15th Anniversary Congress of eahp

european association of hospital pharmacists

Nice, France, 24-26 March 2010

ABSTRACT BOOK

"Focus on pharmacotherapy - hospital pharmacists advancing patient care"

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GENERAL INFORMATION

The poster judging will take place on Thursday, 25 March 2010.

Poster presenters must check in with the hostesses in the poster area (level 3 of congress centre) on Wednesday, 24 March, and they will assist participants with hanging their posters in the proper area.

The poster prize winners must be present at the closing ceremony on Friday, 26 March in order to win.

DISCLAIMER

EAHP makes no representations or warantees of any kind expressed or implied about the completeness, accuracy, reliability, suitability or availability with respect to the content of the abstracts and related graphics and tables. Any reliance you place on such information is therefore at your own risk. In no event will EAHP be reliable for any loss or dammage arrising from or in connection with the content of these abstracts.

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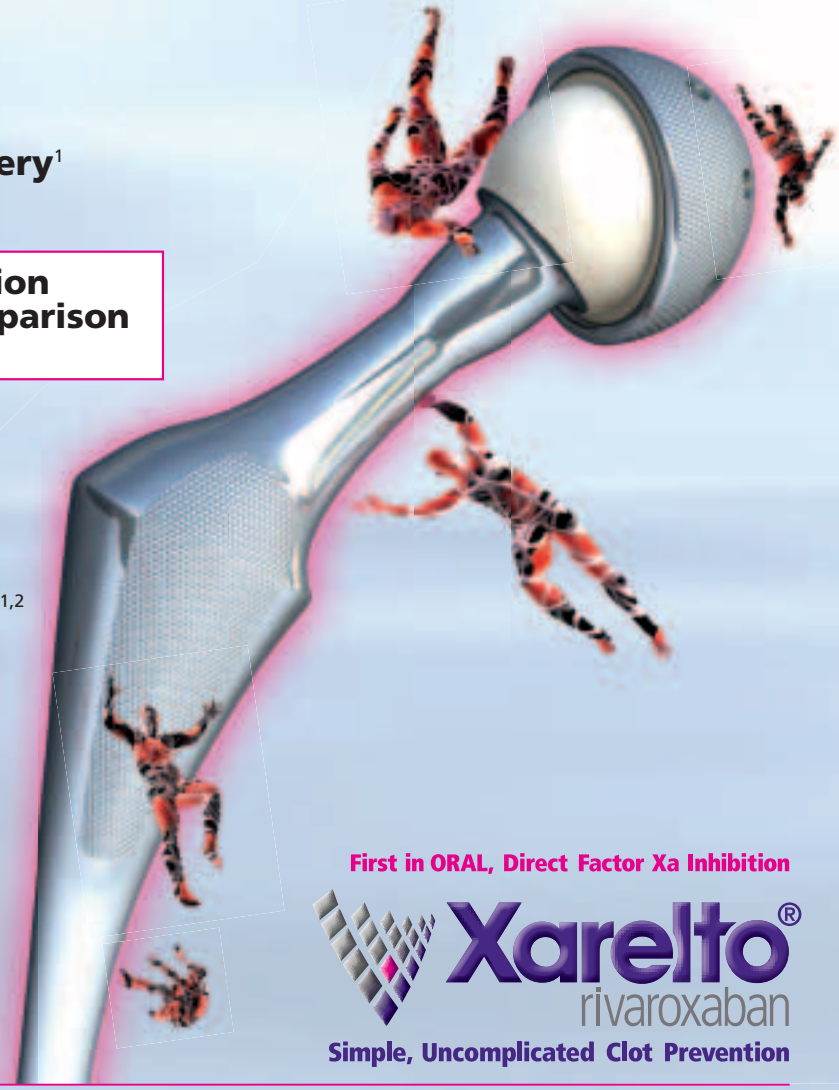

SUPERIOR EFFICACY
in elective hip replacement surgery[1]

70% **Total VTE risk reduction in head to head comparison with enoxaparin**[1*]

REASSURING SAFETY
Similar safety profile compared with enoxaparin[1,2]

* RRR 70%; 95% CI, 49 to 82; (P<0.001) in modified ITT population; total VTE: any DVT, non-fatal PE, and all-cause mortality.

1. Eriksson BI et al. *N Engl J Med.* 2008;358(26):2765–2775.
2. Kakkar AK et al. *Lancet.* 2008;372:29-37

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Qualitative and quantitative composition: Each film-coated tablet contains 10 mg rivaroxaban. Excipients: Each film-coated tablet contains 27.9 mg lactose monohydrate. **Pharmaceutical form:** Film-coated tablet (tablet). Therapeutic indications: Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. **Posology and method of administration:** The recommended dose is 10 mg rivaroxaban taken orally once daily. The initial dose should be taken 6 to 10 hours after surgery, provided that haemostasis has been established. The duration of treatment depends on the individual risk of the patient for venous thromboembolism which is determined by the type of orthopaedic surgery. • For patients undergoing major hip surgery, a treatment duration of 5 weeks is recommended. • For patients undergoing major knee surgery, a treatment duration of 2 weeks is recommended. If a dose is missed the patient should take Xarelto immediately and then continue the following day with once daily intake as before. Xarelto can be taken with or without food. Renal impairment: No dose adjustment is necessary in patients with mild renal impairment (creatinine clearance 50 - 80 ml/min) or moderate renal impairment (creatinine clearance 30 - 49 ml/min) (see section 5.2). Limited clinical data for patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) indicate that rivaroxaban plasma concentrations are significantly increased in this patient population, therefore, Xarelto is to be used with caution in these patients. Use is not recommended in patients with creatinine clearance < 15 ml/min. Hepatic impairment: Xarelto is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk (see sections 4.3 and 5.2). Xarelto may be used with caution in cirrhotic patients with moderate hepatic impairment (Child Pugh B) if it is not associated with coagulopathy. No dose adjustment is necessary in patients with other hepatic diseases. Patients above 65 years: No dose adjustment. Body weight: No dose adjustment. Gender: No dose adjustment. Children and adolescents: Xarelto is not recommended for use in children or adolescents below 18 years of age due to a lack of data on safety and efficacy. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Clinically significant active bleeding. Hepatic disease associated with coagulopathy and clinically relevant bleeding risk. Pregnancy and lactation. **Undesirable effects:** The safety of rivaroxaban 10 mg has been evaluated in three phase III studies including 4,571 patients exposed to rivaroxaban undergoing major orthopaedic surgery of the lower limbs (total hip replacement or total knee replacement) treated for up to 39 days. In total, about 14 % of the treated patients experienced adverse reactions. Bleedings or anaemia occurred in approximately 3.3 % and 1 % of patients, respectively. Other common adverse reactions were nausea, increased GGT and an increase in transaminases. The adverse reactions should be interpreted within the surgical setting. Due to the pharmacological mode of action, the use of Xarelto may be associated with an increased risk of occult or overt bleeding from any tissue or organ which may result in posthaemorrhagic anaemia. The signs, symptoms, and severity (including possibly fatal outcome) will vary according to the location and degree or extent of the bleeding. The risk of bleedings may be increased in certain patient groups e.g. those patients with uncontrolled severe arterial hypertension and/or on concomitant treatment with other medicinal products affecting haemostasis. Haemorrhagic complications may present as weakness, asthenia, paleness, dizziness, headache or unexplained swelling. Therefore, the possibility of haemorrhage is to be considered in evaluating the condition in any anticoagulated patient. Adverse reactions in the three phase III studies are listed below by system organ class (in MedDRA) and by frequency. Frequencies are defined as: Common: ≥ 1/100 to < 1/10 - Uncommon: ≥ 1/1,000 to < 1/100 - Rare: ≥ 1/10,000 to < 1/1,000 - Very rare:< 1/10,000 - Not known: cannot be estimated from the available data. ■ ***Investigations:*** ◆ Common: Increased GGT, increase in transaminases (incl. ALT increase, AST increase) ◆ Uncommon: Increased lipase, increased amylase, blood bilirubin increased, increased LDH, increased alkaline phosphatase ◆ Rare: Bilirubin conjugated increased (with or without concomitant increase of ALT) ■ ***Cardiac disorders:*** ◆ Uncommon: Tachycardia ■ ***Blood and lymphatic system disorders:*** ◆ Common: Anaemia (incl. respective laboratory parameter) ◆ Uncommon: Thrombocythaemia (incl. platelet count increased) ■ Nervous system disorders: ◆ Uncommon: Syncope (incl. loss of consciousness), dizziness, headache ■ ***Gastrointestinal disorders:*** ◆ Common: Nausea ◆ Uncommon: Constipation, diarrhoea, abdominal and gastrointestinal pain (incl. upper abdominal pain, stomach discomfort), dyspepsia (incl. epigastric discomfort), dry mouth, vomiting ■ ***Renal and urinary disorders:*** ◆ Uncommon: Renal impairment (incl. blood creatinine increased, blood urea increased) ■ ***Skin and subcutaneous tissue disorders:*** ◆ Uncommon: Pruritus (incl. rare cases of generalised pruritus), rash, urticaria (incl. rare cases of generalised urticaria), contusion ■ ***Musculoskeletal and connective tissue disorders:*** ◆ Uncommon: Pain in extremity ■ Injury, poisoning and procedural complications: ◆ Uncommon: Wound secretion ■ ***Vascular disorders:*** ◆ Common: Post-procedural haemorrhage (incl. post-operative anaemia, and wound haemorrhage) ◆ Uncommon: Haemorrhage (incl. haematoma and rare cases of muscle haemorrhage), gastrointestinal tract haemorrhage (incl. gingival bleeding, rectal haemorrhage, haememesis), haematuria (incl. blood urine present), genital tract haemorrhage (incl. menorrhagia), hypotension (incl. blood pressure decreased, procedural hypotension), nose bleed ◆ Not known*: Bleeding into a critical organ (e.g. brain), adrenal haemorrhage, conjunctival haemorrhage, haemoptysis ■ ***General disorders and administration site conditions:*** ◆ Uncommon: Localised oedema, peripheral oedema, feeling unwell (incl. fatigue, asthenia), fever ■ ***Immune system disorders:*** ◆ Rare: Dermatitis allergic ◆ Not known*: Hypersensitivity ■ ***Hepatobiliary disorders:*** ◆ Rare: Hepatic function abnormal ◆ Not known*: Jaundice. *) Adverse events have been reported in other clinical studies than the three phase III studies in patients undergoing major orthopaedic surgery of the lower limbs. **Nature and contents of container:** PP/Aluminium foil blisters or PVC/PVDC/Aluminium foil blisters in cartons of 10 and 100 tablets. **Marketing authorisation holder:** Bayer Schering Pharma AG, 13342 Berlin, Germany. **Marketing authorisation number(s)** EU/1/08/472/006, EU/1/08/472/008 **Date of revision of the text:** 04/2009 **General classification for supply:** Medicinal product subject to medical prescription.

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CALL FOR ABSTRACTS
Vienna Congress from 30 March – 1 April 2011

Original contributions from all fields of hospital pharmacy are welcomed for oral or poster presentation.

Deadline for submission: 15 October 2010

Submit your abstract via the EAHP web site's online submission page.

IMPORTANT NOTE: the online submission form does not recognise some symbols from various keyboards, therefore, please proof your abstract after entering into the system.

Format

- Abstracts must be submitted via our online submission programme. No abstract will be reviewed if not submitted via the website, www.eahp.eu. Authors will be notified of the status of the submission in the last week of November 2010. The EAHP Congress Secretariat reserves the right to make electronic adjustments to abstracts. Abstract texts will not be modified without the author's consent. When – in the opinion of the EAHP Congress Scientific Committee – the language of the abstract needs stylistic revision, this will be done by a professional editor. The resulting abstract will be mailed to the first author, who will have 5 working days to respond. Without response within 5 working days, the revised manuscript is final. Should you have any questions, please send a message to **abstract@eahp.eu** .
- Abstracts should be structured in four paragraphs: Background, Methods, Results and Conclusions, the online abstract submission will guide you through this process.
- Abstracts must have no more than 300 words (or less if you use graphs or tables), and be typed in English.
- Acknowledgement may be given at the end of the abstract. Emphasis should be on the results of the study.
- The title of the abstract must be strictly coherent with the data included in the abstract and the conclusions must be warranted by information included in the results section.
- Standard abbreviations may be used. Other abbreviations may be used if they are defined (spell out in full at first mention, followed by abbreviation in parentheses), see below for a short list of common abbreviations.
- Simple tables or graphs in black and white may be included, but not photographs. Symbols and drug structural formulas may be used and should be drawn or printed in black.

The abstract must be set up as follows:

- Title in lower case letters (do not use abbreviations in title)
- Name of every author, preceded by initials. The name of the presenting author should be underlined. Omit degrees, titles or institutional appointments.
- Institution, city, country where the study took place.
- Email address of the presenting author if you wish.
- One blank line
- Commence typing abstract.

Guidance to Poster Presentation and Poster Abstract

Abstracts

1. General recommendation: please try to get an English speaker check your abstract before submission. Note that many abstracts are rejected because of language problems (not understandable, poor English).
2. Use the following backbone in all abstracts
   a. Background
      Explain the general situation around your study in one or two sentences.
   b. Purpose
      i. What do you want to know?
      ii. Why is this knowledge important?
      iii. Is there other knowledge in this field already published (e.g. other indications for the same drug)?
   c. Material and Method

i. How did you get the data?
ii. What did you calculate?

d. Results
Show the key results and discuss them.

e. Conclusion
i. What will the data change in your hospital or in healthcare in general?
ii. Are further studies needed and why is this?

3. Be scientific and avoid narrative
For instance avoid writing “mean age was 63,15 +/- 12,57 years” and prefere 63 +/- 13 years - use decimals only if they give additional information to the fact: if numbers are below 10, then one decimal might be useful, if under 1 two decimals might be useful
4. In case series or in drug use evaluations (DUE): Be sure to present at least 30 patients or cases
There might be exceptions in rare diseases (e.g. Menckes Disease, but not HIV or Hepatitis C)
5. Case reports are only interesting if this is not already published in literature or when the outcome differs from literature (cite literature)
6. If citing literature in your abstract text you must give the information for this at the end of your abstract text
7. Try to avoid tables or figures in the abstract
6. Use know
7. n abbreviations whenever possible and explain other abbreviations the first time they appear. Don‘t use other abbreviations than found in the list below before explanation.
i. List of abbreviations (e.g., see also DrugDex)
1. HPLC
2. MS
3. mL, g, mg, mikrog, L, mmol, IU,
4. AUC
5. MIC
6. Cmax
7. CE: Capillary electrophoresis
8. IR
9. UV: UV-Vis
10. DC
11. MRSA
12. VRE
13. Exponential numbers: e.g., write 10E6
14. Dosage frequency: e.g. q6h (instead of four times daily)
7. Do not use commercial names, use INN and be sure, that you spell it in the right way
8. Drug consumption analysis, drug use evaluations, case series: State why you did this work, what your goal was in terms of future practice in your hospital, conclude what steps will follow your analysis.
9. Conclusion: there is no way to have the only conclusion that “further studies are needed” (to find out something). BUT: please state what comes out of your work (why have you done this and what will happen in the future because of your findings).
Please don‘t write general comments (e.g. “the hospital pharmacists can play an important role ...”) in the conclusion. You might do this on the poster.
10. Check literature: if you study a fact which is already published somewhere just cite and compare literature results with your own results
11. Drug interaction: Please explain mechanism behind drug interaction at least on the poster (cite literature there)
12. Results in case reports or case series: Focus on and show patient outcome
13. Position statements: Try to stick to the given abstract structure

Posters

1. Stick to the given poster size!
2. The top line of your poster must show the title, the authors, the address and an e-mail contact.
3. Please prepare handouts and a pdf-version of your poster to send it to interested colleagues after the congress.

Topic Groups

1) General and Risk Management, Patient safety- including: medication errors, quality control
2) Technology - including: robots for production, Incompatibilities, drug production and analytics, CRS
3) Drug supply / logistics - including: computer-aided drug dispatching and ward pharmacies
4) Drug information - i. Anti-infectives, ii. cytostatics, iii. others
5) Pharmacotherapy: Pharmacokinetics and Pharmacodynamics - including: ADE, TDM, DUE
6) Other Hospital Pharmacy topics including: medical devices
7) Clinical pharmacy and clinical trials - including case series

Reasons for rejection (more than one reason for rejection is possible)

1. Not enough data
2. Nothing new
3. No added value for other hospital pharmacists
4. Case series/DUE: not enough data
5. Not understandable due to poor English
6. Conclusion does not cover aim of study
7. Abstract does not follow given structure

Format

Same as for Abstracts – please see above.

Poster Award

Encouragement prize for investigators.

The best abstracts/posters – with regards to aspects like originality, scientific quality and practical applicability – will be awarded with 3 prizes amounting EURO 750, EURO 500 and EURO 250. The winners will be announced at the closing ceremony of the congress. The winner must be present at the ceremony to receive his/her award.

EAHP - EPSA award

Recognising and honouring the best scientific research manuscript authored by an undergraduate student

During its annual congress, EAHP will offer the Student Science Award to one or several European Pharmaceutical Student Association (EPSA) students, hence recognising and honouring the best scientific research manuscript authored by an undergraduate student. This award recognises a student's significant intellectual contribution which promotes the state of the art in hospital pharmacy and pharmaceutical research methods or theories. EPSA students and members are invited, through their organisation to submit manuscripts to an EAHP jury, who will select the best paper. The later will be presented during the congress and published in EJHP.

16th Congress of

eahp

european association
of hospital pharmacists

30 March – 1 April 2011, Vienna - Austria

"Hospital pharmacists in a changing world – opportunities and challenges"

The European Association of Hospital Pharmacists (EAHP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education

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The European Association of Hospital Pharmacists represents more than 21,000 hospital pharmacists in 31 European countries and is the only European federation of hospital pharmacists in Europe.

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EAHP - EPSA award

Recognising and honouring the best scientific research manuscript authored by an undergraduate student

During its annual congress, EAHP will offer the Student Science Award to one or several European Pharmaceutical Student Association (EPSA) students, hence recognising and honouring the best scientific research manuscript authored by an undergraduate student. This award recognises a student's significant intellectual contribution which promotes the state of the art in hospital pharmacy and pharmaceutical research methods or theories. EPSA students and members are invited, through their organisation to submit manuscripts to an EAHP jury, who will select the best paper. The later will be presented during the congress and published in EJHP.

Nature of the Award:

First author of the winning article will receive free attendance to the 16th EAHP Congress in Vienna, €500 for travel and accommodation expenses, plus official recognition of the winner during the EAHP Congress closing ceremony.

Eligibility Criteria:

Any manuscript under the category of original research, case reports, scientific commentary and review articles, written by any undergraduate hospital pharmacy student(s) submitted for peer review by 15 January 2011 and approved for publication in the EJHP March 2011 issue in either the EJHP Practice or the EJHP Science journal, will be eligible for this competition.

Submission Procedures:

Any EPSA member may submit a manuscript following the EJHP Guidance for Authors. The manuscript shall be submitted to abstract (at) eahp.eu. A complete copy of the manuscript must accompany the submission. A cover letter should be provided that states why the article represents an outstanding contribution to the field of hospital pharmacy and describes how it advances hospital pharmacy research, clinical, scientific, technical, economic and social aspects of pharmacy and therapeutics or affects health policy.

Review and Selection:

The EAHP- EPSA Student Science Award Jury serves as the review and selection committee for the Student Science Award. The jury will select the single best manuscript that shows significant insight into hospital pharmacy research from all those submitted based on its scientific quality and societal relevance. The committee has the discretion to not make the award in any given year.

Award Presentation:

The EAHP-EPSA Student Science Award will be presented during the award ceremony at the EAHP Annual Congress in Vienna, Austria on 1 April 2011.

NOVARTIS MALARIA AWARENESS PROJECT – IMPROVING CARE FOR MALARIA PATIENTS

Malaria is a major cause of morbidity and mortality in various areas of the world. According to the World Health Organization approximately 250 million people get infected each year by the malaria parasite and nearly one million die. Africa carries a disproportionate disease burden - more than 80 percent of malaria cases are in this continent. Pregnant women and children are most affected: every 30 seconds a child dies from malaria in Africa. The devastation of malaria can also be calculated in economic terms. The disease causes an average loss of 1.3% of annual economic growth in countries with intense transmission, perpetuating poverty. Yet malaria is a preventable and curable disease.

In recent years the world assisted to renewed efforts to fight malaria, thanks to the availability of a new class of compounds, the ACTs (Artemisinin-based Combination Therapies) with high, unaltered by resistance, efficacy rates, and to increased funding from the Global Fund and the worldwide community.

Novartis has been up to the challenge by providing more than 300 million treatments of its antimalarial drug, Coartem, not-for-profit for the public sector in the developing countries. It is estimated that this countributed to save more than 750'000 lives. However, drug availability alone is not sufficient and the world organizations, the pharmaceutical companies, the NGOs and the countries affected by malaria should join their efforts to reach the Millennium Development goal of a world free of malaria.

Recently a pediatric formulation of Coartem has been made available by Novartis, Coartem Dispersible. Easily dispersible in water and with a sweet taste, Coartem Dispersible is the first artemisinin-based combination therapy developed specifically for children to facilitate intake and ultimately treatment compliance.

NOVARTIS

NOTES

ORAL PRESENTATIONS

Wednesday, 24th March 2010, 14.00 – 15.30: room Euterpe

1. Interdisciplinary team improves medication reconciliation

D. Bonnerup[1], C.A. Srensen[1], S. Gram[2]
[1]Aarhus University Hospital Hospital Pharmacy Aarhus Randers, Randers, Randers NØ, Denmark
[2]Region hospital Randers, Medical ward, Randers NØ, Denmark

Background
The Danish Society for Patient Safety launched Operation Life in April 2007 as a nationwide campaign for quality and patient safety in Danish hospitals. One part of Operation Life deals with medicines reconciliation. Medicines reconciliation involves comparing the patient's current list of medicines against e.g. the physician's prescriptions upon admission, transfer, and/or discharge.

Method
At the medical ward at Regionshospitalet Randers, Denmark, an interdisciplinary team consisting of two senior doctors, 2 nurses and a pharmacist was formed to work with medicines reconciliation. Initiatives were taken to implement the recommendations; e.g. pocket cards, crowning the doctor of the month and education. 10 patient records were audited every month in a predefined period to find out whether medicines reconciliation was being done according to the recommendations.

Results
Some results from the audits:

	Apr 08	Jul 08	Aug 08	Sept 08	Oct 08	Nov 08	Dec 08	Feb 09	Mar 09	Apr 09	Jun09
Does the medical history follow the hospitals recommendations?	20%	40%	100%	100%	90%	100%	-	-	-	-	-
Is medicines reconciliation done at admission?	-	-	-	40%	60%	60%	70%	70%	60%	70%	80%
Is medicines reconciliation done at discharge?	-	-	-	50%	50%	60%	70%	70%	60%	80%	70%

The results indicate a tendency to improving audit results after the new system had been implemented and following the work of the inter-disciplinary team. As a side benefit the medical ward decided to hire a clinical pharmacist to perform a medicines review in all newly-hospitalised patients on the medical emergency ward.

Conclusion
Awareness of medicines reconciliation and documentation of this improved on this ward during the period. The results indicate that the interdisciplinary team's approaches for implementing changes have worked, even though there is still room for improvement. The interdisciplinary teamwork has resulted in a pharmacist being hired on the medical ward.

