

**Purpose** To demonstrate the necessity for aseptic technique and conditions and preparation by the pharmacy.

**Materials and Methods** For a period of six months 15 patients were prescribed Bergman's solution 500 ml to which was added 5 ml pentoxifylin and 12 ml lidocaine 2% (50 ml vials divided between 4 patients) in the orthopaedic department. This infusion was prepared in the nursing room, by the nurses without suitable aseptic conditions. For the next six months pharmacists prepared this infusion in the hospital pharmacy aseptic facility. 17 patients in the orthopaedic department got this solution.

**Results** The nurses used each 50 ml vial of lidocaine for several patients until the vial was used. The vial was saved for use the following day after initial entry. Within days of application 8 patients required antibiotics and prolonged hospitalisation. Microbiological tests showed MRSA infection. One of the nurses forgot to wash hands before preparing the infusion for 3 patients, one used the same needle for both drugs for 4 patients, and one accidentally touched the needle in 1 patient. In the next six months the hospital pharmacy prepared 17 infusions for 17 patients in the aseptic facility. All patients finished their treatment in very good condition without any complications.

**Conclusions** Nurses' rooms and training are unsuitable for reusing single dose vials for several patients. Subdividing must follow highly controlled environmental conditions, with training and qualifications of personnel and procedures for reuse, which are met by the hospital pharmacy and pharmacists in our hospital.

No conflict of interest.

#### GRP-161 RISK ASSESSMENT FORMS FOR PHARMACY PREPARATION

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**Background** Pharmacists are allowed to prepare medicines for the needs of patients. They have to balance the benefits and risks of the clinical and pharmaceutical qualities. In other words they have to perform a risk assessment for extemporaneous preparation as well as for stock preparation.

To perform a risk assessment the pharmacist should be able to list the benefits and risks and needs a tool to balance them. Some approaches have been published, but they don't deal with all aspects in one view. We think there is a need for a risk assessment tool that is simple, transparent and conclusive and that deals with all relevant aspects.

**Purpose** To analyse the pharmaceutical process for decisive steps, levels of evidence and actors. To incorporate these aspects into a practicable form.

**Materials and Methods** 15 years of feedback from community and hospital pharmacists on former assessment forms, discussions with authorities, 40 years searching for sound reasons for pharmacy preparation, writing an opinion on the Resolution on pharmacy preparation of the Council of Europe, have been used as an input for creating a new form that emphasises the benefit and risk balance.

**Results** Two forms were developed for the pharmacist: for extemporaneous and for stock preparation. They use the same type of benefit and risk aspects but extemporaneous preparation affects an assignable patient and the request is from an assignable physician. Often two pharmacists are involved, the attending pharmacist and the preparatory pharmacist. All four carry responsibility but the preparatory pharmacist has to decide whether to fulfil the request or not. For stock preparations the preparatory pharmacist will put together the information about benefits and risks. The physician, patient and attending pharmacist have to balance them. Stock preparation requires numerous items per batch and serves a number of

patients. This requires a higher level of evidence about the clinical value and a higher quality of design.

**Conclusions** Forms were developed for the risk assessment of extemporaneous and stock preparations. They show decisions and provide transparency, pointing at responsibility and accountability. Practical experience will provide more information about the roles of pharmacist(s), physician and patient.

No conflict of interest.

#### GRP-162 RISK CATEGORIZATION OF STANDARDISED CONTINUOUS INJECTION/INFUSION SOLUTIONS AT THE UNIVERSITY MEDICAL CENTER MAINZ

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**Background** The prescription, preparation and use of parenteral solutions are complex processes composed of many steps, during which mistakes can occur. However, by means of the National Patient Safety Alert 20 (NPSA 20), a risk evaluation of continuous injection/-infusion solutions can be performed.

**Purpose** To evaluate the risks associated with the intravenous drug treatment of intensive care unit patients at the University Medical Center Mainz. We planned to use the results to identify high-risk products and implement measures to reduce potential risks.

**Materials and Methods** The NPSA 20 defines eight different risk factors for the evaluation of overall risk. The risk evaluation was conducted for 78 continuous injection/-infusion solutions used in intensive care unit patients. These parenteral solutions are used in standardised concentrations; 16 of them were prepared as ready-to-use products in the hospital pharmacy. The potential risks of these 16 preparations were compared with the risks of those not prepared centrally in the hospital pharmacy department.

**Results** The risk evaluation of the 78 continuous injection/-infusion solutions revealed that most of the standardised 78 solutions were moderate-risk products (68%). Other solutions were classified as low-risk products (26%). Only 6% of the solutions were high-risk products. The favourable results of the risk analysis can be explained by the hospital-wide use of standardised concentrations. Doses are adjusted by using the infusion rate. For a number of products (12%) the risk category was downgraded from moderate to low, since ready-to-use products were prepared in the hospital pharmacy department.

**Conclusions** Out of 78 drug products administered as continuous injection/-infusion solutions to intensive care unit patients only 6% were categorised as high-risk. This favourable result is explained the use of standardised concentrations and preparation of ready-to-use products in the pharmacy department.

No conflict of interest.

#### GRP-163 RISK MANAGEMENT MEASURES TO PREVENT PHYSICAL-CHEMICAL INCOMPATIBILITIES DURING CONTINUOUS IV INFUSION

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**Background** Patients in critical care (ICU) settings usually require multiple medicines administered as continuous IV infusions. As a reliable IV access is often unavailable, simultaneous administration through the same line is performed using a Y-site connector.

