**USE OF A PROSPECTIVE RISK ANALYSIS METHOD TO IMPROVE THE SAFETY OF THE CANCER CHEMOTHERAPY PROCESS**

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**Background**

The application of cancer chemotherapy is a hazardous activity and numerous cases of errors leading to severe patients injuries are reported in the literature. To improve its safety, we re-engineered the process by centralizing the compounding at the pharmacy and by implementing information technologies at the prescription, production and administration steps. A comparative risk analysis of five consecutive process organisations was performed in parallel, to quantitatively demonstrate the respective impact of centralization and information technologies and to identify residual risks that may be the target of additional actions.

**Process organisations**

1. **Decentralized**
   - Pharmacist validation
   - Standardized production protocols
   - Production in isolators [A]

2. **Centralized [2002]**
   - Pharmacist validation
   - Standardized production protocols
   - Production in isolators [A]
   - Electronic transmission
   - Automatic calculation of the production protocol [C]

3. **Electronic prescribing [2005]**
   - Standardized and pre-filled prescription [B]
   - Electronic transmission
   - Computer-assisted production [D]

4. **Production with CATO® [2006]**
   - Electronic weighing control during production [D]

5. **Bedside scanning [2006]**
   - Electronic control at bedside

**FMECA Method**

The risk analysis was performed according to the Failure Modes, Effects and Criticality Analysis (FMECA) method:

- **Team definition**: 4 pharmacists, 1 oncologist, 1 nurse specialized in oncology
- **Failure modes definition**: Brainstorming: « What could possibly go wrong at each step? »
- **Criticality analysis**: Consensual quotation, based on explicit criteria²
  - Incidence (I) 1-10
  - Potential severity for patients (S) 1-9
  - Detectability (D) 1-9
- **Criticality index** = I x S x D
- **Data analysis**: Comparison of risk in the 5 processes

**Results**

- 27 failure modes → major reduction of the criticality (17↓, 3↑, 7→)
- The greatest improvements concerned the risk of errors in the production protocols (by a factor of 48), followed by readability problems during transmission (14) and product/dose errors during the production (8).
- Among the 6 criticality indexes remaining superior to 100 in the final process, 2 were judged to be acceptable, whereas further improvements were planned for the 4 others.

**Conclusion**

Centralization to the pharmacy was associated with a strong improvement but additional developments involving information technologies also contributed to a major risk reduction. A cost-effect analysis confirmed the pertinence of all developments, as the cost per gained criticality point remained stable all over the different phases.

**References**

2. Bonnabry P et al, Use of a systematic risk analysis method to improve security in the paediatric parenteral nutrition production, Qual Saf Health Care 2005;14:93

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1. Bedside scanning [2006]
2. Centralized [2002]
3. Electronic prescribing [2005]
4. Production with CATO® [2006]
5. Production protocol writing or validation error
6. Material preparation
7. Label edition
8. Administration
9. Delivery to the ward
10. Criticality index = I x S x D

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Conflict of interest: nothing to disclose