

Background

Following MC within the isolator throughout 2018, a comparative study was carried out. The aim was to compare manufacturing and sampling practices with other Hospital Centers (HC) to standardize our practices.

Materials and Methods

A multicentric survey was realized by mail through a web-based survey (Google Form®), from February 2019 to April 2019. This prospective study was carried out at 18 HC supposed to manufacture PN. Three items were studied (work environment, microbiological sampling and isolator cleaning).

Results - Discussion

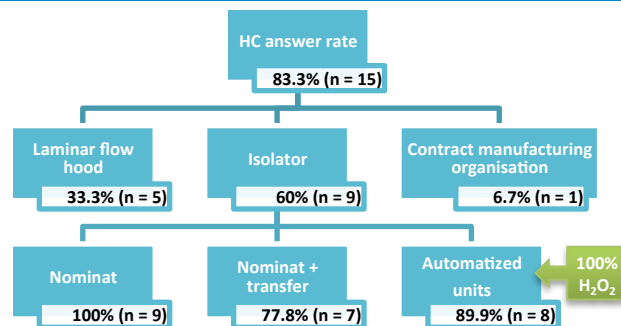


Figure 1 : Work environment

Microbiological samplings were carried out using :

- swabs : 53.4% (n=8)
- contact-agar : 33.3% (n=5)
- other : 13.3% (n=2)

Same microbiological control plan	On Week (%)	On Month (%)
Units using only a nominat to sterilize (n=2)	50	77
Units using a nominat and a transfer to sterilize (n=7)	38.6	57.1
Automatized units (n=8)	47.5	67.5

Table 1 : Percentage of same microbiological control plan

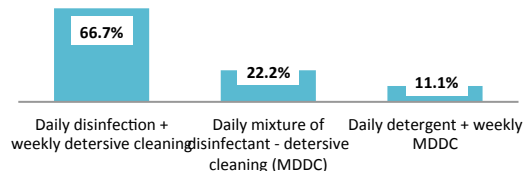


Figure 2 : Percentage of cleaning protocol per HC

In 2018, 88.9% of HC identified microbiological contamination (n=91).

Following positive sampling, 87.5% of HC did a resampling and took corrective measures.

The number of MC compared to the number of manufactured admixtures (MA) varies between 0% and 0.63%, the average rate being 0.21%.



Figure 3 : Main contamination sites

Conclusion

With a MC rate of 89%, PN centers are established to not be fault-free. MC rate is not correlated with yearly production volume. Thus, harmonization of cleaning and control practices, in accordance with the manufacturer, could allow a better and higher quality procedure.