Risk and pharmacoeconomic analyses to improve the safety of the injectable medication process in the paediatric and neonatal intensive care units

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Background

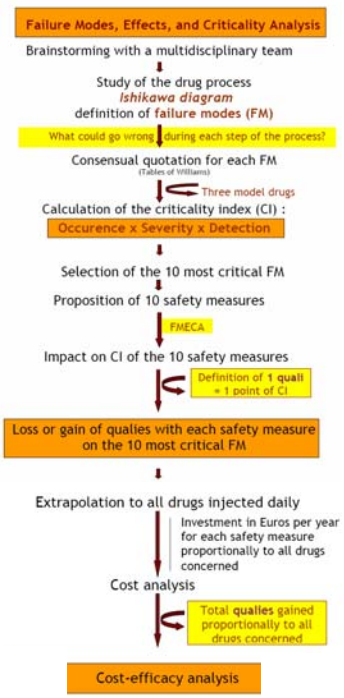
Many studies deal with adverse drug events among adults but there are relatively **few reports concerning children**. Intravenous therapy is a complex process (reconstitutions; dilutions). Dose calculations are a common contributor to medication error, even more in Paediatrics due to weight, age and unadapted formulations of drugs.

To analyse reliability problems, there has been a growing awareness that **prospective risk analysis** approaches used in a number of high hazard industries should be applied to health care. Among other methods, **Failure Modes, Effects and Criticality Analysis (FMECA)** is a well described tool that assesses a process systematically. It identifies possible or likely errors, called **Failure Modes** (FM), and gauges what their effect will be even before they take place. FMECA allows a quantitative evaluation of the criticality of each FM.

Objectives

- To perform a prospective risk analysis using FMECA to quantitatively evaluate the safety of the current medication process of injectables in the paediatric (10 beds) and neonatal (15 beds) intensive care units.
  We focuse especially on the steps of preparation and administration of drugs.
- To compare the potential impact of different safety measures on the risk
- To classify these measures from a pharmacoeconomic point of view

Methods



The 3 model drugs were:
gentamicin - morphine - dopamine

Conclusion

The use of a prospective risk analysis allowed us to quantitatively evaluate the relationship between the medication process of injectables and the paediatric patients' safety. It allowed us to build a strategy for continuous quality improvement by selecting the most appropriate safety measures.

Based on the results of the pharmaco-economic analysis, we decided to invest in the most cost-effective safety measures:

- **Clinical pharmacy**
- **Ready-to-use syringes**

Our institution is currently applying **CPOE**. A pocket **drug planer** was also created. The use of a **vial of dilution** is currently under evaluation in terms of accuracy and precision.

Reference

Williams E, Hosp Pharm 1994;29:331-37

Results

The Ishikawa diagram organized the 31 FM step by step (Fig. 1).

	Failure Modes	Currently Gentamicin	Morphine	Dopamine	Mean CI
Prescription	Dosage error	245	105	48	133
	Prescription omitted	126	54	18	66
	Prescription omitted to be retranscribed	105	12	9	42
Retranscription	Poor writing and reading	224	224	256	235
	Stop order omitted	60	40	16	39
Preparation	Error of writting on the preparation card stuck on the pumps	126	126	144	132
	Wrong selection between two different drugs (sound-alike, look-alike, etc.)	160	7	48	72
	Wrong selection between several dosages or salts of a drug	252	252	8	171
	Wrong selection of the solvent of reconstitution or dilution	162	81	96	113
	Microbial contamination	432	432	432	432
	Preparation of a drug forgotten	245	24	18	96
	Dosage error	343	294	392	343
	Dilution error	336	216	384	312
	Error of calculation of the patient's parameters	168	120	120	136
	Error in labelling of a prepared drug	192	224	256	224
	Precipitation (high concentration)	72	35	35	47
	Chemical degradation of drugs in a mixed preparation	108	105	56	90
	Inaccuracy of small volumes withdrawal	45	60	108	71
Administration	Pump doesn't work	56	48	72	59
	Wrong flow rate	343	294	315	317
	Physico-chemical incompatibilities	336	360	294	330
	Drug given twice	392	126	64	194
	Wrong administration time	378	72	56	169
	Wrong selection between two different drugs (sound-alike, look-alike, etc.)	96	56	32	61
	Wrong selection between several dosages or salts of a drug	336	280	8	208
	Wrong route of administration	28	28	70	42
	Wrong injection site	56	28	98	61
	Wrong patient	196	196	80	157
	Air introduced in central intravenous tubing	48	64	192	101
	Air introduced in peripheral intravenous tubing	24	32	96	51
Storage	Storage (protection for light, temperature control of drugs, expiry date)	48	30	36	38
	Total:	5738	4025	3857	4540

