Anticipating Risk in Medication Logistics: FMECA Applied to the Restocking Automation of a 25-Operating Room Surgical Unit

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Introduction

Drug management in surgical wards is a critical issue. Most drugs used in these settings are high-risk and may be required on short notice in life-threatening situations.
In 2024, the Grand Hôpital de Charleroi merged into a 986-beds campus with 25 operating rooms, each equipped with a new system of computerized cabinets, warranting a risk analysis to establish a sage and efficient medication circuit.

Objectives

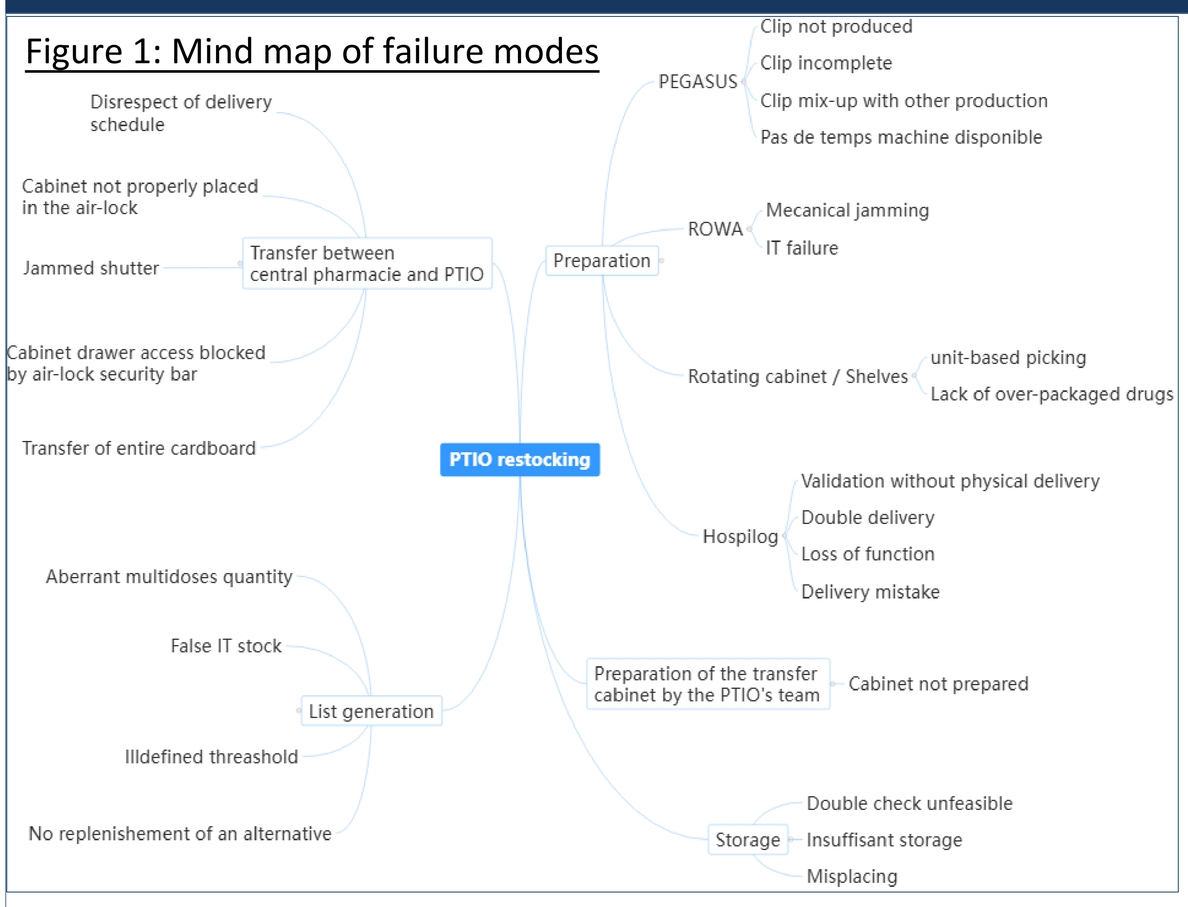
Identify liabilities and provide correctives to ensure a rigorous supply chain

Methodology

The risk analysis was performed through a FMECA (Failure Mode, Effect and Criticality Analysis) to anticipate as many potential issues as possible.
For our FMECA, we applied an institutional grading scale, supplemented with elements from the U.S. department of Veterans Affairs' HFMEA[1], notably the distinction of single points of failure and the grading of causes in addition of failure modes.
Failure modes were identified and organized using mind mapping.

