

**Materials and Methods** We defined four performance indicators and analysed data from 2011 using the Web Reporting software supplied with ADS, and compared them with the 2008 results. Data were collected from the five EP-linked units.

1. Non-prescribed dispensing (NPD): percentage of drugs dispensed with no prescription assigned. It reflects physicians' prescription mistakes, ward dispensing mistakes, or technical problems with EP and EP-ADS interface.
2. Assigned Patient (AP): NPD with assigned patient. This indicator informs us about proper use, mainly in non EP-linked ADS units.
3. Fictional Patient (FP): NPD assigned to the fictional patient every unit has. This indicator reports us about technical problems with the hospital patient census and with the EP. It can also inform us of misuse of the ADS.
4. Discrepancies (DR): stock discrepancies as a percentage of global ADS transactions. These are related to ward dispensing mistakes or pharmacy supply mistakes.

**Results** NPD: 12.4% (25,820/208,957 drugs dispensed), lower than the 2008 results by 2.1 percentage points.

AP: 7.8%, 2.3 percentage point reduction.

FP: 4.6%, 0.3 percentage point increase.

DR: 3.0% (6,250/259,791 transactions), 0.3 percentage point reduction.

**Conclusions** ADS performance indicators have shown effectiveness in monitoring the processes. Between 2008 and 2011 we have improved in NPD, AP and DR results, but we have to work with factors that increased FP. We have found differences between some ADS units so a need for additional training in some wards has been revealed.

No conflict of interest.

#### TCH-004 CENTRALIZATION AND TECHNOLOGY SUPPORT THE HOSPITAL PHARMACIST IN IMPROVING SAFETY, ACCURACY AND ECONOMY IN THE MANAGEMENT OF MONOCLONAL ANTIBODIES

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**Background** Antineoplastic drugs are considered 'high-risk drugs' due to the increased frequency of human technical errors in their preparation. It is essential for pharmacists to be responsible for setting up, centralising and managing cytotoxic drugs (CDs). To this end, the Division of Anticancer Drugs of L'Aquila (Italy) acquired on June 2012 a Robotic System, APOTECACHemo, the first worldwide system for chemotherapy compounding in a controlled atmosphere.

**Purpose** To analyse the impact of centralising and automating CD preparation for all the Departments in the Hospital of L'Aquila, to avoid any possibility of human error and to optimise the use of the remainder of CDs.

**Materials and Methods** Three high cost monoclonal antibodies (bevacizumab, cetuximab and trastuzumab) were chosen for analysis in this study during the period June–September 2012. The criteria for product suitability were evaluated by analysing the APOTECACHemo database in which all stages of the production process are recorded (picture of the bottle used, weight, and dose accuracy). The cost analysis was evaluated by calculating the daily amounts left over of the three drugs that were previously discarded and are now fully re-used.

**Results** The average error was for 168 preparations of bevacizumab + 0.45% (DS = 1.85), for 67 preparations of cetuximab + 0.71% (DS = 1.13) and for 152 preparations of trastuzumab –0.57% (DS = 1.8).

In the period under review, 85.9 g of bevacizumab, 37.5 g of cetuximab and 43.8 g trastuzumab were prepared using material that would previously have been discarded. This provided considerable saving for the three drugs (€29,893) which corresponds to approximately €90,000 per year.

**Conclusions** The centralised system and the use of APOTECACHemo is successful both in terms of patient and operator safety and cost benefit for the Hospital.

No conflict of interest.

#### TCH-005 DEVELOPING A SAFE SYSTEM TO PRESCRIBE, PREPARE AND ADMINISTER CYTOSTATIC DRUGS

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**Background** As the cytostatic medicines are a group of drugs with a narrow therapeutic index, it is necessary to develop new mechanisms to improve safety from prescription to administration in the hospital in order to avoid fatal errors.

