Investigations following increasing complaints about infusion sets for safe administration of cytostatics

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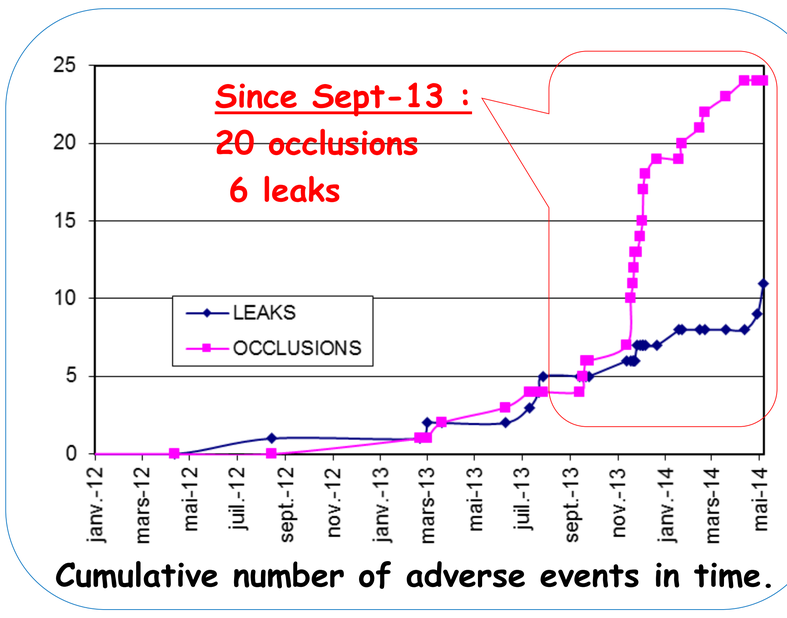
BACKGROUND

The french "Good Compounding Practices" recommend systematic use of flushed infusion lines for chemotherapy drugs administration.

CytoBolus Adapter Set ® (CODAN) is used since October, 2011 in the department of pediatric haematology for cytostatics packaged in syringes.



Cumulative number of adverse events in time.

Consequence of these adverse events

Automated infusion system : **alarm for overpressure**

Occlusions → ↘ Infusion rate → Administered dose?

Leaks → Exposition?

➡ ***Hypothesis: influence of viscosity?***

OBJECTIVE

Identify **risk factors** that lead to CytoBolus Adapter Set ® malfunction, especially **viscosity** as mentioned by the manufacturer.

CONCLUSION & PERSPECTIVE

Viscosity does not appear to be the determining factor that leads to malfunction.

Further investigations would be necessary on both material and human factors.

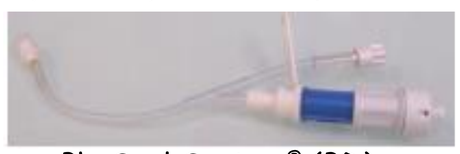
MATERIAL AND METHODS

❖ Meeting nurses, pharmacists and CODAN representatives → design of an Ishikawa diagram.
❖ Carrying out a standard form to collect adverse events.
❖ Describing experimental design: influence of device, viscosity and infusion rate on delivered volume.

ADMINISTRATION DEVICES
Three connectors


Plain tube (VYGON)


CytoBolus Adapter Set® (CODAN) with a 0.2 µm filter


PhaSeal System® (BD): Connector + Injector

SOLUTIONS
Three solutions

Dextrose 10%

Dextrose 5%

Water for injection

VISCOSITY

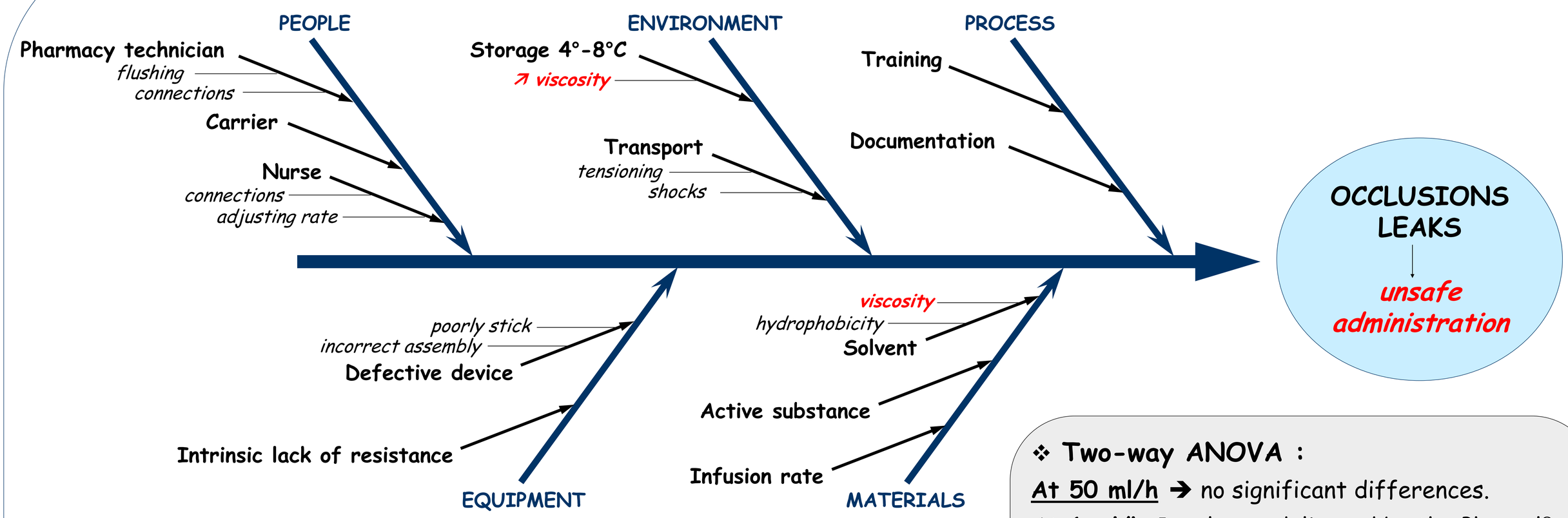
AUTOMATED INFUSION SYSTEM
Orchestra® (FRESENIUS)

Weighing
- Volume estimates based on density of each solution

Observations
- Alarms
- Device deteriorations

Statistics
- Two-way ANOVA test
- k = 12 replications for each combination of device and solution

RESULTS



CALCULATED VOLUMES: MEAN ± STANDARD DEVIATION (mL)						
	Water		Dextrose 5%		Dextrose 10%	
Rate (mL/h)	1	50	1	50	1	50
Plain tube	19.99 ± 0.29	49.79 ± 0.22	19.90 ± 0.21	50.03 ± 0.11	19.83 ± 0.24	49.97 ± 0.24
CytoBolus Adapter Set®	19.72 ± 0.25	50.04 ± 0.25	19.74 ± 0.15	49.85 ± 0.39	19.58 ± 1.04	49.80 ± 0.20
PhaSeal®	19.21 ± 0.29	49.80 ± 0.26	19.82 ± 0.32	49.51 ± 0.62	19.77 ± 0.21	50.16 ± 0.56

❖ **Two-way ANOVA :**

At 50 ml/h ➔ no significant differences.

At 1 ml/h ➔ volumes delivered by the Phaseal® system unexpectedly lower with water for injection than dextrose 5% (p=0.00405) and dextrose 10% (p=0.00334).

➔ **Acceptable results,** in compliance with the 3% accuracy of the automated infusion system (norm NF S 90-251).

❖ **No leak, no defective devices for the 216 experiments.**

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