Application of Failure Mode, Effects, and Criticality Analysis to the Medication-Use Process for Temperature-Sensitive Drugs in a University Hospital

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ABSTRACT

Background: In the hospital setting, the medication-use system for temperature-sensitive drugs is a high-risk process.

Objectives: To analyze the risks associated with the hospital-based medication-use process and to propose corrective and preventive actions for the most critical failure modes.

Methods: A multidisciplinary team was trained to analyze the medication-use process for temperature-sensitive drugs and to identify potential failures using a risk analysis method known as failure mode, effects, and criticality analysis (FMECA). The medication-use process, from initial supply to administration to patients, was investigated using "the 5 Ws and How" method (Who? What? Where? When? Why? How?), and the causes of the failure modes were analyzed using Ishikawa diagrams. The most critical failure modes were selected using the Pareto law, and relevant improvement actions were proposed.

Results: This analysis identified 41 failure modes for the 9 stages of the medication-use process, of which only 36 were deemed assessable by the participants. Eighteen (50%) of these failure modes were critical, according to the Pareto law, with criticality indices between 12 and 60. The stage of tidying up and storage in patient care units had the highest number of critical failures ($n = 5$). A total of 48 corrective actions were proposed.

Conclusion: The proposed action plan prioritized 3 areas for improvement: the documentation system, staff training, and equipment acquisition. A second FMECA should be carried out to reassess the medication-use process after implementation of these improvement actions. The second FMECA, allowing detection of residual risks and identification of new risks, will be part of a continuous improvement process.

Keywords: cold chain, temperature-sensitive drug, risk management, patient safety

RÉSUMÉ

Contexte : Le circuit des médicaments thermosensibles en milieu hospitalier fait partie des processus à risque.

Objectifs : Analyser a priori les risques liés à ce circuit et proposer des actions correctives et préventives contre les modes de défaillances les plus critiques.

Méthodes : Une équipe pluridisciplinaire a été formée pour analyser le circuit des médicaments thermosensibles et identifier les défaillances par la méthode de l'analyse des modes de défaillances, de leurs effets et de leurs criticités (AMDEC). Le processus, qui va de l'approvisionnement jusqu'à l'administration des médicaments aux patients, a été décortiqué en utilisant la méthode « Qui? Quoi? Où? Quand? Comment? Pourquoi? » (QQOQCP) et les causes des défaillances ont été analysées à l'aide de diagrammes d'Ishikawa. Les défaillances les plus critiques ont été sélectionnées par la loi de Pareto, et des mesures d'amélioration pertinentes ont été proposées.

Résultats : Cette analyse a mis en évidence 41 modes de défaillances pour les 9 étapes du circuit, dont uniquement 36 sont jugés évaluables par les membres de l'équipe pluridisciplinaire. Dix-huit modes sur 36 (soit 50 %) sont critiques selon la loi de Pareto, avec des indices de criticité répartis entre 12 et 60. L'étape comprenant le nombre le plus élevé de défaillances critiques est celle du rangement et du stockage dans les services de soins, avec 5 défaillances. Au total, 48 mesures correctives ont été proposées.

Conclusions : Le plan d'action proposé priorisait 3 domaines d'amélioration : le système de documentation, la formation du personnel et l'acquisition d'équipements. Une deuxième AMDEC devrait être réalisée pour réévaluer le circuit après la mise en œuvre des mesures d'amélioration. La deuxième AMDEC permettra la détection des risques résiduels et l'identification de nouveaux risques et s'inscrira dans une démarche d'amélioration continue.

