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INTRODUCTION

In our hospital, portable antibiotic dispensers are prepared for patients at home. The process uses manual filling of the diffusers by the agents, which leads to musculoskeletal disorders (MSD), variability in the accuracy of the preparation and risks of filling errors. The objective of this work is to define and validate a new diffuser filling process that limits MSD and improves the accuracy of preparations.

Définition of the new process

Accuracy et Repeatability

Media Fill Test

Risk Analysis

Formulation

Training

Equipment :

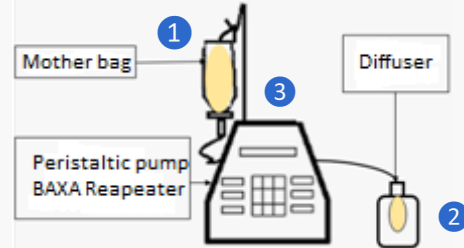
Peristaltic pump
BAXA Reapeater®

Concertation meeting:

- Brainstorming : Pharmacist + PPH
- Blank tests of filling the diffusers with the pump



Validate the accuracy of critical points



- 1 Tests on the production of a Ceftazidime mother bag for 14 diffusers
- HPLC determination of the ATB
- 2 Filling of 14 diffusers with glucose solution and dosing of diffusers n°1 -7 and 14 - Enzymatic dosing
- 3 Repeatability of the volume delivered by the pump: 14 volumes of 110 ml measured with a test tube

Preparation of a TSB mother bag + distribution in 5 pockets (= diffusers)

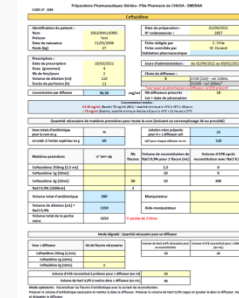
3 days

Same operator
« Worst case » :

- ↑ pump speed
- Percution of septa of multiple TSB vials
- Use of a single spike for the entire preparation

Speed AMDEC :
Brainstorming
Team meeting
Action plan
Fishbone diagram

Documents quality
Production sheet
Label



Empowerment of taff
for the new
preparation process

Preparation of a mother bag and then redistribution to the diffusers using the pump
Allow for an overfill of 1 diffuser to compensate for purging

↓ 58% of 80% of tractions

- 1 Ceftazidime dose of the stock bag: 11.7 mg/mL (VT 11.82 mg/mL) i.e. <1% difference
- 2 The glucose dosage of the diffusers 1 - 7 - 14 of batch n°2 is < 2% of the VT = 32 mM
- 3 The volumes delivered by the pump range from 110 - 111 mL, or < 1%.

Clarity of pockets at D7 and D14
Sterility of agar plates at D7 and D14
→ Sterile process

6 risks identified : of which
1 action plan
-Drafting of a downgraded procedure if the weight of a non-compliant dispenser

Computerisation of the production sheet and labels
Pre-filled calculation of volumes to be taken

Companion training first as a manipulator and then as an assistant manipulator

DISCUSSION - CONCLUSION

This new process allows the concentration of antibiotic in the diffusers to be homogenised and the batch to be filled accurately. The method used in this work to support a change in practice made it possible to control the risks of the new process. The collaboration of the agents throughout the trials is a guarantee of success for the long-term involvement of the teams. A calculation of the cost of retrocession should be carried out.