Results

Figure 1: Mind map of failure modes



		Base criticality			After action		
Main categories	Sub-categories	High	Inter.	Low	High	Inter.	Low
I. List generation	I.A. Creation of 'Process_threshold' missions	2	1	1	0	3	1
II. Logistic from PTIO to BO	II.A. provision of adequate sorting trays based on missions	0	0	1	0	0	1
III. Preparation	III.A ROWA III.B PEGASUS III.C Perfusions III.D Rotary storage units / Shelves III.E Cold room III.F Hospilog	1	2	9	0	0	12
IV. Logistic from BO to PTIO	IV.A. Provision of supplies	0	0	5	0	0	5
V. Storage	V.A Delivery verification V.B Arranging supplies in the PTIO pharmacy	0	1	2	0	0	3

Table 1: Categories of failure modes and spread of criticalities

- 7 of 25 failure modes reached intermediate or high criticality
- 4 single point of failure were identified, 3 of which were related to technological issues (2 software-related and 1 involving a robot)
- After 1 month, all remaining unresolved issues were attributed to skills unavailable within the pharmacy staff.

Table 2: Example of a failure mode analysis

For full results scan the QR-code bellow

Full Results

	Failure mode		Causes	Hazard Analysis: Initial scoring: Severity (1-5)	Probability (1-5)	Criticality (SxP)	Decision Tree Analysis: Single Point Weakness? (Y/N)	Existing Control? (Y/N)	Detectability? (Y/N)	Continue Analysis? (Y/N)	Actions and Outcomes: Action Type	Justification / Action to Implement	Expected outcome	Reviewed scoring: Severity (1-5)	Probability (1-5)	Criticality (SxP)
I.A. List generation	I.A.2 False IT stock	→		3	5	15	Y	N	-	Y				2	4	8
		I.A.2.a	BeTrace sensor mechanical defect	2	5	10	N	N	Y	Y	Control	Continuous inventory of faulty sensors and weekly feedback to BeTrace	Reduced sensor downtime and lower probability of simultaneous failures	2	4	8
		I.A.2.b	IT data flow loss (BeTrace→APO)	3	3	9	Y	N	N	Y	Control	Set up a check for IT data-flow existence for Aexis interventions	Improved detectability and prevention of data loss	2	3	6
		I.A.2.c	Human billing error	2	5	10	N	N	N	N	Acceptance			2	5	10
		I.A.2.d	Data stuck in APO Div	2	5	10	N	Y	Y	Y	Control	Existence of a DTSI-Pharmacy working group for issue management	Fewer blocked messages as root causes are identified and resolved	2	4	8
		I.A.2.e	Pharmacy encoding delay	2	5	10	N	N	Y	Y	Control	Daily scheduling	Reduced mismatch between physical and IT	1	4	4

Conclusion

Applying FMECA prior to full automation enabled the identification and mitigation of critical vulnerabilities within a complex medication circuit. These interventions facilitated the successful implementation of the anticipated supply chain. The study also highlights the need for dedicated IT specialists in the pharmacy address unresolved high-criticality issues and enhance responsiveness in an ever more technical environment. Although resource-intensive, targeted FMECA enhances change management, supports staff engagement, and strengthens patient-safety outcomes.

References

1. https://www.patientsafety.va.gov/docs/joe/Step-by-Step-Guidebook-HFMEA-January2021.pdf - last visited the 28th of July 2025

Abbreviations

BO: Back-Office
PTIO: Interventional and Operative Technical Platform
HFMEA: Healthcare Failure Mode Effect Analysis
FMECA: Failure Modes, Effects, and Criticality Analysis

Acknowledgments

I express my sincere thanks to all those who supported and assisted me throughout the writing of this work. Especially Caroline Brosteau and Olivier Tassin

Read as you walk

Work carried out as part of the **UCLouvain** specialization master's degree in hospital pharmacy

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Annex I : Full results for initially high or intermediate failure modes

