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Background

The Total Parenteral Nutrition (TPN) production facility of the pediatric hospital R. Debré produces **around 20,000 units per year** with 2 Baxa EM2400 compounders.

In June 2012, a shortage of the calcium source (10% sterile solution of calcium gluconate in 500 mL Bottle) occurred. To overcome this problem, we first tried to **import an alternative source** but the administrative delay was too long. The only sources available within a month were **10 mL plastic or glass ampoules**. The estimated consumption was around 300 ampoules per production day.

To maintain efficiency and safety of the TPN facility, it has been decided to settle a **calcium gluconate bags production** from 10mL ampoules by sterilizing filtration to maintain the safety of preparation.

Purpose

Evaluate the **overcost** caused by setting up this production and the **time** raised.

Materials and Methods

The Pharmacy compounded calcium gluconate bags (250 mL) made from plastic ampoules (picture 1) after filtration (0.22µm filters (Sterivex Millipore)) (picture 2), using a Repeater Pump® (Baxter) (picture 3), in a laminar air flow cabinet.

The cost of setting a new procedure and of the compounding were evaluated in different subparts (materials, control, staff).



Picture 1



Picture 2



Picture 3

Results

228 bags were produced for this 20 days of production shortage (19 batches of 12 bags).



Time raised to set up the production (in half day) :

- information search : **10**
- tests sessions out of the laminar air flow cabinet : **2**
- calculate new flow factors : **2**
- writing procedure : **3**
- process validation within the compounding facility : **2**
- personnel training : **3**, and assessment : **4**

Conclusions

Despite a **major overcost**, compounding calcium gluconate bags has ensured the TPN facility to continue its production. From a risk assessment point of view, identification of various suppliers and increasing stocks of the raw materials would allow easier management in case of stockout.