



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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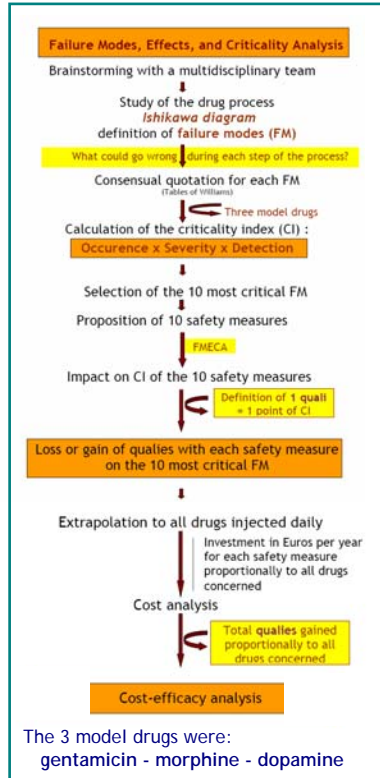
Background

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 focus 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



Results

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

Failure Modes	Currently			
	Gentamicin	Morphine	Dopamine	Mean CI
Dosage error	245	105	48	133
Prescription omitted	126	54	18	66
Description omitted to be retranscribed	105	12	9	42
Poor writing and reading	224	224	256	235
Stop order omitted	60	40	16	39
Error of writing on the preparation card stuck on the pumps	126	126	144	132
Wrong selection between two different drugs (round-alias, 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	372	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	25	25	47
Chemical degradation of drugs in a mixed preparation	108	105	56	90
Inaccuracy of small volumes withdrawal	45	60	108	71
Pump doesn't work	56	48	72	59
Wrong flow rate	343	294	315	317
Physico-chemical incompatibilities	236	360	294	330
Drug given twice	392	126	64	194
Wrong administration time	378	72	56	169
Wrong injection site	56	28	48	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 (protection for light, temperature control of drug, expiry date)	48	30	36	38
Total:	5738	4025	3857	4540

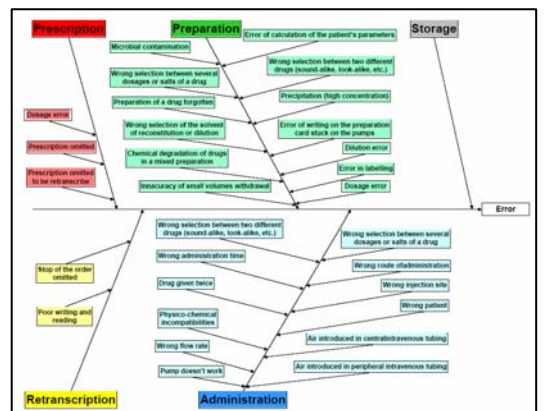


Fig. 1

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.

Tab. 1

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 qualities
 - A maximum of 384 qualities was gained with ready-to-use syringes
 - Intermediate dilution was associated with a loss of 72 qualities

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

Fig. 2

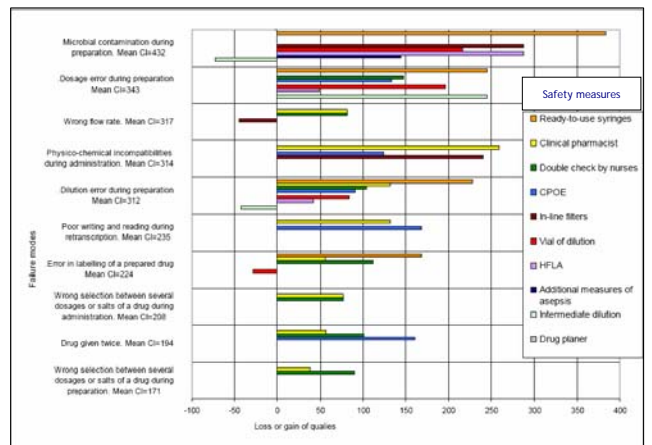
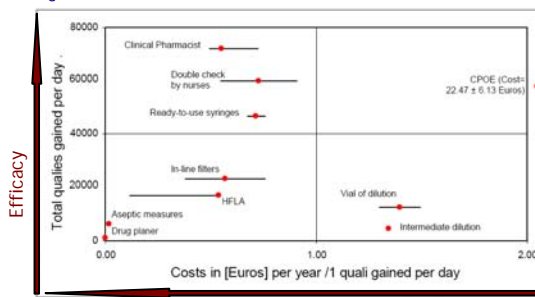


Fig. 3



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

- Clinical pharmacist: 72'060 total qualities; 1 quali=0.54 Euros;
 - Double check by nurses: 59'780 total qualities; 1 quali=0.71 Euros;
 - Ready-to-use syringes: 46'500 total qualities; 1 quali=0.72 Euros.
- The highest ratio was obtained by CPOE, due to the very high costs of investment.

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 pharmacoeconomic 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