Mots-clés : chaîne du froid, médicament thermosensible, gestion des risques, sécurité des patients

INTRODUCTION

The cold chain is the set of logistic links that guarantee maintenance of a temperature between 2°C and 8°C during the stages of storage, handling, transport, and distribution of drugs. Any improper operation in the process of cold chain logistics may have a significant effect on the quality of temperature-sensitive drugs and vaccines, endangering the safety of patients receiving them. For example, power outages, inadequate conditions during transport, or unsuitable storage conditions can lead to a break in the cold chain, causing the degradation of vaccines and other pharmaceuticals.[1,2] In fact, a drug's properties may change with any temperature variation, depending on the temperature reached and the duration of storage at that temperature.[1,3] Certain drugs may lose some clinical effectiveness, whereas others may have a complete loss of activity or may even become toxic.[1,4,5] Thus, the cold chain is a major concern for hospitals, both financially and in terms of patient safety. Managing the operation of the cold chain, defining its players, ensuring its performance, and securing the medication-use process for temperature-sensitive drugs must therefore be included among the hospital's priorities, especially for the pharmacy department. Indeed, the hospital pharmacist represents an essential link in the cold chain, intervening in almost all stages of the system, from purchase and supply to administration to patients. Errors may occur at any stage of the process, with the pharmacist being responsible not only for identifying the failures but also for evaluating them and implementing the measures necessary to correct or prevent them.[6,7]

The objectives of this study were to analyze a priori the potential failure modes of the medication-use process for temperature-sensitive drugs and to propose corrective and preventive actions, by setting up a concrete action plan to minimize the risks and ensure the safety of the system and thus the safety of patients.

METHODS

Study Design and Setting

This study was a failure mode, effects, and criticality analysis (FMECA), carried out in the pharmacy department of a university hospital over a 3-month period (October to December 2019). The FMECA involved 6 steps: training, functional analysis, qualitative study, quantitative study, determination of the hierarchy of criticality, and proposals for improvement.[8-10]

Step 1: Training the Team

A multidisciplinary working group was trained to ensure consistency in the discussion and rating of failure modes. The group was made up of 8 members: 2 pharmacists (H.S., K.B.J.), 1 doctor, 3 pharmacy interns (including I.C.), 1 nurse, and 1 pharmacy assistant. For implementation of the study, 4 bimonthly meetings were scheduled.

Step 2: Functional Analysis: Description of Process

The working group described the medication-use process for temperature-sensitive drugs, from supply to administration, using the "5 Ws and How" method (Who? What? Where? When? Why? How?). This method allowed us to analyze the various stages, to define the main actors at each stage, and to describe the medication-use process clearly and simply.

Step 3: Qualitative Study: Risk Analysis of the Process

The working group identified potential failure modes by brainstorming. For each failure mode, the possible effects on or consequences for both the patient and the temperature-sensitive drugs were defined, the causes of failure were identified, and various means of detecting the risk were found. The causes were analyzed using Ishikawa ("fishbone") diagrams showing the following 5 aspects: personnel (man/labour), machinery (equipment, technology), material (raw materials, consumables, and information), method (process), and measurement or environment.

For each stage of the medication-use process, a summary matrix of failure modes, as well as their causes and effects, was developed.

Step 4: Quantitative Study: Quantification of Risks

The same matrix was used for rating the frequencies, detectability, and severity of failure modes according to proposed scales (Table 1). Decisions were based on voting by the working group, with divergent ratings subject to discussion to ensure consensus.

Step 5: Hierarchy of Criticality Determined by the Pareto Law

The criticality index of each failure mode was calculated as the product of frequency, detectability, and severity. This calculation made it possible to prioritize the various failure modes identified and to appropriately target actions to be taken.

For this purpose, the working group used a Pareto diagram. This type of diagram is based on the empirical law of 80/20, whereby about 20% of causes explain up to 80% of a problem. In this case, 20% of the failure modes were assumed to account for 80% of the criticality index.

After ranking the failure modes in descending order according to their respective criticality indexes, the cumulative criticality indexes and the percentages of cumulative criticality indexes were calculated for application of the Pareto law.

Step 6: Proposal of Improvement Actions

Once the most critical failure modes were identified, corrective action plans were put into place.

RESULTS

Functional Analysis: Description of Process

Figure 1 shows an excerpt of the medication-use process for temperature-sensitive drugs, as described by the "5 Ws and How" method.

Qualitative Study: Risk Analysis

A total of 41 failure modes were identified and subjected to analysis. The highest number of failure modes was recorded for storage stages at the storehouse, in pharmacy units, and in patient care units (n = 9 failure modes for each location). The lowest number of failures (n = 1) was found for the stage of order reception at the storehouse.

