RISK ASSESSMENT OF CYTOTOXIC COMPOUNDING: MANUAL vs ROBOTIC

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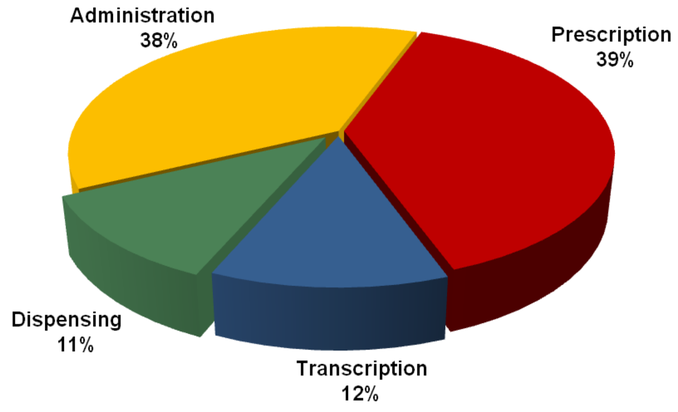
BACKGROUND AND PURPOSE

Errors in cytotoxic drug compounding can cause serious harm to patients due to the low therapeutic ratio. In a previous study[1] , the prescription and the administration errors were reported as the main causes of medication errors in the oncology workflow. However, no data related to the manipulation phase were shown, likely due to the lack of verifications in the routine that makes errors difficult to detect.

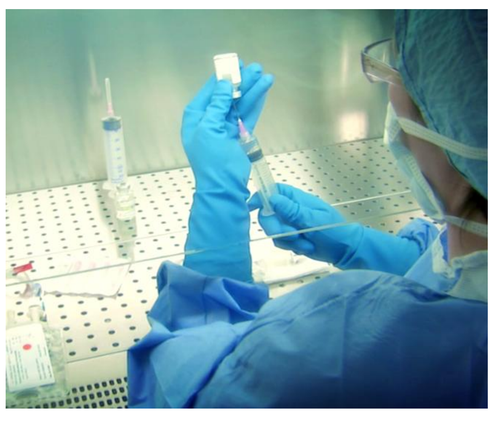
Robots are intended to decrease the risk of medication errors through 100% verification and traceability of the entire production process.

This work is aimed at assessing the risk of medication errors in manual and automated compounding, taking into consideration the procedures and controls applied in both cases.

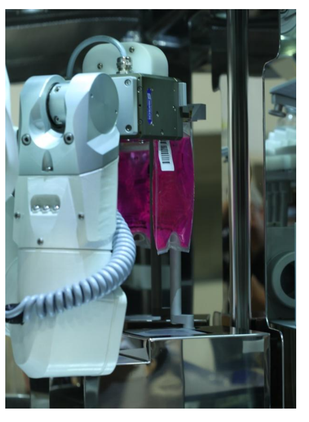


Errors percentage by type of adverse drug events. Data taken from Leape et.al, JAMA 1995, 274, 35.

MATERIAL AND METHOD



Manual compounding



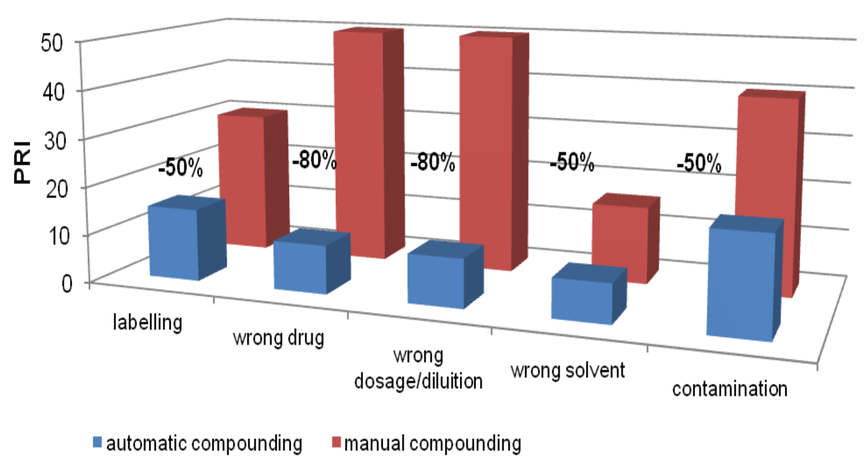
Automatic compounding

The FMECA technique was applied to the procedures for the manual compounding defined in the Recommendations of the Italian Ministry of Health and to the compounding procedures of the APOTECAchemo robot. The analysis involved two Oncology Pharmacies working with automation in daily routine since 2007 and 2011 respectively. 5 macro-failure modes for the compounding process were identified and the corresponding Priority Risk Indexes (PRI) were calculated:

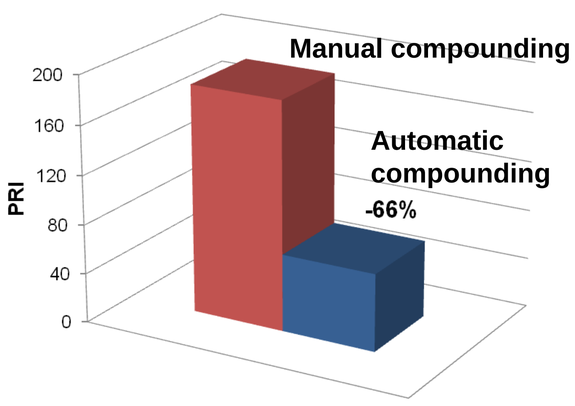
- labelling: sticking the final preparation with the wrong label;
- wrong drug: picking and compounding the incorrect drug;
- wrong dosage/dilution: transcription and administration of a wrong quantity of drug or drug dilution;
- wrong solvent: dilution of drug in the erroneous solution;
- contamination: accidental drug spillage.

RESULTS

The failure modes that show higher benefits in risk mitigation are the wrong drug and wrong dosage with a PRI decrease of 80% (from 50 to 10). Indeed the redundant controls (vision system, scale, photocells) on the loaded vials guarantee the compounding of the right drug. In addition, the drug is dosed with a calibrated syringe pump and independently verified with the scale. The other failure modes reported a risk reduction of 50% and on the whole the total PRI passes from 186 in case of the manual activity to 63 for the robotic one.



CONCLUSION



The FMECA analysis shows an overall reduction of the PRI over 66% with the robotic compounding with respect to the manual production. Automation not only decreases the occurrence of dangerous events thanks to the complete control of every single step of the compounding process, but also develops an error detection system through independent verification processes.

References:
[1] Leape et al. *JAMA* **1995**, 274, 35.

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