Automated unit-dose dispensing system : evaluation of the control method

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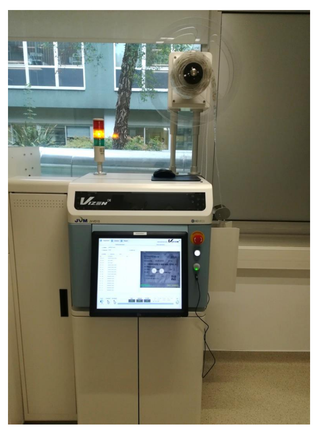
Introduction

- 436 beds supported on november 2018 (care homes)
- Repacking system in wich oral solid forms are removed from the manufacturer's original packs and assembled into single dose bag
- 2 ways of managing drugs ➔ canisters (high prescribed drugs)
  ➔ trays (low prescribed drugs)
- **Splitting drugs also dispensed** by the automated system

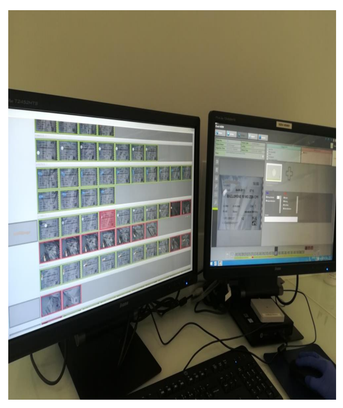
Risky steps because of the human intervention

Automated unit dose dispensing system ATDPS 400– JVM© Slide Type



Automatic inspection machine : Vizen® (JVM©) takes photos of each unit dose and compares to its database

Bags winder and cutter : Wizer® (JVM©)



Technician checks the non conformities (NC) detected by Vizen® ➔ **validation step**

Technician corrects real non conformities

Purpose

Quality and risk management

- Evaluate the performance of the inspection machine
- Ensure the validation step is correctly realised

Method

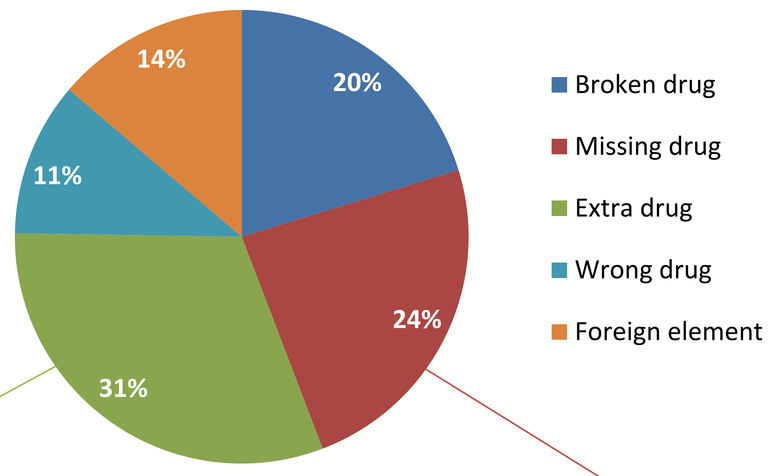
During 12 weeks :

- All bags have been analysed *a posteriori* thanks to the photo took by the Vizen®,
- **The non conformities** (NC) and the **validation errors** have been classified into detection errors (false positives), and **real NC** (*i.e :* missing drug, extra drug, foreign element in the bag, broken drug, wrong medication)

Results – Non conformities (NC)

Unit doses produced (N)	**225 456**
NC (%)	**8,32 %**
Real NC (%)	**1,53 %**
Pourcentage of detection error/total NC	**80,6%**

Repartition of real NC (n =3442)



1/3 of total NC is about 5 drugs
- Diffu K® 600mg
- ½ Seresta® 50mg
- ½ Alprazolam 0,25mg
- ½ Clozapine 25mg
- Alprazolam 0,5mg