**Purpose** To develop a system that ensures that the prescription process, production and administration of cytostatic drugs meet the criteria: right patient, medicine, dosage, route of administration and time.

**Materials and Methods** Along with the centralization of drugs preparation in the pharmacy service, a computer system has been designed for the management of the administration of cytostatic drugs consisting of: portable digital assistant (PDA) with barcode reader, label printer for barcoded medicines, patient-identifying wristband and dedicated software for verifying and recording administration.

**Results** Every chemotherapy prescription is sent to the cytotoxic admixture unit mixer where it is validated by a pharmacist checking the following items: name and number from the patient history, diagnosis, stage, line of treatment, drugs, dose and route of administration. The computer programme generates drug labels containing the bar code which identifies the preparation. Each patient has a label with the bar code of the history number. Before the administration of each cycle, the responsible nurse has to read the patient bar code with the PDA. The drug and the right order for that patient will appear on the screen of the device. Nurses should read the bar code of each drug to be administered and the system checks that it is the right medicine and order, alerting visually and acoustically if error occurs. The system records the nurse and time of each drug administration.

**Conclusions** The project was implemented due to the need for safety mechanisms in the management of high-risk medicines, as cancer treatments are group of drugs with a narrow therapeutic index.

The system checks the safety in five key areas: patient, medicine, dose, route of administration and time.

No conflict of interest.

#### TCH-006 DEVELOPMENT AND VALIDATION OF 3 METHODS – UV SPECTROPHOTOMETRY, FLOW INJECTION ANALYSIS AND LIQUID CHROMATOGRAPHY – FOR THE CONTROL OF NYSTATIN CAPSULES.

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**Background** As an alternative to amphotericin B used for selective digestive decontamination, physicians asked the Hospital Pharmacy for the preparation of nystatin capsules, 500,000 IU.

**Purpose** Three methods were considered for routine checking: UV spectrophotometry, flow injection analysis (FIA) and high performance liquid chromatography (HPLC).

**Materials and Methods** Three batches (3x200 capsules) were prepared with nystatin (INRESA) and mannitol (VWR). All other reagents were of analytical grade.

Preparation of stock solutions of nystatin and capsules content was in reagent-grade methanol for FIA and HPLC (nystatin 72 µg/mL). For UV spectrophotometry, a subsequent dilution (1/50 V/V) with acetate ammonium buffer/methanol, 50:50 (V/V) was needed.

For FIA and HPLC, 10 µL were injected. In all cases, absorbance was measured at 305 nm.

UV spectrophotometry used a double beam spectrophotometer (UV mc<sup>2</sup> – SAFAS).

FIA used an HPLC device (Ultimate 3000 – Dionex) in which the stationary phase was replaced by a capillary flow of water (1.0 mL/min; 25°C).

HPLC equipment was an ELITE LaChrom (VWR/Hitachi). An end-capped C18 stationary phase was used (30°C). The mobile phase was a mixture of 0.05 M acetate ammonium buffer pH = 6.0/reagent-grade methanol (35/65; V/V). Flow rate was 1.0 mL/min; run time was 25 min.

**Results** For UV spectrophotometry and FIA, the development took into account the nystatin concentration to obtain absorbance levels suitable for the precision and the range of linearity. HPLC was developed as an isocratic stability indicating method.

The three methods were fully validated (ICH Q2R1). HPLC ruggedness was studied according the adjustments allowed by the Ph. Eur. (2.2.46). Nystatin content (3 batches) assayed by each method complied with the acceptance limit: 90.0–110.0%.

**Conclusions** For routine checking, UV spectrophotometry or FIA would be the methods of choice (rapid, easy to handle); the HPLC method could be used to perform stability studies.

No conflict of interest.