The working group deemed 5 failures to be non-evaluable, because they were not specific to the medication-use process for temperature-sensitive drugs. Three of these failure modes belonged to the first stage, relating to purchase and supply (error in supply of the product, delay in supply of the product, insufficient amount ordered relative to need); one occurred in the second stage, relating to delivery and transport (delivery error); and one occurred in the seventh stage, relating to dispensing to care units (error in dispensing). In the end, 36 failure modes were selected for evaluation (Table 2).

As an example, Figure 2 shows an Ishikawa ("fishbone") diagram for the failure mode of a power outage.

Quantitative Study

Criticality indexes were calculated for the failure modes identified in the qualitative study. The calculated values were between 4 and 60, as shown in Table 2.

TABLE 1. Scales Considered for Scoring Failure Modes

Scale Designation	Description
Severity (S) of effects	
S1	No impact on the drug (drug stable, packaging intact)
S2	Alteration of packaging, with no effect on the drug
S3	Decrease in duration of stability of the active substance (alteration of active substance)
S4	Degradation of active substance; drug not administered to patients
S5	Degradation of active substance; safety or therapeutic effectiveness compromised in the event of administration to patients
Frequency (F) of occurrence	
F1	Exceptional, no record of occurrence or virtually nonexistent
F2	Rare (1 or 2 times per year)
F3	Frequent (several times per year)
F4	Certain to occur (always)
Detectability (D)	
D1	High: probability is high that failure mode will be detected before it reaches the patient
D2	Possible: failure mode can be detected, but there is a risk of it being overlooked
D3	Unlikely: detection of failure mode is difficult
D4	Impossible: failure mode cannot be detected

Stage n° 1: Purchase and supply					
What?	**Who?**	**Where?**	**When?**	**How?**	**Why?**
• Supply of drugs	• The pharmacist responsible for the supply	• Pharmacy depot	• Before the stock runs out • At the request of doctors	• By establishing a purchase order	• To avoid out of stock • To meet the needs of the hospital • To provide treatment to patients
Stage n° 2: Delivery and transport of TSD					
What?	**Who?**	**Where?**	**When?**	**How?**	**Why?**
• To transport the order to the pharmacy depot	• Agent responsible for transport	• Drug transport truck in coolers	• Following the delivery of the order by the supplier	• By respecting the cold chain and transport conditions using coolers	• To supply the hospital when needed without any delay

FIGURE 1. Excerpt from description of the medication-use process for temperature-sensitive drugs (TSDs), according to the "5 Ws and How" method.

TABLE 2 (Part 1 of 2). Rating of Failure Modes and Calculation of Criticality Indices

