

Julia Rousseau, Kaouther Zribi, Camille Cotteret, Salvatore Cisternino, Joël Schlatter
Pharmacy service, hospital Necker-Enfants Malades - 149 rue de Sèvres, 75015 Paris, France

INTRODUCTION

Our hospital has undertaken an outsourcing of **injectable preparations production**.

However, outsourcing (OS) cannot be considered without a prior risks evaluation and has to take into consideration **the specificity of paediatric preparations**.

Goal → A Global Risk Analysis (GRA) was initiated to guide OS or not decision.

MATERIALS AND METHOD

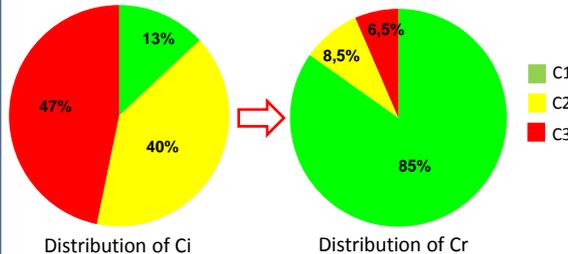
- The GRA was conducted by a **multidisciplinary working**: physicians, pharmacists, interns, nurse managers and pharmacy technicians.
- The GRA allow building **cartography of the dangerous situations** and prioritising them according to action priority index. Hazardous situations that have to be treated in priority are identified in scenarios rated according to their probability, severity and initial criticality (IC) (**acceptable C1, acceptable under control C2, unacceptable C3**)
- Scenarios where IC=C2 or C3 are dealt by implementing **risk reduction actions**.
- An effort scale can rate actions that have to be implemented. A **residual criticality** (RC) is attributed to each scenario after the actions implementation.
- Data analysis was performed using the **Statcart® software** (MAD Environment Company).

RESULTS

The working group identified **51 hazardous situations** to be treated without delay, resulting in **92 accident scenarios** including **43 (47%) with unacceptable criticalities C3**.

The GRA showed that the riskiest scenarios mostly concern:

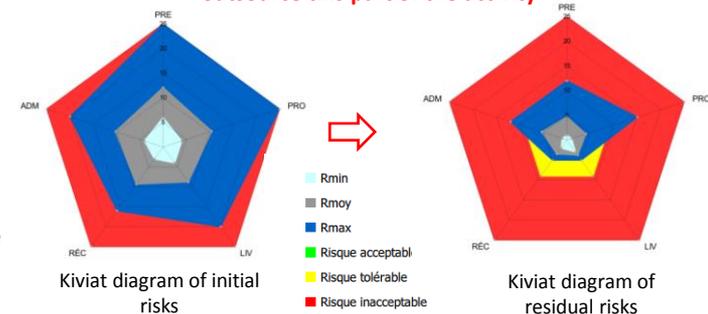
- management** (42%) including organisation and human resources
- hardware and IT equipment** (17.5%)
- logistical matters** (12.4%)



We have reduced the risk rate IC = 3 (47%) to an **acceptable risk rate with 85% with RC = 1** and 8.5% with RC = 2. However, **6 scenarios (6.5%) had a RC = 3**.

- The Kiviat diagrams showed that initially, **all phases of the system have a IC=C3**.
- 25 risk reduction action sheets**, among them **60%** required a **level 3** effort have been written.
- The **prescription (PRE)**, **production (PRO)** and **administration (ADM)** remain with an unacceptable risk RC=C3.
- The RC=C3 scenarios concerning the **preparations with short stability** (< 4 hours) and the **paediatric busulfan preparations** which require dosage adjustment for conditioning regimen.

→ The working group concluded that it is impossible to outsource this part of the activity



DISCUSSION / CONCLUSION

This GRA allowed us to **identify the important risks related to OS injectable preparations production**, particularly with **paediatric and adult preparations**. The majority of risk reduction actions requires a **great effort** to set up and **maintain a residual activity on the ordering site**, which represents a significant cost. It will enable heads of departments to decide whether or not to implement OS.