

The EHRs did not record RF evolution, TDM requests and results or PIs in 53 (70%), 23 (30%), 39 (51%) and 61 (80%) cases respectively.

OR for recorded TDM results related to highly important PIs compared to low-importance PIs, for recorded TDM ordering related to moderate RI compared to normal RF and records for RF evolution related to moderate RI compared to normal RF were 3 (95%CI: 1–9;  $p = 0.046$ ), 0.3(95%CI: 0.8–0.9;  $p = 0.04$ ) and 4(95%CI: 1–16;  $p = 0.029$ ), respectively. A significant linear trend was observed. OR for all other variables was non-significant.

**Conclusions** The low percentage recording of TDM-related variables and pharmacist interventions in EHR potentially limits inter-professional communication and the decision-making process. This fact highlights the need for clinical pharmacists to safeguard the information they have discovered by recording their interventions in the EHR as a clinical episode in comprehensive patient care. This will increase the visibility of the pharmacist and the effect of his/her actions.

No conflict of interest.

#### TCH-049 TOPICAL MORPHINE GELS FOR PAINFUL WOUNDS

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**Background** The use of morphine applied topically to painful wounds has potential advantages such as a lower dose than with systemic administration and fewer side effects. Gels are known to be suitable for treating wounds.

**Purpose** To develop two physicochemically and microbiologically stable gels: a more viscous formulation (F1) and a fluid formulation for spraying (F2), both containing morphine hydrochloride (MH). The effect of viscosity on drug release from both gels was also investigated.

**Materials and Methods** Sodium carboxymethylcellulose-based aqueous gels were prepared and sterilised by autoclaving. The 0.125% w/w (F1) and 1.0% w/w (F2) gels containing MH were compounded using an injectable solution of MH and preservatives (parabens). Preparation and primary packaging were performed inside a horizontal laminar flow hood. Primary packaging consisted of single dose syringes for F1 and 10 mL amber glass bottles with pump sprays for F2. Stability studies were performed using 3 batches of each final formulation. Samples were stored at  $5 \pm 3^\circ\text{C}$ , at  $22 \pm 3^\circ\text{C}$  (light exposed and protected) and  $40 \pm 2^\circ\text{C}/75 \pm 5\%$  RH for 98 days (samples collected at 6 time points). Organoleptic characteristics, pH, viscosity, MH and preservative content were assessed. Sterility tests, microbiological control and preservative efficacy were studied according to Ph. Eur. The MH release profile was evaluated using Franz cells.

**Results** Formulations were odourless, yellowish, translucent and homogeneous. The pH was 6.35 (F1) and 5.70 (F2), viscosity was 52.933 mPa.s at 6.12 s<sup>-1</sup> (F1) and 16.7 mPa.s at 12.24 s<sup>-1</sup> (F2). Methylparaben, propylparaben and MH contents were between 90–110%. Preservatives were effective and preparations remained sterile and stable for 60 days. MH release was slow and inversely proportional to viscosity.

**Conclusions** The MH gels presented suitable physicochemical and pharmaceutical characteristics for topical application to painful wounds. The slow release profile may reduce the number of applications.

No conflict of interest.

#### TCH-050 USE OF ELECTROENCEPHALOGRAPHY (EEG)-BASED METRICS TO TEST THE GUSTATORY PROPERTIES OF LIQUID TRIMETHOPRIM FORMULATIONS

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**Background** It is well known that the gustatory properties of a formulation strongly affect patient adherence to a treatment. However measuring these properties is highly subjective and difficult, especially for the paediatric population. The use of neuropsychophysiological indexes and covert behaviours in assessing the attractive properties of sensorial stimuli has a long tradition in the domain of affective neuroscience. Ways of measuring range from the use of autonomous nervous system activation patterns, to features extracted from electroencephalographic activity or simple and discriminative reaction time tasks. These measurements provide alternative means for assessing the characteristics of commercial products, overcoming the limitations of self reporting-based research, namely social desirability, and for studying populations unable to provide usable verbal responses (e.g. children).

**Purpose** To find out if this methodology can be used for evaluating the gustatory properties of formulations in order to enhance patient adherence.

**Materials and Methods** Trimethoprim formulations were prepared using NF syrup. Flavour was added afterwards. Participants were stimulated with 3 different flavoured formulations (banana, red berry and neutral) for 10 seconds each while subjected to an EEG recording. The order of presentation was fully counter-balanced between subjects. Subjects rated the different solutions for palatability and intensity. Five seconds of the EEG response for each sample were converted to the frequency domain, and the log power and inter-hemispheric asymmetry were calculated for anterior, central and parietal electrodes. Different algorithms, combining different EEG features, were tested for predictive power regarding palatability and type of formula.

**Results** Theta inter-hemispheric activity at parietal electrodes predicted the behavioural assessment of palatability ( $R^2 = 0.35$ ). Moreover, the application of unsupervised learning methods, such as Support Vector Machines, on the log power at different bands from 0 to 12 Hz, could distinguish with up to 95.24% accuracy between flavoured and non-altered solutions.

**Conclusions** This technology can be used in formulation studies that are attempting to enhance the organoleptic properties of a formulation.

No conflict of interest.

#### TCH-051 VALIDATION OF AN AUTOMATED COMPOUNDER SET UP ONCE A WEEK FOR PARENTERAL NUTRITION SOLUTIONS

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**Background** Our parenteral nutrition production (PN) decreased after we introduced standard solutions. To keep just a small number of daily PN items cost-effective, we decided to validate a once a week setting up of an automated compounder device (ACD).

