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Materiovigilance ex ante risk management

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Background

Since the publication of **the April 6th 2011 Decree** on the quality management of medicinal treatment and drugs in health institutions, it has become a priority in hospitals. In addition, in version 2010 of the **High Authority of Health certification manual**, criterion 8d deals with the evaluation requirements and risk prioritization based on defined methods, implementation of preventive, mitigation or recovery actions, staff training in risk analysis, and monitoring and measuring the effectiveness of implemented actions.

Objectives

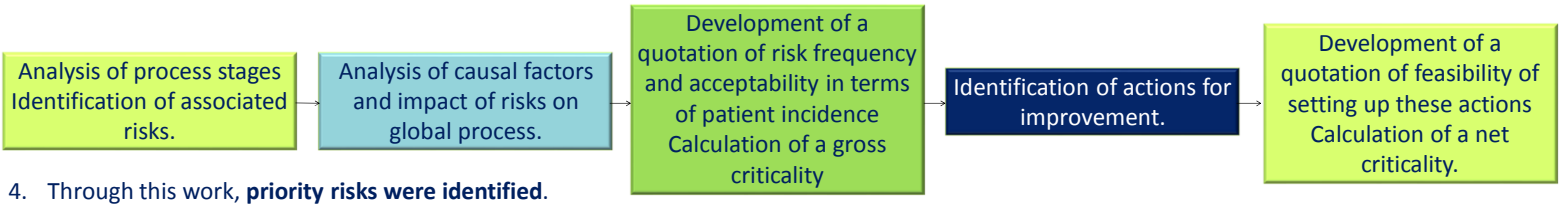
It is in this context that the Organization, Quality, User relations Directorate of our health institution has requested medical device vigilance service to

- initiate a project on quality management.
- develop a materiovigilance ex ante risk assessment tool.

The chosen quality tool was a **risk mapping**, based on the FMEA method (Failure Mode Effects Analyses) which allows to **prioritize risks**, to **identify actions for improvement** and to **develop an action plan**.

Methods

1. A **multidisciplinary group** was created by the project leader.
2. An inventory of the **service documentary system** was performed.
3. The development of the **risk mapping** was started. (Fig. 1 Risk mapping development stages)



4. Through this work, **priority risks were identified**.

Results & Discussion

Five major activities (bottom-up alerts, top-down alerts, staff, documentary system and computer resources management), about **fifty associated risks** and **many scenarios** were identified.

Due to the risk mapping, **three priority actions** (Net criticality ≥ 18) have been identified to be implemented :

- reinforce staff training,
- raise awareness on reporting,
- write fallback procedures.

Those three actions were included in the **action plan 2016**.

Score	Level	Description
Frequency score		
1	Rare	Maximum 1/year
2	Occasional	< 1/month
3	Frequent	> 1/month
Acceptability score		
1	Minor	Acceptable
2	Serious	Less acceptable
3	Major	Unacceptable
Mastering score		
1	Excellent	Action already set up and efficient
2	Bad	Action difficult to implement
3	Good	Action to enhance or easy to implement

Fig 2. Risk scoring model

Activities	Stages	Risks	Causal factors	Impact on global process	Frequency	Acceptability	Gross criticality	Actions for improvement	Mastery	Net criticality
Bottom-up alerts management	Reporting	Not reported event	People : lack of knowledge, omission Method : processes Material : reporting tool ineffective Environment : lack of time	Ignorance of an event. No analysis of the event. Risk of reoccurrence.	3	3	**9**	**Enhance HCL staff training**	3	27
								Promote awarness on reporting among HCL staff	2	18
								Publication of procedures on intranet portal	1	9
								Dematerialization of reporting	1	9
Top-down alerts management	Sending alert	Not sent alert	People :omission Method : processes Material : fax damaged, inbox overload	Referent person is not informed	2	3	**6**	Archiving of reception notice	1	6
								Redaction of fallback procedures	3	18
Staff management	Trainning	Insufficient number of trained person	People : lack of involvement Method : poor communication Environment : lack of time	HCL staff is unfamiliar with materiovigilance	2	3	**6**	**Enhance the organization of HCL Staff training**	3	18
								Improvement of communication on staff training	3	18
								Development of E-learning for HCL staff	2	12
		Inadequate training for students and residents	People : lack of involvement Material : inadequate training tools, inadequate skills assessment tools Environment : lack of time	Alerts mismanagement	2	3	**6**	First training lead by the local correspondent of materiovigilance	1	6
								Develop skills assessment tool (questionnaire)	3	18
								Double control by a pharmacist	1	6

Fig 3. Risk mapping (abstract)

Conclusion

The development of this quality tool is made in the context of the certification of health institutions as well as in the context of a comprehensive approach to improve quality management and patient care in hospitals.

Acknowledgements

Arrêté du 6 avril 2011 relatif au management de la qualité de la prise en charge médicamenteuse et aux médicaments dans les établissements de santé, Légifrance.
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