Stage	Designation	Failure Mode	Severity	Frequency	Detectability	Criticality Index[a]
Delivery and transport	FM1	Noncompliance with cold chain during transport	4	3	2	24
Receipt of order at storehouse	FM2	No temperature control in reception area	5	3	2	30
Storage at storehouse	FM3	Medicines left outside refrigerated cabinet before storage	4	1	1	4
	FM4	Power outage	4	3	2	24
	FM5	Refrigerated cabinet failure	4	1	1	4
	FM6	Door of refrigerated cabinet not closed properly	4	2	1	8
	FM7	Prolonged or frequent opening of door to refrigerated cabinet	1	3	2	6
	FM8	Required temperature not reached in refrigerated cabinet	4	1	1	4
	FM9	Storage of boxes in unsuitable space in storehouse	3	4	1	12
	FM10	Refrigerated cabinets cluttered with medication	2	3	1	6
	FM11	Difference between temperature showing on refrigerated cabinet display and actual temperature	5	2	3	30
Distribution from storehouse to pharmacy units	FM12	Advance preparation of orders for temperature-sensitive drugs	4	1	2	8
	FM13	Noncompliance with cold chain during transport to pharmacy units	4	3	3	36
	FM14	No monitoring of compliance with cold chain in the reception area	5	4	1	20
Storage in the various pharmacy units	FM15	Power outage	4	3	2	24
	FM16	Difference between temperature displayed on thermometer and actual temperature	5	2	3	30
	FM17	Refrigerator failure	4	1	1	4
	FM18	Refrigerator door not closed properly	4	3	1	12
	FM19	Required temperature not reached in refrigerator	4	2	1	8
	FM20	Prolonged or frequent opening of refrigerator door	1	3	2	6
	FM21	Inadequate storage in refrigerator (in vegetable drawer or in door or in contact with freezer compartment or frozen walls of refrigerator)	5	1	1	5
	FM22	Storage of boxes in an unsuitable space within pharmacy unit	3	2	1	6
	FM23	Refrigerators cluttered with medication	3	2	1	6
Dispensing from pharmacy to the various care units	FM24	Advance preparation of orders for temperature-sensitive drugs	5	1	3	15
	FM25	Noncompliance with cold chain during transport to care units	5	4	1	20
Storage in patient care units	FM26	Medication left outside refrigerator before storage	5	3	2	30
	FM27	Power outage	5	2	1	10
	FM28	Refrigerator failure	4	2	1	8
	FM29	Refrigerator door not closed properly	5	3	1	15
	FM30	Required temperature not reached in refrigerator	5	2	4	40
	FM31	Prolonged or frequent opening of refrigerator door	1	3	2	6
	FM32	Inadequate storage in refrigerator (in vegetable drawer or in door or in contact with freezer compartment or frozen walls of the refrigerator)	5	4	1	20
	FM33	Difference between temperature displayed on thermometer and actual temperature	5	3	4	60
	FM34	Storage of temperature-sensitive drugs outside refrigerator (in the cabinet)	5	1	1	5

TABLE 2 (Part 2 of 2). Rating of Failure Modes and Calculation of Criticality Indices

Stage	Designation	Failure Mode	Severity	Frequency	Detectability	Criticality Index[a]
Administration to patients	FM35	Extended interval between taking medicine out of the refrigerator and administering it to patient	5	2	2	20
	FM36	Error in preparation of temperature-sensitive injectable drugs: injection without prior warming	1	2	4	8

FM = failure mode.
[a]Criticality index was calculated as the product of severity × frequency × detectability.

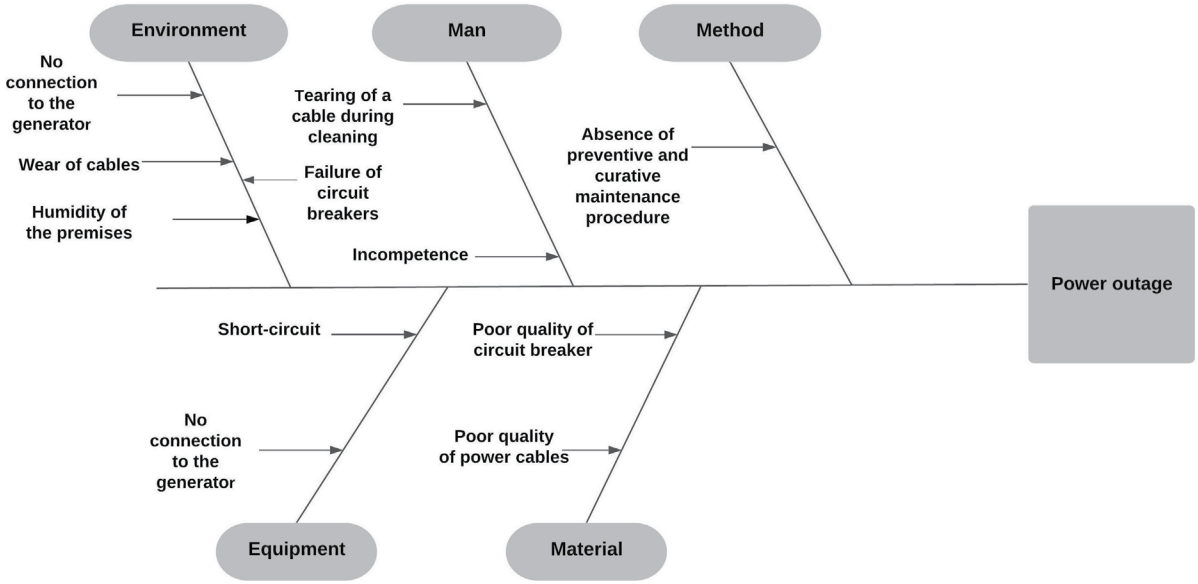

FIGURE 2. Example of an Ishikawa ("fishbone") diagram for the failure mode of a power outage.