Hazard Analysis											Actions and Outcomes					
			Initial scoring			Decision Tree Analysis							Reviewed scoring		
Failure mode		Causes	Severity (1-5)	Probability (1-5)	Criticality (SxP)	Single Point Weakness? (Y/N)	Existing Control? (Y/N)	Detectability? (Y/N)	Continue Analysis? (Y/N)	Action Type	Justification / Action to Implement	Expected outcome	Severity (1-5)	Probability (1-5)	Criticality (SxP)
I.A. List generation	**I.A.1 Aberrant multidose quantity**	→	3	5	15	N	Y	Y	Y				2	5	10
		I.A.1.a Article file configuration	1	1	1	N	Y	Y	N	Acceptance			1	1	1
		I.A.1.b Incorrect billing information	3	5	15	N	Y	Y	Y	Control	Use of buffer stock to compensate for the failure mode	Physical compensation of a drug shortage in the OR to prevent patient impact	2	5	10
		I.A.1.c Iterative application of coefficient	3	5	15	N	Y	Y	Y	Elimination	Identification of the cause and elimination (APO-Hospilog parameter)	Elimination of the problem	0	0	0
I.A. List generation	**I.A.2 False IT stock**	→	3	5	15	Y	N	-	Y				2	4	8
		I.A.2.a BeTrace sensor mechanical defect	2	5	10	N	N	Y	Y	Control	Continuous inventory of faulty sensors and weekly feedback to BeTrace	Reduced sensor downtime and lower probability of simultaneous failures	2	4	8
		I.A.2.b IT data flow loss (BeTrace→APO)	3	3	9	Y	N	N	Y	Control	Set up a check for IT data-flow existence for Aexis interventions	Improved detectability and prevention of data loss	2	3	6
		I.A.2.c Human billing error	2	5	10	N	N	N	N	Acceptance			2	5	10
		I.A.2.d Data stuck in APO Div	2	5	10	N	Y	Y	Y	Control	Existence of a DTSI-Pharmacy working group for issue management	Fewer blocked messages as root causes are identified and resolved	2	4	8
		I.A.2.e Pharmacy encoding delay	2	5	10	N	N	Y	Y	Control	Daily scheduling	Reduced mismatch between physical and IT	1	4	4
		I.A.2.f Failure to close BeTrace replenishment in Hospilog	2	5	10	Y	N	Y	Y	Elimination	1. Procedure reminder 2. Daily validation by supervising pharmacist before list generation	Elimination of cause via daily supervisor check in case of technician oversight	0	0	0
		I.A.2.g Validation of non-dispensed lines	2	4	8	Y	N	N	Y	Control	Procedure reminder	Reduced frequency	2	3	6
I.A. List generation	**I.A.4 No replenishment of an alternative**	→	4	3	12	N	N	Y	Y				4	2	8
		I.A.4.a Article file misconfiguration	3	2	6	N	N	N	Y	Control	Update shortage-management procedure (Hospilog & BTR settings)	Reduced frequency	3	1	3
		I.A.4.b BTR alternatives configuration	3	2	6	N	N	Y	Y	Control	Procedure for proper BTR use in the PTIO		3	1	3
III.A ROWA	**III.A.1 Mechanical jam**	→	2	4	8	Y	N	N	Y				1	4	4
		III.A.1.a Large-volume conveyor issue	2	4	8	Y	N	N	Y	Control	1. ROWA troubleshooting procedure (decision tree) 2. Restart talks with BD on conveyor issues	Reduced severity via shorter downtime	1	4	4
		III.A.1.b Robot error (no bins, internal error, unrecognized bins)	2	5	10	Y	Y	Y	Y	Control	1. ROWA troubleshooting procedure (decision tree) 2. Review BD remote-access with DTSI for	Reduced severity via shorter downtime	1	5	5
III.D Rotary storage units / Shelves	**III.D.2 Lack of over-packaged drugs**	→	3	5	15	Y	N	N	Y				2	3	6
		III.D.2.a No overpackaged druggs produced	3	5	15	Y	N	N	Y	Elimination	Bring over-packed & non-over-packed drug stocks closer; add production cards to monitor inventory	IT-independent tracking of re-production to eliminate cause	0	0	0
		III.D.2.b Overpackaged drugs produced but quality checked	2	5	10	Y	N	N	Y	Control	Daily scheduling	Reduced frequency via effective planning	2	3	6
		III.D.2.c Pharmacy technician didn't know that the drug required over-package	2	5	10	Y	N	N	Y	Elimination	Add labels on hybrid-reference bins to specify services requiring over-packaged drugs		0	0	0
III.F Hospilog	**III.F.1 IT validation without physical replenishment**	→	3	4	12	Y	N	Y	Y				2	2	4
		III.F.1.a Validation of the PTIO's missions by someone in charge of another zone	3	4	12	Y	N	Y	Y	Control	Create custom filters by zones	avoid risk of confusion, error.	2	2	4
		III.F.1.b Validation of a missing product	3	4	12	N	N	Y	N	Control	Training		2	2	4
V.A Delivery verification	**V.B.1 Double check unfeasible**	→	2	4	8	N	N	N	Y				1	3	3
		V.A.1.a No history of process_threshold tasks	2	4	8	N	N	N	Y	Control	Create a custom filter for movement-flow analysis to compare physical vs. IT reception match	Allow easier identification of movement to compensate for lack of history for specific	1	3	3

Criticality	Low	Intermediate	High
	[1-5]	[8-12]	[15-20]
Action status on July 31th 2025	Action completed	Action ongoing	Action not yet started