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The University of Manchester

The Leeds Teaching Hospitals NHS Trust

Evaluating the Ability to Standardise the Validation of Automated Compounding Devices for the Preparation of Parenteral Nutrition in NHS Hospitals

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Introduction

This research evaluated the ability to standardise the validation of Automated Compounding Devices (ACDs) across National Healthcare Service (NHS) hospitals in the United Kingdom (UK). The need for standardisation was driven from the wide variation in validation practices between NHS hospitals which could affect the safety and efficacy of Parenteral Nutrition (PN) products produced on ACDs and can result in fatal incidents especially in clinically vulnerable patients (1). It was also driven from the lack of specific published guidance related to how to effectively validate an ACD for the preparation of PN (2).

Methods

- A **questionnaire-based study** was conducted to gather data from NHS hospitals about how PN products are prepared, the use of ACDs and the related validation processes they adopt.
- PN preparation procedures and ACD **validation documents were also collated** as part of the questionnaire.

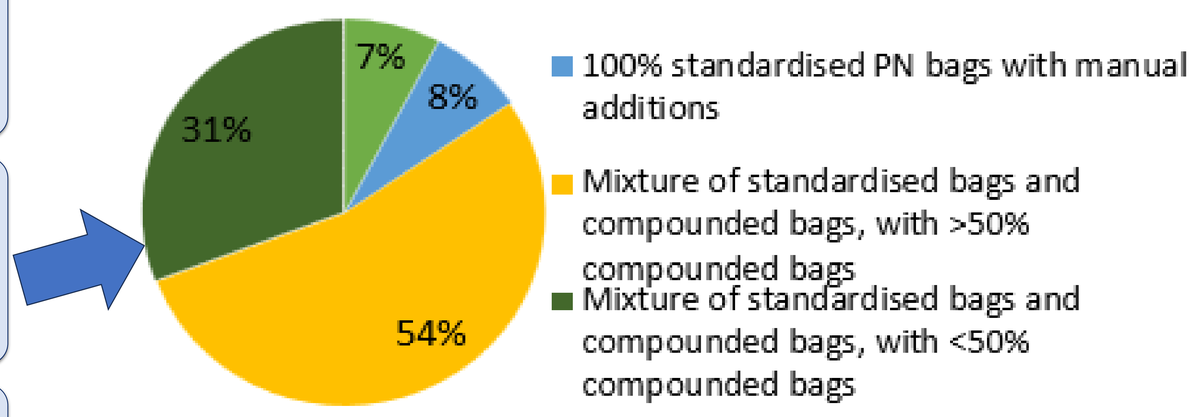
Results

Number of Responses

- **32** different hospitals
- **45%** of the hospitals who prepared PN used an ACD