Conflict of Interest
No conflict of interest

Thursday, 25th March 2010, 08.30 – 10.00: room Euterpe

2. Clinical trials from a doctor's perspective - the importance of involving hospital pharmacy

G. Dreyer[1], C. Harper[2], S. Garner[2], R. Popat[3], A. Farrell[4], M. Yaqoob[5]
[1]Barts and The London NHS Trust, Renal Department, London, United Kingdom
[2]Mawdsley Brooks UK, Clinical Trials, Doncaster, United Kingdom
[3]Royal London Hospital, Pharmacy, London, United Kingdom
[4]Royal London Hospital, Clinical Trials Pharmacy, London, United Kingdom
[5]Royal London Hospital, Renal department, London, United Kingdom

Background
Doctors motivated to conduct a randomised controlled trial (RCT) often have very little exposure to the process of designing and managing trials and may be discouraged from undertaking important medical research. We describe how the combination of nephrology doctors, hospital pharmacists and industry collaborators has worked effectively to design, implement and produce an investigational medicinal product (IMP) for an RCT comparing oral ergocalciferol to placebo in patients with chronic kidney disease and vitamin D deficiency.

Method
The study protocol was written by the nephrology team in conjunction with clinical trial and hospital pharmacists who provided pharmaceutical advice and liaison with industry partners. 64 patients (32 per arm) are required for this study each receiving either 50,000 IU of ergocalciferol or a matching placebo weekly for one month and then monthly for five months.

Results
Ergocalciferol was sourced by hospital pharmacists in conjunction with industry partners (Mawdsley Brooks, Doncaster, UK) and was imported under licence from sanofi-aventis in the USA. To produce an identical, matching placebo, the ergocalciferol was over-encapsulated into empty, hard gelatine capsules (size 00) and a matching placebo containing lactose was produced concomitantly (Ipswich hospital pharmacy, UK). IMP labelling and QP release was performed by the importing company. Stability-indicating assays on the over-encapsulated ergocalciferol are underway to confirm that the use of the manufacturer's original expiry date is valid. The clinical trial has been approved by all regulatory and ethics committees and is actively recruiting.

Conclusions
Hospital pharmacy can play an active role in supporting clinical research by providing links between clinicians, industry and pharmacy services and advising on the current legislation surrounding clinical trials. These collaborations can facilitate the design, implementation and running of an RCT including the *de novo* manufacture of an IMP and should be encouraged in order to facilitate future clinical research.

Conflict of Interest: No conflict of interest

3. Role of bevacizumab in combination with irinotecan in the treatment of high grade gliomas: outcomes of a 29-patient series

P. Bartecki[1], K. Hassani[1], L. Taillandier[2], M. Labrude[1]
[1]Hopital Central CHU de Nancy, pharmacie, Nancy, France
[2] Hopital Central CHU de Nancy, pharmacie, neuro-oncologie, Nancy, France

Background
High-grade gliomas, represented by glioblastoma multiforme (GBM) as the most common type, are rare but dangerous in terms of prognosis, particularly in recurrence situations. Although the initial treatment is well codified, the efficacy of concomitant radio-chemotherapy (Stupp protocol) is well established in only some patients, such as patients under 70. The lack of a standard alternative for patients who can't undergo the Stupp protocol, frequent recurrences and the toxicity of second-line chemotherapy (such as procarbazine, lomustine, and vincristine, PCV) are leading neuro-oncologist teams to look for new, efficient therapeutic strategies. At present, there is increasing evidence that anti-angiogenic drugs may be beneficial for patients with high grade gliomas. They show encouraging results in terms of survival and imaging, as a result many ongoing clinical trials are evaluating their benefit. The association of an angiogenesis inhibitor with a "classical" cytotoxic such as bevacizumab / irinotecan is one of the options used by the neuro-oncologists of the Nancy teaching hospital.

Objective
Over a period of 8 months (November 2007-June 2008), we examined how and when the combination of a neo-angiogenesis inhibitor with a "classic" cytotoxic agent could find its place in the management of patients with high grade gliomas. The criteria used to evaluate the efficacy of this combination were imaging and clinical response.

Method
Patients treated with bevacizumab / irinotecan were identified through the chemotherapy prescription software (CHIMIO). Medical data describing the population and oncology treatment history were collected from computerised patient records (SUSIE v4).

Results
Twenty-nine patients (11 females and 18 males) were treated with bevacizumab / irinotecan. The median age at diagnosis was 48.4 years and 51.9 at initiation of the first cycle. As a variety of therapeutic strategies was used, this combination was the 3rd or 5th line treatment in 80% of cases. It is almost always given as a 2nd or a 3rd line chemotherapy. In terms of MRI response 14 patients (49%) showed regression and 4 (14%) showed stabilisation, while from a clinical perspective 6 patients (21%) improved and 9 (31%) stabilised. These observations are consistent with the encouraging results observed in the literature. Following the first cycle of bevacizumab / irinotecan, 13 patients were assessed as non-responders (clinical status and/or MRI): the therapeutic strategy was changed for 3 patients, 8 went to symptomatic treatment and 2 died. The effect of tumour size, production of pro-angiogenic factors or upregulation of pro-invasive molecules (in favour of increasing infiltrative tumour growth) could explain the resistance to anti-angiogenic therapy.

Conclusion: Preliminary results with bevacizumab / irinotecan in the treatment of patients with high grade gliomas are encouraging and are supported by the results observed in the literature. A further study with more patients would be very interesting to in order to obtain as complete an inventory as possible.

Conflict of Interest
No conflict of interest

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4. Identification of medicines with specific drug administration times

M. Kieran[1], A. Merrins[1], M. Creed[1], C. Meegan[1]
[1]Mater Misericordiae Hospital, Pharmacy Department, Dublin, Ireland (Rep.)

Objective
A whole-hospital Standardised Drug Administration Times Policy has been in place in the MMUH for many years. It aimed to standardise the daily drug administration round process, to foster best practice regarding patient care and patient safety. This study examines the most appropriate times at which individual drugs should be administered. The information will then be incorporated into hospital policy to highlight particular drugs requiring specific administration times. This should further improve the timing of drug administration.

Methodology
- All available reference sources were assessed for information on specific administration times. The electronic BNF (eBNF) was chosen as the standard reference for this search.
- All drug monographs in the eBNF were checked for specific drug administration times, using the search terms mane, nocte, tarde etc.
- All clinical pharmacists were surveyed for input on drugs that they routinely endorsed as having specific administration times.
- Summaries of Product Characteristics were consulted to validate any pharmacists' recommendations that had not been noted in the eBNF search.

Results
- 192 drugs were found to have specific administration times detailed in their licenses. This information was collated and included the indication for the specific administration time.
- The drugs were also grouped according to therapeutic category.
- Relevant medicines/therapeutic categories were identified and the policy was updated to include details of drugs with specific administration times.

Conclusion
Improvements were made to the MMUH standardised drug administration times policy by incorporating specific administration times necessary for specified medicines. This will help improve the understanding of doctors, nurses and pharmacists of appropriate administration times for drugs throughout the hospital.

References
1. British National Formulary no. 56. London: BMJ Group and RPS Publishing; 2008.
2. IPHA Medicines Compendium website, www.medicines.ie
3. The Electronic Medicines Compendium, www.emc.medicines.org.uk

Conflict of Interest: No conflict of interest

5. Pharmaceutical intervention in HIV+ outpatients in the hospital setting

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Background
The purpose of highly active anti-retroviral therapy (HAART) is maximum and prolonged suppression of the viral load and reconstitution of the immune defences. Several factors may be associated with treatment failure, including suboptimal adherence, pharmacokinetic problems and adverse effects. Given the complexity, it is agreed that HAART dispensing should be carried out by specialised pharmacists, skilled in tackling drug-related problems (DRPs).

Methods
This study included all HIV+ patients (1650) treated in the pharmacy department outpatients' section of EgasMoniz Hospital - CHLO in the year 2008 When dispensing medicines, we evaluated the possibility of DRPs. The definition and classification of DRPs adopted was that recommended by PCNE (Pharmaceutical Care Network Europe) V5.01. The DRPs detected were properly recorded and all pharmaceutical interventions (PI) were evaluated by the PCNE method. In parallel, the clinical significance of PIs was evaluated as proposed by Overhage et al. and they were performed by an independent auditor (pharmacist).

Results
About 131 DRPs were detected in 126 patients, mean aged 44.8 years, 66.6% male and 33.3% female. We mostly identified adherence (54.2%) and inadequate doses and dosing intervals (23%). The use of inappropriate drugs (7.6%) was due to prescribing errors and inappropriate selection of regimens. Treatment-related toxicity and potential interactions were detected infrequently. Regarding the type of PI, the advice given to patients or caregivers (45% were given advice) proved to be relevant. In 35.1% of the cases we made recommendations to the physician, with an acceptance rate of 93%. The clinical outcomes of PIs were positive, fully resolving 38.2% of DRPs. The PIs made were clinically significant in 80% of cases.

Conclusion
Hospital pharmacists are performing relevant work in the prevention, detection and resolution of DRPs in HIV patients on HAART regimens. The PCNE method allows systematic documentation of clinical pharmacy services.

Conflict of Interest
No conflict of interest

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6. Clinical team pharmacists' context and role in Italy: the experience of San Giovanni Battista Hospital, Turin, Italy

F. Cattel[1], R. Arione[2], M.C. Azzolina[2], S. Boffa[1], E. Cerutti[1], E.J. Pennone[1], M. Scaldaferri[1], E. Sciorsci[1], G. Fazzina[1], S. Stecca[1]
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[2]A.O.U San Giovanni Battista, Sanitary Direction, Turin, Italy

Background
Since 2005, in San Giovanni Battista Hospital of Turin, the Clinical Team Pharmacist (CTP) has been identified as a tool to improve therapeutic appropriateness, in terms of safety, efficiency and cost savings, and to focus on integrating knowledge and multidisciplinarity as instruments of care processes governance.

Method
We have built a methodology combining traditional activities of Italian Hospital Pharmacists with standard international activities of ward pharmacists, such as participation in rounds, admission or discharge medicines reconciliation, drug-class specific services, risk management. This approach has required a shift in traditional knowledge and skills, introducing the concept of formulary, guidelines and safe storage of drugs to the ward, to bring about integrated management of treatment.

Results
Pharmacists are now working in 12 wards belonging to Uro-Nephrology Department, Emergency and Admittance Department and Onco-Haematology Department. On these wards, the pharmaceutical cost/diagnosis-related group index rose from 189 in the second half of 2006 to 123 in the second half of 2008. Error monitoring of 200 medical records of January 2009 enabled 1.47 errors/patient to be detected, corresponding to 1.56% of total prescriptions, with only 4 potentially serious errors. Awareness of off-label use of drugs is high in these wards, so that, since 2007, 32% of alerts regarding off-label use and 59% of off-label use acceptances by the hospital pharmaceutical committee have come from these wards. The number of reports of drug-related adverse events has also been increasing. 7 clinical trials, designed together with physicians, are currently in progress.

Conclusions
Our results show that, despite a pharmacist/doctor ratio of 1:66 and clinical pharmacists/doctors of 1:700 in our hospital, which is very different from that found in foreign examples of clinical pharmacy, it has been possible to build an effective collaboration. This is based on the time spent by pharmacists on ward activities and on the information acquired and passed on by all the members of the ward clinical team.

Conflict of Interest
No conflict of interest

POSTER AWARD NOMINEE PRESENTATIONS

Wednesday, 24th March 2010, 14.00 – 15.30: room Euterpe

C2. Cost-efficacy analysis of cetuximab in first-line treatment of KRAS wild-type metastatic colorectal cancer patients

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Background
In recent years the treatment of metastatic colorectal cancer (mCRC) has evolved from single-agent chemotherapy (fluorouracil with leucovorin modulation) to combination regimens that include irinotecan or oxaliplatin (FOLFIRI and FOLFOX).The introduction of target therapeutic agents such as cetuximab has greatly increased the associated costs. This drug was recently approved for first-line setting use, based on results published in the first half of 2009. The aim of this study was to evaluate the cost-efficacy relation of cetuximab, in the first-line treatment of KRAS wild-type mCRC patients.

Method
Based on the CRYSTAL and OPUS studies, was evaluated the efficacy of FOLFIRI or FOLFOX respectively, with or without cetuximab. The treatment costs were calculated based on the direct cost of the drugs in 2009. This study was conducted from an institutional perspective - the hospital perspective.

Results
Adding cetuximab to FOLFIRI resulted in a marginal efficacy of 0.10 years, which represents only 36 days, when compared with FOLFIRI alone. The associated cost was 33.127 €. The incremental cost-efficacy ratio calculated for FOLFIRI + cetuximab was 331.275 €.
The addition of cetuximab to FOLFOX makes even less difference to lifespan (0.04 years = 14 days) when compared with FOLFOX itself. The associated costs were 25.588 €. The incremental cost-efficacy ratio calculated for FOLFOX + cetuximab was 639.706 €.

Conclusions
Based on this analysis, the incremental cost-efficacy ratios calculated for the cetuximab regimens are too high to be considered cost effective. With limited budgets, cost-efficacy analyses are useful tools for drug and therapeutics committee decisions on drug selection, and for clinics in their therapeutic decisions.

Conflict of Interest
No conflict of interest

H12. Microcalorimetry: an early identification method for bacterial growth

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[2]Universidad de Vigo, Física Aplicada, Vigo, Spain
[3]Hospital Xeral-Cíes de Vigo, Servicio de Microbiología, Vigo, Spain
[4]Universidad de Vigo, Física aplicada, Vigo, Spain

Introduction
Early diagnostic methods allow early treatment and improved treatment outcomes in infectious processes. Bacteria in culture medium convert part of the energy from the C supplied into ATP, freeing the rest as heat.

Objective
To evaluate the use of microcalorimetry as a method of identifying bacterial growth.

Methods and materials
We used a Calvet microcalorimeter, inside which two Teflon screw-capped stainless steel cells are located (sample and reference). The caps are perforated through their centres so that a needle connected to a syringe can pass through. A constant temperature of 37ºC is maintained within the microcalorimeter. We started with S. aureus (ATCC 20203) stock, with its concentration adjusted to a turbidity of 0.5 on the McFarland scale (Densichek calorimeter), and diluted it with physiological saline solution to obtain final concentrations of 106,105,103, and 10 CFU/mL.
Digested liquid soy-casein medium was used. In the Calvet microcalorimeter, 7 mL of culture medium and 1 mL of physiological saline solution were injected into the reference cell and 7 mL of culture medium into the sample cell. Both cells were then left in the microcalorimeter and allowed to stabilise for an hour and a half. After stabilisation 1mL of test solution was injected into the test cell at the aforementioned concentrations.

Results
Plotting the difference in calorific potential over time we obtained growth charts for S. aureus at various concentrations, in which the lag, exponential, stationary and death phases could be identified. At high concentrations (106,105,and 103 CFU/mL), maximum growth was observed before 5 hours, whilst in the10 CFU/mL sample maximum growth was observed after 10 hours.

Conclusions
Microcalorimetry allows us to measure bacterial growth from the heat liberated during microbial metabolism and can identify if a sample is contaminated in a few hours.

Agreement:
We thank María Perfecta Salgado González and Sofia Baz Rodríguez for their collaboration with the technical measures

Conflict of Interest
No conflict of interest

I6. Monoclonal antibodies assigned to ATC Code L01XC: Assessment with regard to occupational safety

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[2]Johannes Gutenberg-University, University Medical Center, Mainz, Germany

Background
Today the health and safety risk with handling most anticancer drugs is well recognized and as a result of regulatory requirements safety measures have been established. At the moment little is known about the occupational risk caused by monoclonal antibodies (MAbs) approved for anticancer therapy. Therefore a German working party with members of the national occupational safety and health organisation 'Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege' (BGW) and the German Society of Hospital Pharmacists (ADKA e.V.) evaluated the hazard risk of monoclonal antibodies assigned to ATC Code L01XC.

Methods
A systematic literature review was performed, European public assessment reports and other official documents were checked and expert opinions were obtained with regard to the carcinogenicity, mutagenicity, reproductive toxicity and sensitising properties of MAbs. The MAb active substances were categorized following the classification and labelling regulations of the European Commission for dangerous substances, published in Annex VI of Directive 67/548/EEC. The results were agreed in a joint committee, including representatives from pharmaceutical companies, pharmacists and experts for occupational safety.

Results
All monoclonal antibodies examined were assessed as substances with developmental toxicity. In addition the gemtuzumab ozogamicin conjugate was categorised as mutagenic. Because of the high molecular weights and the proteinogenic nature of monoclonal antibodies the route of exposure is limited to inhalation for healthcare workers, except in the case of an accident.

Conclusions
Employers should implement necessary administrative and engineering controls, e.g. for pregnant workers, and employees should follow the standards in order to avoid occupational exposure. The assessments of the occupational risks of MAbs will be incorporated in the German Technical Rules for Hazardous Substances.

Conflict of Interest
No conflict of interest

L13. Quality control of parenteral nutritions: analysis of inorganic ions by capillary electrophoresis

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Background
Parenteral nutrition (PN) is the practice of feeding a person intravenously, with nutritional formulas containing essential nutrients such as glucose, amino acids, electrolytes and vitamins. In our hospital, individualised solutions are prepared daily and standardised formulations are also regularly produced, using a MM12 MicroMacroR compounder. An error in the concentration of the electrolytes increases the risk to the patient, especially in neonates. The objective of this study was to develop a quality control method to check the main electrolytes in TPN before administration to the patient.

Method
A simple method based on capillary electrophoresis with a capacitively coupled contactless conductivity detector (CE-C4D) was developed for the determination of potassium, sodium, calcium and magnesium in PN. A hydro-organic mixture, consisting of 100 mM Tris-acetate buffer at pH 4.5 and acetonitrile (80:20, v/v), was selected as the background electrolyte. The applied voltage was 30 kV, and sample injection was performed in hydrodynamic mode. All analyses were carried out in a fused silica capillary with an internal diameter of 50 µm and a total length of 64.5 cm.

Results
The CE-C4D method was validated. Trueness values between 98.6% and 101.8% were obtained for the four cations with repeatability and intermediate precision values of 0.4-1.3% and 0.8-1.8%, respectively. No interference due to amino acids, vitamins or another compounds usually present in PN was observed. Moreover, with a run time of 4 minutes, analysis of PN can be performed in the pharmacy before delivery to the ward for administration to the patient.

Conclusions
The method developed was found appropriate for checking potassium, sodium, calcium and magnesium in PN formulations and it has been successfully introduced into our daily quality control.

Conflict of Interest
No conflict of interest

E16. In search of biomarkers related to wound healing

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[2]Inselspital Bern University Hospital, Division of Endocrinology Diabetes & Clinical Nutrition, Bern, Switzerland

Background
Weekly, the Clinical Nutrition Team consults a selection of in-patients receiving parenteral nutrition. Some of these patients suffer from hard-to-heal wounds that are generally hidden i.e. covered by dressings left in place for several days or by VAC (vacuum assisted closure) devices. As essential and semi-essential substrates are able to improve wound healing, the Clinical Nutrition Team would greatly appreciate having diagnostic data on the wound status. However, no effective non-invasive diagnostic tools currently exist to assess the critical biological activities or impairments within the wound. Thus, there is a need to identify the most reliable non-specific parameters from routine blood tests as a source of information and upon which to base decisions about nutraceutical therapy.

Methods
Before a consultation the patient's clinical records and data sheets from the central chemical laboratory are assessed. Analyses of pO2, total protein, albumin, C-reactive protein, urea, zinc, copper, weight change, energy requirement, the present phase of healing, possibly the microbiology of the exudate and the clinical assessment contribute to assessing the wound and nutritional status and to defining the individual nutritional therapy.

Results
Over a 5-month period, a selection of 14 patients have been receiving special wound care focussing on nutritional treatment. 7 patients suffering from wounds in the inflammatory state and treated by VAC showed a C-reactive protein level of > 100 mg/L, all of them combined with low albumin levels of < 30 g/L, but not all with high urea levels of > 7.7 mmol/L. An additional 3 patients had moderately elevated CRP and normal albumin levels. Zinc blood level, rarely determined, showed no deviation from the reference range. Symptomatic therapy was the treatment of choice, combined with adequate parenteral nutrition. Another 4 patients in more advanced phases of wound healing were diagnosed as malnourished and / or energy deficient. High-energy and arginine, copper, and zinc-enriched drinks were the treatment of choice for these patients.

Conclusions
Non-specific biomarkers of inflammatory status can hardly give more than a confirmation of a clinical assessment. More specific biomarkers, possibly assayed from exudate rather than from plasma would be welcome to assist in determining specific wound healing-focused nutritional treatment. Nitric oxide, intermediates of arginine, ornithine, citrulline and glutamine metabolism, cytokines, growth factors, and enzymes such as nitric oxide synthases or matrix metalloproteinases are expected to be among these specific biomarkers.

Conflict of Interest
No conflict of interest

POSTER PRESENTATIONS

GROUP A: HOSPITAL PHARMACY

A1. Adverse events study related to antineoplastic and inmunosupressive agents in hospitalized patients

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Background
Adverse events associated with antineoplastic and immunosuppressive agents (AEAIAs) comprise a problem in hospitalised patients in medical practice, with a great impact in terms of hospital stay and financial costs. The objective was to identify AEAIAs in hospital discharge reports, frequency, drugs involved and their characteristics.

Method
Retrospective study from January to December 2008, in a 673-bed tertiary hospital. Adult patients' discharge reports including ICD-9-CM code E933.1 (antineoplastic and immunosuppressive drugs causing adverse effects in therapeutic use) were selected using the minimum basic data set. Demographic characteristics, clinical department, AEAIAs and causal drug were obtained from the hospital information system.

Results
AEAIAs were detected in 146 (0.4%) of 33,477 hospital discharges in 2008. Of those patients, 51% was male and 49% were female. The mean age was 59 (24-84) and 43% of the patients were > 65 years old. In 16 cases (9.6%), the causal drug was known. Of these cases, in 3 patients (18. 8%) the AEAIAs was unknown and in 10 patients (62.5%), the AEAIA was stated in the summary of product characteristics. Classifying by clinical department, 121 patients (83%) were from the oncology service, 10 (8.3%) in haematology service, 4 (2.7%) in nephrology service, 3 (2%) in internal medicine service and the rest in others.
The main drugs implicated in AEAIAs included cisplatin and cytarabine in 3 cases (18.8%) and capecitabine in 2 (12.5%). Principal AEAIAs were febrile neutropenia 52 (21.3%), thrombocytopenia 31 (12.7%), anaemia 29 (12%), neutropenia 21 (8.6%) and mucositis 21 (8.6%).

Conclusions
This study revealed more than the 0.1% AEAIAs indicated in the literature and revealed a considerable proportion of cases in which the causal drug was unknown. These facts suggest more pharmacist involvement is warranted to prevent AEAIAs.

Conflict of Interest
No conflict of interest

A2. Parenteral Nutrition in oncohematological patients in a 600-bed Hospital: Impact on nutritional parameters and clinical outcomes.

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Background
Some of the advantages of Parenteral Nutrition (PN) are a positive effect on nutritional parameters, less time in hospital, positive effect on quality of life and probably on overall survival. Primary objective: to learn more about the cancer / haematological patients put on PN in our hospital. Secondary objective: to monitor the response to PN.

Methods
From January to September 2009 data were collected from 26 patients. Data for monitoring the clinical response to PN were collected at three points: before PN, at an intermediate point and immediately after PN finished. SPSS was used for statistical analysis.