If any drug/drug or drug/solvent incompatibilities occur, physical-chemical reactions may occur at the Y-site expressed as clouding, colour variation, emulsion breaking. These reactions can give rise to clinically significant complications such as reduction of bioavailability and therapeutic effect, catheter obstruction, parenchymal deposits. The potential impact, in terms of increase of morbidity/mortality and prolonged hospitalisation, could be important.

**Purpose** To create a working tool to help health professionals make responsible and evidence-based decisions when administering several medicines to critical patients.

**Materials and Methods** A systematic search for stability/compatibility information for injectable drugs was performed (Tris-sel's, Stabilis, King's Guide to Parenteral Admixtures, Micromedex database, Martindale, Summary of Product Characteristics).

A literature review of data concerning compatibility for intravenous administration of 119 drugs and 4 diluents commonly used in anaesthesia and intensive care was undertaken.

**Results** 7488 drug/drug and drug/solvent compatibilities were analysed, showing: 44% compatibility, 12% physical and/or chemical incompatibility, 4.5% limited compatibility (depending on solvent, concentration, contact time, temperature). The data collected conflicted in 1.8% of references.

All data were summarised in a colour-code wall chart, which admits, circumscribes or denies the possibility of simultaneous infusion (green: compatible, red: incompatible, violet: limited data, yellow: conflicting data, white: no information). This working tool was shared with health staff and made available in the ward for a safe and quick search.

**Conclusions** The use of this visual working tool in ICUs and other units may reduce adverse events due to physical-chemical incompatibility of infused medicines, thus improving care quality and patient safety.

No conflict of interest.

## GRP-164 RIVAROXABAN VERSUS ENOXAPARIN: COMPARISON OF OUTPATIENT TREATMENT ADHERENCE IN CLINICAL PRACTISE

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**Background** Rivaroxaban (Riv) is a selective, direct Factor Xa inhibitor indicated in the prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery (HKRS). [1] It was introduced into the pharmacotherapeutic formulary of the Hospital Centre of Cova da Beira (CHCB) in February 2011. It is administered orally, which is a potential advantage in terms of compliance when compared to enoxaparin (Eno).

**Purpose** To compare adherence to Eno versus Riv in adult patients undergoing elective HKRS. The occurrence of adverse drug reactions (ADRs) was also compared between the groups.

**Materials and Methods** Cross-sectional study of outpatient compliance to Eno or Riv, in patients undergoing HKRS in CHCB, from February/2011 to April/2012. Medicines adherence was evaluated using a validated questionnaire and the occurrence of ADRs was evaluated in a structured interview.

**Results** The study included a total of 60 patients, who underwent elective knee (29 patients) or hip (31 patients) surgery; 41 patients were treated with Eno (17 knee + 24 hip) and 19 with Riv (12 knee + 7 hip). In all, 91.7% patients were considered adherent to the treatment, but a significant difference ( $P = 1$ ) was not observed

between patients anticoagulated with Eno (92.7% adherent) or Riv (89.5% adherent). Similarly, there was no significant difference ( $P = 0.35$ ) in treatment adherence between patients undergoing knee or hip surgery. However, there was a significantly higher occurrence of ADRs ( $P = 0.001$ ) in patients treated with Eno (39.0%; hematoma at the site of injection) when compared to patients treated with Riv (no ADRs were attributable to this drug).

**Conclusions** Although a significant difference in adherence to subcutaneous Eno vs oral Riv was not observed, which may be potentially attributed to the short-term anticoagulation treatment (2 to 5 weeks), the occurrence of ADRs was significantly lower in patients treated with the oral anticoagulant. This difference in drug-related adverse events differs from other studies that detected similar adverse-event profiles.[2] From a methodological point of view, this is a small cross-sectional study and our results must be considered exploratory in nature.

## References

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No conflict of interest.

## GRP-165 ROOT CAUSE ANALYSIS AS AN OPPORTUNITY TO IMPROVE THE SAFETY OF PAEDIATRIC CARE

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**Background** Patient safety is a serious global public health issue. Causal analysis with a systematic and participatory approach is a useful tool for improving safety.

**Purpose** To perform a root cause analysis (RCA) in a medication error in order to identify improvement opportunities, to propose actions aimed to increase patient safety and to promote a collaborative approach in the health team.

**Materials and Methods** Retrospective study by the Patient Safety Team using RCA to investigate the cause of a medication error that happened in the paediatric unit in a tertiary level hospital, Spain. It included the following steps: identification and selection of the error, data collection and description of the event, construction of facts map, analysis of contributing factors and study of barriers that may prevent damage and finally, developing solutions and an action plan.

**Results** An administration error in a paediatric patient was selected. The patient received a single dose of antibiotic instead of a dose every 24 hours. RCA permitted the identification of human and patient factors as well as latent system failures associated with organisational factors and factors related to equipment, procedures, working conditions, education and training. Electronic prescribing and an individualised dispensing system failed as the main barriers.

The action plan proposed by the interdisciplinary team included: modification of the individualised dispensing system for the paediatric unit, improved electronic prescribing software, systematic visitor pass medical-nurse, and review of returns in the individualised dispensing system to detect errors.

**Conclusions** The analysis of a medication error by RCA identified the factors that caused the event and was a learning opportunity for the health team. Its use permitted a patient safety improvement through the identification and correction of latent system failures.

No conflict of interest.