

to SAD products could be observed, the relative decrease could indicate a positive effect.

The simulation study indicated that specific design features such as yellow background colour, Tall Man lettering and consistent design improved safety in the medication process. However, the new label design is complex implying a potential for misinterpretation of the features if the users are not familiar with the design.

**Conclusions** The effect of the new design depends on several factors such as the user's knowledge of the design, the complexity of the design and the context of use. Errors related to misinterpretation of labels remains a problem and research into good label design remains a relevant topic.

No conflict of interest.

#### GRP-071 EVALUATION OF THE PRESCRIPTION OF INTRAVENOUS NON-STEROIDAL ANTI-INFLAMMATORY DRUGS COMPARED TO THE RECOMMENDATIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS

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**Background** Acute renal failure is a side effect of NSAIDs.

**Purpose** To assess the appropriateness of the intravenous prescription of dexamethasone according to the dosage specifications depending on renal function following the recommendations of the Summary of Product Characteristics.

**Materials and Methods** An observational, retrospective study that analysed dexamethasone prescriptions in surgical patients admitted to a tertiary hospital from January-September 2011. The estimated glomerular filtration rate (eGFR) was calculated by the CKD-EPI formula, of reference in the hospital.

The Summary of Product Characteristics advises using the following posology for dexamethasone:

- 150 mg maximum daily dose for a maximum duration of 48 hours.
- In patients with renal impairment:
  - GFR < 50 mL/min: administration contraindicated
  - GFR 50–80 mL/min: 25 mg/12 h. Maximum: 50 mg daily.
  - GFR > 80 mL/min: No dosage adjustment required.

**Results** Prescriptions from 1946 patients were analysed. Of the patients, 54.3% were male and 45.7% female, with a mean age of 59.8 years (17–103). The mean serum creatinine levels were 0.84 mg/dL  $\pm$  0.43 and the mean eGFR from the CKD-EPI calculation was 83.05  $\pm$  26.17 mL/min/1.73m<sup>2</sup>.

In 58% of the admissions the drug was not prescribed correctly. Of these:

- 270 patients were prescribed dexamethasone when the eGFR was less than 50 mL/min/1.73m<sup>2</sup>;
- 550 of them had an unadjusted prescription with an eGFR 50–80 mL/min/1.73m<sup>2</sup>.
- 370 patients with an eGFR > 80 mL/min/1.73 m<sup>2</sup> were prescribed NSAIDs for longer than 48 h.

**Conclusions** 58% of the intravenous NSAID prescriptions did not conform to the SPC recommendations. Due to this fact and in order to prevent renal toxicity it is recommended:

1. To establish protocols for pain management during hospitalisation to limit the duration of these drugs to 48 hours and adjust the dose to the patient's renal function.
2. To enhance the proactive role of the pharmacist in individualised patient monitoring.

No conflict of interest.

#### GRP-072 EXPOSURE TO ANTINEOPLASTIC AGENTS IN ONCOLOGY DEPARTMENTS: PRACTISE SURVEY AND INFORMATION TO THE PERSONNEL OF THREE ONCOLOGY DEPARTMENTS

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**Background** The exposure of pharmacy technicians to antineoplastic agents (AAs) has been widely studied, but less is known about risks of exposure and awareness of nurses, nursing auxiliaries and cleaning personnel.

**Purpose** To evaluate the practice and the awareness of oncology nurses (ONs), nursing auxiliaries (NAs) and cleaning personnel (CP) concerning exposure to AA.

**Materials and Methods** Three questionnaires were distributed to ONs, NAs and CP in three oncology wards including one paediatric ward. Participants were asked 10, 11 and 12 questions respectively about their practices and awareness of exposure to AAs.