Results
26 patients were given PN (20 men, 6 women). There were significant differences between the ages by sex (men 57.2 ± 17.02 women 71.5 ± 10.65 p 0.027).Diagnosis: 22 solid tumours (digestive tract 15, ovary 3 prostate 2, breast 1 and testicular 1) and 4 haematological tumours (2 NHL, 1 AML). 12 patients (46%) underwent surgical procedures , 18 (69%) were on chemotherapy, and 9 (34.6%) had both. Mean days of PN was 9.65+/-4.85 (range 3-25). Further data was not available for most patients. 7 patients (27%) died. Neither the nutritional support (amounts of nitrogen, lipid, glucose) nor other parameters analysed affected the clinical outcome.

Conclusions
Little data was available with which to monitor the response to PN. Only in 12/26 of the patients was possible to compare an analytical parameter before and after PN. None of the nutritional parameters analysed affected the outcome.

Conflict of Interest
No conflict of interest

A3. Treatment of chronic hepatitis B in clinical practice at a university hospital

N.T.L. Trovato López Alejandro Nicolás[1], S.P.P. Sergio Plata Paniagua[1], V.E.V. Vicente Escudero Vilaplana[1], I.C.R. Isabel Castillo Romera[1], A.A.L. Arantza Ais Larisgoitia[1], D.R. Diego Rincón[2], M.S. María Sanjurjo
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[2]Hospital General Universitario Gregorio Marañon, Liver Unit, Madrid, Spain

Background
The recent emergence of new molecules has revolutionised the treatment of chronic hepatitis B (CHB) by opening up new possibilities and strategies. In Spain, these drugs are dispensed at the hospital where they are prescribed, thereby facilitating pharmaceutical follow-up. The aim of our study is to describe treatments of CHB used at a university hospital.

Method
We conducted a cross-sectional observational study of adult outpatients who were treated for CHB with antiviral agents and who collected medicines at least once between May and September 2009. Prophylaxis for patients with cancer, HIV and/or HCV-co-infected patients was excluded. We studied the last treatment provided and obtained data from electronic medical records and pharmacy records. Patients were classified as treatment-experienced (TE) if, before inclusion, they had been prescribed a different antiviral regimen for CHB in our institution.

Results
We included 141 patients with a mean of 52 years old (19.9% women). At inclusion, 23.1% were HBeAg-positive and 33.3% had had a liver transplant (LT). Twenty-five patients used HBV antivirals as prophylaxis for LT (undetectable viral load at baseline) and all of these were non-TE (accounting for 27.8% of non-TE patients). Drug doses were standard in all patients except one, whose treatment was adjusted due to renal failure. Combination therapy was used in 22.0% of cases and in 53.0% of TE patients. The table shows treatments prescribed.

TREATMENT	DRUGS	TOTAL (N=141) N (%)	non-TE (n= 90) N (%)	TE (n= 51) N (%)
Monotherapy	Lamivudine (LAM)	55 (39.0%)	54 (60.0%)	1 (2.0%)*
Monotherapy	Adefovir (ADV)	16 (11.3%)	11 (12.2%)	5 (9.8%)*
Monotherapy	Entecavir (ETV)	21 (14.9%)	13 (14.4%)	8 (15.6%)*
Monotherapy	Tenofovir (TDF)	18 (12.8%)	8 (8.9%)	10 (19.6%)*
Combination Therapy	LAM+ADV	28 (19.9%)	3 (3.3%)	25 (49.0%)*
Combination Therapy	TDF+LAM	1 (0.7%)	1 (1.1%)	0
Combination Therapy	TDF+ emtricitabine	1 (0.7%)	0	1 (2.0%)
Combination Therapy	TDF+ETV	1 (0.7%)	0	1 (2.0%)

* p<0.0005 for distribution of each drug in non-TE vs. TE

Conclusion
Lamivudine is still commonly used in patients with CHB, mainly in non-TE patients. However, new antivirals and combination therapy also play an important role mainly in TE patients.

Conflict of Interest
No conflict of interest

A4. MRSA in Clinical Hospital Osijek during 2004-2008
A.A.A. A.Antolovic-Amidzic[1], S.S.S. S.Stiblik-Stipesevic[1], D.V. D.Vukovic[2]
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[2]Clinical Hospital Osijek, Microbiology, Osijek, Croatia

Background
MRSA is frequent, highly-resistant cause of nosocomial infections. The aim of the work is to present the incidence of MRSA on clinics/wards of Clinical Hospital Osijek and its resistance to antibiotics.

Method
Five-year retrospective analysis of antibiograms, obtained from the department of microbiology and processed in the hospital pharmacy.

Results
In the observed period a constant increase in MRSA isolates was detected despite a steady reduction in the number of patients on clinics/wards:

Year	Number of isolates	Number of patients
2004	150	392828
2005	206	390386
2006	230	377280
2007	231	372013
2008	232	368739

The largest number was isolated in ICU, 72 in 2004, 98 in 2005, 96 in 2006 and 84 in 2008. In the surgical wards the number of MRSA increased from 37 in 2006 to 75 in 2007 and 83 in 2008. On Neurosurgery, Neurology, Haemodialysis, Paediatrics and Infectology the number of isolates was less than 20 per year. MRSA is often isolated from trachea aspirates, incision smears and trachea smears. The number of pathogens isolated from trachea aspirates grew from 48 in 2004 to 66 in 2007 and fell to 53 in 2008. From incision smears, the number grew from 39 in 2004 to 79 in 2008. Trachea smear isolates oscillated from 7 in 2004, 24 in 2006 to 10 in 2008. Resistance of MRSA to netilmicin is less than 1% but to gentamicin is over 90%. Resistance to ciprofloxacin is also over 90%. Sensitivity to mupirocin increased greatly from 50% in 2005 to 90% in 2006, then fell slightly to 88% in 2008. Sensitivity to linezolid, vancomycin and teicoplanin is almost 100%.

Conclusions
The drug of choice for treating infections caused by MRSA in our hospital is vancomycin. Mupirocin is the drug of choice for local use. Continuing monitoring of resistance of the pathogens isolated is a product of cooperation between microbiologists, clinical pharmacologists, physicians and pharmacists.

Conflict of Interest
No conflict of interest

A5. Development of the cost of antineoplastics in Clinical Hospital Osijek during the period 2004-2008
S.S. Stiblik-Stipesevic[1]
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Objective
The aim of the work is to show the cost of using the ATC-L drugs (antineoplastics and immunomodulators) in Osijek Clinical Hospital during the period 2004-2008.

Method
Retrospective analysis of drug consumption on clinics/wards of our hospital, based on computer data obtained from the pharmacy department.

Results
The proportion of the total drugs budget spent on ATC-L drugs (cytostatics) increased in the given period from 20% in 2004 to 40% in 2008, compared to the total medicines budget in the hospital. The major increase was observed in subgroup ATC-L01, which rose from 8% in 2004 to 39% in 2008. Expenditure on subgroup ATC-L01 increased significantly, from 266,666 euros in 2004 to 2,666,666 euros in 2008 for ATC-L01X (other antitumour drugs). Expenditure on ATC-L01XC, monoclonal antibodies, increased the most from 93,330 euros in 2004 to 106,700 euros in 2005, followed by further increases to 293,300 euros in 2006, 933,300 euros in 2007 and 1,800,000 euros in 2008.
In subgroup ATC-L01XC, the cost went up steadily for trastuzumab, ATC-L01XC03, 200% from 2007 to 2008 (400,000 to 1,200,000 euros); also, the number of 150 mg vials used increased from 789 in 2007 to 1987 in 2008.
In 2007 bevacizumab, ATC-L01XC07, was added to the Croatian health insurance institute drug list. The use of this drug increased from 69 400 mg vials in 2007 to 392 in 2008. The use of the drug bevacizumab was the major cause of expenditure increasing from 53,330 euros in 2007 to 386,700 euros in 2008.

Conclusions
The introduction of new “smart“ antineoplastic drugs to the health insurance drug list is essential for the quality treatment of patients with malignant disease in Croatia, as well as in our hospital. However, the expense has multiplied, so there is a need for continuing follow up and checks of the treatment.

Conflict of Interest
No conflict of interest

A6. Evaluation of a pharmaceutical care programme in patients with hepatitis C: a study of adherence and satisfaction
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[1]Hospital Virgen de Altagracia, Pharmacy, Manzanares (Ciudad Real), Spain

Objectives
To detect, prevent and solve drug-related problems (DRPs) while monitoring patients with chronic hepatitis C.

Method
Design: observational prospective study. Scope of application: chronic hepatitis C patients who collect their medicines at the Outpatient

Pharmaceutical Care Unit (OPCU) of a 100-bed regional hospital. Duration: January-December 2008. Sources: the data was recorded on a standardised, printed form named "History of Pharmaceutical Care" which included:

1. the patient's details (identification, anthropometric details, main diagnosis, background (surgery, pathologies, family/social history, allergies/intolerances), pharmacotherapeutic history, diet, lifestyle, other relevant blood picture and microbiological details;
2. details of the doctor in charge and the department; and
3. records of DRPs, their possible causes and severity (Schneider scale), any pharmaceutical interventions and their clinical suitability. The relevant information was obtained from the patient's records and the interviews held with patients at the OPCU. The patient's doctor was informed of any serious DRPs in person or by telephone. The patients were offered oral and written health education and information. 2 months after the first visit, they were asked to complete a questionnaire on therapeutic adhesion and satisfaction.

Results
20 patients were on the pharmaceutical care programme (13 men and 7 women) with an average age of 42 (24-61). 75% of the patients showed HCV genotype 1b; in one case there was a co-infection with HIV and in another there was a co-infection with HIV and HBV. In most cases, the origin of the infection was unknown (80%). 16 patients were taking peginterferon alfa-2A combined with ribavirin; one patient was taking peginterferon alfa-2B and ribavirin; and three patients were following a single treatment: one with peginterferon alfa-2A, and two with peginterferon alfa-2B.A DRP was detected in 12 patients (60%), with the total number of DRPs identified reaching 18 (1.5 DRP/patient). The most frequent types of DRP were safety (55.6%), fundamentally inappropriate dose/interval for the patient, and indication (33.3%), fundamentally therapeutic duplicity. Only two serious DRPs were detected: one of anaemia and another of neutropenia, of which they were informed by telephone and which required the doses of pegylated interferon to be modified. Full adherence to the treatments was 95%. One of the patients had difficulties with administration. Patient satisfaction with the care and information given was very high: 90%.

Conclusions
Personal monitoring of patients with hepatitis C has enabled us to detect, solve and communicate different DRPs. The health education and information given to patients with hepatitis C provides them with greater knowledge about their illness and treatment, enabling them to improve their therapeutic adherence and satisfaction.

Conflict of Interest
No conflict of interest

A7. To evaluate the suitability of standard parenteral nutrition (PN) with respect to potassium requirements

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Objective
To evaluate the suitability of standard parenteral nutrition (PN) with respect to potassium requirements and to identify situations that produce alterations in serum potassium concentrations in patients fed by PN.

Method
Retrospective observational study of patients who received standard PN alone during January 2008. Age, sex, days of PN, abdominal intervention, diarrhoea, vomiting, diabetes, oedema, serum creatinine level, urea, glucose, potassium, bicarbonate, serum pH and administration of glucose, potassium, spironolactone, amiloride, insulin, verapamil and beta-adrenergic blockers was recorded.
Hypokalaemia was classified as mild (3.0-3.5 mEq/L), moderate (2.5-3.0 mEq/L) or severe (<2.5 mEq/L). Hyperkalaemia was classified as mild (5.5-6.5 mEq/L) moderate (6.5-7.5 mEq/L) or severe (> 7.5 mEq/L).
The standard potassium content of PN was 32 mEq /day in peripheral PN and 60 mEq /day in central PN.

Results
50 patients were studied 28 men and 22 women; mean age was 65 years (28-91).
Hypokalaemia (n=19). Mild: 16 cases, 8 before beginning treatment with PN, 6 after receiving peripheral PN for more than 4 days, 2 patients after receiving central PN. Moderate: 2 patients were hypokalaemic before beginning PN treatment, in both cases the reason was losses from the gastrointestinal tract. Severe: 1 case due to severe diarrhoea. The drug most frequently involved was furosemide, 10 patients. 8 patients underwent abdominal surgery.
Hyperkalaemia (n=1). Mild: after receiving a parenteral dose of 90 mEq/day for more than 4 days to correct mild hypokalaemia.

Conclusions
Potassium levels should be checked and corrected when needed before starting PN. Administration of standard peripheral nutrition for more than 4 days could encourage hypokalaemia. It is advisable to monitor potassium in patients who receive furosemide or in abdominal surgery patients.

Conflict of Interest
No conflict of interest

A8. Study of albumin 20% use on critical and surgical patients

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Background
The benefit of using albumin 20% in comparison with crystalloid plasma expanders (CPE) in critical and surgical patients is unclear and albumin is much more expensive than CPE. Our hospital's Drugs Committee agreed to use albumin only in patients whose serum albumin concentration (SAC) is < 2.0 g/dL and who have hypovolaemia.

Objective
To analyse albumin 20% use and find strategies for reduce the money spent on albumin when administration is not necessary.

Method
Albumin use was studied for 1 month. Blood albumin concentration, nutritional state and support, blood pressure, haemoglobin concentration and CPE administration before albumin treatment were recorded.

Results
23 patients were given albumin 20%. 15 men, 8 women, average age 74. Mean dose was 33± 5 g/day (Mean ± SD), treatment duration was 4 days ±2 (range [1-9 days]
Initial SAC: 6 patients (26%) had between 2.4 and 2.0 g/dL, 17 patients <2.0 g/dL
Mean SAC at the end of albumin administration was 2.6 ± 0.4 g/dL 16 patients (69%) had hypovolaemia. Mean haemoglobin level at the beginning of treatment was 9 ± 2 g/L. 3 patients (13%) received CPE before albumin 20% was administered.
20 Patients (87%) had nutritional deficiencies and all patients received nutritional support. 16 patients (70%) received hyperproteic nutritional support.

Discussion
Albumin 20% was used in patients with severe hypoalbuminaemia and hypovolaemia.
Hypoalbuminaemia was mainly caused by surgery and pathological situations.
In some cases crystalloids could be considered a less expensive alternative.
It may be appropriate to build consensus on when to stop administration of albumin.

Conflict of Interest
No conflict of interest

A9. If it ain't broke, why fix it? Changing a successful prescribing policy

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Background
A Night Sedation Treatment Protocol was implemented in January 2007 in the Mater Misericordiae University Hospital (MMUH). An audit of hypnotic usage in July 2007 revealed that the prescribing of hypnotics in the hospital was standardised and the number of hypnotics routinely stocked on wards was reduced to one.

Objectives
To review the current prescribing practices for night sedation in the MMUH
To establish hypnotic usage levels in the MMUH and compare with previous years
To consider if zopiclone is still the most appropriate first choice agent

- **Methods**
  Literature Review
- Cross-sectional study of hypnotic prescribing in the patient population of the MMUH in 2008
- Data search of MMUH Hospital Information System
- Discussions with consultants in Psychiatry and Substance Abuse MMUH

Results
The results included:
Hypnotic usage
- 87% of hypnotic dosage units used in 2008 were the recommended formulary agents (zopiclone or temazepam when zopiclone is contraindicated)
- Only 1 hypnotic agent is stocked at ward level - with the exception of the psychiatric and infectious diseases wards

Prescribing Practices
- 39% (n=179) of patients in the cross sectional study were prescribed a hypnotic
- 71% (n=127) of hypnotic prescriptions were in the PRN section

Formulary agent review
- Zopiclone was prescribed in the majority of patients commenced on Night Sedation Treatment in the MMUH. However, it was identified that zolpidem was the preferred agent of the Substance Misuse team in patients with the potential to abuse hypnotics
- Zolpidem has a similar pharmacological and economic profile to zopiclone

Conclusion
Overall compliance with the Night Sedation Treatment Protocol was high. However, as zolpidem is the preferred agent of the Substance Misuse Team, the prescribing recommendations were reviewed to ensure:
· Standardised prescribing throughout the hospital for all patient groups
· That stock of hypnotics at ward level could continue to be rationalised.
The formulary agent has been changed to zolpidem. The revised protocol was implemented in March 2009. This audit has highlighted the importance and usefulness of re-audit.

Conflict of Interest
No conflict of interest

A10. Use of Bortezomib in kidney transplant rejection treatment - two case-reports

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Background
The incidence of acute rejection in Portugal in 2007 was 17.1% in the first year post kidney transplant. Acute and chronic rejection were two of the major causes of graft loss (10% and 35% respectively). More effective treatments are needed.
Bortezomib is a selective and reversible inhibitor of the 26S proteasome approved for the treatment of multiple myeloma. Recent studies suggests that bortezomib could be an alternative treatment for humoral and cellular kidney transplant rejection (KTR). The aim of this study was to report the use of bortezomib in 2 cases of KTR.

Method
A literature search was undertaken about the use of bortezomib in KTR. A retrospective study was performed in two KTR patients treated with bortezomib, including laboratory values, clinical and pharmacotherapeutic history from the diagnosis until graft loss or hospital discharge.

Results
Patient 1, female, 64 years old, type 2 diabetes mellitus, with a diagnosis of humoral acute rejection 8 days after a kidney transplant, was treated with rabbit anti-thymocyte globulin, methylprednisolone and two cycles of rituximab and intravenous immunoglobulin (IVIG) without reversal. 6 days after conventional therapy bortezomib was initiated. After one dose ($1.34 g/m^2$) she developed leucopenia ($1.8x10^9/L$), thrombocytopenia ($18x10^9/L$), fever, cytomegalovirus infection and lost the graft (27days after bortezomib treatment). Patient 2, male, 34 years old, with chronic rejection 5 years after a kidney transplant, was treated with IVIG without reversal. After four doses of bortezomib ($1.02 g/m^2$ D0; $0.51 g/m^2$ D16, D20 and D24) he was discharged with serum creatinine =2.02mg/dL and no significant toxicity (urinary infection). After 3 months without readmission his blood picture remained normal and serum creatinine =2.06mg/dL.

Conclusions
Studies about the use of bortezomib in KTR are few, with a small population and a short follow up. Patient 1 had several complication and lost the graft; Patient 2 tolerated the treatment well but the short follow up didn't allow conclusions to be drawn about bortezomib's efficacy. Further studies are required to establish the efficacy and safety profile of bortezomib in KTR.

Conflict of Interest
No conflict of interest

A11. The added value of the hospital pharmacist in Sudan hospitals

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Background
"The Salam Centre for Cardiac Surgery" became operational in April 2007. Built and run by the Italian NGO "Emergency", it is located near Khartoum and is dedicated to adult and paediatric patients suffering from congenital and acquired heart disease. It performs an average of 4/5 open-heart operations per day. All services are free of charge. The pharmacy manages drugs and medical devices for the 9 internal departments, the Paediatric Centres in Mayo and Bangui, and also provides an information service.
The problems to be addressed by the pharmacy have been challenging, especially from a logistical point of view. In order to improve the flow of materials, streamline the budget and continually monitor stocks, reorganisation of the management system started in March 2008. The problems have been related to the supply of particular products, in a continuous and time-effective way.

Method
Ongoing monitoring by an international hospital pharmacist.

Results
It was decided toeliminate a series of products from the management database because they were not considered aligned with the needs of the Centre. In March 2008, the pharmacy managed a total of nearly 2100 products. Over 1 year of activity the products inventory has fallen to 1791 items. To date, the pharmacy is managing 1384 products. The

total stock value is € 2,400,000 and the goal is to reduce this to under 1.5 million by the end of 2010. The target is reachable after this substantial reorganisation.

Conclusions: The intervention proposed and implemented by the Salam Centre, starts from a different approach; it is not just basic assistance but also introduces excellence in quality of service. The management of the pharmacy by the hospital pharmacist is a key element of this approach, which aims to provide high quality patient care.

Conflict of Interest
No conflict of interest

A12. Test of pleuraseal in cardiothoracic surgery at Amiens hospital

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Background
Prolonged parenchymal air leak is one of the complications frequently faced after pulmonary surgery. Pleuraseal is a synthetic sealant intended for use as a surgical sealant during elective pulmonary resection as an adjunct to standard closure techniques of visceral pleural air leaks. With the aim of referencing this medical device at the Amiens Hospital, the Committee of Drug and Medical Devices (COMEDIMS) of the Amiens Hospital requested a preliminary assessment of the product.

Methods
This trial was carried out in the Department of Cardiothoracic Surgery, Amiens University Hospital. Patients showing intra-operative air leaks when recovering on ventilation were included in this test. The assessment criteria were: presence of air leaks in the postoperative stage, duration of chest tube drainage and duration of hospitalisation.

Results
Pleuraseal was used in 5 patients. 4 patients were identified as having a history of smoking and chronic obstructive pulmonary disease. The surgery indication was carcinologic resection for all patients. After Pleuraseal had been applied, we observed a persistent air leak in 1 patient, air leakage at a single point for 1 patient, sporadic air leakage for 1 patient and no further air leakage for 2 patients. Thoracic drainage remained in place for 3 days when there was no air leakage and could vary from 4 to 11 days if air leakage appeared.

Conclusion
Although the panel for implementing this trial was limited, it appears that stopping air leakage in the postoperative stage decreases the duration of chest tube drainage but does not affect the duration of hospital stay. Several downsides have been identified by surgeons: too long lead-time for polymerisation using the pulverisation system, lack of glue in the device. In the light of these results, the COMEDIMS considers it is necessary to reference a lung sealant at Amiens Hospital, but we need to test another product to choose the best one.

Conflict of Interest
No conflict of interest

A13. Analysis Of Drugs Returned To The Hospital Pharmacy By Patients

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Background:
The aim of this study was describe the patterns of returned drugs and count the total cost that patients and insurance companies spent in the Czech Republic per one year.

Method
Material was collected in one hospital pharmacy for one year (August 2007 - July 2008). This material was composed of unusable drugs people return to pharmacy for liquidation. The first concept was to deal with them in two ways – used/unused drugs and drugs with a valid expiry date/expired drugs. The second concept was to deal with ATC groups, subgroups and medicinal substances.

Results
4,672 drugs were discovered in containers. The average number of returned drugs was 389 per month. The cardiovascular system had the most packages – 20.5%. The most-used medicinal substance was ibuprofen with 88 packages and diclofenac (80 packages). Anti-inflammatories, analgesics were the most common therapeutic group with 344 packages. Paracetamol 500 mg was the most common single drug (1%).
Used and expired drugs constituted 42.4%, nevertheless unused drugs with valid expiry dates constituted 11%. The largest number of unused drugs was discovered in the hormonal system and cardiovascular system classes. The most unused packages in terms of ATC subgroup were antibiotics (49%).
Total costs of returned drugs were 40 000 euro. Of that 23 754 euro were spent on unopened packages. Calculation of total costs per one year in the Czech Republic was 108 million euro for unusable drugs for which insurance companies paid approximately 80 million euro.

Conclusions:
Due to this research we know how many drugs are thrown away unnecessarily. We want to draw the public's and the medics' attention to the waste of drugs.

Conflict of Interest
No conflict of interest

A14. Linezolid: a retrospective study in a Portuguese hospital

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Background
Linezolid (LNZ) is the first in a new class of antibiotics – the oxazolidinones, active against Gram-positive microorganisms. It is approved in Garcia Orta Hospital for Enterococcus spp. and meticillin-resistant Staphylococcus aureus (MRSA) infections including pneumonia. However a prescription requires the approval of the local antibiotic committee. The objective was to study the use of LNZ in Garcia Orta Hospital.

