

There were therapeutic indications in 129 of the prescriptions, of which 22.5% were for skin and soft-tissue infections, followed by 15.5% complicated urinary tract infections and 9.3% pneumonia. Amoxicillin-clavulanate was the most prescribed antibiotic for treatment and prophylaxis purposes (48.1% and 29.8% respectively). According to syndrome, worst guideline compliance was observed in complicated urinary tract infections 57.9% and skin and soft-tissue infections (65.5%).

**Conclusion** In our setting, adequate acquisition definition, compliance with local guidelines, obtaining of microbiological samples and certain clinical syndromes (skin and soft tissue and urinary) were the main variables identified to prioritise ASP-targeted intervention.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 4CPS-249 IMPLEMENTATION OF AN INTEGRATED SOFTWARE FOR CLINICAL TRIALS MANAGEMENT AND AUTOMATED PREPARATION OF INVESTIGATIONAL DRUGS IN A HOSPITAL PHARMACY

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**Background** In conducting clinical trials (CT), the hospital pharmacy is responsible for receiving, handling and dispensing investigational drugs while ensuring a high level of quality. All CT-related data are to be documented and reported in compliance with the CT protocol and good clinical practice, thereby encouraging the implementation of an information technology system to support and improve standard operating procedures management.

**Purpose** The aim of this pilot study was to evaluate a software, specifically designed for managing investigational and non-investigational medicinal products (IMPs/NIMPs), fully integrated into the robotic compounding platform of injectable drugs.

**Material and methods** The software was installed in the pharmacy-based Clinical Trials Unit in July 2018. IMPs/NIMPs, individual patient data, sponsor and investigator data were entered into the software database according to the ongoing CT protocols. Detailed reports were recorded, including the delivery to the CT site, the inventory at the CT site, the use by each patient, the accountability, and the return to the sponsor or alternative disposition of unused investigational drugs. Any changes to the CT protocols were traced. In addition, through the integration with the robotic compounding platform, individually prescribed doses for parenteral administration were prepared by using the supporting device for manual preparation which verifies dosing accuracy by gravimetric control and ensures identity by photographic recognition.

**Results** Two months after the installation, about 20% of the 60 ongoing cancer CT were managed through the software, involving, overall, 25 patients. In total, 10 investigational medicinal products were entered, of which four for oral administration and six injectable drugs. Overall, 39 individually prescribed doses were manually prepared by using a workflow system for compounding. Before implementation,

the dose errors were not recorded. After implementation, the mean absolute dose error amounted to  $\pm 1.56\%$  ranging from  $\pm 0.13\%$  to  $\pm 4.29\%$ . The automated data handling and record-keeping were ensured, thus improving quality in the preparation process and reports' traceability. The centralised management of all documents reduced time for data entry by the pharmacy staff and minimised human errors.

**Conclusion** The software for managing cancer CT in the hospital pharmacy, currently under validation, was successfully implemented, thereby encouraging the insertion of further CT protocols.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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#### 4CPS-250 INFLUENCE OF TIME AND STORAGE CONDITIONS IN THE STABILITY OF NEONATAL TOTAL PARENTERAL NUTRITION ADMIXTURES

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**Background** Ternary mixtures in parenteral nutrition have a complex composition. Thus, interactions between those components can occur and lead to instability of the mixture, compromising its safety. It is possible that a process of destabilisation of the lipid emulsion starts due to aggregation of fat globules.

**Purpose** To analyse the stability and safety of neonatal total parenteral nutrition admixtures (TPN) as a function of globule size, time and storage conditions.

**Material and methods** We studied eight TPN compositions (100 ml) designed following the premature infants' protocol in our hospital for TPN prescription and elaboration. All the samples were macronutrients (glucose, lipids and proteins) and micronutrients ternary mixtures, calculated according to the nutritional requirements of a 1 kg neonate during the first 8 days of life. The globule size was measured by laser diffraction (Beckman Coulter LS I3 320) on the preparation day (day 0) and after 7 days. The samples were stored at refrigerated and room temperature. They were prepared in duplicate. We used the SPSS v20 program to perform the statistical analysis.

Abstract 4CPS-250 Table 1

Sample	lipids (g)	Globule size	Globule size	Globule size
		(microns)	(microns)	(microns)
		DAY 0	DAY 7 (ambient)	DÍA 7 (refrigeration)
TPN1	0.714	0.373	0.390	0.396
TPN2	1.138	0.401	0.395	0.397
TPN3	1.478	0.257	0.249	0.203
TPN4	1.750	0.250	0.263	0.244
TPN5	2.160	0.270	0.273	0.256
TPN6	2.580	0.266	0.267	0.269
TPN7	2.990	0.269	0.247	0.257
TPN8	4.000	0.256	0.247	0.256