PN Workload

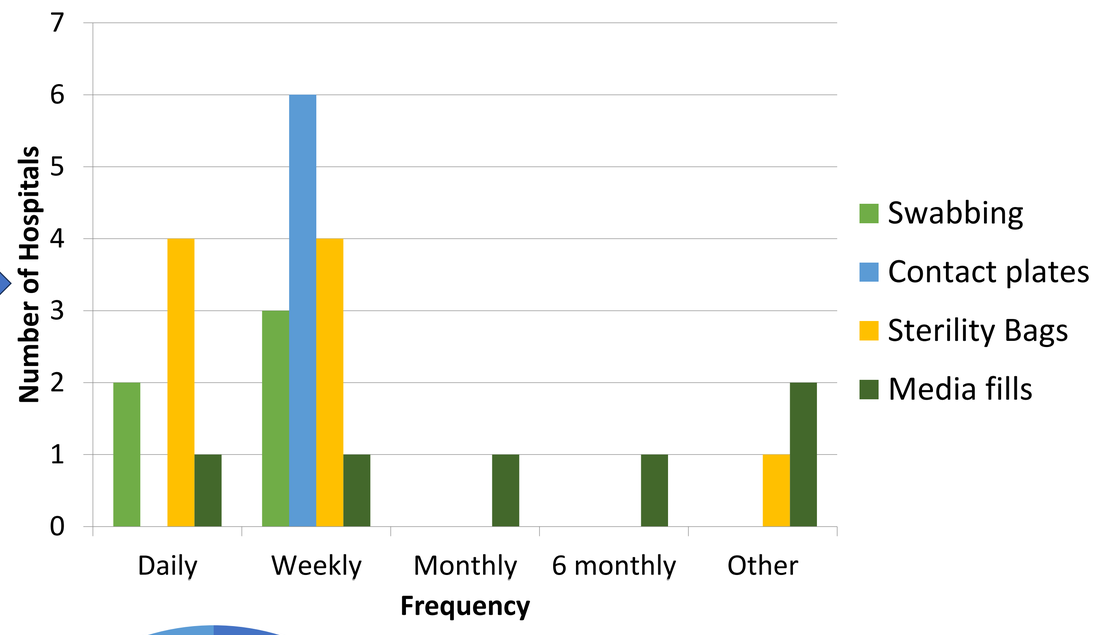
- Hospitals that prepared PN using an ACD provided PN products to either **children and neonates (31%) or both children and adults (69%);** none of them just prepared for adults.



ACDs

- **2** types of ACD in use, **71% used Baxa EM2400**
- **85%** housed ACDs in Laminar Flow Cabinets
- All the hospitals prepared **glucose, amino acids and water** on the ACD

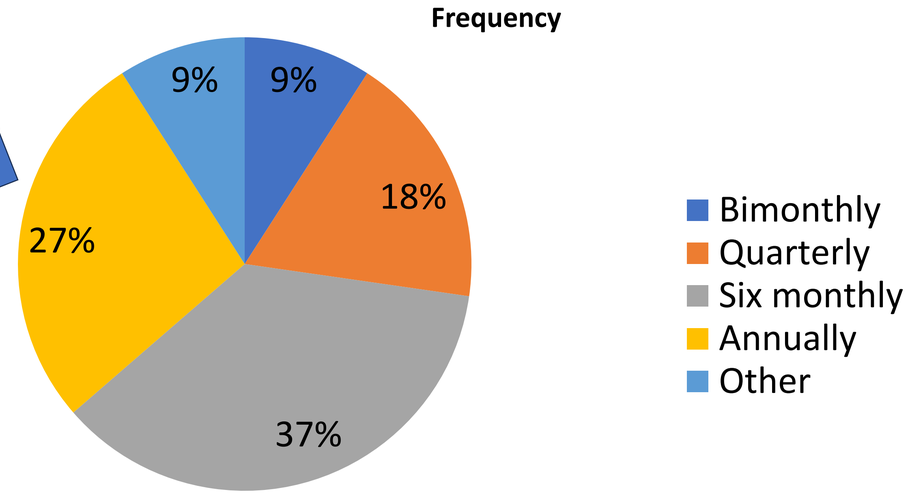
Microbiological Monitoring



Chemical End Testing

- **42%** performed chemical analysis of the PN prepared on the ACD
- **Sodium, potassium, magnesium, glucose, and calcium** analysis were performed
- Performed **in house and not outsourced**

Frequency of On-going Performance Qualification of ACDs



Validation Documents

- **6** hospitals provided validation documents for review
- Operational, installation and performance qualification methods compared; variation and similarities were observed.

Conclusion

In conclusion, the standardisation of ACD validation processes across NHS hospitals was found feasible and as a result a guidance document was prepared in order to provide NHS hospitals with a reference document they can refer to when validating an ACD. This in turn should lead to a more standardised approach to the validation of ACDs which in turn increases the assurance of the final PN product's safety, efficacy, and quality.

References

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2. Benjamin I. ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures. Am J Heal Pharm [Internet]. 2022; Available from: https://academic.oup.com/ajhp/advancearticle/doi/10.1093/ajhp/zxac004/6514383?login=true#327476778

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