Method
Retrospective study of LNZ prescriptions (January 2002 – May 2009). Data were obtained from the unit dose software in the pharmacy and clinical history reviews.

Results
We evaluated 86 patients treated with LNZ (51 men, median age 56.80±19.43 years) mostly from the intensive care unit (29.1%), surgical (16.3%) and infectious diseases wards (8.1%). The most common diagnoses were pneumonia (30.2%) and sepsis (30.2%). In 29.1% of patients the treatment was empirical but in 70.9% we had isolated the causal agent. The agents isolated most often were MRSA (60.6%) and Enterococcus faecium (8.2%). In 42 patients, LNZ was prescribed for an off-label indication: sepsis due to Gram-positive microorganisms (10), endocarditis (3), abdominal infections (4) and central nervous system infection (2).Some prescriptions (51.2%) were reviewed by the antibiotic committee and 2 applications were rejected. In these 2 cases the alternative therapy (vancomycin plus meropenem or gentamicin) suggested by the antibiotic committee was accepted by the clinical service. The median duration of treatment with LNZ was 12.44±6.28 days. In 31 patients vancomycin was prescribed as first-line treatment and median duration of treatment was 11.29±9.22 days. In 17 cases the LNZ was associated with meropenem, piperacillin+tazobactam or ceftazidime.

Conclusions
The use of linezolid during the study period showed great variability. To prevent emerging resistance as well as growing expenditure new anti-infective drugs should be controlled by methods such as restricted prescribing or the advice of an antibiotics committee.

Conflict of Interest
No conflict of interest

A15. Rheumatoid arthritis therapy with Rituximbab

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Background
Rituximab is indicated for treatment of adults with rheumatoid arthritis (RA) who have an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs), including treatment with at least one TNF-alfa inhibitor. The aim of this study was to evaluate the effectiveness of treatment with rituximab after TNF-alfa inhibitor therapy, according to DAS28 (Disease Activity Score 28) from EULAR (European League Against Rheumatism).

Methods
A retrospective study of patients with RA who were given rituximab until September 2009. Demographics and clinical parameters were collected from the clinical history and pharmacy records. The DAS was measured at the start of treatment and 12 and 24 weeks after it. An adequate response was defined as an improvement in DAS28 of 1.2 points or more.

Results
During the study period, 12 patients were treated with rituximab (1 male, 11 female median age 57.16±14.05 years [range 20-74 years]). All patients received treatment with TNF-alfa: infliximab (5), etanercept (2) or both (5). In the infliximab group the median of treatment was 6.77 treatments (range 3-10) and in the etanercept group it was 14.1 treatments (range 3-39). At the start of the rituximab treatment all patients had DAS 28 more than 3.2. The main reason for the switch in therapy was ineffectiveness of TNF-alfa therapy (DAS>3.2). Five patients needed a second treatment with rituximab. In 9 patients the DAS (week 12) decreased by 1.23 points and in 2 it had increased by 1.12 points. At week 24, 5 patients had decreased by 0.45 points and 2 had increased by 0.89 points. The annual cost per patient was 13,178 € for Etanercept, 6,869 € - 22,897 € for infliximab (depending on the patient's weight) and 7,069 € -14,137 € for rituximab (1 or 2 treatments/year).

Conclusions
Rituximab seem to be an effective alternative for the treatment of RA in patients who have an inadequate response to, or intolerance of, other disease-modifying anti-rheumatic drugs (DMARDs), including treatment with at least one TNF-alfa inhibitor, without a major economic impact.

Conflict of Interest
No conflict of interest

A16. Treating the hyperthyroid patient with radioiodine: evaluation of the quality and efficiency of a clinical radiopharmacy service

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Background
Before treatment with radioiodine can proceed, detailed patient counselling is required to explain the benefits and risks, along with explanation of possible drug interactions and confirmation that the patient cannot be pregnant. With knowledge of radioactive and non-radioactive drugs, as well as good patient counselling skills, the radiopharmacist is well placed to offer this service in conjunction with the clinician who has final responsibility for the treatment.
This review of a radiopharmacist-led service examines its efficiency and patient satisfaction with the advice received.

Method
1. Waiting time from receipt of referral to appointment slot was assessed via a retrospective review of dates of receipt of referral and appointment over a three-month period.
2. The patient's journey through the department on the day of treatment was examined by logging various time points.
3. Patient satisfaction with the service was assessed using a patient satisfaction survey.

Results
- Mean waiting time was 11 days for all patients, except those requiring appointments within the first 10 days of their menstrual cycle.
- A substantial delay was identified whilst waiting for the pregnancy test result (range 68 to 148 minutes).
- The majority of patients were satisfied with the advice given.
- Comments made included unrealistic time frames and dissatisfaction with the explanation of radiation protection issues in the appointment letter.

Conclusions
1. Waiting times were considered satisfactory. No additional appointment slots are required.
2. Arrangements for pregnancy testing require review. Brightly coloured 'urgent' stickers have since been introduced for samples.
3. Patient information literature has been reviewed to clarify radiation protection requirements and give a more accurate indication of waiting times.
4. The patient satisfaction survey and assessment of waiting times within the department will be repeated in light of the changes described. It is proposed that this be repeated annually.

Conflict of Interest
No conflict of interest

A17. Consumption of antimycotics for systemic use according to ATC/DDD methodology in paediatric patients

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Background
Paediatric defined daily doses (DDDs) have not been established by the World Health Organisation. We have developed alternative DDDs, calculated as average maintenance doses for the most common indications for children with a body weight of twenty kilograms.

Method
We compared consumption by the number of DDDs per 1000 patient days for ATC class J02 in the period January 2005 - June 2009. The number of DDDs was calculated according to the formula:
Number of DDDs = Unit dose x Quantity /DDD/Number of patient days x 1000. DDDs for fluconazole, itraconazole and caspofungin were the same as for adults. Voriconazole DDD is half an adult and ketoconazole DDD is one third of the adult dose. DDD for conventional amphotericin B is half that of the WHO DDD, but the DDD for lipid formulations is twice as large

Results
The number of DDDs for ATC group J02 were 17.96, 24.35, 35.5, 44.44 and 39.12 from 2005 to 2009.
Fluconazole is the most used antimycotic, use of which increased from 5.43 DDDs in 2005 to 23.11 in 2008 and 19.45 in 2009. Consumption of voriconazole is also in increasing: 0.41, 0.9, 1.53, 7.28 and 4.94 from 2005 to 2009.
Use of amphotericin B was 4.24, 6.75, 8.05, 6.84, 7.76 from 2005 to 2009. But, expenditure on amphotericin B is growing because of greater consumption of lipid formulations.
In 2008, we started to use caspofungin. Number of DDDs was 0.76 and 0.86 in 2008 and 2009.

Conclusions
The consumption of antimycotics is high and is growing steadily, especially that of expensive antimycotics such as voriconazole, caspofungin and lipid formulations of amphotericin B.
This way of calculating DDDs is better than presenting the quantity only, because DDDs obtained in this way are similar to prescribed daily dose. Presentation of medicines consumption is one of the activities of hospital pharmacists and the basis for further communication among healthcare providers, in order to improve prescribing policies to minimise costs.

Conflict of Interest
No conflict of interest

A18. Underestimated costs of pharmaceutical services in sponsored clinical trials
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Background
The majority of sponsored clinical studies negotiations for financial remuneration for pharmaceutical services tend to be unsatisfactory. Pharmaceutical companies (the sponsors) and Clinical Research Organizations (CRO) usually do not have the practical pharmaceutical background to estimate accurately the time and effort that hospital pharmacists need to put into sponsored clinical studies. This means initial offers for financial remuneration are usually far too low, and subsequent contract negotiations are protracted and often end in a financial loss for the hospital pharmacy.

Method
The time taken for the pharmaceutical services to set up, run and conclude an international, multi-centre, single-blind phase-II study was documented and compared with the financial remuneration by the sponsor.

Results
Overall for every one hour paid for, the pharmacist actually worked 2.8 hours. Or, to put it another way, the sponsor only paid for 35.4 % of the pharmaceutical services undertaken.
While the hourly remuneration for the patient-specific tasks (drug preparation) was only marginally out (2.7 h paid for vs. 3.7 h actually taken), the remuneration for administrative tasks and for setting up the study differed greatly (5 h vs. 22.9 h and 9.7 h vs. 22.5 h respectively).

Conclusions
The remuneration for pharmaceutical services from the sponsor in the study analysed was far too low, resulting in a financial loss for the hospital pharmacy.
Furthermore as only 1 patient was included at our centre, the time spent on administrative tasks and setting up the study was disproportionate to the time spent on the actual preparation of medication.
Since it is not the role of hospitals to finance the research of pharmaceutical companies, pharmacists should be aware of the high workload clinical studies generate and insist on adequate and realistic remuneration by the sponsor.

Conflict of Interest
No conflict of interest

A19. Evaluation of the use of Bosentan
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Background
In recent years the use of bosentan has increased, in part because of the emergence of the new diseases for which it is used. Our purpose was to evaluate the use of this drug.

Method
We conducted a cohort study evaluating patients who were treated with bosentan from 01/01/09 to 30/06/09.
We assessed the pathology, age, follow-up (dose monitoring and blood tests for liver function), toxicity, efficacy and cost. We reviewed the medical records of patients and data were collected from outpatients unit prescription software.

Results
In total 35 patients were treated with bosentan: 62.86% with secondary pulmonary hypertension, 14.29% arteriopathy in diabetic patients, 11.43% scleroderma, 8.57% primary pulmonary hypertension and 2.85% CREST syndrome (a limited form of scleroderma).
The median age was 78 years (63-81 years).
2.86% of patients started treatment with bosentan 125mg/12h.
31.43% of patients had no blood tests, 45.71% had one blood test and 22.88% had two or more blood tests. The group of patients with primary pulmonary hypertension was the highest percentage of patients who had no blood tests during this period (33%).
Two patients were forced to withdraw from Bosentan treatment due to liver toxicity.14.28% had a dose reduction for toxicity. The effectiveness was not assessed in the group of patients with pulmonary hypertension because of the patient characteristics and the lack of evidence of progression. The patients with arteriopathy, scleroderma and CREST syndrome have improved from a clinical point of view and in two cases there has been healing. Hospital spending generated by bosentan during this period amounted to 396.621 euros

Conclusions
This study demonstrates the lack of monitoring of treatment of these patients, both as regards safety and efficacy.
Due to the high toxicity and cost of bosentan we should focus in its proper use in order to increase safety.

Conflict of Interest
No conflict of interest

A20. Study of the resistance pattern in patients with febrile neutropenic post-chemotherapy
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Background
Bacterial infections are the main cause of morbidity and mortality among neutropenic patients. Prompt administration of empirical antimicrobial therapy for febrile neutropenic patients is considered vital. The main aim in this study was to determine the bacterial spectrum and pattern of antimicrobial susceptibility of organisms causing infections in febrile neutropenic patients who are receiving chemotherapy.

Method
Observational study over a period of 5 months from January to May 2009. The samples collected from inpatients with febrile neutropenia in the Department of Oncology and Haematology were analysed.

Results
Out of 319 patients receiving chemotherapy over a period of 5 months (251 oncology and 68 haematology) 9.9% were admitted to hospital with febrile neutropenia (20 M and 8 F), the median age was 70 ± 12 years. 25% of these patients were admitted for febrile neutropenia twice, 3.6% three times and 7.1% four times. A total of 43 episodes of febrile neutropenia occurred, of which 74.4% were associated with oncology and 25.6% with haematology.
Multiple cultures were obtained. Despite that the origin of the fever was identified in only 42.8% of patients (n=12) and in 16.2% a mixture of microorganisms was isolated. 61.9% of the microorganisms isolated were Gram-positive cocci, 28.6% Gram-negative, 4.8% anaerobes and 4.8% were fungi.
57% of the microorganisms were resistant to meticillin; 61.9% to quinolones and 30.7% of Gram-positive cocci were resistant to imipenem. Despite the recommendations of the European Conference on Infections in Leukaemia and due to meticillin resistance in 57.1%, the

use of vancomycin + aminoglycosides was required.

Conclusions
A high percentage of resistance to first-line antibiotic treatment was shown for febrile neutropenia; therefore combination antibiotic therapy had to be used.

Conflict of Interest
No conflict of interest

A21. Use of drugs in patients with enteral feeding tubes
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Background
The appropriate form of drug is important in patients using enteral feeding tubes (EFT) to avoid complications and to ensure safe and effective treatment. We describe the use of drugs in patients with EFT at a University Tertiary Hospital in Madrid (Spain).

Method
In a system for distributing single-dose medicines, the pharmacist prospectively collected data on the medicines of patients subjected to an enteral feeding tube for one month. A form was designed and the following information was collected daily: indication for enteral nutrition (EN), nutrition characteristics, days the tube was used, pharmacological therapy, drug/EN interactions, number of tube exchanges per patient and complications. The pharmacist checked the information he collected about the medicines administered by tube with the information recorded by the nurse. Thus the route of administration and any handling of the medicines could be confirmed, enabling recommendations to be made for the best formulation for administration.

Results
Of 2306 inpatients, a total of 43 (1.9%) medical charts were examined of patients who had used EFT, which represented a mean of 1.4 patients per day. The median age of the patients was 59 years (range: 19-86) and 51% were male. The mean number of drugs prescribed per patient to be administered by tube was 9.2 (SD=2.5). About 117 different drugs were prescribed.12% of these required a change in form for administration. Twenty-seven pharmaceutical interventions were made in 19 patients (that is 44.2% of patients using enteral tubes). The chance of changing the enteral tube was greater for patients who took more than five drugs enterally (OR = 13.4) and who had to take more than 10 doses per day (OR = 6.5) and who used enteral nutrition for more than 10 days (OR=6.8).

Conclusion
This study provides evidence that patients using more drugs enterally have a greater chance of needing their enteral tube changed. Furthermore, it suggests a lack of knowledge on behalf of the health team with regard to the appropriateness of drug formulations for this route.
Conflict of Interest
No conflict of interest

A22. Patients suffering from beta thalassaemia major. Treatment, approaches and methods in general hospitals of Western Greece
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Background
Beta thalassaemia major or Cooley's anaemia is a severe inherited disease that is frequent in Greece and other Mediterranean countries. Anaemia results from the inheritance of a recessive trait responsible for interfering with the rate of haemoglobin synthesis. It is the homozygous form of beta thalassaemia, first observed in infancy. The affected infants are normal at first but, by the age of 6 to 9 months, they develop faulty erythropoiesis with anaemia and other related severe manifestations.
There is no specific treatment. Conventional management is based on regular red blood cell transfusions with continuous iron chelation, splenectomy and prevention or treatment of related medical conditions. In Greece this is the most common hereditary disease and almost 3200 individuals suffer from it, while 8% of the population are carriers of the disease (in some areas up to 20%).

Method
A preventive programme has been running for the last ten years (mainly through prenatal checks). Data collected in this period from Agrinio General Hospital were compared with data from other hospitals in Western Greece. The results were taken from a questionnaire given to patients dealing mainly with their quality of life.

Results
The programme has reduced the number of children born with thalassaemia from 200 in previous years to 5 per year. Nowadays there are 180 people in the Mediterranean anaemia unit in the University Hospital of Patras and 20 in the General Hospital Agrinio unit. Modern methods of transfusion, combination therapy and the use of modern devices and medical equipment have greatly improved the quality of life of these patients. Similar results emerge from the analysis of the questionnaire.

Conclusions
Study conclusions confirm that in recent years, modern methods and the use of promising drugs has resulted in increased survival and reduced morbidity in these patients.

Conflict of Interest
No conflict of interest

A23. Biological therapies in patients with rheumatic disease. Current situation in a general hospital
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Background
The incorporation of the biotechnological drugs into the therapeutic arsenal has revolutionised the treatment of inflammatory autoimmune disease. Nowadays in Spain we have 7 "biological" drugs that act on specific targets in the pathology of this disease: TNF inhibitors (infliximab, etanercept, adalimumab); IL-1 and IL-6 receptor antagonists (anakinra, tocilizumab); a CD20 (B cell) antibody (rituximab) and a T Cell co-stimulation modulator (abatacept).
The objective of the present study is to describe the current situation in our health area, which serves 220,000 inhabitants.

Method
We reviewed the records of biological treatments supplied by the pharmacy department using the Silicon and Oncopharm programmes. The expense per patient / month was calculated from information held on the Sinfhos hospital management program. SPSS 15.0 was used for the statistics.

Results and conclusions
At present 331 patients are being treated by biological drugs for rheumatic conditions (average age 54.64 years; 62.5% women). The most used drug is infliximab (35.3%). The most prevalent condition is rheumatoid arthritis (57.1%). 4.8% of the conditions treated are outside the indications authorised in Spain. The average cost per patient / month is 930.71 €.

1. Patient demographics	
Patients	331
Age (years)	54.64 (95% CI 53.16 - 56.12)
ex (% men /% women)	37.5 / 62.5
2. Drugs (%)	
Infliximab	117 (35.3)
Etanercept	112 (33.8)
Adalimumab	68 (20.2)
Rituximab	27 (7.9)
Abatacept	8 (2.4)
Tocilizumab	1 (0.3)
3. Diseases (%)	
Rheumatoid arthritis	189 (57.1)
Ankylosing spondylitis	76 (23.1)
Psoriatic arthritis	48 (14.5)
Polyarticular juvenile idiopathic arthritis	2 (0.6)
Unauthorized indications	16 (4.8)

The efficiency of the anti-TNF in our health area will be described by the bibliography (1 in 3 patients do not respond to these drugs). The increasing diversity of therapeutic targets offers a wide range of possibilities. Which is the best option for our patients? In addition, the overhead cost that these agents impose on the health system, directs research towards one of the big challenges of the future: genetic predictors of response.

Conflict of Interest
No conflict of interest

A24. Protocol of use of clopidogrel in non-approved neurological indications

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Background
The extensive use of clopidogrel for the most common neurological indications, backed by clinical trials but not approved on the drug specifications, implies the processing of each particular case as off-label medication. The procedure carries an administrative burden and makes accessibility difficult.

Methods
A review of the medicinal literature (1999-2008) and a risk-benefit evaluation were carried out. A consensus about the protocol was arrived at between the pharmacy and neurology departments.
All the patients on clopidogrel for non-approved indications were evaluated through a retrospective, observational study from February until October 2009.
Variables evaluated: number of patients on clopidogrel for neurological indications, protocol adherence and relative value units (RVU) as a product complexity measure - understanding it in this case as time in minutes taken by the pharmacist.

Results
A protocol was designed and uploaded to the hospital website. It included a concise application form with: informed consent, non-approved requested indication list and risk-benefit declaration. This form was authorized by the hospital medical administrator and the competent Spanish authority (AEMPS) as an internal protocol, which guaranteed acceptance of the procedure for the indications contained.
Over the study period, 23 out of 34 patients on clopidogrel were treated for neurological indications. Of those, 13 were new patients and all adhered to protocol, reaching 100% adherence. Before the protocol was designed, all the new patients on clopidogrel for non-approved indications had to be processed as off-label, using 22RVU/patient at the first dispensing. After the protocol was introduced, this figure dropped to 6.05RVU/patient. 207.35RVU were saved, or 15.95RVU/new patient.

Conclusions
The improvement in the process allowed us to reduce the RVU consumed per new patient and therefore reduce the time spent on this activity; extra time was made available that could be used for pharmaceutical care. There are other clopidogrel indications that require off-label processing that could benefit from a similar protocol.

Conflict of Interest
No conflict of interest

A25. Stability of heparin in 5% dextrose

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Background
Heparin is commonly given by continuous intravenous infusion in 0.9% saline. For special occasions heparin should also be available in 5% dextrose. The aim is to develop a stable ready-to-use solution in 5% dextrose (20,000 IU/480 mL) to be kept on the ward in stock.

Methods
Several solutions of heparin in 5% dextrose without and with different concentrations of phosphate buffer were produced, adjusted to pH 7.0, filled into polypropylene bags and autoclaved. Additionally, heparin solutions in polypropylene bags and plastic syringes (20,000 IU/48 mL) were produced aseptically by adding highly concentrated, 0.9% saline-based sterile solution of heparin to 5% dextrose. The heparin activity was determined by factor Xa inhibitor assay. As control thrombin clotting time was determined.

Results
The pH of the non-buffered solution decreased upon autoclaving to 4.1 and no heparin activity could be observed. The result was confirmed by determination of the thrombin clotting time. The heparin activity before autoclaving was 41.4 IU/mL (99%). The more buffer the solution contained the less the pH decreased and the higher the activity. However the solution became yellowish. With 4 mM and 16 mM phosphate buffer pH decreased to 4.4 and 5.0, respectively, by autoclaving and the activity was only 2.3 IU/mL (6%) and 15.3 IU/mL (37%), respectively. The pH of the aseptically produced solutions were 5.4 and 6.2, respectively, and the activity 42.0 IU/mL (101%) and 419 IU/mL (101%), respectively. Stability tests performed over a period of 12 months showed no loss of the activity either stored in the refrigerator (2 – 8 °C) or at room temperature.

Conclusion
Heparin in 5% dextrose loses its activity by autoclaving. But aseptically-produced ready-to-use solutions of heparin in 5% dextrose remain stable over a period of at least 12 months.

Conflict of Interest
No conflict of interest

A26. A retrospective study of benzodiazepine poisonings in the Intensive Care Unit: frequency and severity

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Background
Exposure to poisons frequently gives rise to visits to casualty, but only some of them are considered serious poisonings. Among these, stands

out the abuse and evil of prescribed medicines such as anxiolytics. We describe the frequency and severity of benzodiazepine poisonings in the Intensive Care Unit (ICU).

Method
A retrospective observational study carried out from January 2004 till December 2008. We report all the patients who were admitted to ICU with a diagnosis of benzodiazepine poisoning during the period of study. We checked the following information from the medical reports: sex, age, psychiatric antecedents, previous poisonings, oral/intravenous administration, antidote, need for mechanical ventilation, resulting complications and mortality. SPSS 11.5 was used for statistical analysis of the information.

Results
The study included 37 patients, 48.6% women and 51.4% men. The mean age was 36 ± 12 years. 67.6% of the patients had a history of mental illness, which correlated significantly ($p < 0.0001$) with the suicide attempt in 25 of 37 patients. With regard to episodes of previous poisonings, we found a total of 17 (45.9%) who had suffered a previous poisoning as opposed to 20 (54.1%) who had not presented previous episodes of poisoning. Flumazenil was used in 36 of the 37 patients who suffered benzodiazepine poisonings. 67.6% of the patients needed mechanical ventilation; this correlated significantly ($p < 0.05$) with the development of complications, fundamentally bronchoaspiration (24.3%) and pneumonia (16.2%). The mortality rate was 13.5%.

Conclusions
Acute benzodiazepine poisonings occurred in young patients, generally women with a history of mental illness, as an attempt at suicide.
The associated mortality was high.

Conflict of Interest
No conflict of interest

A27. Position paper on future of German hospital pharmacy
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Background
In German hospitals hospital pharmacist support of physicians has not advanced as much as in other countries. In addition there are only 0.3 hospital pharmacists to one hundred beds in Germany, fewer than in most other countries. But in the last few years things have started to change. There are some plans to delegate work from physicians to nurses. Some hospital pharmacists have already started supporting hospital doctors regarding drugs. The German Society of Hospital Pharmacist has published a paper to demonstrate what it is possible to delegate to hospital pharmacists. It also aims to increase the numbers of hospital pharmacists.