Hierarchy of Failures: Pareto Law

According to the Pareto law, 18 of the 36 failure modes were critical, having criticality indexes between 12 and 60. Figure 3 illustrates the Pareto chart.

Most of the critical failures (n = 11) were related to the storage stages: in patient care units (n = 5), in the storehouse (n = 3), and in the pharmacy units (n = 3).

Improvement Actions

According to the most critical failure modes selected by the Pareto law, the working group proposed several ameliorative, corrective, and preventive actions. These actions will be implemented gradually over time, with deadlines for action in the long, medium, and short terms, according to the hospital's financial resources (Table 3).

Monitoring indicators were put in place to measure the impact of these improvement actions. The first indicator chosen by the working group was the number of temperature alerts, an indirect measure of the efficacy and safety of temperature-sensitive drugs. The second monitoring indicator was the state of operation of cold chain equipment, to identify maintenance needs, with the goal of preserving the quality of temperature-sensitive drugs. This indicator is used for operational purposes (i.e., updating the maintenance plan).

DISCUSSION

Controlling the cold chain remains a topical issue for hospitals. It is linked to a triple risk: a financial or economic risk, a regulatory risk, and above all a risk to patients if the quality of a drug is altered.[11] As intervenors in the cold chain, pharmacists play an important role in preserving the integrity and safety of each drug.[12]

In this study, the a priori analysis of risks associated with the medication-use process for temperature-sensitive drugs was carried out by the FMECA method because it is the most suitable method for the hospital setting, according to several previous studies.[9,13-15] It has been recommended by the French Haute Autorité de Santé (National Authority for Health)[16] as a reference method for risk analysis and has been recommended by several other health organizations, in particular the Institute for Healthcare Improvement,[17] the Institute for Safe Medication Practices Canada,[18] and the American Association of Physicists in Medicine.[19]

The FMECA method is based on the concept of brainstorming. This method of combining ideas is 1 of the 7 basic tools of quality.[20] It is a creative technique that allows the emergence of new ideas in groups.[21] The CHU Sainte-Justine in Montréal, Quebec, applied this technique in the search for failure modes for an evaluation of the various stages of drug administration.[22] The major strengths of FMECA are its simplicity and the quantitative evaluation it allows through a combination of 3 parameters: frequency, severity, and detectability. Moreover, the FMECA helps in identifying the most important critical events, which is helpful for deciding upon and prioritizing improvement actions.[22] However, the FMECA methodology does not specify the procedure to be followed for prioritization. In the AMELIORE study, the team opted for a criticality threshold beyond which recommendations were made[23]; however, they did not explain their choice of threshold value. Arenas Villafranca and others[24] classified failure modes according to their relative importance. They subsequently developed a checklist to determine the "most critical aspects of the process". Again, however, the method of selecting priority risks was not specified. In the current study, the Pareto law was used to define critical failure modes. This choice was approved by all participants, given the method's advantages, including time savings. The criticality index can be rated according to a scale that allows visual assessment using a colour code: green for acceptable, yellow for tolerable, and red for unacceptable.[25] In other studies,[9,14] the criticality index was positioned in a matrix developed by the working group. It can be divided into 3 or more levels, for example, acceptable, tolerable, and unacceptable risk or, alternatively, low, high, and major criticality. Improvement actions are then prioritized according to these categories.

The Pareto law allowed us to select 18 critical failure modes. The stage with the most failure modes was storage in patient care units. Conversely, the stages of delivery and transport and of receipt of the order at the storehouse had the least critical failure modes.