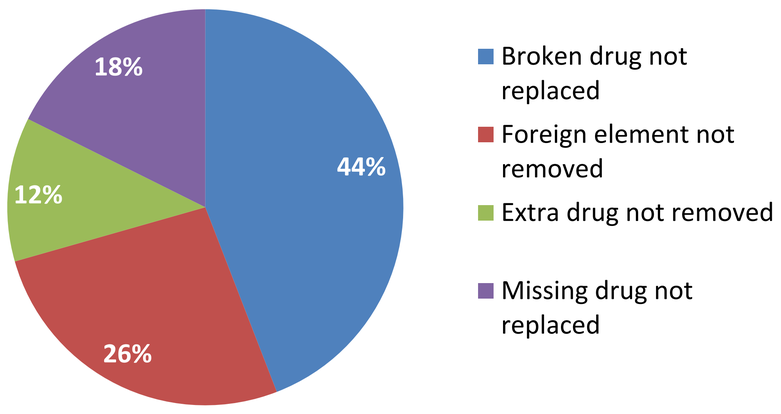
1/4 of detection errors (false positives) is only about 4 drugs
- Seresta® 10mg
- ½ Alprazolam 0,25mg
- Ramipril 1,25mg
- ½ Seresta® 50mg

Extra drug
50% of bags with extra drug➔**½ Seresta® 50 mg**
30% of bags with extra drug ➔**Diffu K® 600 mg**

Missing drug
Diffu K 600 mg represents 60% of bags with wrong medication

Results – Validation errors

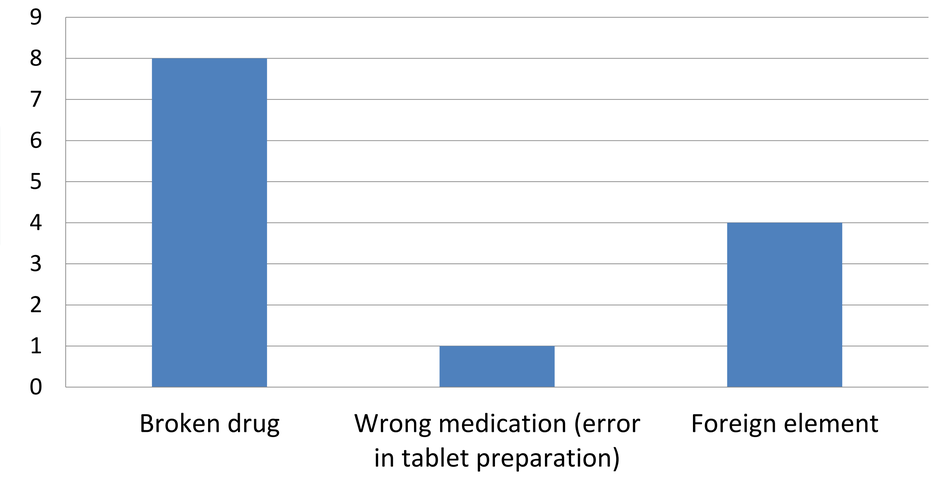
Validation errors = bags with a real non conformity, declared non conformed by the Vizen®, but wrongly classified in detection error by the technician.



Only 34 validation errors = 0,015% of the bags analysed during 3 months

Results – NC not detected by Vizen®

13 NC have not been detected by the Vizen®



Broken drugs (mostly ½ tablets) represent 40% of the NC not seen by Vizen
➡ During the study we realised that the color of ½ tablets hasn't been analysed. For security reason this parameter has been modified.

Discussion/Conclusion

- Automated dispensing of **splitting drugs** is more safe for patients but it **generates most of NC**.
- This study also highlighted that our team spend time and pay attention to false NC which represent **80%** of the NC detected by the Vizen® .
  We are committed to decrease NC by :
  - ➔ removing drugs from the automated system (i.e: **Diffu K® 600 mg)**
  - ➔ reviewing prescription (i.e : **Seresta® 25 mg➔ 2 Seresta ®10 mg)**
  - ➔ working with JVM © team to improve the NC detection

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