Method
As the first step board members and some specialists in pharmaceutical care suggested some roles, which describe hospital processes that may be delegated to pharmacists. Then all hospital pharmacists were requested to describe their support to physicians in terms of these roles. The next step was to publish a statement, describing what support hospital pharmacists are able to provide and giving some practical examples.

Results
We found several roles we wanted to take on:
1. On admission of the patient to the hospital:
- Medical history/checking medication safety
- Modification of medicines, which combines well with advising the patient
- Preparing the patient's medicines with regard to operations

2. During the patient's stay:
- Checking medication: safety, calculating laboratory values, dosing and compliance
- Educating and advising patients
- Documentation of adverse effects
- Ensuring continued therapy if patients move to another ward
- Advising on treatment changes and high-risk medicines

3. At discharge from hospital
- Preparing for continuing medication and preparing documentation
- Checking medication safety
- Advising patients

Conclusion
There are many ways in which pharmacists can offer support to physicians and nurses. We should aim to introduce them, especially as the law requires us to optimise cooperation with nurses and physicians.

Conflict of Interest
No conflict of interest

A28. Evaluation of drug dispensing systems at a university hospital
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Background
Due to the coming introduction of computerised physician order entry (CPOE) and electronic patient record systems at the Inselspital Bern University Hospital the drug dispensing and administration process have been analysed. A number of different technical approaches were investigated to determine if they could support these critical processes with regard to patient safety.

Methods
Four types of support systems for dispensing and administration were compared. A value / benefit analysis was performed and the financial and operating efficiency was calculated for each case. The medication use data were obtained from a representative selection of wards.

Case A: Medicines dispensed manually on the ward (today's practice)
Case B: Computer-assisted medicines dispensing on the ward
Case C: High-security dispenser system on the ward
Case D: Unit-dose system with patient-specific doses of medicines prepared by the hospital pharmacy.

Results
As the first step five relevant ways of scoring the different scenarios were defined: process risk and quality (weighted 40%), operation on ward (25%), functionality (20%), operation in central pharmacy (10%) and general aspects (5%). The comparison of the scenarios revealed that case B ranks number one by the value / benefit score (476 points) and the financial benefit (CHF 0.9 million after 6 years). Case D was the runner-up (388 points) but could not contribute a positive financial return (CHF -1.73 million) compared to Case A. Case C achieved fewer points (305) than today's practice.

Conclusion
Based on the results, scenarios B and D show a process improvement but only scenario B exhibits a positive financial return. It was recommended to examine case B more in detail and carry out a pilot project to assess the practicability on the ward. Nevertheless, none of the scenarios B – D can completely replace the system in use today (scenario A).

Conflict of Interest
No conflict of interest

A29. Analysis of potential vial use reduction in immunoglobulin therapy with larger size vials
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Background
Dosage and frequency of intravenous immunoglobulin (IVIG) administration varies depending on patient weight, the condition being

treated and severity. The objective of this study was to determine if larger vial sizes of IVIG could help reduce the number of vials needed per dose.

Methods
Pharmacy claims for an IVIG product were extracted from a 2006 US database. The minimum number of vials required to reach the dose prescribed if a 25g or a 30g vial had been available was calculated and compared to: 1) the actual number of vials dispensed per dose and 2) the optimal way of reaching the prescribed dose using the least number of vials, based on currently available vials (1, 2.5, 5, 10 and 20g).

Results
2,200 patients were included in the study, representing 27,764 unique doses. 65.5% and 55.5% of the doses prescribed were over 25g and 30g, respectively. The most frequent doses were 30g (13.3%), 40g (10.39%), 25g (8.0%), and 35g (6.8%).
Of the patients who were prescribed at least 25g, 79% (1329 out of 1674) would benefit from the availability of a 25g vial. Similarly, 88.0% (1,246 out of 1,416) of the patients who were prescribed at least 30g would benefit from the availability of a 30g vial.
On average, 3.56 and 3.69 vials were used to dispense prescriptions equal or greater than 25g and 30g, respectively. These averages could have equalled 2.81 and 2.91 vials if prescriptions had been dispensed more efficiently with currently available vial sizes and could decrease by more than 30% (to 2.47 vials) and by more than 40% (to 2.16 vials) if a 25g and a 30g vial were available (p<.001).

Conclusion
The availability of additional vial sizes could reduce the number of vials necessary to reach the dose prescribed, decreasing the time spent on pharmacists' preparation and pooling.

Conflict of Interest
Yes: Corporate-sponsored research: Employee

A30. Outcomes of an outpatient medication therapy management service in a Singapore hospital
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Objectives
To provide medicinal treatment management (MTM) services to patients so as to (1) identify potential drug-related problems (DRPs) and optimise the use of medicines and (2) improve medicines adherence through counselling and education.

Methods
This prospective study involved patients seen at Changi General Hospital specialist outpatient clinics in Singapore from June 2008 to August 2009.
Patients were enrolled for the MTM service by referral by their doctors or pharmacists, or self-referral based on any of the six criteria: (1) receives medicines from more than one prescriber, (2) on five or more long-term medicines, (3) has new/complex medicines regimen, (4) abnormal lab values that could be improved with medicines, (5) non-adherence to medicines or (6) concern about the cost of medicines. MTM sessions ran by pharmacists were conducted in line with the APhA/NACDS* model framework.

Outcome measures included type and frequency of Drug-Related Problems detected, services performed and patient/caregiver's feedback on MTM service.

Results
Of the 111 patients referred for MTM, 80 (72.1%) of them were seen. Pharmacists reviewed an average of 10.4 (± SD 3.7) medicines per patient and identified a total of 118 DRPs (average of 1.5 per patient). Some 68.8% (55) of our patients had at least one DRP identified and the most common DRP was non-adherence to medicines regimen. Nineteen (16.1%) DRPs required physician intervention. About half of these interventions involve a change in dose and approximately 30% involve addition of a medicine.
Pharmacists provided a variety of educational services including, medicines use (96.3%), adherence (56.3%), and self-care (30.0%). In addition, medicines were sorted, repacked and relabelled with the latest dosing instructions for 46 patients. Survey results showed that the services were well received.

Conclusions
MTM is a valuable patient-centred service that sieves out potential DRPs. Healthcare professionals can collaborate through MTM to enhance patient care.

Results
Of the 111 patients referred for MTM, 80 (72.1%) of them were seen. Pharmacists reviewed an average of 10.4 (± SD 3.7) medicines per patient and identified a total of 118 DRPs (average of 1.5 per patient). At least one DRP was identified in 68.8% (55) of our patients and the most common DRP was non-adherence to the medicines regimen. Nineteen (16.1%) DRPs required physician intervention. About half of these interventions involved a change in dose and approximately 30% involved addition of a medicine.
Pharmacists provided a variety of educational services including medicines use (96.3%), adherence (56.3%), and self-care (30.0%). In addition, medicines were sorted, repacked and relabelled with the latest dosing instructions for 46 patients. Survey results showed that the services were well received.

Conclusions
MTM is a valuable patient-centred service that sieves out potential DRPs. Healthcare professionals can collaborate through MTM to enhance patient care.

Abbreviations
American Public Health Association
National Association of Drug Stores

Conflict of Interest
No conflict of interest

A31. Developing a postgraduate training course for hospital pharmacists: what should be taught and how?
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Background
In Finland the undergraduate pharmacy curriculum is primarily designed to develop skills for community pharmacy practice, which is the major employment sector. Knowledge and skills needed in hospital settings have long been recognised, but there have not been the resources to establish a postgraduate hospital pharmacy training programme since the previous programme was discontinued in 2001. Due to the growing need for hospital pharmacy specialists the Ministry of Education allocated funding for curriculum development in 2009. The project was carried out in cooperation between all three universities involved in pharmacy training in Finland (University of Helsinki, University of Eastern Finland and Åbo Akademi).

Methods
The curriculum development was started by a national e-survey to hospital pharmacy practitioners to assess their opinions on the core contents of the training programme and feasible teaching methods. Open-ended questions were used for listings of "must know" and "should know" topics. The survey was emailed to all members of the Finnish Hospital and Health Care Pharmacy Association with an email address available (n=296) and chief hospital pharmacists (n=18). The response rate was 24% (n=75).

Results
Compounding was most often listed as an essential study module

("must know") by the respondents (82%), followed by ward pharmacy (33%); pharmacology/toxicology (27%); clinical pharmacy (26%); interactions (16%); and medication reviews (14%). Of the teaching methods distance learning with the support of e-learning (73%), lectures and seminars (57%), residency training (53%) and working on projects (47%) were rated as most feasible for hospital pharmacy training.

Conclusions
The study provided insights into the priorities of Finnish hospital pharmacy practitioners for the curriculum development. The insights of the practitioners will be complemented with topics raised by recent international trends and developments in hospital pharmacy and safe medication practice.

Conflict of Interest
No conflict of interest

A32. Evaluation of adherence on switching from twice-daily to once-daily therapy for HIV-infected patients

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Background
Adherence to antiretroviral therapy is critical to treatment outcomes. Adherence studies in other therapeutic areas of medicine suggest that once-daily regimens improve adherence when compared to twice-daily therapy. An expansion in the range of once-daily antiretrovirals is making once-daily treatment possible for persons with HIV infection. The aim of this study is to assess the improvement in adherence to antiretroviral therapy in our patients.

Methods
Retrospective study of HIV-infected poli-treated adults in the hospital who were switched from twice-daily regimens to a triple combination, single-tablet regimen of efavirenz, emtricitabine and tenofovir, marketed as Atripla, in persons with complete virological suppression (<50 copies/ml). Subjects were assessed for adherence using the simplified medicines adherence questionnaire (SMAQ) and checks of drugs dispensed during 12 weeks of follow up.

Results
A total of 39 patients were included in the study. Of all patients, 28 were men and 11 women, mean age was 42 years. All subjects enrolled had been taking one of the following regimens for a minimum of one year: 29: emtricitabine/tenofovir (Truvada) + efavirenz (Sustiva); 6: lamivudine/zidovudine (Combivir) + efavirenz (Sustiva); 2: abacavir/lamivudine/zidovudine (Trizivir); 1: lopinavir/ritonavir (Kaletra) + lamivudine/zidovudine (Combivir) and 1, abacavir/lamivudine (Kivexa) + efavirenz (Sustiva).
At baseline, the adherence observed in the study population exceeded 95% in 70% of patients. After 12 weeks, 75% of patients maintained high adherence and quality of life. Everybody remained virologically suppressed.

Conclusions
Patients switching from twice-daily to once-daily treatment demonstrated less of a decline in adherence over 12 weeks, in persons already highly adherent to medication.
These data suggest that once-daily therapy is preferred by patients who initially reported good adherence.

Conflict of Interest
No conflict of interest

A33. Use of palivizumab in respiratory syncytial virus prevention in a risk campaign

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Background
Palivizumab is a monoclonal antibody indicated for the prevention of serious lower respiratory tract diseases requiring hospitalisation in children at high risk of respiratory syncytial virus (RSV).
The recommended dose is 15mg/kg body weight administered monthly during periods with a risk of RSV infection (October-March) with a maximum of 5 doses per season.
The objectives were to analyse the number of patients who received palivizumab in the 2008-2009 campaign, to check if the prescriptions and patient record were correct, check the suitability of the dose, number of doses and period when administered, as well as checking the effect of these types of studies and identifying areas for improvement.

Methods
Descriptive, retrospective, observational study conducted in the Ribera Health Department, Valencia (Spain).The sources of information were the hospital's electronic medical records and manual records of patient nursing. The variables analysed were the number of patients receiving medicines, the prescription of treatment and the reference in the patient's electronic medical record, the dose (depending on patient weight), number of doses and length of treatment.

Results
The total number of patients who received palivizumab in the 2008-2009 campaign was 38 children, according to lists provided by the paediatric ward of the supply by the pharmacy department. Only one case was recorded in the treatment section of their electronic medical record, which means that 97% of patients do not have the drug administration recorded in the electronic medical record. In 30% of patients, there is no reference in the electronic health record to the prescription or administration of palivizumab.
In no cases were the dose, number of doses or date of administration recorded in the patient's medical history, although these were noted in nursing records when they were administered.
In 100% of cases, the dose was correct regarding the child's weight, although 66% of cases had been given a higher number of doses than that recommended in the summary of the product characteristics.

Conclusion
The administration of palivizumab was successful in terms of indication and dosage, but incorrect in the number of doses administered to patients.
Drug use studies identify areas for improvement. Specifically from this study, the Pharmacy and Therapeutics Committee has developed a series of recommendations for recording the prescription and administration of palivizumab in the electronic medical history and the possibility of centralising the preparation of treatment in the pharmacy department. This is intended to ensure the correct number of vials is used, the right dose in terms of weight, and preparation under sterile conditions.
Conflict of Interest
No conflict of interest

A34. Clopidogrel desensitisation solutions: preparation, safety and efficacy

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Background
Dual antiplatelet therapy with aspirin and clopidogrel has become the cornerstone for stent thrombosis prophylaxis after an intracoronary stent has been fitted.
However, allergic rash is a common side effect of clopidogrel, which leads to its discontinuation. Switching to ticlopidine may be an option for these patients but this drug is associated with a higher risk of haematological adverse reactions. Thus, clopidogrel desensitisation can be a suitable choice.
The aim of this study is to report a clopidogrel desensitisation protocol, devised in our hospital, and to evaluate its safety and efficacy.

Method
The desensitisation procedure consisted of taking 8 escalating doses given orally at 30-minute intervals for 4h. Starting dose was 0.05mg, followed by increasing doses: 0.15, 0.5, 1.5, 5, 15, 45 and 75 mg of clopidogrel.
A 5mg/mL clopidogrel suspension in water was prepared in the pharmacy department (suspension A). This suspension was sequentially diluted to achieve clopidogrel concentrations of 0.5 (suspension B) and 0.05mg/mL (suspension C). From suspensions A, B and C, escalating doses of clopidogrel were placed in individual oral syringes.
The protocol was prescribed for two patients whose coronary stent had been replaced who developed a maculopapular pruritic rash due to clopidogrel. Patients were monitored for hypersensitivity symptoms and haemodynamic instability. Follow-up period was 30 days.

Results
The protocol was followed in full in both patients. No dermatological adverse reactions or cardiovascular events were reported. After the increasing doses had been taken, a therapeutic dose of clopidogrel (75mg daily) was continued for 30 days, while the patient was at home, without signs of hypersensitivity. The clopidogrel suspension was freshly prepared on the day of administration. Individual oral syringes facilitated its administration and hence it was well accepted by patients.

Conclusion
Clopidogrel desensitisation was successfully performed on two patients who had experienced clopidogrel hypersensitivity after intracoronary stent replacement. No adverse effects were observed.
The protocol is easy to devise, the solutions simple to prepare and they are accepted by patients.

Conflict of Interest
No conflict of interest

A35. Efficay and safety of Omalizumab in persistent allergic asthma

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Background
Omalizumab is a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human IgE at the same epitope on the Fc region that binds to high-affinity receptors present on the surface of mast cells and basophils.

Objective
To evaluate the efficacy and safety of omalizumab in patients with severe persistent allergic asthma.

Method
Retrospective study of patients treated with omalizumab from January 2007 to September 2009. Demographics and clinical parameters were collected from the clinical history: age, gender, diagnosis and dosage of omalizumab. It was verified that the patients fulfilled the following criteria: positive skin test, reduced lung function (FEV1<80%), IgE>76 IU/mL and previous treatment with corticosteroids and beta2 agonists.
Efficacy was evaluated by reduction in number of exacerbations, asthma-related emergency visits or hospitalisations, treatment with oral corticosteroids and by clinical response. Safety was evaluated by the adverse drug reactions (ADR) shown by our patients.

Results
We report on seven patients (57% men, 43% women). The mean age was 49 years (25-61) and mean dose of omalizumab was 485 mg/month (150 - 375 mg administered every 15 days) in 5 patients and every month in 2 patients. All met the established indications. Before treatment all patients experienced exacerbations, 6 patients needed emergency visits or hospitalisation and all patients needed treatment with oral corticosteroids. After initiating treatment, only 3 patients experienced exacerbations, 1 patient needed emergency visits or hospitalisation and 2 patients continued treatment with oral corticosteroids. All patients increased FEV1. The mean value was 11.3% (61.43 - 73.3%). ADRs were: difficulty breathing (2 patients) and loss of voice (1 patient).

Conclusions
Omalizumab is being used appropriately, meeting the established criteria for the drug. All patients experienced subjective improvement, reduced their use of oral corticosteroids and increased their FEV1.
The safety profile was acceptable and ARs were mild. Further studies are required to establish the value of omalizumab in the treatment of severe persistent allergic asthma.

Conflict of Interest
No conflict of interest

A36. A drug kit for inborn metabolic disorders

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Objective
To define and standardise the drugs that comprise the kit for inborn metabolic disorders and the process for dispensing the kit to the Paediatric ICU.

Method
We selected drugs needed for a metabolic emergency kit, checking the standard dose, by consensus with the paediatric ICU. Selection of the drugs was based on a review of the literature, urgency of treatment and the availability of drugs. Medicines were intended to cover a 3-day treatment for a children of 10 kg maximum weight. We developed a protocol for management and a work table that contained the brand name, the drug, the dosage form and conditions of administration.
A system was designed for dispensing metabolic medicines kits.

Results
Kit components are listed in the table:

Drug	Brand name	Dosage	Number of units
Sodium phenyl butyrate	Ammonaps 940 mg/g oral granules	250-500 mg/Kg/day	1 bottle of 266 g
	Sodium benzoate 25% injection 10 mL.	250-500 mg/Kg/day	10 injections
	Sodium benzoate Prepared oral liquid formulation 250mg/mL	250-500 mg/Kg/day	1 oral liquid formulation
Carglumic acid	Carbaglu 200 mg tablets	100-200 mg/Kg/day	10 tablets
Arginine	L-Arginine 20% injection	200-600 mg/kg loading dose followed by 250 mg/kg over 24 hours	20 injections
Carnitine	Carnicor 1g/5 mL injection	100 mg/kg/day	10 injections
	Carnicor® 1g/10ml oral solution	100 mg/kg/day	1 oral solution

Biotin=Vitamin H	Medebiotin forte 5mg/1 mL injection	10 mg/day	10 injections
Hydroxocobalamin=Vitamin B12	Megamilbedoce 10 mg/2 mL injection	1 mg/day	10 injections
Riboflavin= Vitamin B2	Riboflavin ingredient for formulation	100 mg/day	3 doses

Conclusions
The presentation of a metabolic disease can be a vital emergency. A kit was necessary with all those drugs for emergency use .

Conflict of Interest
No conflict of interest

A37. Multiple resistance of coagulase-negative staphylococci to antibiotics
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Background
Multiply-resistant coagulase-negative staphylococci (CoNS) are usually the cause of nosocomial infections when a patient has had a foreign body implanted. This is due to bacterial polysaccharide components that allow the CoNS to attach and persist on implants in the body. The right use of antibiotics among resistant strains can help fight this type of nosocomial infection.

Method
A 6-month retrospective study, from January to June 2009, of antibiograms collected from all the Institute for Orthopaedics and Surgery departments and classified in the pharmacy department.

Results
259 antibiograms were collected during the 6 month period. CoNS were found in 34 bacteriological samples, which is 13.12% of all antibiograms. 55.88% of samples were from male and 44.11% from female patients. The table shows the resistance of CoNS strains to carbapenems, piperacillin-tazobactam and third generation cephalosporins. During this 6 month period CoNS showed a 100% sensitivity to vancomycin.

Month	Percentage resistance to selected antibiotics
January	63.63
February	25
March	83.83
April	50
May	50
June	85.71

Conclusions
Collecting this data has helped in presenting the percentage CoNS resistant to specific antibiotics. Due to the increasing prevalence of CoNS as pathogens in recent years, it is very important for the Institute's pharmacy department to regularly evaluate antibiograms of samples taken from patients who have NI caused by CoNS resistant to multiple antibiotics. By determining this resistance to specific antibiotics, intravenous treatment of the NI can successfully deal with the CoNS biofilm that forms on a foreign body surface implanted into the patient.

Conflict of Interest
No conflict of interest

A38. Experience in the dispensation of antineoplastic oral agents in a pharmacy service of a reference hospital
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Background
From 1 January 2009 in the Region of Murcia, Spain, it became obligatory under order 4/2008 of the Murciano Health Service for some oral antineoplastic agents to be dispensed by hospital pharmacies.

Objectives
To describe and assess the impact on the dispensing of some oral antineoplastic agents in outpatients.

Method
Retrospective observational study of prescriptions dispensed from January to August 2009. The data from the outpatients dispensing program (Dipex) were: patient name, type of antineoplastic agent, dosage schedule and indication. The expenditure was obtained from Sinfhos management program. The pharmaceutical care given these patients was classified into first appointment, for patients starting treatment, and successive appointments, in which the treatment was monitored.

Results
1. The oral antineoplastic agents dispensed were: imatinib, sorafenib, lenalidomide, dasatinib, sunitinib, erlotinib, bexarotene, nilotinib, lapatinib and capecitabine.
2. The expenditure for these drugs was: January 103,035 €, February 259,389 €, March 303,256 €, April 278,506 €, May 252,365 €, June 289,819 €, July 326,900 € and August 265,108 €. The maximum was July with 326,900 €.
3. 424 new patients were included: 38 taking imatinib, 17 with sorafenib, 21 with lenalidomide, 4 with dasatinib, 22 with sunitinib, 71 with erlotinib, 1 with bexarotene, 1 with nilotinib, 6 with lapatinib and 243 taking capecitabine.
4. 550 first appointments and 499 follow-on appointments were made.

Conclusions
1. The prescription of antineoplastic oral agents grew during 2009.
2. The outpatients area in our hospital has increased work, due to the arrival of new patients who require a close monitoring by the pharmacist, and increased expenditure, due to the high cost of these drugs.

Conflict of Interest
No conflict of interest

A39. Customer expectation and satisfaction of an outpatients pharmacy in Singapore
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Background
To examine factors that are important to customers visiting a pharmacy and identify factors influencing customer overall satisfaction in an outpatient pharmacy in Singapore.

Method
A cross sectional survey was carried out among customers whose prescriptions were dispensed at Changi General Hospital outpatient pharmacy from 3 November to 12 December 2008. The survey was conducted by face-to-face interviews using a structured questionnaire. Respondents were asked to rate the importance of 11 factors and the pharmacy's performance on a 5-point Likert scale. Ordinal regression analysis was used to determine the factors that affected customer satisfaction. The time the customer expected to wait was also explored based on the number of prescription items collected.

Results
A total of 245 customers participated in the survey. Based on mean respondent ratings, clear explanation of medicines (4.42± SD 0.55), pharmacy cleanliness (4.32± SD 0.62) and competency of dispensing staff (4.29± SD 0.60) were the 3 most important factors to customers while privacy (3.89± SD 0.81), adequate contact time (3.84± SD 0.78) and noise level (3.69± SD 0.92) were deemed less important. Courtesy of staff, time spent waiting to collect medicines and availability of seats in the pharmacy were found to influence overall customer satisfaction significantly ($p<0.05$).
Of the respondents collecting 1 to 2, 3 to 5 and 6 or more medicines during peak times, most of them expected to wait 5-10min (42.1%), 11-15min (39.6%) and 11-15min (61.7%) respectively to collect their medicines.

Conclusions
Understanding patients' expectations and factors that affect patient overall satisfaction can identify deficiencies in the system and provide feedback to maintain service excellence.