These results cannot be directly compared with any study in the literature because we found no prior studies using FMECA to analyze the medication-use process for temperature-sensitive drugs. Instead, we compared our results with those of studies using the FMECA method and studies on improvement of the cold chain. One study of the latter type, conducted in a health care establishment, highlighted 14 critical points along the entire medication-use process for temperature-sensitive drugs, beginning with delivery by suppliers and ending with delivery to patients[11]; by comparison, we found 18 points of critical failure. Some failure modes were common to the earlier cold chain study[11] and our analysis, namely, noncompliance with the cold chain during transport from the supplier, absence of temperature indicators in the medication packages, noncompliance of pharmacy refrigerators and cold rooms, noncompliance with the cold chain during transport to clinical departments, and storage conditions for products requiring temperature control in compliant refrigerators in clinical departments. Indeed, the delivery and transport stage in our study showed a single critical failure with a criticality index of 24, suggesting noncompliance with the cold chain during transport. This crucial stage must be appropriately controlled, given it is the first link in the entire cold chain. The study by Saint-Lorant and others[11] similarly showed that the transport stage is critical. The only efficient way to transport temperature-sensitive drugs is to use a refrigerated truck, to equip the packages with a USB temperature recorder, and to train logistics staff. The stage of order reception at the

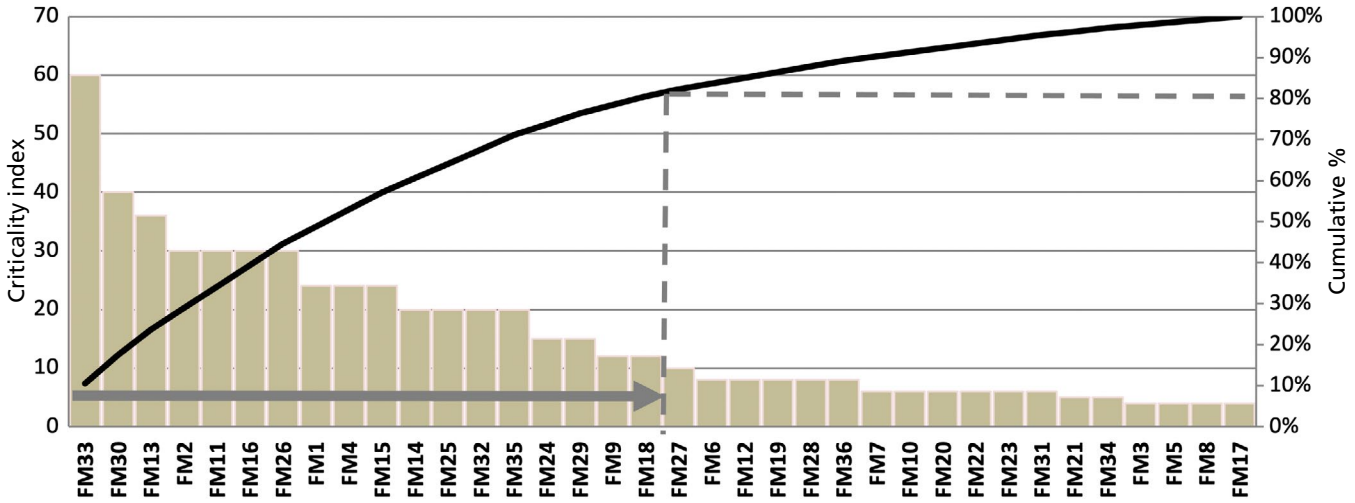

FIGURE 3. Pareto chart. The failure modes (FMs) are presented along the horizontal axis in descending order of their criticality index. The solid black curve depicts the cumulative percentage of the criticality index. The point along the horizontal axis intersecting the 80% value on the right-hand vertical axis (as shown by dashed grey lines) defines the failure modes that were deemed to be critical (spanned by the horizontal grey arrow).

