COM20-53007 - The benefits of the Global Risk Assessment (GRA) to secure the centralized production of chemotherapies

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INTRODUCTION

The French National Authority for Health (HAS) recommends the implementation of retrospective but also prospective risk management approaches using a qualitative and quantitative method

The **objective** of this work is to implement a prospective analysis using the GRA method, to assess its feasibility and the impact of the results obtained

MATERIALS AND METHOD

GRA Method:

- 8 30-minutes meeting
- Workgroup: pharmacist, pharmacy student, pharmacy technicians

Functional analysis → **System GRA** → **Scenario GRA** → **Risk Reduction Plan**

- **Functional analysis** of the entire process, from receipt of the prescription to delivery of preparations to the clinical ward.
- **System GRA** : Following this analysis, a cartography of dangerous situations (DS) is constructed by the working group, and a priority index is assigned to each DS (Priority 1 for high-priority DS, Priority 2 for non-priority DS, Priority 10 for the DS excluded from the analysis and have to be processed by an appropriate working group).
- **Scenario GRA** : The priority DS are developed into scenarios to which a likelihood and severity index is assigned. From these two indices, we determine the initial criticality (Ci) (acceptable **C1**, tolerable under control **C2**, unacceptable **C3**).
- **Risk reduction plan**: The scenarios with Ci = C2 and C3 are treated by risk reduction actions (RRA), to achieve a residual criticality (Cr) lower than Ci. The means necessary for the implementation of the RAA are quantified using an effort scale.

RESULTS

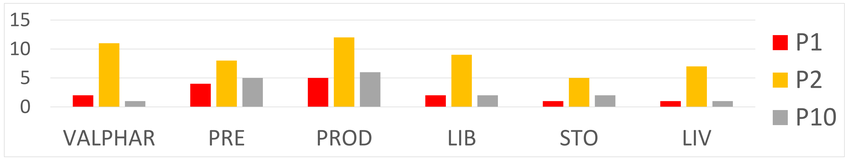
Functional analysis :

Split into 6 functions : Pharmaceutical validation (VALPHAR), material picking (PRE), drug production in isolator (PROD), pharmaceutical release (LIB), storage (STO) and delivery (LIV).

System GRA :

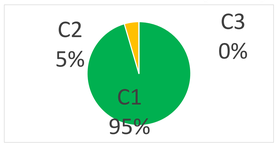
The DS cartography highlights 82 SD

Priority	Priority 1	Priority 2	Priority 10
Number of DS	**15**	52	15

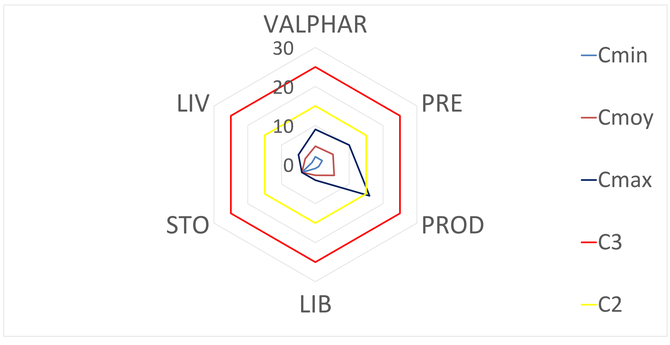


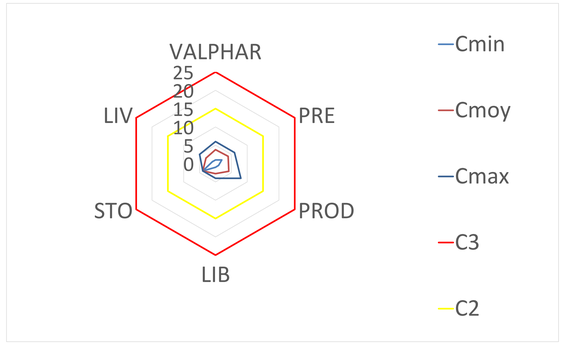
Risk reduction plan :

The working group has developed a risk reduction plan including 9 risk reduction action (RRA).



The revision of our handling procedure in order to integrate per-process controls and their traceability allows the disappearance of scenario C3 (preventive action)



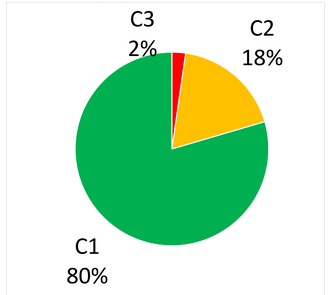


Kiviat diagrams before and after risk reduction plan

Decrease in average criticality and maximum criticality across all functions

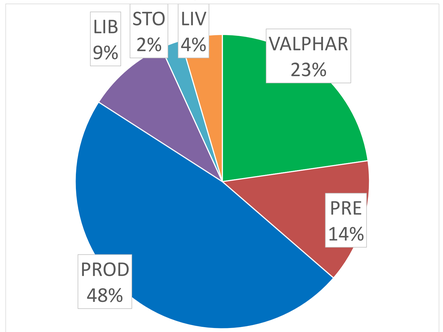
Scenario GRA :

The working group determined 44 accident scenarios (1 C3; 8 C2 et 35 C3)



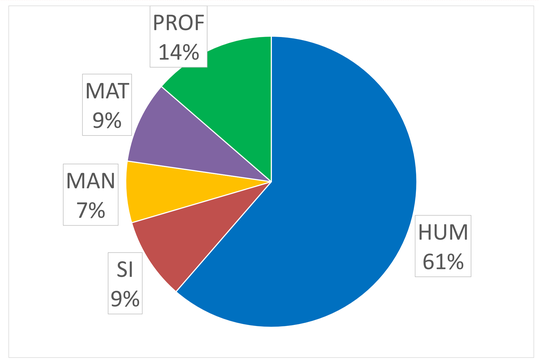
Breakdown of initial criticality

C3 scenario: remainder mistake during the isolator stage (anthracyclins inversion for example)



Breakdown of scenarios by function

The PROD step concentrates 48 % of the scenarios. VALPHAR et PRE represent 23 % and 14 % of the scenarios.



Breakdown of scenarios by danger

- HUMAN risk (*operators mistakes*) : 61 % of the scenarios
- PROFESSIONNAL risk (*exposure to cancer drugs or sterilant agent*) : 14 % of the scenarios
- Material risk (MAT), Management (MAN) and information system (SI) : 9%,7% et 9 % of the scenarios.

Effort :

- Weak (*Procedure reminder, one-off audit, storage modification*) : 1 RRA
- Medium (*Procedure modification, periodic audit, investment < 1000 €*) : 3 RRA
- High (*Written document creation, external audit, training, investment> 1000 €*) : 1 RRA

Expected effectiveness:

- Very effective solutions (*Process Standardization or simplification)* : 2 RRA
- Moderately effective solutions (*Improved documentation, reminders or checklist*) : 2 RRA
- Weakly effective solutions (*Labels, Training, new procedure*) : 5 RRA

DISCUSSION - CONCLUSION

The GRA method allowed us to quickly identify; prioritize and manage the risks in the production process. This method is a suitable method for risk assessment in chemotherapy production units, and can be implemented for each major production change. GRA method has demonstrated itself to be an efficient way to improve the quality level of the chemotherapy production unit.

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