**Results** For ONs (n = 38), gloves are more often worn when manipulating syringes than when manipulating infusion bags (60.5% vs. 36.8%, p < 0.05). 26.3% considered themselves well informed but 97.4% thought information could be improved. 81.6% of ONs suspected that AAs had teratogenic effects and 10.5% of them thought that AAs did not have mid- or long-term toxic effects. For NAs (n = 14), wearing gloves while washing patients or eliminating excreta was more frequent than mask wearing (64.3% vs. 5.3%). 28.6% considered themselves well informed but 92.9% thought information could be improved. 85.7% of NAs suspected that AAs had teratogenic effects and 14.3% of them thought that AAs did not have mid- or long-term toxic effects. For CP (n = 10), 62.5% wore gloves for bed making and 80.0% for sanitation cleaning. All of them considered themselves not sufficiently informed and 90.0% thought that AAs had teratogenic effects whereas 10% of them thought that AAs did not have mid- or long-term toxic effects. All (n = 62) reported routine use of water and soap (46.8%) or hydro-alcoholic solution (25.8%) after a potential exposure to AAs.

**Conclusions** Lack of information suggested the necessity of informing the nursing and cleaning personnel on the oncology ward in some fields. A teaching session was arranged by department.

No conflict of interest.

#### GRP-073 FAILURE MODE AND EFFECT ANALYSIS IN IMPROVING THE SAFETY OF THE CHEMOTHERAPY PROCESS

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**Background** Medication errors in chemotherapy have a high potential to cause harm. Errors may occur during different steps of the medication process.

Failure Mode and Effect Analysis (FMEA) is a proactive risk assessment method that enables potential risks to be identified and prioritises actions to improve safety.

**Purpose** To apply FMEA methodology to the chemotherapy process: prescribing, pharmaceutical validation, compounding and dispensing.

**Materials and Methods** Prospective study, in a tertiary level hospital, using the FMEA technique developed by the Veterans Affairs Healthcare System for the chemotherapy process. An interdisciplinary working group was created and meetings held over three months. Processes and subprocesses were described; potential failure modes and possible causes were identified. Main sources used were brainstorming and cause-effect-diagramming. For each failure

mode, a Hazard Score (HS) was calculated by multiplying the probability of occurrence (Remote = 1, Uncommon = 2, Occasional = 3, Frequent = 4) and severity of effect (Minor = 1, Moderate = 2, Major = 3, Catastrophic = 4). If  $HS \geq 8$ , corrective actions were proposed. If  $HS < 8$ , failure mode was evaluated based on: lack of detection, criticality and absence of effective control measures. All data were collected in a validated worksheet.

**Results** A flow diagram was obtained. Twenty-seven failure modes were identified, and twenty had a  $HS \geq 8$ . Failure modes with the highest HS were: wrong dose calculation and wrong protocol (Prescribing); incorrect production protocol in the computer system and non-detection of wrong dose calculation (Pharmaceutical validation); wrong medicine is chosen, incorrect volume of drug added to diluent and labelling error (Compounding); Delivered to wrong nursing unit or patient (Dispensing). Corrective actions proposed were: policy of weighing patient for proper dose calculation, chemotherapy database updated, double checking, gravimetric control on prepared chemotherapy, procedures for proper patient identification (barcode identification system or radiofrequency dispensing system).

**Conclusions** FMEA contributes to the development of a very clear and shared vision of the chemotherapy process, taking into account different perspectives: oncologist, pharmacist, technician and nurse.

FMEA is a useful tool for identifying critical parts of the chemotherapy process, prioritising corrective actions, minimising potential risks and improving the quality and safety of patient care.

No conflict of interest.

#### GRP-074 FREQUENCY OF VALPROIC ACID-INDUCED HYPERAMMONEMIA IN ADULT PSYCHIATRIC SETTINGS

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**Background** Valproic acid (VPA) is widely prescribed by paediatric neurologists as an antiepileptic drug. VPA-induced hyperammonaemia can lead to encephalopathy and coma; it is well documented among the paediatric population. Severe urea cycle enzyme deficiencies are often revealed in early youth when VPA is administered. Such mild genetic deficiencies can remain unnoticed until adulthood and be discovered if VPA is taken for bipolar disorder.

**Purpose** To evaluate the frequency of VPA-induced hyperammonaemia in adult psychiatric settings and to sensitise the medical community to a potentially severe adverse effect of a widely-prescribed drug.

