Quality control issues not detected by chemotherapy video monitoring system

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Introduction

Preparing chemotherapies (CT) **= high-risk process** → Video automatic error recognition system (**Drugcam ®**) = **assist, monitor preparation and release** of the CT → Review of **the limits of our process** → **Analysis** of a sample of the preparations, looking for **undetected quality control issues** (QC)

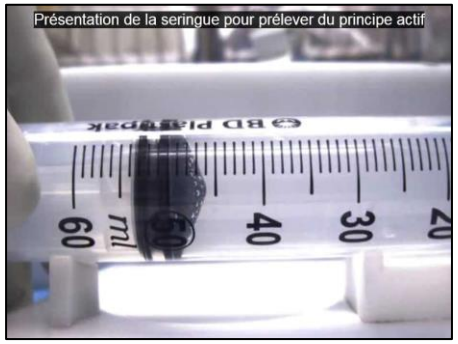
Material and method

- Complete analysis of the videos of a sample of preparations prepared in **2023**
- **Manipulators: Unit's pharmacy technicians** (PPH) and **on-call pharmacists**
- Analysis **5 types of preparations** (chosen for the diversity of theirs preparation steps)

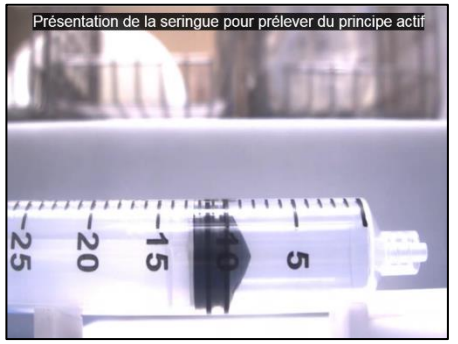
CARFILZOMIB	Reconstitution step
BUSULFAN	Use of a needle and air intake
PACLITAXEL	Specific infusion line
CYTARABINE	Conditioned in a syringe
5-FLUOROURACIL (5-FU)	Conditioned in an infusor

Results

- 199 videos analyzed (preparations made by 12 PPH and 11 pharmacists) → 2 % of non-compliance (4 preparations):
  - 2 preparations of **CARFILZOMIB** bags: injection of the medication without showing the volume of the solution to the camera → the manipulator "pleased" the system by showing a syringe filled with air
  - **5 FU** portable infusor preparation: underdosed, injection of solvent instead of the product (57 % of prescribed dose)
  - **BUSULFAN** preparation: polycarbonate access device (PAD) used instead of a needle and an air intake (risk of container-content interaction)



Syringe filled with 5-fu



Syringe filled with air

Discussion and Conclusion

- The automatic error recognition system of Drugcam® is **not 100 % reliable** → it does not detect whether the syringe contains a liquid or not, only the position of the plunger
- Non-compliant preparations → lack of traceability:
  - 2 **CARFILZOMIB** → no proof of conformity of the final product
  - **5-FU** infusor → no way the system could automatically detect this error
  - **BUSULFAN** → risk of particles being released from the PAD due to the incompatibility between the polycarbonate and the excipients of the busulfan
- Three of these non-conformities **could have been detected** by:
  - Checking the full preparation video before product release
  - Using an analytical QC of the finished preparation
- Current work load → does not allow the pharmaceutical team to watch the complete videos of all the preparations checked by this system
- **Actions taken** :
  - Remind the operators of procedures
  - Presentation of these results to the unit to discuss improvements to be made