Process optimisation to improve aseptic unit efficiency with large volume solutions

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Introduction

When adequate feeding through the alimentary tract is not possible, nutrients may be given by intravenous infusion, thus bypassing the gut. When patients require tailored nutrients, a stable regimen of compounded parenteral nutrition is formulated using a mix of macro and micro ingredients.

Thousands of parenteral nutrition bags are compounded each month in the United Kingdom, with a growing demand on capacity in a market with a growth rate of approximately 6.3% per annum.[1] To maximise the limited aseptic capacity, compounding units are required to focus their time on operational gains and not just infrastructure and workforce expansion, whilst incorporating a reduction in carbon footprint and maintaining quality.

The aim of this study was to identify and understand the impact larger volume containers have on optimising aseptic production. This is of particular importance against the backdrop of aseptic capacity, operational challenges, and workforce pressures.

Methods

This time and motion study was conducted in B. Braun's aseptic unit. Observational data was collected between December 2022 and March 2023, five days of observations were recorded for both the 500 ml and 1000 ml Lipidem® bottles.

Lipidem®; a lipid emulsion macro ingredient, containing Omega-3-acid triglycerides from Fish Oil, forms part of the final lipid containing 3-in-1 regimen.

The time to complete the four transfer stages (collectively referred to as 'transfer time') was recorded (Figure 1). Bottle change duration, and total volume of Lipidem® pumped and wasted was also recorded.

Information on pallet size, individual item prices and gross item weight was collected retrospectively.

Figure 1: Transfer stages and number of disinfection wipes used per stage.

Results

Overall, there was a 46% reduction in total compounder downtime across the observational period for the 1000 ml containers compared to the 500 ml containers; 47 minutes 53 seconds and 1 hour 28 minutes and 24 seconds respectively.

Significantly fewer number of 1000 ml bottle changes, and thus aseptic manipulations (p=0.012) accounted for the reduction in total compounder downtime observed (Figure 2).

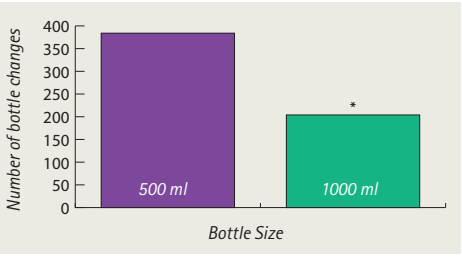

*Figure 2: Number of Lipidem® bottle changes and aseptic manipulations during the 5 day observation, (*p=0.012).*

When looking at transfer time in isolation, the use of the 1000 ml containers translated into time efficiencies. There was no significant difference in the total transfer time (p=0.73) between the two container sizes, however 41% fewer 1000 ml bottles were required to pump 16% greater volume.

Furthermore, the volume of Lipidem® wasted was not significantly different between the two container sizes, p=0.214. The total number of wipes used during the transfer stage for the 1000 ml bottles was 12% less compared to the 500 ml bottles, equalling a cost difference across the 5-day observational period of £10.74 in favour of the larger container.

The use of the larger container is supportive of the NHS' sustainability agenda. Table 1 demonstrates the reduction in gross weight of production materials that can be achieved by utilising the 1000 ml containers. This has implications both in terms of reducing the unit's carbon footprint and the cost associated with disposal of material waste.

Table 1: Gross weight of containers

500 ml Lipidem®	
Number of bottles	384
Gross weight (all materials)	0.338 kg
Total gross weight	129.8 kg
1000 ml Lipidem®	
Number of bottles	204
Gross weight (all materials)	0.534 kg
Total gross weight	108.9 kg
Difference in total gross weight	**-20.9 kg**

A pallet of 1000 ml Lipidem® holds 20% greater volume compared to a pallet of 500 ml Lipidem® (Image 1). This has the potential to offer not only more efficient pharmacy storage, but also further environment benefits, such as reduced transport due to fewer pallets required for a given volume.

Image 1: Lipidem® pallets; 1000 ml (left) and 500 ml (right).

Conclusion and Implications

From this study we concluded that compared to the 500 ml, use of the 1000 ml Lipidem® bottles translated into end-to-end time efficiencies; in the transfer stages, reduced total compounder downtime and shorter compounder sessions freed up staff for other tasks.

Process and quality improvements have been achieved through the reduction in the number of aseptic manipulations during the production process. This reduces the risk for the final product and adheres to MHRA's guidance for specials manufacturers[2]. The unit has also seen a reduction in the total number of items required as fewer disinfectant wipes are required during the transfer stages for the 1000 ml bottles, offering both cost and environmental benefits.

Although compounder capacity is dependent on the volume that can be pumped during the session, the results from this study highlight how small changes such as product volume has the potential to unlock significant operational gains.

The findings from this study can be extrapolated to aseptic units of different sizes and containers across different products.

Based on the results from this study, a recommendation to implement larger containers across the Aminoplasmal® line has been made.

For Healthcare Professionals Only

Prescribing Information available on request.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to B. Braun Medical Ltd (tel 0800 2980299).

References

1. Pharmacy & Medicines Optimisation Team (2019). Pharmacy Aseptic Services in England
2. MHRA. MHRA Guidance for Specials Manufacturers. 2021 Jan.

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