TABLE 3 (Part 1 of 2). Critical Failure Modes Selected by Pareto Law and Proposed Improvement Actions[a]

Designation	Failure Mode	Stage	Criticality Index		Actions	Time Frame
			Value	Cumulative %		
FM33	Difference between temperature displayed on thermometer and actual temperature	Storage in patient care units	60	10	Set up a preventive maintenance procedure for refrigerators Calibrate the thermometer Train and sensitize paramedical staff Establish a standard sheet for daily temperature monitoring (3 times/day)	Short term Long term Short term Short term
FM30	Required temperature not reached in refrigerator	Storage in patient care units	40	17	Set up a preventive maintenance procedure for refrigerators	Short term
FM13	Noncompliance with cold chain during transport to pharmacy units	Distribution from storehouse to pharmacy units	36	24	Train paramedical staff Draft procedures Put in place suitable packaging and isothermal bags for transport Install thermometers in packages	Short term Short term Medium term Medium term
FM2	No temperature control in reception area	Receipt of order at storehouse	30	29	Place the USB temperature recorder inside the package from the time of order delivery to allow visualization of the temperature variation curve Train storehouse staff Set up a procedure to organize the receipt of temperature-sensitive drugs	Medium term Medium term Short term
FM11	Difference between temperature showing on refrigerated cabinet display and actual temperature	Storage at storehouse	30	34	Set up a preventive maintenance procedure for refrigerated cabinets Qualify refrigerated cabinets	Short term Long term
FM16	Difference between temperature displayed on thermometer and actual temperature	Storage in the various pharmacy units	30	39	Establish a preventive maintenance schedule Calibrate thermometers	Medium term Long term
FM26	Medication left outside refrigerator before storage	Storage in patient care units	30	45	Designate an agent responsible for collecting the order and putting it away Raise awareness and train paramedical staff on the importance of respecting the cold chain Develop a procedure for receipt of temperature-sensitive drugs in patient care units	Short term
FM1	Noncompliance with cold chain during transport	Delivery and transport	24	49	Plan the departure time of the truck according to traffic conditions, and choose the shortest route possible Assign the truck driver only one task (to collect the order of the temperature-sensitive drugs) Acquire a refrigerated truck and a USB temperature recorder Train and sensitize the driver Develop a procedure to organize the transport stage of temperature-sensitive drugs	Short term Short term Medium term Short term Short term

TABLE 3 (Part 2 of 2). Critical Failure Modes Selected by Pareto Law and Proposed Improvement Actions[a]

Designation	Failure Mode	Stage	Criticality Index		Actions	Time Frame
			Value	Cumulative %		
FM4	Power outage	Storage at storehouse	24	53	Install an audible alarm system Establish a preventive maintenance schedule Train staff Implement a procedure in case of a break in the cold chain Install a preventive system for activation during natural disasters	Long term Long term Short term Short term Long term
FM15	Power outage	Storage in the various pharmacy units	24	57	Install an audible alarm system Connect the power generator Ensure regular maintenance of the electrical installation	Long term Short term Medium term
FM14	No monitoring of compliance with cold chain in reception area	Distribution to pharmacy units from storehouse	20	61	Equip packages with calibrated thermometers Set up a procedure to organize the receipt of temperature-sensitive drugs	Medium term Short term
FM25	Noncompliance with cold chain during transport to care units	Dispensing from pharmacy to the various care units	20	64	Acquire coolers or isothermal packets for delivery to clinical services Equip packages with calibrated thermometers	Medium term
FM32	Inadequate storage in refrigerator (in vegetable drawer or in door or in contact with freezer compartment or frozen walls of refrigerator)	Storage in patient care units	20	68	Train paramedical staff on rules for storage Perform pharmaceutical audits in clinical departments	Short term
FM35	Extended interval between taking medicine out of refrigerator and administering it to patient	Administration to patients	20	71	Inform and train paramedical staff on rules for using temperature-sensitive drugs Distribute tasks within the service for better organization	Short term
FM24	Advance preparation of orders for temperature-sensitive drugs	Dispensing from the pharmacy to the various care units	15	74	Take temperature-sensitive drugs out of refrigerated storate at the last minute before they are dispensed Train staff	Short term
FM29	Refrigerator door not closed properly	Storage in patient care units	15	76	Train staff Ensure regular maintenance of equipment	Short term Medium term
FM9	Storage of boxes in an unsuitable space	Storage at storehouse	12	78	Empty boxes of temperature-sensitive drugs and transfer to refrigerated cabinet upon receipt Organize the frequency of orders for temperature-sensitive drugs as needed	Short term
FM18	Refrigerator door not closed properly	Storage in various pharmacy units	12	80	Train staff Ensure regular maintenance of equipment	Short term Medium term