**Purpose** To test the operation and performance of an ACD (Baxa MM12) for a once a day and a once a week use.

**Materials and Methods** Accuracy (mean in % of the expected value) and precision (Coefficient of Variation) of the ACD was evaluated by weighing different volumes of water 10 times (0.5 to 40 mL; daily operational qualification) and different volumes of

nutrients (0.5 to 100 mL; daily performance qualification) over 3 consecutive days. The concentration of nutrients (glucose, Na and K) in PN, particulate contamination and media-fill tests were checked each day while the machine's settings were only adjusted once a week (3 consecutive weeks). Some bottles were changed during the week and other remained in place, according to a predefined protocol. The ACD was installed in a laminar airflow hood GMP Class A with a cleanroom Class B background and a temperature around 20°C.

**Results** Daily operational and performance results:

	0.5 mL		40 mL		100 mL	
	Accuracy	Precision	Accuracy	Precision	Accuracy	Precision
Water	100.9%	3.2%	98.9%	0.3%		
Nutrient	99.3–102.7*	2.7–3.9%*			100–100.4%*	0.7–1.5%*

\* Depending on nutrient

The concentrations of nutrients in PN products made weekly always met the specifications (internal limits  $\pm 15\%$  for Na,  $\pm 10\%$  for glucose and  $-15\%$  to  $+10\%$  for K). No particles or microbiological contamination were detected.

**Conclusions** Validation proved the acceptable accuracy, precision and aseptic conditions in the course of the week. A sepsis can only be guaranteed by a strict application of GMP in a high quality compounding environment. In those conditions, PN products can be produced safely for one week with the same settings. Setting it just once a week saves technician time (300 hours/year) and money (15,000 Euro/year).

No conflict of interest.

#### TCH-052 VALIDATION OF AN AUTOMATED METHOD FOR COMPOUNDING MONOCLONAL ANTIBODY PATIENT DOSES: CASE STUDIES OF BEVACIZUMAB, INFlixIMAB AND TRASTUZUMAB.

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**Background** Automated devices have recently come onto the market as an alternative to manual preparation of drugs for intravenous administration. Automated methods have so far been focused on rapid and time-saving procedures that might harm delicate substances such as monoclonal antibodies (mAbs). Many summaries of product characteristics (SmPCs) of mAbs state that they require gentle swirling to aid reconstitution and that drawing into a syringe should be done slowly.

**Purpose** To assess whether automated preparation can be performed with mAbs without affecting the aggregation state of the proteins.

**Materials and Methods** Three frequently used mAbs were studied: infliximab (Remicade) and trastuzumab (Herceptin) in lyophilised form, and bevacizumab (Avastin) as a liquid formulation. Brand names are mentioned because biosimilars exist. The effects of different procedures to prepare the patient doses on antibody aggregation were evaluated. Remicade and Herceptin were reconstituted both manually and by an automated arm (i.v.STATION, Health Robotics). Additionally, the effect of vigorous shaking during reconstitution was investigated. The effects of rapid aspiration and dispensing on antibody aggregation were investigated for all three mAbs. The aggregation state was assessed by UV-Vis absorbance, 90° light scatter, fluorescence spectroscopy, Nile red fluorescence microscopy, and field flow fractionation without cross and focus flow.

**Results** Samples reconstituted by an automated process showed similar findings compared to manual reconstitution if performed

exactly according to the summary of product characteristics (SmPC). Vials that were shaken vigorously showed a significant increase in aggregates. Similarly, rapid aspiration/dispense cycles resulted in a strong increase in the number and sizes of aggregates for all three mAbs; this result was observed after just one rapid aspiration/dispense cycle.

**Conclusions** Our study showed that automated preparation of mAbs is feasible if the machine is programmed exactly according to the SmPC, indicating that automated preparation can be used to achieve reproducible high-quality preparation for delicate formulations.

No conflict of interest.

#### Drug supply/logistics (including: computer-aided drug dispatching and ward pharmacies)

##### DSL-001 A MULTIDISCIPLINARY APPROACH TO FURTHER IMPROVEMENTS IN PATIENT SAFETY IN A HOSPITAL WITH COMPUTERISED MEDICAL RECORDS

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**Background** Antineoplastic treatments administered at the Medical Day Hospital Unit (MDHU) are high risk for the patient because of their toxicity and mutagenicity and complex pharmacotherapeutic processes. In our hospital medical records are fully computerised and all prescriptions are electronic. So, it is desirable to standardise criteria in a consensus document that minimises variability among professionals to maximise the safety and clinical effectiveness for oncology patients.

**Purpose** To identify the key points of information that should appear in the consensus document to ensure the correct administration of antineoplastic treatments.

**Materials and Methods** A multidisciplinary group was created (two physicians, one pharmacist, one nurse and quality managers). The initial criteria for determining the key points to be imparted were patient safety, clinical effectiveness, organisational coordination and traceability in the Information System. These criteria led to the establishment of 12 key points of information to develop a standard operating procedure (SOP) for each antineoplastic treatment.

**Results** The 12 key points that were agreed to establish SOPs for each treatment were: indications and usage; prescription form in the Electronic Health Record; pharmaceutical validation to ensure correct indication, dose, volume and type of diluent and infusion time; general and specific nursing indications; contraindications; monitoring of vital signs and anthropometric measures necessary; premedication and time spent on it; preparation of the medicine; possible adverse reactions to the infusion and their management; causes of suspension of treatment; patient information; responsibilities of each professional.

**Conclusions** The development of SOPs to standardise the pharmacotherapeutic process in the MDHU contribute to improving the safety and efficiency of antineoplastic treatments. In addition, in a hospital with medical records and where all prescribing is electronic, SOPs contributes to improving the organisation of a complex nursing unit such as the MDHU.

No conflict of interest.