Conflict of Interest
No conflict of interest

A40. Relationship between plasma level of digoxin and Beers' criteria
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Background
According to Beers' criteria, digoxin doses in people older than 65 must not be higher than 0.125 mg.
The objective of this study will be to determinate if this adjustment in the dose is necessary or not and whether the clinicians were monitoring the patients´ plasma levels properly.

Method
- Unit dose application of the Farmatools programme.
- Servolab programme.

This was a retrospective study, with 71 hospitalised patients, older than 65, dosed with digoxin doses higher than 0.125 mg, between July and September of 2009.
The patient list was obtained using the Farmatools program. Afterwards, using the Servolab programme, their plasma levels of digoxin were collected.

Measurements
- Percentage of patients whose plasma levels were monitored properly (number of patients whose digoxin levels were determined / total number of patients).
- Percentage of patients older than 65, with digoxin doses higher than 0.125 mg, whose plasma levels were outside the therapeutic margin for digoxin (0.8-1.2 ng/ mL) (number of patients with plasma levels outside the therapeutic margin/ number of patients whose plasma levels were determined).

Results
Data regarding the plasma levels were found in 46 patients out of 71 included in this study (65%). This figure suggests that in 35% of patients older than 65 dosed with digoxin the digoxin plasma levels were not investigated. Of those whose digoxin bloods level was determined, 27 patients (60%) had digoxin levels outside the margin.

Conclusions
Decreasing the dose of digoxin in patients older than 65 should be considered. Blood levels are not being properly monitored even with the known narrow therapeutic margin of this drug.

Conflict of Interest
No conflict of interest

A41. Characterization of treatment-naive patients initiating therapy for HIV-1 infection: two years experience
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Background
International guidelines recommend the initial assessment of several factors before starting antiretroviral (ARV) therapy in treatment-naive patients. The purpose of this study was to assess some of the main factors (CD4 T-cell count and viral load) and identify the preferred regimens.

Method
A retrospective study was developed determining the total of number of treatment-naive patients initiating ARV therapy, from January 2008 to August 2009. Data were obtained from medical report and pharmacy database. International guidelines were reviewed.

Results
A total of 219 patients were identified (27% women). Mean age was 41 (range 20-77).

		n (%)
Initial ARV Therapy	2NRTIs+NNIRTI	175 (80)
	2NRTIs+IP	44 (20)
CD4 T-cell count	<200	103 (47)
(cells/mm^3)	200-350	90 (41)
	>350	24 (11)
	n.d.*	2 (1)
Viral load	<3,000	22 (10)
(copies/mL)	3,000-10,000	122 (56)
	>100,000	64 (29)
	n.d.*	10 (5)
Total		**219 (100)**
* not determined		

Conclusion
The results show that these factors were in line with international guidelines.

Conflict of Interest
No conflict of interest

A42. Evaluation of antiretroviral treatment adherence through direct and indirect methods
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Objective
To evaluate the adherence of patients attending a hospital outpatients unit to antiretroviral treatment (ART) through the combination of a questionnaire/dispensing records (indirect methods) and Viral Load (VL) / CD4 levels (direct methods).

Methods
Descriptive and prospective study (October-08 to January-09) of HIV-infected patients on ART who collect medicines monthly in the outpatient care unit of the pharmacy department.
A data collection sheet was developed to record age, gender, tablets/day, VL and CD4 levels.
To evaluate adherence the following parameters were used: the Simplified Medicines Adherence Questionnaire SMAQ, pharmacy dispensing records, CD4 levels and VL.
Patients who took more than 95% of prescribed doses in the last week or who came to pick up medicines within 2 days of running out of tablets were considered adherent.

Results
During the study period 82 patients were interviewed (71.9% men) with a mean age of 43.9±7.4 years (26-71). Depending on the treatment 90% of patients took more than one tablet/day and only 10% took one tablet daily.
The self-administered SMAQ showed that 46.3% of patients presented ≥95% adherence. According to dispensing records, 53.7% of patients were considered adherent. Finally, according to the criteria defined in this study, 35 patients (42.7%) were classified as adherent.
VL was undetectable in 74.3% of patients and CD4 levels were greater than 350 cell/mcL in 86.5% of patients.
Undetectable VL was seen in 88.5% of adherent patients, while 80% of patients with high VL were not adherent.

Conclusions
Combination methods used to assess adherence to ART are effective.
Were noted an association between achieving a high level of adherence and good control of VL.
Studying adherence to ART is becoming an essential tool in developing intervention programmes, whose main objective is to get as many people as possible adherent to ART.

Conflict of Interest: No conflict of interest

A43. Do patients know what medications they are taking?
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Background
Our perception is that most patients are not knowledgeable about their medicines. We decided to assess how much patients knew about them.

Method
Hospital patients were surveyed. The questionnaire consisted of 11 questions about the medicines.

Results
Total surveyed: n=50. Men: 27. Mean age: 69(23-86). Upon admission, 46.9% remembered exactly how many medicines they were taking, 26.5% remembered some. 32% were able to say exactly what medicines they were taking, while 34% did not remember any. Furthermore, 56% knew what illnesses the medicines were for, 36% were unaware or mistaken. In terms of dosage and time of administration, 60.4% and 77.3%, respectively, said they were taking them correctly. Then, 67.4% related at what time they took the medicines with their meals.
As for side effects, 87.5% responded that nobody had explained these to them. Identification of the medicines by colour and/or shape was useful for 43.7%. Half of the patients said they always or nearly always read the information leaflet while the other half never or hardly ever. When asked if they would like to have more information about their medicines, 42.9% showed little interest and 10.2% had none.
When asked which health professional should inform them of the drug treatment prescribed, their preferences were: 53.1% the physician and pharmacist, 42.9% only the physician and 2% only the pharmacist.

Conclusions
1. In general, the results reflect the perception we had about patients knowing little about their drug treatment.
2. The best responses were about the dose and time of administration.
3. The survey revealed that patients had little interest in knowing more about their drug treatment. Nevertheless, we think it is vital for patients to be given information about the benefits of taking their medicines correctly.

Conflict of Interest: No conflict of interest

A44. Clinical investigations ethics committee: modifications requested in the patient information leaflet
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Background
Article 2 of the "Real Decreto 223/2004, de 6 de febrero por el que se regulan los ensayos clínicos con medicamentos" defines the Ethics Committee and Clinical Investigation (ECCI) as an independent body to protect the rights and safety of subjects participating in a clinical trial (CT). It also describes the informed consent form for taking part in a CT; it must be written, dated and signed voluntarily after the patient has been informed and given documentation about the type, size, implications and risks of the CT. The patient information leaflet (PIL) is a very important element. The objective of this study was to analyse and quantify ECCI interventions in the patient information leaflet of the CTs being evaluated.

Method
A 24-month (October 2007-September 2009) prospective study. Modifications requested in the PIL by the ECCI were recorded. Modifications were considered either relevant or not relevant to deciding on the approval of the CT. Modifications were classified in two groups: Modifications to improve the comprehension and/or to extend patient information and modifications to adjust to current legislation.

Results
During the study period 75 CTs were evaluated. In reference to the PIL 35 modifications were requested, 12 (34.3%) were relevant and 23 (65.7%) not relevant. Of the requested modifications, 60% were about patient information whereas 40% were to adapt the PIL to legislation. Six (50%) of the relevant modification and 14 (61%) of the non-relevant modifications related to changes in patient information (p=no significance).

Conclusions
The majority of ECCI modifications requested to the PIL were required to improve patient information. Generally, these modifications did not prevent CT approval. A large number of PILs that did not meet current legislation were observed. The ECCI does an important job on protecting patient and makes sure study promoters comply with the legislation.

Conflict of Interest
No conflict of interest

A45. Impact of pharmaceutical interventions on medication errors in computerized prescribing of chemotherapy schedules
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Background
Computerised prescribing is a means of preventing medication errors, especially in oncology. The main aims of this prospective study were (i) to assess the residual risk of error (ii) to determine the relevance of the pharmaceutical interventions within a completely computerised and standardised system of chemotherapy prescribing (iii) to estimate the clinical and financial effects of this pharmaceutical service.

Method
The study was carried out in Beclere hospital (Clamart, France). It included all the protocols introduced between 01/07/2007 and 30/09/2009. All the prescriptions were validated pharmaceutically before preparation. Pharmaceutical interventions were collected prospectively and their consequences were analysed.

Results
Over the study period, 9015 consecutive prescriptions (445 patients) were examined and generated 319 pharmaceutical interventions (3.5%). 68% of the interventions resulted in a revision of the initial prescription

by the prescriber. 45.5% had a potentially significant clinical effect (48% were a problem of prescribed dose, 12% of protocol error). An excessive dose was found in 37% of cases, especially “non renewal of a previous change due to toxicity”. Dramatic cases were avoided by 2 interventions.
On the other hand, 32% of the interventions resulted in significant cost avoidance under the French "good use of medicines" convention (Savings of 16819 €).

Conclusion
Our study showed that 3.5% of the prescriptions required action, a rate lower than those usually described with traditional prescribing systems (12%), demonstrating the efficiency of computerised prescribing in chemotherapy.
However, a residual risk was clearly identified. Adding risk avoidance to cost reduction in cancer treatment proves that the return on investment in a pharmacist is highly positive.

Conflict of Interest
No conflict of interest

A46. Pharmacogenetics of hip fracture for individualized therapeutic response: routine tools for clinical application
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Background
Hip fractures are the most threatening osteoporotic fractures, because mortality can reach 30% by one year after the fracture. The effectiveness of treatments used for osteoporosis is only 48%. Furthermore, the change in bone mineral density (BMD) caused by antiresorptive drugs explains approximately only 15% of the reduction in risk fracture. Some genetic determinants relating to the BMD, the bone strength, bone turnover markers and non-skeletal features have been characterised. Moreover, it is known that clinical response including adverse reactions to antiresorptive treatment is highly variable among treated individuals. Hence our objectives are to review genetic variants (SNPs) involved in hip fractures and to determine the relevant pharmacogenetic clinical impact at hospital level.

Method
A bibliographical review was performed of different databases (PharmGKB, PubMed). We searched the clinical impact of SNPs in Caucasian populations with osteopenia osteoporosis affecting femoral neck BMD and antiresorptive drug responses.

Results
There are specific variations in the genes associated with risk of hip fracture. A table compiling all documented SNPs putatively involved in homeostasis bone pathways has been built. It contains the necessary molecular biology specifications for easy routine clinical application. The genes of related pathways are also known: Osteoclastogenesis [OPG(rs4355801-rs3102735), RANK(rs3018362), RANKL(rs9533155-rs9594759)]; Wnt [(LRP5(rs3736228-rs4988321), LRP6(rs2302685)]; Oestrogen [ERα(rs2234693-rs9340799), ERβ(rs4986938)], Vitamin D receptor [VDR(rs1544410-rs11574010-rs731236-rs10735810)], Mevalonate [FDPS(rs2297480). In addition, the SNPs of the CYP-2C8(rs1934951) may be associated with bisphosphonate-related osteonecrosis of the jaw. In this way, the present work provides a simple tool for establishing a hospital routine methodology for determining each SNP.

Conclusion
Because of the risk of suffering a hip fracture needs to be approached in an individualised manner, the simplification of routine clinical tools in hospital could be highly valuable in predicting, treating and preventing these fractures and their adverse consequences.

Conflict of Interest
No conflict of interest

A47. Medicines reconcilation study at Gastroenterology Internal Medicine Department
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Objective
To compare the home medicines list and drugs prescribed in hospital to identify errors related to differing medicines. To assess the severity and type of errors identified.

Method
Prospective study conducted during February 2009 with patients admitted to the Gastroenterology Internal Medicine ward. Transplant patients and those transferred from other wards were excluded. A pharmacotherapeutic history was compiled by collecting data from different sources: emergency admission chart, nursing assessment chart, review of previous admissions, patient and / or family interview and written information provided by the patient. Medicines reconciliation was conducted on admission and at discharge and an assessment was made of discrepancies. Those not justified were queried.

Results
The study included 60 patients. The average age was 59.75 ± 19.81 years and the average number of chronic medicines 4.6 ± 3.2 per patient. 263 discrepancies were detected at admission, 4.38 discrepancies per patient. 92% of the differences found were justified by the change in treatment: 46% new drugs prescribed, 30% drugs that the patient was taking regularly but that were not prescribed in their new clinical situation and the remaining 16% were drugs that were replaced by therapeutic equivalents. 8% of total discrepancies were not justified. 5.7% were omissions of drugs needed by the patient. Of the latter, the therapeutic group most involved was nervous system drugs, particularly neuroleptics and anxiolytics. The 1.52% non-justified discrepancies were the same drug prescribed twice and 0.39% incomplete prescriptions. Reconciliation was performed at discharge on 50% of patient prescriptions, finding a total of 66 discrepancies: 8.6% chronic medicines omitted and 13% inaccurate prescriptions at discharge.

Conclusion
The high number of discrepancies identified shows that medicines reconciliation is a necessary process in clinical practice. Both on admission and at discharge, the most common problem was the omission of chronic medicines, typically drugs affecting the nervous system. The difficulty of creating the most accurate list possible of all medicines a patient is taking and comparing that list against the physician’s admission, transfer and/or discharge prescriptions, highlights the need to introduce electronic medical records so that the patient stays on the correct drugs throughout his/her time in hospital.

Conflict of Interest
No conflict of interest

A48. Intravenous clonidine as therapy for sedative drugs tolerance: a case report
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Background
Sedation is usually based on opioids, benzodiazepines and propofol. However, some patients require higher doses than usual. Adjuvants may be possible to reduce the dosage and improve sedation control. This report describes the case of a patient who developed tolerance to sedatives and the use of clonidine as adjuvant.

Method
A 53-year-old man was admitted to the Intensive Care Unit after emergency surgery. He was sedated with propofol and morphine and required artificial ventilation. He needed parenteral nutrition. To avoid handling two lipid solutions, the sedation was changed to midazolam and fentanyl. However, the patient presented agitation and propofol was prescribed again. The patient required increasing doses of propofol (up

to 2.8 mg/kg/h) and the addition of remifentanil (up to 9 mcg/kg/h) plus haloperidol (5 mg every 4h). On the 9th day, the patient presented hypertriglyceridemia (440 mg/dl). Propofol and remifentanil were stopped. The sedation scheme changed to morphine (up to 0.06 mg/kg/h), midazolam (0.2 mg/kg/h) and haloperidol. But the agitation continued. Clinicians considered using intravenous clonidine. Our pharmacy department researched its bibliography and obtained it as a galenic formulation.

Results
On the 10th day, clonidine was added to the sedation cocktail. 8.5 mcg/kg was administered for 12 hours. The next day, 13 mcg/kg was administered as a 24 hour infusion. On the 12th day, clonidine was stopped as it was causing hypotension. The patient was sedated with fentanyl and midazolam. On the 14th day an attempt was made to extubate the patient. The sedation scheme changed to clonidine (8.5 mcg/kg per 24 hours) and haloperidol. The extubation was successful. On the 16th day the clonidine was reduced (6.5 mcg/kg for 24 hours) and then stopped. Bibliographical research showed that a loading dose of 150-300 mcg is usually administered and then an infusion of 1 mcg/kg/h. 4.2 mg per day are well tolerated. Withdrawal must be progressive.

Conclusion
In our case, clonidine was an effective option to avoid high doses of sedatives, despite not fitting the usual pattern.

Conflict of Interest
No conflict of interest

A49. Mistakes in checking drugs for penicillin allergy cross reactions
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Background
To establish the degree of knowledge possessed by the nurses involved with drug administration regarding allergic penicillin cross reactions with a view to improving standards and to evaluate how well a new service was accepted.

Method
The extent of knowledge was determined anonymously using a test in which participants had to say which of the given antibiotics in the pharmacotherapy guide could be administered safely, cautiously, or should be avoided, in a patient allergic to penicillin.
Once the tests had been assessed, a pocket-sized card was made, which resembled traffic lights, in which antibiotics that can be administered safely were included in the green section, those that require caution in the yellow section and those that should be avoided by patients allergic to beta-lactams in the red section. Then, to determine if this card was accepted and being used the following questions were posed: Are you carrying the card on your person? Has it made your daily tasks easier or more difficult? What would you change? What do you like best about this service?

- **Results**
  Fourteen of the twenty tests distributed were answered (70% participation). The percentage of wrong answers was 30.5%.
- The results of the assessment were as follows: 85.7% were carrying the card on their person.

The proposed changes were as follows: follow up this initiative with educational lectures, include the word penicillin (next to beta-lactams), etc. What subjects most liked about the initiative was that it involved them in patient safety.

Conclusions
- The high percentage error found justifies the need for pharmaceutical interventions so as to raise the knowledge of the nursing staff.
- The card created an opportunity to be more involved with the nurses and to get better acquainted with their ways of working.

Conflict of Interest
No conflict of interest

A50. Accuracy of syringes prepared in anaesthesiology
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Background
The use of intravenous drugs in anaesthesiology is associated with critical risks including wrong drug and wrong dosage. Many intravenous therapies are prepared in the operating theatre, to manage the anaesthesia during the patient's operation. The objective of the study was to asses the accuracy of intravenous drugs prepared in anaesthesiology, by analysing the content of syringes.

Method
Four test drugs representative of different preparation techniques were selected. Fentanyl (10, 20, 25 50 mg/mL) and atracurium (1, 2.5, 5mg/mL) were diluted from ampoules. Thiopental (5, 25, 50 mg/mL) was diluted after reconstitution from vials (powder) and lidocaine (10mg/mL) was simply drawn up from the ampoule into the syringe. Syringes were collected at the end of operations in different theatres and the drug content was quantified using 4 validated UV-vis methods.

Results
Five hundred syringes were analysed:150 fentanyl, 150 atracurium, 150 lidocaine and 50 thiopental. Overall, 34% of the preparations were outside ± 10% of the target concentration, 18% were outside ± 20% and 8% were outside ± 50%. Fentanyl showed the higher rate of discrepancy (mean concentration ± SD: 146.4 ± 104.5%) followed by thiopental (109.1 ± 70.4) and atracurium (97.6 ± 13.5). For lidocaine (101.8 ± 10.2), only one case of double concentration was detected.

Conclusion
Only two-thirds of syringes prepared in an operating theatre had concentrations of active drug corresponding to the European pharmacopoeia requirements. In 8% of cases, the dose was far away from the expected concentration, suggesting not inaccuracy, but an error during drug preparation. These results strongly support the need for strict preparation procedures (i.e. preparation protocols) and the production of ready-to-use syringes in GMP conditions at the pharmacy.

Conflict of Interest
No conflict of interest

A51. Utilization of a electronic formulary as standardisation procedure for initiation visit in clinical trials
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Background
190 clinical trials are currently taking place in our hospital

Objective
The principal objective of this study was to design a standard procedure to obtain information about managing the investigational product during the study initiation visit with the monitor.

Method
- A form that can accommodate these items was designed in our Access trial database:
- Reception: interactive voice response systems (IVRS), fax, do new supplies need to be requested by the pharmacy?
- Storage: Is a controlled temperature required? type of storage, records.
- Prescription: type, link to model prescription
- Randomisation:
- Preparation: Cytotoxic agent? pharmacist blinding.
- Dispensing: type, number of kits to be dispensed; supplies labels storage.
- Returned containers/products: collected by pharmacy, empty vials, labels, accountability.

There were also entries for observations and hyperlinks to instruction documents in randomisation, preparation, blinding and dispensing.

Results
Since the system was implemented, in January 2009, all the initiation visit records have been electronic. The model prescription and the dispensing instructions document for each trial are obtained from the database, too, after data entry.
55 initiation visits were performed between January 2009 and September 2009. 27 trials needed IVRS, 51 fax confirmations. In 7 trials the pharmacy was responsible for requesting new supplies, in 7 trials temperature recording was required during transport.
For investigational products kept in the pharmacy, the sponsor needed to monitor records of the ambient temperature in 24 trials, fridge temperature in 24 trials, freezer temperature of –70ºC in 1 trial.
Any trial initiated in this period was randomised or blinded by pharmacists. In 24 trials investigational products were prepared by the pharmacy, 19 were cytotoxics.
Dispensing was individualised in 54 trials. 23 needed to be dispensed in numbered kits. In three trials, pharmacists had to insert investigational product labels in drug logs.
In 10 trials, the pharmacy collected empty used vials; in 14, labels (cytotoxic products, generally), in 6, returned bottles.

Conclusions
The information about investigational product management can be standardised and stored in electronic records. Working in a systematic way facilitates control of supplies.

Conflict of Interest
No conflict of interest

A52. A preliminary Italian study for the development of a radiopharmacy department
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Background
With the increase in diagnostic imaging techniques, proper management of the radiopharmaceuticals, at first restricted just to the nuclear medicine department, is today becoming even more important for the hospital pharmacy department. The main aim of our department was to come into line with the new European and Italian regulations, to create a radio pharmacy department with specialised competence.

Method
Legislative Decree no. 219 of 24 April 2005, following the criteria of European directive 2001/83/CE, sets out all the regulatory requirements regarding good clinical practice (GCP) and the use of radiopharmaceuticals. This decree requires an observant monitor to assure quality, safety and efficacy by establishing effective and reproducible methods. The development of this practice has allowed us to recruit a radio pharmacist to the specialised staff. The role of this expert is to set up appropriate safety and monitoring systems, thus to be responsible for quality assurance during all stages of preparation and use.

Results
The radiopharmaceuticals are now of a higher quality before clinical use. This outcome has been obtained by accurate control of the preparation procedures, a strong emphasis on quality and safety, more stringent operational protocols, correct use of instrumentation and stricter monitoring of the result. At last, the presence of the radiopharmacist “on site” has enabled us to record, for the first time, a considerable number of suspected adverse events and to identify new data regarding the radiopharmaceuticals.

Conclusions
The presence of a radiopharmacist during the preparation stages has improved radiopharmaceuticals management. We now work in accordance with GCP and technicians are at lower risk when handling radioactive substances.

Conflict of Interest
No conflict of interest

A53. Setup of a pharmaceutical care programme in a social care center
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Background
The regional public healthcare service provides pharmaceutical care from hospital pharmacy services to social care centres. On February 2009, our hospital’s Pharmacy Department started a pharmaceutical care programme in a centre where drugs were supplied by prescription through a retail pharmacy. The aim of this study is to analyse all prescriptions and drug-related problems (DRP) since this programme began.

Method
A clinical pharmacist reviewed the prescriptions and recorded in a data base these variables: age, sex, pharmacological treatment, drug-related problems and pharmaceutical interventions suggested to the physician. Prescribed drugs were classified according to the ATC (Anatomical, Therapeutic, Chemical) classification system.

Results
The pharmacotherapeutic profiles of 36 patients were studied (16 men and 20 women) with a mean age of 79.5 ± 10.0. The mean number of drugs prescribed per patient was 5.3 ± 3.2 (1 to 12). The most-consumed pharmacological group was nervous system (41.8%) followed by digestive system (18.1%), cardiovascular system (16.4%) and blood and hematopoietic organs groups (14.1%). The clinical pharmacists suggested 79 interventions: 48 generic substitutions and 29 active principle changes to follow the hospital pharmacotherapeutic guide. 2 treatment duplications were detected. The physician accepted every intervention.

Conclusions
Most patients (78.3%) took 4 or more drugs.
Drugs belonging to the nervous system group were most often prescribed.
The predominant intervention at the beginning of the pharmaceutical care programme was a change of medicine.
Changing prescriptions to follow the hospital’s pharmacotherapeutic guide reduces the variety of drugs prescribed, optimising the drug treatment.
The study showed a potential for pharmacist-initiated interventions to improve drug therapy in the social care centre.

