

# Management of a contamination episode in a Parenteral Nutrient Mixture preparation unit

R. Bettayeb<sup>1</sup>, M. Durand<sup>1</sup>, J. Leenhardt<sup>1</sup>, R. Mazet<sup>1</sup>, MD. Desruet<sup>1</sup>, P. Bedouch<sup>2</sup>

<sup>1</sup> UM Pharmacotechny, Pharmacy Division, Grenoble Alpes Hospital and University Centre, France ; <sup>2</sup> Head of the Pharmacy Division, Grenoble Alpes Hospital and University Centre, France

The unit of Pharmaceutical Preparation of CHU Grenoble Alpes prepare 9000 bags of Parenteral Nutrition (PN) adults and 4200 bags of PN pediactrics.

Sterility of parenteral nutrition mixtures is verified by anaerobic and aerobic seeding of preparations incubated for 5 days (BACTEC™). For each bag produced a sample is conserved in preparation unit for perform a recontrol (physicochemical or bacteriological)

**In May 2019, an aerobic test was positive for BGN Pseudomonas putida on a bag for adult Parenteral Nutrition (PN).**

**The product batch involved patients followed at home.**

**The objective of this work is to present the acute management of this incident, the investigations carried out to identify the origin of the contamination and the corrective actions to be implemented.**



05/29/2019 at 22h30, an aerobic BACTEC™ sample of PN was positive

- ▶ **Responsible pathogen** - *Pseudomonas putida*, Gram-negative Bacillus
- ▶ **Contaminated Bags** = one of the bag of adult NP produced on the morning of 29/05
- ▶ **Detection delay** = 6h after the production

## Immediate Actions

1. Define an exactly list of patients potentially concerned with the help of lot folder, ordering number, production order
2. Inform the doctors of the department concerned and define for each patient an substitution for parenteral nutrition
3. Call all patients for stopping administration if necessary and put each bag in quarantine
4. Do a monitoring table with patient name, chronological order of production, number of sample, delay of positive Bactec, bacteriological results
5. Sending all samples of the lot for inoculation and analysis
6. Inform Hospital Hygiene Department, d responsable of structure and Pharmacy department
7. Inform the Regional Health Agency

## Investigations

1. Searching causative agent :
  - Supplementary sampling of surfaces in all preparation unit
  - Analysis of microbiological sampling results realized during the production : environmental surfaces and hand of operators
  - Investigation of the agents concerned and detailed retrospective analysis
  - Bacteriological results of all PN bags samples
2. Analysis and observation of cleaning practices
3. Identification of batches of raw materials used
4. Intensive cleaning of all unit with peracetic acid

## Corrective actions

- **24 hour delay** for the dispensing of all Parenteral Nutrition bags
- **Removal of the single channel automaton** used for the lipids → integrating the lipids on the mutlirate coumpounding device.Medimix Multi 4120R configuration
- Formation of operator have been reevaluated

## Results

- 69 environmental samples carried out on 05/31/2019
- Absence of *pseudomonas putida* et of *microbacterium species*
- Some pratice defects with operator of production but nothing which can explains bag contamination
- Analaysis of production and bag composition
- \* 22 bags of PN adult were contaminated :
  - Only ternary adult formulation
  - Binary adult formulation are negative
  - No bags of PN pediatric were contaminated : binary formulation or use of ready ti use ingredient with lipids
- For adult production, lipids are prepare with a specific coumpounding device with a single way

The chronology of the incident and the investigations allowed us to objectify that the contamination was linked to the use of the single-channel automaton.

In addition, corrective actions were implemented in order to secure the return of production activity in the unit.

The idea of developing a rapid diagnosis method of samples would make it possible to deliver preparations more quickly, particularly for pediatric departments that receive patients whose needs change from day to day.