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

P. Bonnabry[1], L. Cingria[1], M. Ackermann[1], F. Sadeghipour[1], L. Bigler[2] , N. Mach[2]

[1]Pharmacy, [2]Oncology, University Hospitals of Geneva (HUG), Switzerland

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

2 Centralized [2002]
- Pharmacist validation
- Standardized production protocols
- Production in isolators **[A]**

3 Electronic prescribing [2005]
- Standardized and pre-filled prescription **[B]**
- Electronic transmission
- Automatic calculation of the production protocol **[C]**

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 criteria[2]

Incidence (I) 1-10
Potential severity for patients (S) 1-9
Detectability (D) 1-9

Criticality index = I x S x D

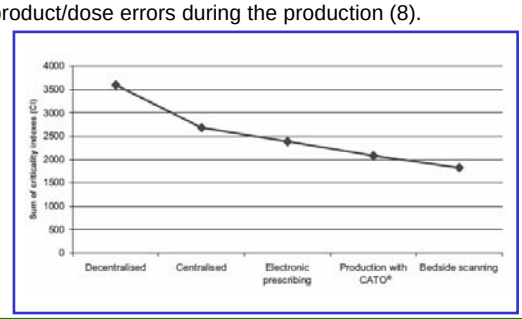
Data analysis
Comparison of risk in the 5 processes
Quantification of the gained security
Acceptability of the residual risk
Further safety improvements

Step	Failure modes	Criticality indexes (CI)					
		Decentralised	Centralised	Electronic prescribing	Production with CATO	Bedside scanning	
Prescription	Prescription protocol writing or validation error	175	175	175	175	175	?
	Choice of the wrong protocol	147	147	147	147	147	?
	Prescription error (i.e. dose, patient, route)	135	135	54	54	54	
Transmission	Late or forgotten transmission	42	42	42	42	42	
	Readability problems	98	70	7	7	7	
Validation	Failure to detect prescription error	343	175	175	175	175	?
Production protocol	Production protocol writing or validation error	-	63	63	63	63	
	Dosage error in production protocol	432	108	9	9	9	
Label edition	Error in label	75	45	18	18	18	
Material preparation	Error in material preparation	135	81	54	54	54	
	Use of expired drug	27	12	12	12	12	
	Needed product is missing	9	6	6	6	6	
Production	Late or forgotten production	6	8	8	8	8	
	Production error (product/dose)	432	288	288	54	54	
	Labelling error (inversion)	140	112	112	42	42	
	Microbial contamination during production	288	144	144	144	144	!
	Operator contamination	54	18	18	18	18	
Delivery to the ward	Delivery to the wrong ward	8	24	24	24	24	
Administration	Wrong patient	105	84	84	84	21	
	Wrong administration route	144	144	144	144	72	
	Wrong flow rate	120	120	120	120	48	
	Wrong administration day/time	40	40	40	40	20	
	Wrong conservation or drug expired	60	60	60	60	30	
	Nurse contamination	45	45	45	45	45	
	Patient contamination	32	32	32	32	32	
	Microbial contamination during administration	252	252	252	252	252	!
	Extravasation	252	252	252	252	252	?

! : Final risk accepted **?** : Further improvements were planned

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

1) Bonnabry P et al, Use of a prospective risk analysis method to improve the safety of the cancer chemotherapy process, Int J Qual Health Care 2006;18:9

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

Pharmacie

Download at http://www.hcuge.ch/Pharmacie/rd/posters.htm

11th Congress of the European Association of Hospital Pharmacists

Palexpo Congress Centre, Geneva, Switzerland
22 - 24 March 2006

HUG Hôpitaux Universitaires de Genève

Conflict of interest : nothing to disclose