

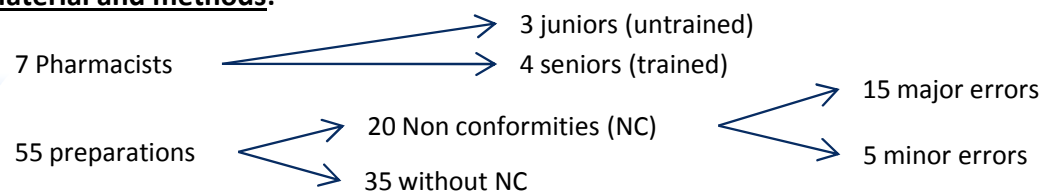
Assessment of pharmaceutical control release of chemotherapy preparations using errors simulation program

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Introduction: Control release of preparations is mandatory referred to French good manufacturing practices⁽¹⁾ even for tailor-made cytotoxic preparations. However, the release process is based mainly on **human multiple checks**. Our work aimed to assess the reliability of pharmacists involved in this control using **simulation program** including intentional non-conformity (NC).

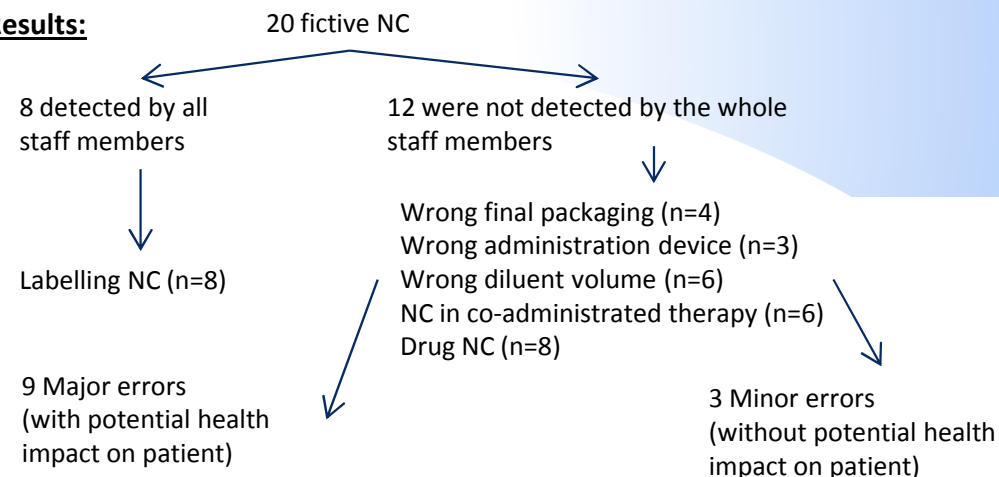
Material and methods:



Non conformities classification :

Errors related to drug (e.g. wrong dose, wrong final concentration)
Wrong diluent (e.g. NaCl vs glucose)
Wrong administration device (e.g lack of required filter)
Lack of checks controls (drug, diluent device)
Errors related to co-administrated therapy (e.g. lidocaine or MESNA forgotten)
Errors in labelling (e.g label exchanges, errors of beyond to use date)
Final packaging (e.g. UV protect)

Results:



	Mean NC undetected	Time per preparation		
		Mean	Max	Min
Trained pharmacists	1.5	27,4 ± 11,4s	60s	12s
Untrained pharmacists	5.33	37,2 ± 17,9s	90s	11s
Trained and untrained		32,6 ± 15,6s	90s	11s

Conclusion: Untrained pharmacists were less efficient in NC detection. However, whatever the status, unnegligible number of errors were not detected by all pharmacist justifying implementation of an education training program for pharmaceutical control release validated by the simulation program based on errors simulation.