58.6% were prescribed the correct first dose. Compliance to monitoring was better, with 89.7% of patients having their concentrations taken at the correct time. Only 24.1% had a therapeutic first vancomycin concentration, and 70.4% were under the therapeutic range. For the second vancomycin concentration, 61.9% were in therapeutic range. Overall, there was good compliance with the guidelines but room for improvement. Significant changes were made to the electronic prescription and concentration report templates. Guidelines were recirculated to all paediatric prescribers. In the second cycle, large improvements were seen in both prescribing and monitoring. 92.6% were prescribed the correct frequency, and 71.4% were prescribed the correct first dose. 96.2% of patients had their concentrations taken at the correct time. However, only 19.2% had a therapeutic first vancomycin concentration, and 65.4% were under the therapeutic range. For the second vancomycin concentration, 57.9% were in therapeutic range.

Conclusions This two-cycle audit showed that incidences of non-compliance with prescribing were due to prescribers following BNFC recommendations, rather than the trust guidelines. Compliance was improved through changes to electronic prescribing and recirculation of guidelines to all paediatric prescribers. Despite improvements in prescribing and monitoring of intravenous vancomycin in children, therapeutic drug concentrations were still not achieved in over 80% of patients. Sub-therapeutic vancomycin concentrations in children within current dosing recommendations has been highlighted in the literature, and sub-therapy is a clinical issue and potential driver for antibiotic resistance.[3] Our findings warrant an urgent need for the re-evaluation of vancomycin guidelines to overcome the increasing prevalence of vancomycin resistance[4] and sub-therapy.

REFERENCES

1. Joint Formulary Committee. British National Formulary for Children. 2017th–8th ed. London: BMJ Group and Pharmaceutical Press. 2018.
2. Nash C, Gooding N, Muller H. Intermittent intravenous vancomycin in children aged over 1 month: Empirical dosing for optimum trough levels. Report to the Neonatal and Paediatric Pharmacist Group January 2016 Neonatal and Paediatric Pharmacists Group. 2016;1–40.
3. Bakke V, Sporsem H, Von der Lippe E, *et al*. Vancomycin levels are frequently subtherapeutic in critically ill patients: a prospective observational study. *Acta Anaesthesiologica Scandinavica* 2017;**61**:627–35.
4. Weiner LM, Webb AK, Limbago B, *et al*. Antimicrobial-resistant pathogens associated with healthcare-associated infections: summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2011–2014. *Infect Control Hosp Epidemiol* 2016;**37**:1288–1301.

P16 AUDIT ON OUTSOURCING INVESTIGATIONAL MEDICINAL PRODUCT (IMP) PRODUCTION

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Aim In autumn 2020 there was a National report for the Department of Health and Social Care by Lord Carter of Coles on 'Transforming NHS Pharmacy Aseptic Services in England'. His report highly emphasized the importance of moving towards standardisation of aseptic units across England to create high quality, effective and efficient services as part of the National aseptic transformation work.[1] Aseptic services provide foundation for much of the National Health Service (NHS) contribution to clinical trials, supporting advances in medicines and contributing to the United Kingdom (UK) economy.[1] At this hospital there is no onsite aseptic unit. Therefore, the trust relies on using outsourced products. An audit was carried out to identify the resilience of certain third-party companies used at this hospital, for the outsourcing of IMP production by identifying late deliveries of IMP, which resulted in delayed treatment.

Method Retrospective data was collected ranging from six to twelve months for three different clinical trials, from two different manufacturing units. Manufacturing unit 1 was 63 miles away from the hospital. Whereas manufacturing unit 2, was only 5.9 miles. Data was collected by checking temperature data loggers, as an indicator of what time the IMP arrived at the hospital clinical trials unit (CTU). Any IMP that arrived the CTU after 1300h was defined as 'delayed treatment', as this resulted in patient/parent and nursing staff having to stay past their intended finish time for IMP.

Results A total of 33 items were received from manufacturing unit 1, over a one-year period. 71.86% were classed 'late', resulting in delayed treatment. A total of 23 items were received from manufacturing unit 2, over a 6-month period. 30% were classed as 'late' (majority were due to late prescribing at site), resulting in delayed treatment.

Conclusion Results highlight that logistically, the closer the manufacturing unit the better. This does not necessarily guarantee better resilience. There are several issues with delayed treatment such as patient safety concerns, unnecessary stress for patients and patients/parents staying later than expected. All which could impact negatively on the studies (patient withdrawal). Delayed treatment relies on staff staying late, which is a cost implication to the trust. Scoping potential for an offsite manufacturing unit or increasing use of local aseptic unit as part of National aseptic transformation work, could reduce the impact on delayed treatment and improve both patient safety and experience. As this would rely less on manufacturing units further away from the hospital. This would also align with Lord Carter of Coles recommendations about transforming aseptic services in England.[1] Clear set Key Performance Indicator's (KPI's) should be agreed with the third-party companies and monitored regularly, allowing us to deliver a high quality, effective and efficient service to our patients. Also ensuring prescribing in a timely manner at the hospital would also improve patient experience.

REFERENCE

1. Coles C. Transforming NHS pharmacy aseptic services in England. *A national report for the Department of Health and Social Care by Lord Carter of Coles* 2020;**1**:3–51.

P17 LICENSED, UNLICENSED OR OFF-LABEL? A SNAPSHOT OF MEDICINES USED IN NEONATAL INTENSIVE CARE

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Background Medicines in the UK are licensed for use by the MHRA. The term 'unlicensed' describes medicines without a marketing authorisation in the UK.[1] whereas an off-label medicine is a licensed product used outside of the terms of its licensing, i.e., for a different age/population, dose or route.[1] The use of unlicensed medicines presents many challenges, including inconsistent supply, high cost and lack of information together with increased risk of medication errors and adverse drug reactions.[1] [2] Despite these significant drawbacks,