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

Pauline FREMAUX1, Amélie FIEDLER2, Joachim LE BOIT3, Virginie COGULET4
1Pharmacie Cavale Blanche – CHRU Brest, Issoudun Tréguier Péganet, 22200 Brest, FRANCE

Introduction

• 436 beds supported on november 2018 (care homes)
• Re-packing system in which 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

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 tool 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)

<table>
<thead>
<tr>
<th>Unit doses produced (N)</th>
<th>225 456</th>
</tr>
</thead>
<tbody>
<tr>
<td>NC (%)</td>
<td>8,32 %</td>
</tr>
<tr>
<td>Real NC (%)</td>
<td>1,53 %</td>
</tr>
<tr>
<td>Percentage of detection error/total NC</td>
<td>80,6%</td>
</tr>
</tbody>
</table>

Repartition of real NC (n=3442)

| Broken drug | 20% |
| Missing drug | 14% |
| Extra drug | 11% |
| Wrong drug | 31% |
| Foreign element | 24% |

Broken drug
50% of bags with extra drug
\(\times\) 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

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
- Ranimil 1,25mg
- ½ Seresta® 50mg

Results – Validation errors

| Broken drug not replaced | 44% |
| Foreign element not removed | 12% |
| Extra drug not removed | 26% |
| Missing drug not replaced | 18% |

Only 14 validation errors = 0,015% of the bags analysed during 3 months

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 ➔ Seresta® *10 mg) ➔ working with JVM® team to improve the NC detection

Results – NC not detected by Vizen®

| Broken drug | 9 |
| Wrong medication (error in tablet preparation) | 5 |
| Foreign element | 3 |

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.

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