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Key words:
 Drug stability,
 Drug distribution,
 Storage systems

BACKGROUND

Continuous control, optimization and mastery of the cold chain of cold drugs remains a priority for the institutions, taking into account all the risks associated with the quality of these drugs and therefore with the patient's medication management.

WHAT WAS DONE?

Our study aimed to map the process of management of medicines requiring a strict cold chain control at a referral pediatric hospital and to identify the critical points associated to this process in order to realize a risk analysis using the FMEA method.

WHY WAS IT DONE?

The strict control of medicines cold chain is linked to a triple risk for a hospital: a risk for the patient through the efficiency and safety of the drug, a financial risk, and a regulatory risk.

HOW WAS IT DONE?

The method used is FMEA for a priori inductive risk analysis which aims to identify potential system failures. These failures are analyzed to determine their criticality by establishing an index for each failure that will be scored and calculated using the formula: **Criticality index = frequency × severity × detectability**. The rating of each criterion is based on predetermined rating tables.

WHAT HAS BEEN ACHIEVED?

Process Mapping: The mapping of the process allowed identify 7 major actors: the supplier, the general store, the logistics platform for product reception, the transportation, the logistics department of hospital, the pharmacy and the patient (Figure 1).

Identification of the critical points: All failures modes that were ranked between 201 and 504 on criticality index are considered as main critical points. The rating of each criterion is based on predetermined rating tables: Problem of breakdown of electricity and its management: 504 Respect of the cold chain at the level of the care services until administration: 448 Temperature indicators at the level of care services: 384 Conditions of transportation: 315 Temperature monitoring at pharmacy level: means and management: 245 Logistics agents transport time management: 210 (table 1-2).

Implementation of improvement actions: Corrective and preventive improvement measures have been defined and implemented, such as: setting up alternatives to power outages, periodic temperature assessments at all critical levels, and integration of remote control and monitoring computer devices.

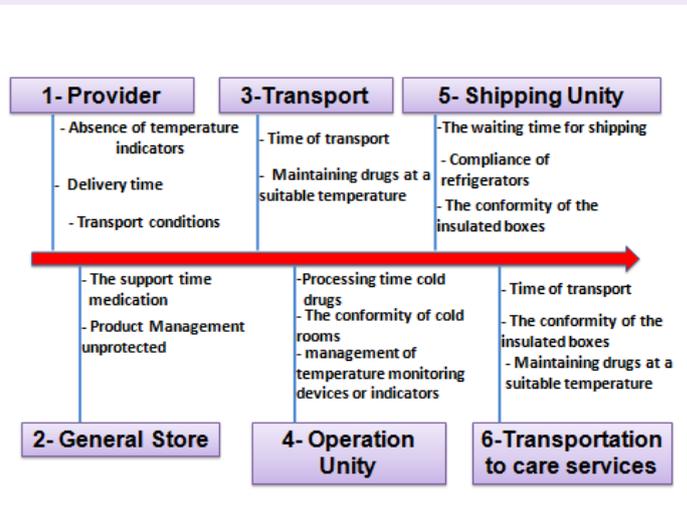


Figure 1: process mapping and corresponding failures

Table 1: Rating Tables

SEVERITY	DESCRIPTION	INDEX
ENUI LIGHT	MAY AFFECT THE SYSTEM	1
SYSTEMIC PROBLEM LIGHT	MAY AFFECT THE PRODUCT	2-3
MAJOR SYSTEMIC PROBLEM	MAY AFFECT THE PRODUCT	4-5
ATTEMPTED MINOR OF THE PRODUCT	MAY AFFECT THE PRODUCT	6
REACHING MAJOR PRODUCT	REACHED MAJOR PATIENT	7
ATTEMPTED PRODUCT TERMINAL	UNUSABLE PRODUCT-FATAL DANGER FOR PATIENT	8-9
DETECTABILITY	DESCRIPTION	PROBABILITY
VERY HIGH	SYSTEM WILL ALWAYS DETECT ERROR	9 /10
HIGH	HIGH PROBABILITY OF DETECTION	7 /10
MODERATE	MODERATE PROBABILITY OF DETECTION	4-5/10
LOW	LOW PROBABILITY OF DETECTION	2/10
NO EXIST	IMPOSSIBLE DETECTION	0
FREQUENCY	DESCRIPTION	PROBABILITY
NO EXIST	NO KNOWN OCCURRENCE	1/10000
LOW	POSSIBLE, NO EXISTING DATA	1/5000
MODERATE	DOCUMENTED, BUT LITTLE FREQUENT	1/200
HIGH	DOCUMENTED AND FREQUENT	1/50
VERY HIGH	ERROR PRACTICALLY CERTAIN	1/20

Table 2: Criticality indices and corresponding scores

FAULT MODE	SCORE
Problem of breakdown of electricity and its management	504
Respect of the cold chain at the level of the care services until administration	448
Temperature indicators at the level of care services	384
Conditions of transportation	315
Temperature monitoring at pharmacy level: means and management	245

WHAT NEXT?

The continuous improvement of the medicines' cold chain remains an important topic for the institutions in view of the overall risks associated with the quality of these medicines, therefore to the medical treatment of the patient.