Tab. 1

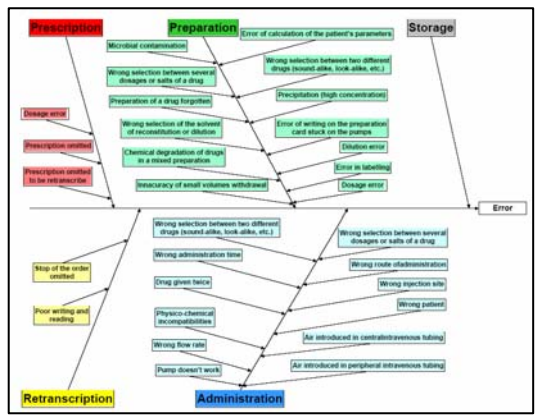


Fig. 1

The 10 most critical FM are presented in grey on Table 1. The most critical FM was the same for each model drug: **the microbial contamination during the preparation**. Among the 3 model drugs, gentamicin totalized the greatest sum of CI, followed by morphine and dopamine.

The impact of each safety measure on the 10 most critical FM is shown in Figure 2.

For the microbial contamination:

- 5 safety measures allowed a gain in qualies
- A maximum of 384 qualies was gained with ready-to-use syringes
- Intermediate dilution was associated with a loss of 72 qualies

Clinical pharmacist allowed a gain in qualies for 8 of the 10 most critical FM.

Fig. 2

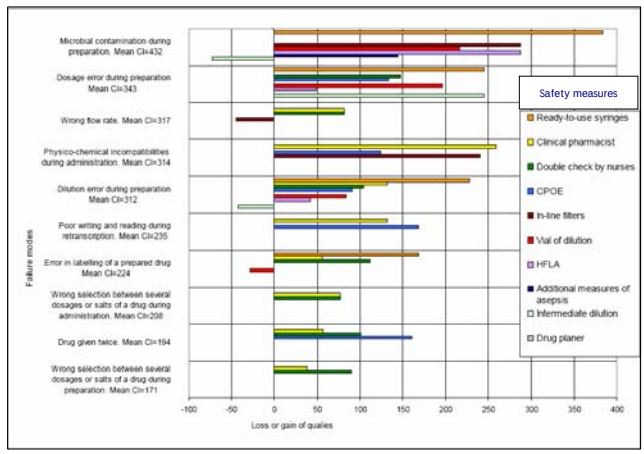
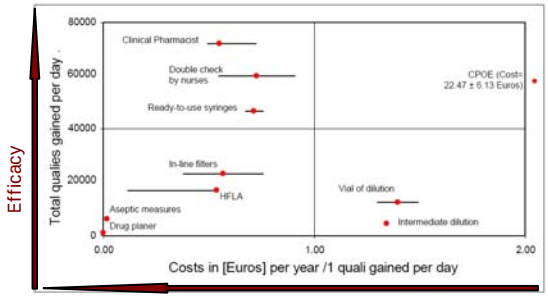


Fig. 3



Cost-efficacy ratio

The safety measures with both the best efficacy and cost-efficacy ratios were (see fig.3):

- **Clinical pharmacist**:
  72'060 total qualies; 1 quali=0.54 Euros;
- **Double check by nurses**:
  59'780 total qualies; 1 quali=0.71 Euros;
- **Ready-to-use syringes**:
  46'500 total qualies; 1 quali=0.72 Euros.

The highest ratio was obtained by CPOE, due to the very high costs of investment.