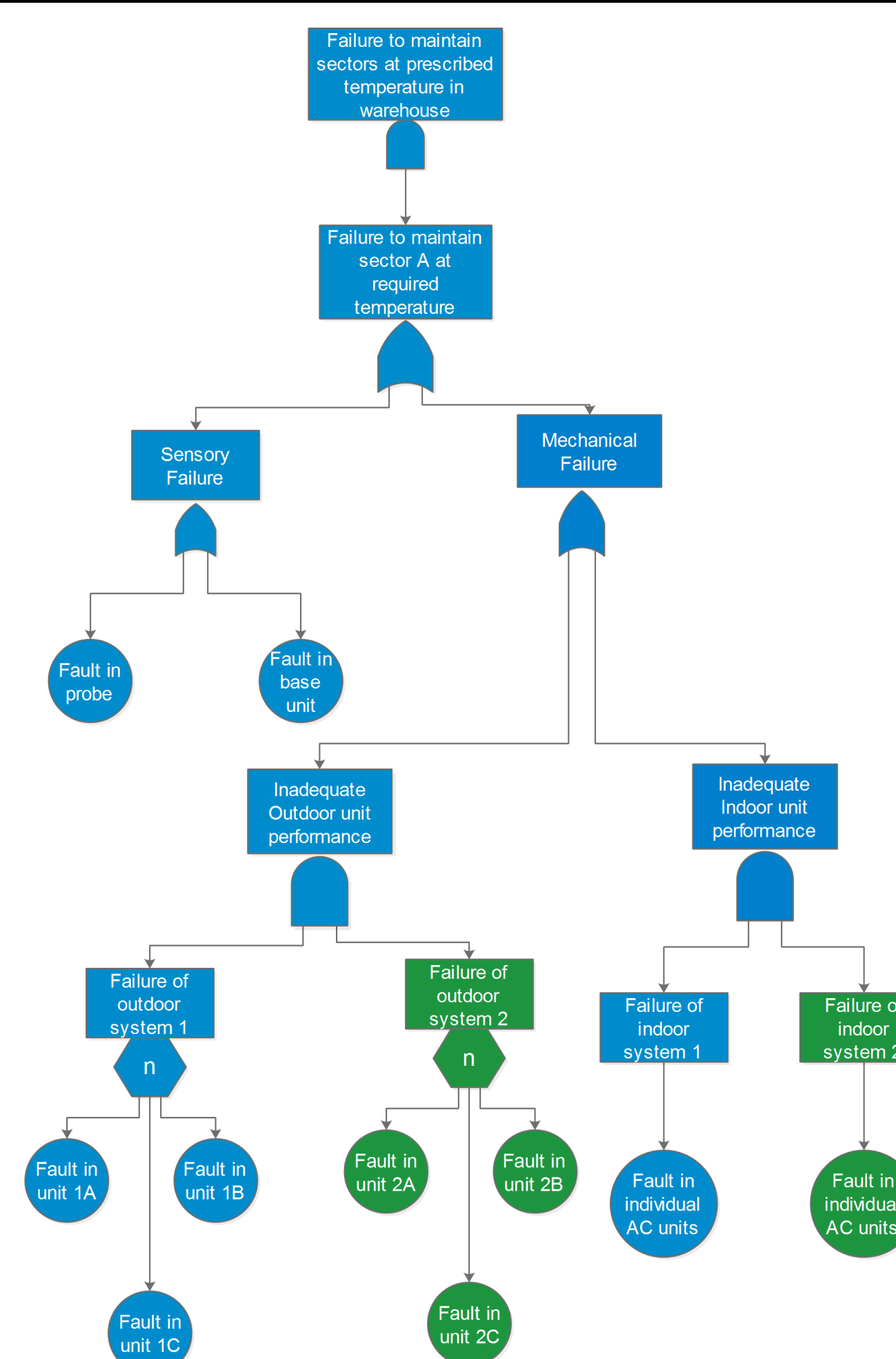


Figure 3. An excerpt from the fault tree

CONCLUSION

Upon presentation of temperature log results, the Responsible Persons at CPSU remarked that temperature fluctuation could result from multiple factors including daily volume of work, air-condition maintenance and environmental temperature. Unless there is a constant surge of temperature above 25°C or erroneous probe readings close to the 25°C mark, these fluctuations should not be cause for concern. A number of factors need to be taken into consideration before making executive decisions concerning such failures. One has to keep in mind the environmental temperature at the time of failure since if the failure occurs in summer, the risk of warehouse temperature exceeding 25°C is considerably higher. The duration of failure is another factor which might affect the actions taken. In this study, an unlimited duration of failure was assumed when assigning an RPN score, however in practice the risk of damage to stock will be determined by how long the failure is expected to last. In all risks, the action to be taken is to contact the supplier of the systems and repair within 24 hours. Relocation of stock in a different area of the warehouse can be considered, depending on the severity of the risk.