**Materials and Methods** The study was carried out a two-week period in a psychiatric hospital. It included every full-time hospitalised patient treated with VPA for at least 4 days (corresponding to 5 drug half-lives). Ammonia and VPA blood measurements were performed once and an electroencephalogram when ammonia exceeded 70  $\mu\text{M}$  (normal range: 10 to 35  $\mu\text{M}$ ). Ethics committee approval was obtained before starting the study.

**Results** 122 patients were included in this study. 68 patients (55.8%) presented ammonia blood levels exceeding 35  $\mu\text{M}$  and 4 of them (3.3%) exceeded 70  $\mu\text{M}$ . One patient reached 118  $\mu\text{M}$  one week after VPA initiation. No encephalographic abnormalities were observed. No correlation was found between ammonia and total VPA levels. Different oral forms of VPA were used and this study showed that they affected VPA blood levels.

**Conclusions** VPA-induced hyperammonaemia is a frequent, generally well-tolerated, adverse effect. Ammonia blood level monitoring combined with clinical monitoring are essential to avoid hyperammonemic encephalopathy. Communication within the hospital led to the medical community becoming aware of the problem and new monitoring recommendations were defined including

initial ammonia level measurement after VPA initiation and biannual monitoring of this biological parameter. Total VPA level determination doesn't seem to be useful for predicting hyperammonaemia whereas the importance of measuring the free VPA has recently been highlighted.

No conflict of interest.

#### GRP-075 GASTROPROTECTION WITH NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AT HOSPITAL DISCHARGE: DO WE FOLLOW LOCAL GUIDELINES?

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**Background** Studies have shown overuse of proton pump inhibitors (PPIs) that does not meet accepted criteria.

**Purpose** The aim of this study was to determine the prevalence and appropriateness of gastroprotection with PPIs in patients who were prescribed non-steroidal anti-inflammatory drugs (NSAIDs) at tertiary level hospital discharge.

**Materials and Methods** Data for this retrospective study were obtained from the pharmacy claims database 1–31 January 2012.

We identified patients under 65 years with a concomitant PPI and NSAID and who were not taking antiplatelet drugs, anticoagulants or steroids and revised the discharge report; we considered gastroprotection appropriate if it contained a history of ulcer disease, bleeding or gastroduodenal perforation or comorbidity or treatment indicated at the time of admission.

**Results** During January 2012 a total of 1776 patients were dispensed at least one prescription medicine at discharge.

388 patients were dispensed an NSAID and PPI, of whom 144 also received antiplatelet treatment, anticoagulants or steroids and for whom therefore gastroprotection was recommended. We analysed the age of the 244 remaining patients. 76 of them were  $\geq 65$  years and then we also considered PPI gastroprotection appropriate. We reviewed the discharge report of the remaining 168 patients who were under 65. The result of this analysis showed that 133 patients did not fit criteria for PPI use (34.3% of patients receiving NSAIDs and PPIs); gastroprotection was correct in 27 patients and the discharge report was not recovered in 8 patients (2.1%).

**Conclusions** In this retrospective study, 63.6% of patients who were dispensed NSAIDs at discharge received appropriate PPI gastroprotection and 34.3% of patients received an unnecessary PPI prescription (79.2% of patients under 65).

Patient prescription at hospital discharge should be reviewed to prevent overuse of proton pump inhibitors, especially in patients under 65 years of age.

No conflict of interest.

#### GRP-076 GASTROPROTECTIVE AGENTS IN THE EMERGENCY ROOM OF A TERTIARY-LEVEL HOSPITAL

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**Background** Gastroprotective agents are widely used in both hospital and community settings, and they are generally perceived as safe drugs.

**Purpose** To find out whether the prescription of anti-ulcer drugs in the Emergency Room (ER) accords with their approved indications, and the financial impact of their inappropriate use.

**Materials and Methods** Indications for use of proton pump inhibitors (PPIs) and H<sub>2</sub> antagonists (via the Spanish Medicines