Conflict of Interest: No conflict of interest

A54. Switch therapy with levofloxacin in pneumologic patients
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Background
The bioavailability of levofloxacin (98%) makes it an ideal antibacterial agent to be changed from IV to the oral route when both the clinical situation and the patient’s status allow it; this is known as *switching therapy*. The aim of our study was to determine whether the pneumology specialists in our hospital were doing this on time in clinically stable patients treated from the beginning with intravenous levofloxacin.

Method
Observational retrospective study involving all the pneumology patients treated with IV levofloxacin between June 2007 and March 2008. We considered the switch to be done “on time” if the oral route was started within the first 72 hours of treatment; it was “delayed” if the change happened after this time and, if all the treatment was IV, we regarded it as “no switch”.

Results
Of the 300 original patients, only 233 met all inclusion and no exclusion criteria. Most of the excluded subjects (26 out of 67) were treated with levofloxacin for less than 48 hours, therefore no switch was indicated. Almost 59% of the patients included (n=137) were switched on time; 87 (37.3%) were changed to oral levofloxacin after the first 72 hours of treatment and only 9 patients (3.9%) didn't receive oral levofloxacin at all. In our study, more patients were switched on time than in similar studies where less than 25% of the patients were switched on time in without a pharmacist's intervention.

Conclusions
The pneumology specialist in our hospital proactively switched more than half of the patients to oral treatment during the first 72 hours of treatment with levofloxacin. Although this result is superior to similar studies, pharmacist intervention could probably decrease the percentage of switching delayed or not performed. This will be the aim for future interventional studies in our institution.

Conflict of Interest
No conflict of interest

GROUP B: MANAGEMENT AND STRATEGY

B1. Pharmaceutical expenditure on dispensing of medicines to heathcare centres

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Background
To compare expenditure on medicines (proprietary medicinal products and enteral nutrition) dispensed by the hospital for five months to healthcare centres versus the traditional system of dispensing by prescription in the retail pharmacy.

Methods
Consumption of medicines by the healthcare centre assessed at wholesale price (A) and retail price (B).
Cost per prescription of medicines not dispensed by the hospital at retail price (C), because they are not included in the pharmacotherapeutic guide or are out of stock.
We considered that expenditure of these healthcare centres with the traditional system of dispensing by prescription in the retail pharmacy was: consumption of medicines assessed at wholesale price (A) plus the cost per prescription of the medicines not dispensed by the hospital at retail price (C).
Expenditure of these healthcare centres with the traditional system of dispensing by prescription in the retail pharmacy was: consumption of medicines assessed at retail price (B) plus the cost per prescription of the medicines not dispensed by the hospital at retail price (C).

Results
Consumption of medicines assessed at wholesale price in the five month period was €25,730.91 (A), with a mean monthly cost of €5,146.12. Consumption of medicines assessed at retail price in the five-month period would be €7,1913.34 (B).
The cost per prescription of the medicines not dispensed by the hospital in these five months was €54,705.62, with a mean monthly cost of €10,941.12.
Total expenditure with the hospital dispensing system was €80,436.53, but would have been €126,618.96 with the traditional dispensing system by prescription in the retail pharmacy.
Therefore, dispensing of medicines to healthcare centres by the hospital resulted in a cost saving of 36.5%.

Conclusion
Dispensing of medicines by the hospital to healthcare centres results in a large saving in pharmaceutical expenditure.
The hospital pharmacist plays an important role in controlling dispensing of medicines to healthcare centres not only because of financial savings, but also because of the possibility of monitoring the treatment of these patients.

Conflict of Interest
No conflict of interest

B2. Post discharge compliance to venous thromboembolism prophylaxis in major orthopaedic surgery: results from the ETHOS study(For the ETHOS Investigators)

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Background
The risk of venous thromboembolism (VTE) persists for weeks following major orthopaedic surgery. The ETHOS study showed that 67% of major orthopaedic surgery patients actually received post-operative prophylaxis as recommended by the American College of Chest Physicians (ACCP) guidelines. The analysis presented here assessed patient compliance with VTE prophylaxis prescribed at discharge and evaluated predictive factors for poor compliance.

Method
Consecutive patients undergoing hip fracture surgery, hip arthroplasty or knee arthroplasty in the previous 6 weeks, who had received in-hospital prophylaxis, were enrolled at discharge from 161 randomly selected centres in 17 European countries. Compliance was analysed in patients prescribed ACCP-recommended anticoagulant prophylaxis at discharge. Actual prophylaxis used was collected from patient diaries. Good compliance was defined as proportion of days covered during the prescribed period ≥80% with no more than 2 consecutive days without treatment. Multivariate analysis was performed to assess predictive factors for bad compliance.

Results
Of 4388 eligible patients, 3484 (79.4%) received an ACCP-recommended prescription for prophylaxis at discharge (94.0% low-molecular-weight heparin (LMWH) alone, 3.9% vitamin K antagonist (VKA), 1.1% fondaparinux and 0.9% LMWH and VKA). The median duration of prophylaxis prescribed at discharge was 24 days. 2999/3484 (86%) patients returned evaluable diary information. In total, 87.7% of those were compliant with the discharge regimen. The majority of non-compliers (12.0% of overall population) were covered with treatment <80% of days, 0.3% had more than 2 consecutive days without treatment. The mean percentage of treatment administered during the prescription period was 91.5% (standard deviation 18.8). Geographical differences were noted. The multivariate analysis showed higher level of patient education was the only individual predictive factor for bad compliance.

Conclusion
After major orthopaedic surgery, compliance with prolonged LMWH prophylaxis is good, with 87.7% of patients with a diary available receiving ≥80% of discharge treatment.

Conflict of Interest
Yes: Corporate-sponsored research: sanofi-aventis

B3. Evaluation of suppliers in a Hospital Pharmacy Service

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Background and Objective
In a hospital pharmacy department, there are two types of suppliers, medicines suppliers and non-medicines suppliers, which specialise in different types of services and products that are not medicinal products. In the context of ISO 9001:2000 certification we evaluate and select suppliers according to our organisational requirements. In this paper, we set out the criteria we considered necessary when evaluating suppliers and their weighting in the light of the pharmaceutical service we provided at the time of the study. Finally, we analyse the results of the assessment of the selected medicines suppliers.

Design
First, we determined what parameters could be important for the pharmacy and how to quantify them. The selected period of evaluation was from June 2008 to June 2009. Next, 165 suppliers were evaluated under the criteria A-G described in Main Outcome Measures.

Setting
Quality department of the pharmacy service.

Main Outcome Measures
(A) Previous experience with the supplier (out of stocks and minimal order requirements would reduce this score); (B) Up to date price lists were submitted; (C) Written quotation (that matched the documentation filed by our administrative staff); (D) Delivery times; (E) After sales service; (F) Relationship with the Pharmacy Service (whether the pharmaceutical company regularly schedules appointments with pharmacy); (G) ISO 14001 certification.

Results
Were stratified by the criteria above, as a percentage of providers considered in the study:
(A) Experience with the supplier: 70% excellent, 28% acceptable, 2% unacceptable. (B) Up to date price list supplied: 65% sent price lists vs. 35% did not send price lists, (C) Written offers: 68% sent written offers vs. 32% did not send written offers . (D) Delivery schedules: 10% same day or within 1 day, 78% delivered within 2-3 days, 8% >3 days, 4% >7 days. (E) After sales service: 98% had a good and reliable after-sales service vs. 2% acceptable. (F) Ongoing relationship with the pharmacy: 43% yes vs. 57% no. (G) Only 8 suppliers sent a copy of ISO 14001 certification. As result, all providers except 3 met our criteria for approval by achieving at least half the maximum possible score.

Conclusions
The results show that most of the companies achieved the minimum homologation score, and therefore met the criteria to become a supplier. In order to improve our evaluation of supplier performance and differentiate well-performing from average suppliers we will have to record data about all supplies in a systematic way.

Conflict of Interest
No conflict of interest

B4. A report of the activities of a Drug Quality and Safety Committee in a tertiary hospital

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Objective
To institute an active Drug Quality and Safety Committee in order to provide a system for the safe and effective use of medicines, in a multidisciplinary context.

Methods
A retrospective study (2007-2008) was carried out in a hospital with 1,500 beds by a committee created in October 2006 to assess the current situation. The committee established strategic lines: Goal A: To improve the practice of health care and the drug process. Goal B: To promote a quality and safety culture. Tools: the creation of working teams, development of protocols, training courses, dissemination of educational materials and information.

Results
Actions taken to achieve strategic goals: Action A1: Creation of a medicines reconciliation team for drug treatments at admission and discharge. The team also prepared and approved the reconciliation protocol. Action A2: Creation of a drug administration team to prepare the administration protocol and conduct self-assessment interviews of nurses. Action B1: Formation of a drug event reporting team who developed a system for voluntary reporting of medication incidents and promoting a culture of notification. Action B2: Two 20-hour courses plus workshops and training sessions were held on quality and safety. Action B3: Communication of activities and teaching materials: 2000 leaflets about reconciliation, administration and reporting protocols, 100 posters on the committee's 2006-2010 action plan and 350 elements of static advertising. Action B4: Healthcare professionals were encouraged to participate: 13 became members of the committee, 23 became involved in working groups, 173 attended courses and workshops. The committee held 6 meetings and working groups held 18 meetings.

Conclusions
The hospital is improving the pharmacotherapy process and promoting a quality and safety culture among the health professionals. To achieve this will require training, the introduction of technology in the medication use system and a "sentinel events" policy.
Conflict of Interest
No conflict of interest

B6. "Promising young pharmacists", a training course to prepare pharmacists for executive roles

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Background
German pharmacists receive thorough training in basic sciences, pharmacology and drug treatment. While this skills set is sufficient for the daily routine of a pharmacist, it may not prepare for a managerial position in hospital pharmacy.
In order to increase qualifications in this particular sector, the German Society of Hospital Pharmacists (ADKA) decided to offer a course for interested pharmacists.

Course
The course, known as "Promising young pharmacists" was first held in 2000 and has since been repeated five time. It includes five weekends, each day filled with eight hours of training. Nearly 18 months is needed to do the whole course.
- Key topics are:
- Speaking and presentation techniques
- Management and training for disputes
- Employment law
- Good behaviour, manners and style of clothing

On average the course has been offered every alternate year

Trainees
All hospital pharmacists who are members of the ADKA are eligible to apply for the course. The board members decide upon enrolment based on the specialisation, the curriculum vitae and prior activities of the applicant. Everyone who successfully completes the course is encouraged to apply for leadership positions in hospital pharmacy.

Results
So far approximately fifty hospital pharmacists have successfully completed the course. Most of them have contributed significantly to working groups within the ADKA (more details on the poster). Some but not all have meanwhile taken positions as director of a hospital pharmacy. All attendees have agreed to prepare a poster presentation about the course and also to attend seminars and report about the contents in our journal "Hospital Pharmacy".

Conclusion
Feedback from the attendees as well as the fact that many of the "Promising young pharmacists" have meanwhile accepted managerial positions either within a hospital pharmacy or in the German Society of Hospital Pharmacists demonstrates the success of this course, which we hope to continue in the future.

Conflict of Interest
No conflict of interest

B5. Critical incident reporting system of German hospital pharmacists? twelve months of experience

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Background
Medication errors cover the whole process from prescribing to administration of medicines and are a major problem for patient safety. The ADKA (German Hospital Pharmacists' Association) has developed a critical incident reporting system (DokuPIK) to collect data in the field of medication errors. Medication error reports can be submitted on line. The system can be used stand-alone in a single hospital or can be used nationwide to detect major risks. User anonymity is ensured by restricted access, which prohibits access to database fields that might contain user-specific information.

Method
Data was extracted as Excel files from a one-year period, analysed for major risk factors, major types of reported errors, patient outcomes and drugs most frequently associated with medication errors. The aim was to learn from the accumulated and individual medication errors.

Results
There were 221 registered users and 2196 reported errors in the DokuPIK system in September 2009. Commonly reported errors were wrong dosage (21%), interaction (16%), wrong documentation (7%). Causes of errors were lack of knowledge (52%), high work load (10%) and communication errors (7%). Classification by the reporters were: error occurred, reached the patient, did not cause harm (36%), error occurred, did not reach the patient (32%), incidents or circumstances that could result in an error (12%). (The poster will present actual data, which could differ from abstracted data.)

Conclusion
DokuPIK is proving successful and is an important strategy by which to gather information on medication errors and their causes. Error reduction strategies deriving from analyses of the reports are contributing directly to patient safety.

Conflict of Interest
No conflict of interest

B7. Activities for improving the role of hospital pharmacists in FYRO Macedonia

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Background
Hospital pharmacy, as a specialised field of pharmacy, is the profession for continuous pharmaceutical care of patients to the highest standards in a hospital setting. In FYR Macedonia a transition process in the health care system started five years ago. In this process changes were made mainly in community pharmacies, only affecting the ownership, which changed from state owned to privately owned. Hospital pharmacies stayed as part of hospitals which were state property and the role of hospital pharmacies was unchanged. The pharmacist's role was mostly procurement and dispensing of medicinal products.
So we founded the hospital pharmacy section in 2006 within the Pharmaceutical Chamber of Macedonia, with the clear goal of developing strategic plans for hospital pharmacy services in connection with the role, level and scope of services for the patients.

Method
The activities are directed to changes to achieve the missions of hospital pharmacists, such as: being part of medication management in hospitals, the entire way in which medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the outcomes for the safety and quality of all medicines-related processes affecting hospital patients and to ensure the 7 "rights" (right patient, dose, route, time, drug, information and documentation). In 2008 we established a working group to investigate the level and scope of hospital pharmacy services. A structured questionnaire was prepared consisting of 5 sections (drug information services, management of ADEs, admission drug histories, participation in medical rounds and drug protocol management). The questionnaire was pre-tested in 5 hospital pharmacies out of 15 in Macedonia to assess the quality of questions and the relevance of the questions to the topics being investigated.

Results
The outcomes of the survey clearly demonstrate the need for improvements in at least two major health care outcomes: length of stay, and medication errors. Pharmacokinetic monitoring was not associated with improvements in any of the outcomes because all hospital pharmacies did not have a sufficiently educated staff to provide this service. Equally problematic are the multiple descriptors attached to pharmacists.

Conclusions
This disunity of responsibility divides our profession, confuses patients and other health care professionals as to our role, and compromises our ability to provide services with the goal of achieving optimal health outcomes. For most of the patients in these hospitals the pharmacists are personnel who are behind the counter, spatula in hand, with not a patient in sight. So pharmacists have problem in communicating with most patients.

Conflict of Interest
No conflict of interest

B8. Strategy for involving patients in optimising drug treatment

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Background
Promoting a culture of safety and training and information to patients to involve them in their care are strategies proposed by multiple health agencies and societies. The aim is to establish a strategy for patient participation in the review of their medication and to involve them in their care.

Methods
A strategy to promote the participation of outpatients in the review of their medication at the time drugs are dispensed at the pharmacy department of a general hospital. A) Development of training and information tools for patients. B) Methodology for effective comunication. C) Evaluation method. D) Method of external validation of the program.

Results
A) Training and information tools have been developed: a) A learning checklist (to verify knowledge) including eight questions: What drugs (name) am I taking?, What are they for?, When and how should I take them?, For how long?, What side effects can I expect?, Should I avoid other drugs, foods, activities as long as I am taking the treatment?, What controls should I undergo?, How should I keep them?, b) Registration form for drugs, including medicinal plants, and c) written information; B) A methodology for effective communication, mainly based on empathy, active listening and motivation has been defined; C) A satisfaction survey for patients has been developed for the evaluation of the program; D) Two experts (pharmaceutical care and quality of care) have been defined as external validators.

Conclusions
A strategy that integrates training, communication and information aspects in order to promote patient participation in the review of their medication has been designed. In a second phase following validation of the program, the strategy will be implemented in the outpatient area.

Conflict of Interest
No conflict of interest

B9. Pharmacists: never settle for second best: Recruiting pharmacists for Southampton University Hospitals Trust (SUHT)

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Background
A recent review highlighted vacancy rates of 13% for NHS hospital pharmacists in England [1]. Junior grades vacancy rates were 22%. Within Southampton University Hospital Trust (SUHT) recruitment mirrored the national picture. This level of vacancies was seriously compromising the service and no additional services could be offered to develop patient care.
Traditional advertising methods had previously been used to recruit to posts. In the UK the majority of hospital pharmacy jobs are advertised in

the pharmaceutical journal. This achieved poor response rates for SUHT in 2008

Method
The trust viewed pharmacists as a valuable resource for which demand exceeded supply. Investment was given to develop a recruitment campaign.
A recruitment plan was formulated and a budget agreed.
A company was identified to lead on promotion & recruitment.
A micro site (www.pharmafirst.org.uk) a logo and linked slogan were developed. The campaign was launched after Easter (April 2009) and repeated in August 2009.
All staff were asked to support additional publicity via their automatic email signatures.
All short-listed candidates were interviewed over a few, centrally coordinated, days and appointments made.

Results
Table showing how individuals found our website

Media	Views (%)	Views (%)
	1st campaign	2nd campaign
Google Organic Pay per click	64	81
Direct Traffic	22	12
Other on-line methods	14	7

Table showing the pattern of recruitment.

Campaign date	No. of vacancies	No. of views on NHS Jobs	Number of applications	Number shortlisted	Number of appointments	No. external Appointments
August 2009	8	1365	27	9	7	7
April/May 2009	15	2647	64	29	10	7
2008	14.5*	1409	42	Unknown	8	4

*Figure includes all posts classified as similar by the author but excludes posts advertised more than one time. Actual number of posts advertised was 23.5

Conclusion
Stepping out of the traditional mould of advertising has allowed us to successfully recruit to many of our vacancies. The microsite has enabled us to appeal to a wider audience, including our international colleagues.
This change in practice has resulted in a significant cost saving to our organisation per individual employed. It has provided consistency with recruitment. It is also clear from our data where future investment should be placed when advertising. The use of Google for advertising gave us 3 times as many hits on our site than the combined use of traditional advertising in conjunction with personal advertising via our own automatic email signatures.

Acknowledgements.
The support of the entire department has allowed this initiative to be a success. However particular thanks are due to Andy Fox, Jacqui McAfee, Steve Harris, Lorna Mills, Simon Wills, Adriane Mackay and the team at 33.

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Conflict of Interest
No conflict of interest

B10. Ready-to-use syringes:building a decision tool to help select drugs to develop in priority

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Background
It is now well known that ready-to-use syringes (RTUS), produced at the pharmacy under GMP conditions, can markedly improve the safety of use of powerful intravenous drugs. However, their development is costly and time consuming and it is therefore essential to set priorities by targeting the best candidates.

Method
In order to gather the various important criteria, an observational study was carried out of RTUS use in an intensive care unit and an emergency room. Interviews were recorded among the nursing staff. Based on the information collected and the literature, a list of criteria was drawn up. Three experienced hospital pharmacists assigned scores to each item on this list to balance the importance of the criteria. Finally, a decision algorithm was built and tested.

Results
The list included 16 criteria in four fields: safety (n=6), asepsis (6), economics (2), and ergonomics (2). A score ranging from 0 to 3 points was assigned to each criterion. The items “intrathecal drugs” and “drugs needed in an emergency” had the highest score (3). They were followed by “drugs with extreme consumption (used either very frequently of very seldom)”, “drugs with a low therapeutic index”, “drugs prepared ahead of need”, and “drugs promoting microbial growth” with a score of 2. A cumulative score of 10 points was chosen as a cut-off point for considering the product a valuable candidate. The final selection was thereafter based on an algorithm including the score, availability of resources, cost and stability data.

Conclusion
Considering the various key elements involved in developing RTUS, the development of a decision tool will be helpful in selecting the most suitable drugs to be produced as a priority, especially in a context of limited resources.

Conflict of Interest
No conflict of interest

GROUP C: PHARMACOECONOMICS

C1. Project "Osservatorio innovazione": horizon scanning and simplified cost effectiveness appraisals on new products

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Background
In 2008, the Italian Society of Hospital Pharmacy (SIFO) started a project called "Osservatorio Innovazione" with the aim of monitoring innovation in the field of drugs and medical devices and of carrying out simplified cost-effectiveness appraisals ("valutazione economica semplificata", VESs). We present the web-based method of conducting the project and the results that have been produced so far.

Method
A total of 71 pharmacists throughout Italy are involved in the project.
There are four different working groups who are responsible for the activities of: a) horizon scanning (n=3) based on the major international journals; b) analysis of individual clinical trials to establish if criteria for carrying out a VES are met (n=3); c) execution of individual VESs (n=65); d) final check of the appraisals and posting on the internet at www.osservatorioinnovazione.org (n=5). A VES can be of two different types depending on the finding resulting from the comparison between the innovative and the reference product: VES-CEA (where the incremental benefit resulting from the innovative therapy is converted into an economic counter-value; CEA=cost-effectiveness analysis) and VES-CMA (where the innovative product does not confer an incremental benefit; CMA=cost-minimisation analysis).

Results
By September 2009, 66 files (56 VES-CEA and 10 VES-CMA) have been created, 9 of which refer to new medical devices.
In the comparison of value-based prices and real prices, a favourable financial profile was found for the innovative product in 18 cases and an unfavourable one in 34 cases; for the remaining 15 cases, this ratio could not be calculated because the product was not available on the Italian market.

Conclusions
In Italy, the concept of "value for money" has not yet become widely understood. Hence, this SIFO project represents a unique pilot experiment that can hopefully be a reference point for both our national and local therapeutic committees.

Conflict of Interest
No conflict of interest

C2. Cost-efficacy analysis of cetuximab in first-line treatment of KRAS wild-type metastatic colorectal cancer patients

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Background
In recent years the treatment of metastatic colorectal cancer (mCRC) has evolved from single-agent chemotherapy (fluorouracil with leucovorin modulation) to combination regimens that include irinotecan or oxaliplatin (FOLFIRI and FOLFOX).The introduction of target therapeutic agents such as cetuximab has greatly increased the associated costs. This drug was recently approved for first-line setting use, based on results published in the first half of 2009. The aim of this study was to evaluate the cost-efficacy relation of cetuximab, in the first-line treatment of KRAS wild-type mCRC patients.

Method
Based on the CRYSTAL and OPUS studies, was evaluated the efficacy of FOLFIRI or FOLFOX respectively, with or without cetuximab. The treatment costs were calculated based on the direct cost of the drugs in 2009. This study was conducted from an institutional perspective - the hospital perspective.

Results
Adding cetuximab to FOLFIRI resulted in a marginal efficacy of 0.10 years, which represents only 36 days, when compared with FOLFIRI alone. The associated cost was 33.127 €. The incremental cost-efficacy ratio calculated for FOLFIRI + cetuximab was 331.275 €.
The addition of cetuximab to FOLFOX makes even less difference to lifespan (0.04 years = 14 days) when compared with FOLFOX itself. The associated costs were 25.588 €. The incremental cost-efficacy ratio calculated for FOLFOX + cetuximab was 639.706 €.

Conclusions
Based on this analysis, the incremental cost-efficacy ratios calculated for the cetuximab regimens are too high to be considered cost effective. With limited budgets, cost-efficacy analyses are useful tools for drug and therapeutics committee decisions on drug selection, and for clinics in their therapeutic decisions.

