



CENTRE HOSPITALIER JACQUES CŒUR

Isolator's total breakdown in a production unit: how to face the emergency ?

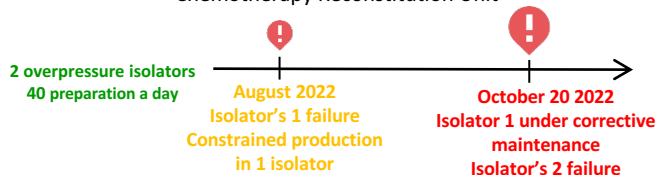
M. Fontaine ; L. Eyquem ; B. Laluque

Pharmacie à Usage Intérieur, Centre Hospitalier Jacques Cœur, 18000 Bourges



Introduction

Chemotherapy Reconstitution Unit



- **Maintaining** the **availability** of chemotherapies
- **Managing** the **risks** associated with an unexpectedly degraded mode

Material and methods

October 20 2022 = total breakdown

Multi-disciplinary meeting :



- pharmacist
- oncologists
- coordinator nurse
- hospital management

Decision to maintain the original program as far as possible

Identified risks

- Bacteriological contamination of preparations for immunocompromised patients
- Agents exposure to cytotoxics
- Defect of the MSC II zone : polluted air not evacuated
- Unprecedented and poorly anticipated situation
- Duration = 12 days of production

Results - Discussion

1 – Proposed degraded methods:

- **Closed system:**

- ✓ Connects to all vial used
- ✓ Toxi-Guard® air-cleaning technology = guaranteed sterility for the preparation and the environment, safety for the operator

- **Laminar flow hood:**

- ✓ Bacteriological risk under control
- ✗ Non-recycled air = **risk of cytotoxics exposure for the operator**

2- Selected method:

Combining the two methods → closed system used under the laminar flow hood

Tevadaptor®
(syringe adaptor + vial adaptor)

<https://www.bbraun.co.uk/en/products-and-therapies/infusion-therapy/tevadaptor-.html#chemfort-components>



Average production: 40 preparations/day = **No reduction in production**

Excess cost:

- **4,000** euros : **closed systems** (not usually used)
- **3,000** euros : leftover unused products for safety reasons

This exceptional situation enabled us to measure the ability of our medical and pharmaceutical teams to adapt and collaborate and to prepare for:

- ✓ a potential recurrence of the incident
- ✓ isolator's replacement in autumn 2023

A declaration of serious adverse event was notified to the French regional health agency