#### TCH-007 DEVELOPMENT OF A BETAMETHASONE (DIPROPIONATE) TOPICAL EMULSION 0.1% (W/W) (1MG/G) FOR CUTANEOUS T-CELL LYMPHOMA

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**Background** Cutaneous lymphomas are a heterogeneous group of lymphomas characterised by T and B clonal lymphoproliferative infiltrates that appear and remain confined to the skin without evidence of involvement of other organs/systems in the six months following diagnosis.

Some subtypes of cutaneous T epidermotropic lymphomas respond favourably to topical treatment with steroids. Betamethasone dipropionate is a synthetic high-potency glucocorticoid with anti-inflammatory and immunosuppressive action used as the main topical treatment in the early stages of LNH-T–Mycosis Fungoides, or as an adjuvant treatment in advanced stages of the disease.

In the Portuguese pharmaceutical market only a 0.05% (w/w) (0.5 mg/g) cream is available although for this therapeutic indication strengths in a range of 0.025%–0.1% (w/w) are required. This was already an off-label clinical use and a higher concentration was required due to insufficient response to the concentration available.

**Purpose** To prepare and characterise a topical 0.1% (w/w) (1 mg/g) betamethasone (dipropionate) cream and evaluate the overall response in cutaneous T-cell lymphomas.

**Materials and Methods** Several batches of a compounded W/O emulsion containing betamethasone 0.1% (w/w) (1 mg/g) were prepared and analysed for macroscopic characteristics, pH, rheological properties and microbiological quality (total germs, fungal, yeasts and E. coli).

Patients were evaluated monthly and the overall response was recorded (CR-cutaneous lesion totally disappeared; PR-partial remission – objective response >50%<100%; Stabilized disease if cutaneous lesions were similar; No response if cutaneous lesions worsened).

**Results** We obtained a white, homogeneous, opaque and odourless cream with a pseudoplastic behaviour. The pH of the formulations at 22 ± 3°C was 5 (±0.5). Microbiological control for non-sterile products revealed no growth of micro-organisms.

By the end of the first month one patient (11.1%) showed partial remission, the others (88.9%) had their cutaneous disease lesions stabilised.

**Conclusions** The topical emulsion developed has pH values and rheological characteristics suitable for drug stability and topical skin application. Clinical data is still insufficient for any conclusions.

No conflict of interest.

#### TCH-008 DEVELOPMENT OF A HYDROCHLOROTHIAZIDE 0.5 MG/ML ORAL SOLUTION FOR CHILDREN

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**Background** In The Netherlands there are no licenced medicines available with hydrochlorothiazide that are suitable for children. Lack of children's formulations in general may lead to a variety of mixtures of different quality and strength. This may cause medication errors, especially when children receive the same active substance in different formulations and strengths during their hospital stay and after discharge.

**Purpose** To develop a standardised hydrochlorothiazide liquid formulation with a shelf life supported by stability studies, in order to provide standardised and safe care for children.

**Materials and Methods** National standard procedures were applied to assess the therapeutic rationale and to design an oral solution for children. HPLC was used to develop a method of indicating stability in order to establish shelf life. A patient information leaflet was designed, also by following a standard procedure.

Nationwide, the quality of hydrochlorothiazide oral liquid preparations was determined pre- and post-introduction of the standardised formulation.

#### Results

- A therapeutic rationale was established for diuresis.
- A formulation for a robust hydrochlorothiazide 0.5 mg/ml oral solution was optimised for solubility, stability and taste.
- An HPLC method was developed to test stability.
- A shelf life of 6 months was established.
- Publication in the Dutch Formulary.
- A patient information leaflet was produced providing information on indication, use, precautions, interactions and storage.
- Hydrochlorothiazide formulation errors decreased nationwide from 35% to 13%.

**Conclusions** A robust and stable oral liquid formulation was developed containing hydrochlorothiazide 0.5 mg/ml, which remains stable for 6 months. A patient information leaflet was made available. Standardization and publication in the Dutch Formulary has demonstrably improved the quality of hydrochlorothiazide oral liquid formulations nationwide.

No conflict of interest.