FM = failure mode.
[a]Rows are presented in descending order.

pharmacy storehouse also had a single failure (lack of temperature control in the reception area), which was deemed to be critical, according to the 80/20 law. To secure this stage, it is important to check the USB temperature recorder of the order upon receipt, to prioritize documentation of receipt of temperature-sensitive drugs, and to put them away promptly. Saint-Lorant and others[11] suggested limiting the number of people involved in accepting medication deliveries and to make the receptionist aware of the importance of this task.

Eleven of the 18 critical failure modes identified in the current study involved storage: at the storehouse, in the various pharmacy units, and in patient care units. Three failure modes related to storage in the storehouse were deemed critical. The first was a difference between the temperature shown on the display and the actual temperature. To remedy this potential failure mode, the working group proposed qualifying the refrigerated cabinets, to verify that the device continued to operate well under actual conditions of use over time (monitoring of continuous temperature recording, regular verification of proper functioning of the alarms, renewal of the characterizations of the refrigerated cabinet), calibrating the thermometers, and putting in place preventive maintenance procedures. The second critical failure mode was a power outage, for which the main action proposed was installation of an audible alarm system. A remedial procedure in case of a break in the cold chain and the establishment of a preventive maintenance schedule for electrical installations were also proposed. Saint-Lorant and others[11] planned to group temperature-sensitive drugs into categories according to their stability, to allow their retrieval in case of a break in the cold chain. The third critical failure mode was the storage of boxes containing temperature-sensitive drugs in the refrigerated cabinet, a situation in which the temperature could exceed 8°C. To address this potential failure mode, staff were asked to unpack the drugs quickly before storing them.

The stage of storage in the various pharmacy units had 3 critical failure modes according to the Pareto law: a difference between the temperature displayed by the thermometer and the actual temperature, power outage, and refrigerator door not closed properly. The proposed improvement actions were to train staff and ensure preventive maintenance of equipment.

Storage in the patient care units represents the penultimate stage of the medication-use process; it is crucial because it is the last step before drug administration. This stage also had the greatest number of failure modes of any stage: there were 9 failures, 5 of which were critical according to the Pareto law: difference between the temperature displayed by the thermometer and actual temperature, required temperature not reached in refrigerator, medication left outside the refrigerator before storage, inadequate storage in the refrigerator (e.g., in the door or the vegetable drawer), and refrigerator door not closed properly. The corrective actions were as follows: training of paramedical staff and sensitization to the challenges of the cold chain, monitoring the temperature of refrigerators 3 times daily, and returning to the pharmacy any temperature-sensitive drugs not administered to patients (to avoid cluttering refrigerators on the care units). Regular pharmaceutical audits within the various clinical services have also been proposed. Saint-Lorant and others[11] have also provided for pharmaceutical audits in clinical services to remedy fault points and to put in place any corrective actions needed to improve the cold chain.

Similar to other work using FMECA,[26,27] subjectivity in the rating of each risk was the main limitation of this study. In fact, the identification of failure modes and their rating are mainly based on the risk perceptions of various health care professionals, given that everyone participates and reacts according to their own experience.

CONCLUSION

In this study, storage in patient care units was the stage of the medication-use process with the most critical failure modes and required the most interventions to ensure patient safety. Securing this high-risk process is a means of ensuring the efficiency of patient care within the framework of continuous quality improvement. Admittedly, implementation of quality improvement measures appears to be difficult, time-consuming, and expensive; however, such an approach makes it possible to prevent the deterioration of temperature-sensitive drugs and thus to reduce the financial losses due to breakdown of the cold chain. A second FMECA should be carried out to reassess the medication-use process after implementation of improvement actions.

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