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 guide-lines. 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.<sup>3</sup> Our findings warrant an urgent need for the re-evaluation of vancomycin resistance<sup>4</sup> and sub-therapy.

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## 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> 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.

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## 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> <sup>2</sup> Despite these significant drawbacks,

the dearth of products licensed for the neonatal population necessitates the routine use of these medicines.<sup>1</sup> Various studies have shown that the use of unlicensed and off-label medicines is common in a neonatal intensive care setting: in the UK in 1999,<sup>2</sup> and more recently in Brazil<sup>3</sup> and Norway.<sup>4</sup>

Aim Prospectively record the license status of medicines prescribed on a tertiary neonatal unit to determine the relative numbers of licensed, off-label and unlicensed medicines administered.

Method Medication prescription charts were reviewed for a four-week period on a tertiary regional neonatal unit. Each medicine prescribed was recorded and the license status determined, taking into account the indication, patient characteristics and formulation used. Information was gathered on the number of different drugs used and the number of patients that they were prescribed for.

Results Over the study period a total of 72 distinct medications were prescribed 404 times for 68 patients. Of the 404 prescriptions analysed during the study period, just over half (53%) were licensed medicines being used within their licensed indication. 31% were licensed medicines being used off-label and 15% were unlicensed medicines. 43% of the 72 medicines used were licensed but being used off-label. 36% were licensed medicines being used within their licensed indication and 21% of medicines were unlicensed. Of the licensed medicines being used off-label, the most common reason was that the indication/age was not covered by the summary of product characteristics (SPC). However, the detail given in the SPCs varied greatly and it was often challenging to determine whether specific uses were within the license. The top 3 most commonly prescribed medicines (gentamicin, benzylpenicillin and caffeine citrate) accounted for 29% of all prescriptions recorded and were all being used within their license.

**Conclusion** This study found that the majority (64%) of medicines used in neonatal intensive care during the study period were unlicensed or off-label, similar to other recent work in neonates.<sup>3</sup> However, when analysed by the number of prescription events, the majority of these (53%) were licensed. This was mainly due to a small number of licensed drugs which are used often, including antibiotics and caffeine citrate. A licensed form of caffeine citrate was released in 2012, which may partly explain why the proportion is higher in this study than Conroy et al in 1999 <sup>2</sup> who found only 35.4% of prescriptions were licensed. While this is a trend in the right direction, more work is needed to license medicines specifically for this vulnerable group of patients.

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# P18 PRESCRIBING ERRORS IN PICU: IDENTIFYING PREVALENCE BY DRUG AND ERROR TYPE

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Context Patient safety is a priority for healthcare organisations worldwide and is a key factor in providing high quality healthcare. Prescribing medications correctly is critical to ensuring safety, especially in the setting of a Paediatric Intensive Care Unit (PICU) where patients are vulnerable to being exposed to incidents due to highly complex care and illness severity. In our 21 bedded PICU, any prescribing errors detected by critical care pharmacists are recorded on a prescribing error database each day (Microsoft Access). Information inputted includes the drug involved in the error, the route of administration, prescriber identifier number, type of error and category of error based on the NCC MERP<sup>1</sup> classification system. Information is extracted monthly from this database to further populate a prescribing errors dashboard, highlighting the total number of prescribing errors each month and sub-categorising the number of errors according to drug cause and error type.

Data collected in 2021 was analysed by our Trust's Quality Improvement (QI) Team who generated pareto charts for the highest reported prescribing errors according to drug and error type. Although pharmacist data showed that many drugs were responsible for prescribing errors, pareto analysis by the QI team identified that Teicoplanin, Heparin, Fentanyl, Chloral Hydrate and Octenisan<sup>®</sup> were the drugs associated with the most frequent number of errors and causing the biggest cumulative impact on our prescribing error data. In terms of error type, pareto analysis identified that 80% of our cumulative errors were attributed to the wrong route, wrong dose or missing route of administration.

Conclusion A pareto chart is a graph that indicates the frequency of defects as well as their cumulative impact. By applying this statistical control process to PICU prescribing error data for 2021, we were able to identify the drugs and error types responsible for the majority of our cumulative errors. Using the 'Brilliant Basics' methodology,<sup>2</sup> we followed a two-step approach in dissecting our data. For step one, we analysed the data that we had and then in step two, using this analysis, we were able to agree and introduce measures to our prescribing systems in order to mitigate the risk of the errors re-occurring. These measures have included redesigning our PICU prescription to add or adapt prescribing recommendations for Teicoplanin, Heparin and Fentanyl, updating prescribing advice in our PICU electronic drugs formulary for Chloral Hydrate and placing an additional daily task on our nurses' electronic task list to ensure Octenisan<sup>®</sup> is used. In terms of error type, we have raised awareness of the prevalence of the errors causing the biggest impact on reported prescribing errors, through the medium of pharmacy newsletters, which are disseminated to all PICU staff and by educating new PICU prescribers as part of their induction to the unit. To assess whether the above changes have contributed to an improvement in our reported errors by drug and type, we will continue to perform statistical analysis on prescribing data collected throughout 2022.

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