Conflict of Interest
No conflict of interest

C3. Cost minimisation of palivizumab immunization through vial sharing

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Background
Respiratory syncytial virus (RSV) is the most important pathogen in lower respiratory tract infection in infants and young children. High-risk populations, such as premature infants, may develop severe, sometimes fatal, lower respiratory tract infections. Furthermore, the possible increased risk of asthma following RSV infection in infancy must be considered.
Seasonal prophylaxis with palivizumab is effective in reducing the risk of hospitalisation secondary to RSV infection. During the 2008-2009 RSV season we aimed to strictly coordinate the delivery of prophylaxis while minimising drug cost through vial sharing.

Method
For the purposes of this study the 2008-2009 prophylaxis season was assumed to run from November to April. Palivizumab was administered to 24 high-risk children as prophylaxis. The dose was 15mg/kg by intramuscular injection (once per month for a total of 5-6 doses). The cost of 50mg and 100mg vials of Synagis were € 490.37 and € 814.35. Once reconstituted by the hospital pharmacist, the shelf life of palivizumab is 6 hours.
The infants were grouped in cohorts of 5 and attended the Ambulatory Ward on 5 successive afternoons. In total 6,800 mg was bought and 6,022 mg was given to patients. Total drug cost was € 56,706.92 representing a saving of € 23,380.17 (29%) due to vial sharing.

Result
Like any expensive healthcare intervention, palivizumab immunisation must be used judiciously. Our experience shows that is possible to minimise the cost by cohorting. This allowed us to maximise the use of 100mg vials in preference to the more expensive 50mg vials. However this required tight coordination between hospital pharmacist and ward and patient selection to discard ineligible children.

Conclusion
The use of palivizumab can be optimised through a model in which children are prospectively identified and vials are shared. Such a model ensures that all patients receive appropriate immunisation and positively affects the cost-benefit ratio of palivizumab prophylaxis.

Conflict of Interest
No conflict of interest

C4. Costs associated with Routine Management of Febrile Neutropenia in Three Tumor Types in Germany

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Objectives
Febrile neutropenia (FN) is the most frequent dose-limiting toxicity of myelosuppressive chemotherapy. To date there is little German data on the financial consequences of FN management.

Method
Prospective, multi-centre, longitudinal, observational study with lymphoma, NSCLC and primary breast cancer (PBC) patients, enrolled consecutively at the start of first- or second-line (immuno-) chemotherapy in 4 German hospitals. Patients receiving myeloablative chemotherapy with stem cell support were excluded. Adverse drug reactions were monitored according to the NCI Common Terminology Criteria for Adverse Events *v3.0* (*CTCAE*) and WHO causality criteria. FN was defined as fever ≥ 38ºC associated with an absolute neutrophil count (ANC) <1x109/L. In case of non-availability of the nadir ANC, febrile leucopenia (FL) was assessed (LC <2x10^9/L and fever ≥38ºC). Data were collected from pre-planned chart reviews. Costs are presented from a hospital perspective.

Results
325 medical charts (47% lymphoma, 37% NSCLC, 16% PBC; 46% women; 38% age ≥65 years) including 68 FN/FL episodes were reviewed. FN/FL occurred in 22% of lymphoma patients, 8% of NSCLC patients, 27% of PBC patients and 18% of all patients. The table shows a comparison of FN/FL patient characteristics stratified by tumour type. 55 FN/FL episodes were associated with at least one hospital stay (lymphoma n=34, NSCLC n=10, PBC n=11). Median (min-max) cost per FN/FL-episode requiring hospital treatment amounted to €2,355 (€134-€31,924) and varied between €3,056 (€135-31,924) for lymphoma, €2,255 (€134-12,782) for NSCLC and €1,969 (€293-3,241) for PBC. 12 episodes of FN/FL (lymphoma n=9, NSCLC n=3) were associated with costs higher than the two-fold median (>€4,710) and accounted for 60% of the total financial burden. Basic hospital services represented 60% of total costs (lymphoma 55%, NSCLC 71%, PBC 83%), followed by expenses for drugs (lymphoma 22%, NSCLC 11%, PBC 9%).

Conclusions
FN/FL-associated costs vary between tumour types and are highest for lymphoma patients. Cost drivers are hospitalisation and drugs. The impact of clinical characteristics on asymmetrically-distributed costs needs further evaluation.

	All (n=58)	FN/FL Lymphoma (n=35)
Regimen		54% CHOP-like
Female	33 (57)	16 (46)
Age ≥ 65	22 (38)	16 (46)
ECOG≥2	6 (10)	4 (11)

Conflict of Interest
No conflict of interest

C5. Financial evaluation of the introduction of a filgrastim biosimilar in a university hospital

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Objectives
To evaluate the financial impact of switching from filgrastim (Neupogen) to filgrastim (Ratiograstim) and to analyse the acceptance of prescribing physicians through the use of alternatives.

Method
Consumption and cost of filgrastim were analysed by comparing the two brands, during the period before the introduction of substitution (January to December 2008) and after (January to March 2009). Average monthly consumption of each of the granulocyte colony stimulating factors (G-CSF) before and after switching was introduced were analysed.

Results
The monthly cost of L03A group (colony stimulating factors) was reduced from 21,888 ± 2707 € / month to 16,830 ± 1367 € / month, a difference of 4998 € / month, a statistically significant reduction (p <0.01), representing an annual saving of 60,000 €.
Cost per patient in the period before the change in policy was 483.63 ± 35.47 € / month and cost per patient in the post-change period was 378.50 ± 36.73 € / month. This means a saving of 105.13 € per patient per month.
The policy change was accepted. During the three months (January to March) consumption did not shift to other G-CSF (lenograstim or pegfilgrastim).
No difference was found in the use of pegfilgrastim before and after the introduction of switching; consumption was 2.8 ± 1.1 units / month and 3.0 ± 1.4 units / month, respectively. The consumption of lenograstim was insignificant in 2008 and nil in the first three months of 2009.
Regarding the consumption of filgrastim, no difference was found, with consumption of 368 ± 48 and 361 ± 72, before and after the switching policy was introduced.

Conclusions
The introduction of the filgrastim biosimilar increased the financial efficiency of treatment, reducing costs significantly.
The degree of acceptance has been very positive: since the biosimilar was introduced consumption has not switched to other, less efficient, alternatives such as pegfilgrastim.

Conflict of Interest
No conflict of interest

C6. The degree of acceptance and financial effect of checking the use of proton pump inhibitors

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Objective
To evaluate the degree of acceptance and financial effect of checking the use of proton pump inhibitors (PPI) omeprazole and esomeprazole, in clinical units with a Unit Dose Drug Dispensing System (UDDS).

Methods: Retrospective, descriptive study (January-June 2009) in 197 beds with UDDS. Intravenous PPI prescriptions were checked daily. If the patient was able to take food and/or other drugs by mouth we suggested to the physicians changing to oral omeprazole /esomeprazole.
These recommendations were recorded in Excel and 24-48 hours later were classified as accepted or rejected.

In the economic analysis, we only considered the cost of purchasing the drugs.

PPI	Route	Usual dose/day	Cost/ 24 h
Omeprazole	Oral	20mg	1 €
	IV	40mg	49.8 €
Esomeprazole	Oral	20mg	0.8 €
	IV	40mg	107 €

Results
29 recommendations were made for sequential treatment. 72.4% were accepted, 27.6% was rejected. (4 treatments were changed 3-12 days after our recommendation, in 2 of them the treatment was withdrawn and 2 patients were transferred to other wards without UDDS.)

Degree of acceptance according to Clinical Unit

UNIT	No. of recommendations	Accepted	Rejected
Surgery	9	6	3
Neurology	2	1	1
Ophthalmology	1	0	1
Traumatology	15	13	2
Pneumology	2	1	1
TOTAL	29	21 (72.4%)	8 (27.6%)

The next table compares the cost of continuing intravenous treatment of patients in which the recommendation was rejected and the cost of the same treatment if the recommended change to oral treatment had been accepted. A 49.7% cost reduction would have been obtained (3005.8 € projected cost vs. 5981 € actual cost) if the advice had been accepted by the physicians (for further details see paper).

UNIT	No of recommendations rejected	Cost of IV treatment (real cost)	Cost of oral treatment (estimated cost)
Surgery	3	2011 €	1249 €
Neurology	1	2144 €	869 €
Ophthalmology	1	398.4 €	56.8 €
Traumatology	2	987.5 €	631 €
Respiratory	1	440 €	200 €
TOTAL	8	5981 €	3005.8 €

Conclusions
We obtained a high rate of acceptance (72.4%) and are now examining how we can promote this type of treatment change in clinical units without UDDS. The high cost of these IV formulations provides an opportunity to expand the role of hospital pharmacists and to optimize PPI use. This results in less intravenous treatment and provides a safer, more cost-effective option.

Conflict of Interest
No conflict of interest

C7. The burden of chemotherapy-induced toxicity in routine hospital care

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Background
The majority of chemotherapy (CT) patients receive care outside of clinical trial settings. In contrast little is known about frequency and severity of CT-induced toxicity and its economic consequences in routine care

Methods
Prospective, multi-centre, longitudinal, observational study with lymphoma and NSCLC patients enrolled consecutively at the start of 1st or 2nd line (immuno-)CT in four German hospitals. Patients receiving myeloablative chemotherapy with stem cell support were excluded. ADRs were monitored according to the NCI CTCAE v3.0 and WHO causality criteria. Data were collected from pre-planned chart reviews. Cost in €2007 are presented from provider perspective.

Results
273 patients (n=153 lymphoma, 47% of courses were CHOP-like, n=120 NSCLC, 78% of courses were platinum-based) undergoing a total of 1004 CT-cycles were evaluable. Mean age was 60.1 years (SD 13,0); age≥65 years 40%; female 36%; ECOG≥2 11%; tumour stage≥3 56%; history of comorbidity 80%. 50% of cycles were associated with grade 3-4 toxicity and 37% (n= 371) with at least one hospital stay (normal care n=257, intensive care n=19; outpatient/day care: n=154). Mean toxicity management costs (TMC) amounted to €1,032 SD 3,187 per cycle. 5% of CT-cycles (n=53) were associated with costs ≥€5,000 and accounted for 56% of total expenses. The table shows cost stratified by severity and number of ADRs. Hospital basic services and personnel represented 74% of total costs, followed by expenses for drugs (18%) and diagnostics (6%).

Conclusion:
Half of CT-cycles in lymphoma and NSCLC routine care are affected by grade 3-4 toxicity. TMC were particularly high in these cycles and rose exponentially with the number of severe ADRs. With 5% of cycles contributing to 60% of total costs this entails not only clinical but also economic consequences and emphasizes the importance of targeted supportive care strategies.

Cycles	n	Mean costs/cycle in € (95% confidence Interval)	Multiples of reference subgroup
All	1004	1,032 (835-1,230)	NA
No grade 3/4 toxicity	502	319 (225-413)	1.00 (ref.)
grade 3/4 toxicity	502	1,746 (1,372-2,120)	5.47
1-2 AEs grade 3/4	402	866 (689-1,042)	2.71*
3-4 AEs grade 3/4	80	3,884 (2,727-5,042)	12.18*
>4 AEs grade 3/4	20	10,881 (4,698-17,064)	34.11*
No grade 3/4 infections	923	500 (413-588)	1.00 (ref.)
grade 3/4 infections	81	7,093 (5,299-8,887)	14.19*
*P<0.05 versus reference group			

Conflict of Interest
No conflict of interest

C8. Economic study and seasonal variation of antibiotic consumption in an Athens tertiary hospital

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Background
A substantial increase in the use of antimicrobial agents has been observed in Evangelismos General Hospital during the last few years. This increasing antibiotic consumption leads to the development of resistant bacteria and increased bacterial colonisation along with a noticeable increase in the total cost of treatment.

Method
In this study the annual antibiotic consumption for 2008 in Evangelismos

G.H. (929 beds) was assessed in accordance with the ATC/DDD - Anatomic Therapeutical Chemical classification-Defined Daily Dose measurement unit. The quarterly analogue use was estimated in order to highlight any seasonal variation in antimicrobial use not only in the overall consumption, but also in particular clinics, e.g. intensive care units, pathology department, surgical, heamatological and chest diseases wards. Quarterly consumption was broken down into antibiotic class; hospital-specific antibiotic consumption was studied too. All data were analysed using the statistical package SPSS.

Results
In 2008, the total hospital antimicrobial therapy corresponded to 81.6 DDDs per 100 bed-days. The analysis of antibiotic consumption data showed a slight decline during the third quarter. Minimum and maximum antibacterial consumption was observed in August (66.2 DDDs) and February (87.7 DDDs), respectively. With the exception of the pneumonological clinic, minor seasonal variation was observed in the departments under study. Beta lactams were the most frequently prescribed antibiotics (39.3 DDDs) followed by quinolones (13.4 DDDs). The higher percentage of antibiotics consumed corresponded to hospital-specific antibiotics (third- and fourth-generation cephalosporins, penems, carbapenems, monobactams, newer quinolones, glycopeptides).

Conclusion
In Evangelismos G.H., although a relatively large amount of money was spent on the antimicrobial therapy, the consumption data reveaed minor seasonal variation, indicating that the level of hospital antibiotic use is not dominated by seasonal fluctuations in the incidence of upper respiratory tract diseases.

Conflict of Interest
No conflict of interest

C9. Pharmacoeconomic comparison of antineoplastic and immunomodulating cytotoxic agents in two general hospitals
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Background
"Agios Georgios" Chania General Hospital on the island of Crete is the only General Hospital in a county with a population of 150000 while Sismanoglio General Hospital is in Athens. Each hospital has 480 beds.

Method
We examined the pharmacoeconomics of the antineoplastic cytotoxic agents and immunomodulating agents for the year 2008 in order to see the differences and similarities between the hospitals. All the data were extracted from our data information system.

Results
31,471 patients were hospitalised in Chania hospital and 21,811 patients in Sismanoglio in Athens during 2008 with a mean number of nursing days 4.06 vs. 7.00. The total cost of drugs for the year 2008 was 16,187,509€ vs. 11,812,527€ respectively, while for the cytotoxics it was 4,879,115€ vs. 2,774,844.39€. This cost represented 30.14% vs. 23.49% of the total cost of drugs in the hospitals respectively.

The highest percentages of drug costs were for the categories:
- antineoplastic agents 59.31% vs. 50.08%,
- endocrine therapy 1.80% vs. 1.93%,
- immunostimulants 25.25% vs. 24.96% and
- immunosuppressants 13.64% vs. 23.03% (P<0.05).

The highest percentages of the drug costs were for the substances:
- pemetrexed 4.99% vs. 5.34%,
- paclitaxel 2.29% vs. 2.91%,
- docetaxel 3.29% vs. 7.40%,
- oxaliplatin 4.10% vs. 0.11% (P<0.05),
- trastuzumab 18.8% vs. 16.74%,
- bevacizumab 5.93% vs. 2.96%,
- interferon beta 7.20% vs. 9.03%,
- pegfilgrastim 7.74% vs. 1.5% (P<0.05),
- beta-1b-interferon 3.89% vs. 2.28%,
- infliximab 6.04% vs. 18.15% (P<0.05) and
- lenalidomide 3.46% vs. 4.22%.

Conclusions
We found only minor statistical differences between the pharmacoeconomic policies in the two hospitals. The very active rheumatology unit of Sismanoglio hospital caused the increased cost of infliximab while the oncology department in Chania hospital explains the elevated cost for the use of oxaliplatin. The cystic fibrosis department situated in Sismanoglio was responsible for the cost of using immunosuppressants in Athens due to the large number of patients needing lung transplantation.

Conflict of Interest
No conflict of interest

C10. Study of drug consumption: prescription pattern of oral bisphosphonates
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Background
Bisphosphonates are primary agents in the current pharmacological arsenal against osteoclast-mediated bone loss. The objective of this study was to assess the prescription trends for oral bisphosphonates (OBP) in a primary care area of 375,000 people.

Method
A retrospective study of patients with OBP therapy from January to December 2008. The variables analysed included age, sex, cost of OBP, DDDs (Defined Daily Dose) and frequency of administration of each active substance. The data are taken from the computerised system for Spanish National Health System prescriptions.

Results
In our area 7,765 patients were prescribed OBP (2.25% of the total population of the area). Eighty-five per cent were over 55 years and the proportion of women to men was 15:1. Overall cost of all prescriptions of OBP was EUR 2,467,396 in 2008.

OBP	Nº DDDs 2008	Cost € 2008
clodronic acid	60	406,56
etidronic acid	2445	646,29
ibandronic acid	454,140	524,683.08
alendronic acid	602,812	538,351.86
risedronic acid	1,006,684	1,403,308.23

Frequency of administration	clodronic acid	etidronic acid	ibandronic acid	alendronic acid	risedronic acid
daily	100%	100%	0%	0.54%	0.62%
weekly	np	np	np	99.46%	99.37%
monthly	np	np	100%	np	np

np: there is no pharmaceutical form available on the market.

Conclusions
The most commonly used active substances are risedronic acid and alendronic acid, in accordance with clinical guidelines.
Regarding the frequency of administration, data showed that the prescription pattern follows the longest possible interval. That is the reason why it is observed that when there are two presentations available, weekly administration is preferred to daily dosing. In case of Ibandronic acid, it is always prescribed at monthly intervals even though daily presentations are marketed.

Conflict of Interest: No conflict of interest

GROUP D: PHARMACEUTICAL TECHNOLOGY

D1. Development of a sterile nasal solution of lignocaine 4% for quick relief of Cluster Headaches

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Background

The Cluster Headache is described in medical literature as one of the most severe headaches, which causes peaks of severe pain, strictly unilateral, with an orbit, supra-orbit and/or temporal localisation.
A prevalence of 1/1000 is estimated in the Portuguese population and the incidence is highest in males around 20 - 40 years old.
A sterile solution of lidocaine 4%, designed for intranasal administration as drops, has been developed in order to relieve this pain.

Method

The minimum conditions required for the small scale production of a sterile nasal solution of lidocaine 4% were researched, including the necessary bibliographic research and the sequential elaboration of the required monographs.

Results

The plan adopted of the final process includes three steps: one strictly dedicated to preparing the solution and the other two to the physical chemistry quality control of the raw material (lidocaine hydrochloride) and the final product (sterile nasal solution of lidocaine 4%).
The formulation of lidocaine 4% must be prepared in a horizontal laminar flow cabinet, using an aseptic technique plus sterile filtration. A 0.20 µm pore dimension membrane is used to filter to the sterile primary packaging.
The final solution is then submitted to quality control, where a set of selected assays has been defined that ensure that both raw material and final product are of assured quality.

Conclusions

It was possible to accomplish this challenge, and create the conditions to start the small scale production of our first batch of this formulation: a sterile solution of lidocaine 4%.
A preliminary validation process is in progress to ensure the physical chemistry stability as well as microbiological control of a pilot batch.

Conflict of Interest

No conflict of interest

D2. Evaluation of automated medication dispensing systems in a Hospital´s Emergency Department

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Background

Automated medicines dispensing systems (Pyxis Medstation) provide computer controlled storage, dispensing, tracking and documentation of medicines distribution on a care unit. Before June 2008, the emergency areas of our hospital had a drug stock with medicines requested by Emergency department staff and the pharmacy prepared and dispensed drugs to these areas. If an urgent drug was required, an urgent prescription would be required for it.
The aim of our study was to assess the automated medicines dispensing systems in the hospital's Emergency department.

Method

The Emergency department started to use Pyxis in June 2008. One year after (June 2009), we carried out a retrospective observational study to determinate:

- Workload distribution.
- Number of drugs requested urgently.
- Overall cost and cost per emergency patient attended.

Results

One year after implementation:

1. Workload has decreased in the Emergency department because requesting and stocking medicines is now performed by pharmacy staff. The workload has increased in the pharmacy, which now spends 980 minutes per week doing this work instead of 88 minutes that were spent before the implementation.
2. There has been a 45% reduction in urgently requested drugs (from 161 to 88 prescriptions per month).
3. Overall consumption in the Emergency department has reduced by 76% (from 337,600€ in 2008 to 81,200€ in 2009), and cost per emergency patient attended has also decreased by 76% (from 6.1€ pre-implementation to 1.5€ post-implementation).

Conclusions

Workload has increased in the Pharmacy department but decreased in the Emergency department with fewer drugs requested urgently, so this time can be spent in patient care. Moreover, overall consumption and cost per patient is reduced by 76%.

Conflict of Interest

No conflict of interest

D3. Stabilty of tiapride in solution

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Background

Tiapride is a substituted benzamide classified as an atypical neuroleptic. It is used in alcohol withdrawal syndrome, extrapyramidal disease and anxiety. To the best of our knowledge there are no published data about the stability of tiapride prepared as a continuous intravenous infusion despite its regular use in medical practice. The current investigation was intended to determine its stability in two different infusion solutions and concentrations over 48 hours, which is the maximum time for which infusion solutions will be used.

Method

Triplicate samples of tiapride were prepared in 0.9% sodium chloride (NS) and in 5% dextrose (D5W) solutions at final concentrations of 1 and 2 mg/mL. Samples were collected in glass bottles without photoprotection and at room temperature (25 ± 2 ºC).
Sampling times at 0, 1, 3, 6, 12, 24 and 48 hours included a visual inspection for colour changes and appearance of precipitation as well as determination of pH.
Tiapride was quantified at selected times by mass spectrometry using high-performance liquid chromatography (LC-MS). Both pH values and tiapride concentration in the samples corresponding to 0 hours were given a reference value of 100%. According to the European Pharmacopoeia (2nd edition) and Lawrence A. Trissel "Handbook on injectable drugs", 14th edition, tiapride concentrations in subsequent samples greater than 90% were considered stable.

Results

No colour change and/or precipitation were observed during the study period. pH values were within a 2.7% range. At 48 hours, the concentration of remaining tiapride in NS 1 mg/mL and in NS 2 mg/mL were 93.8% and 91.6% respectively. The tiapride concentration in D5W 1 mg/mL and 2 mg/mL were 96.8% and 94.1%, respectively.

Conclusion

Dilution of tiapride in 0.9% sodium chloride and in 5% dextrose solution, at concentrations of 1 mg/mL and 2 mg/mL, in glass bottles and at room temperature behaved stably both physically and chemically within 48 hours of preparation.

Conflict of Interest

No conflict of interest

D4. Electronically assisted prescribing will minimise drug dispensing errors

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Objective

To assess the impact of administration errors when transcribing erroneous treatments in a manual transcription sheet, and to estimate the impact of "Electronically Assisted Prescribing (EAP)" in minimising these errors.

Method

A prospective study in hospitalised patients, recording the transcription errors made when a manual nursing transcription sheet is used. The errors were detected when checking the discrepancies between the medical prescription and the nursing transcription sheet. In a representative sample changes of treatment in the 24 h before the analysis are analysed. All transcription errors were recorded, and classified according to clinic or ward, type of error, mode of administration and their potential danger. The possible reduction in new errors per day if the EAP were to be introduced in all units was estimated. At the moment, EAP has been introduced in 40% of the hospital.

Results

Of the 416 prescriptions recorded, the overall percentage of transcription errors was 12.4%, 9.8% in medical units and 15.2% in surgical units. Errors were most common when a new medicine was added (29.4%) and the frequency of administration was changed (27.4%). With regard to their potential gravity, 98% did not harm the patients, and 57.7% were filed as "Category C". Taking into account that 1 change of treatment is made per patient per day, the introduction of the EAP is predicted to prevent 64 new errors daily in the hospital.

Conclusions

There are so many transcription errors that they should be taken into account when designing strategies to improve the quality of pharmaceutical care. Electronically Assisted Prescribing is an efficient tool with which to eliminate the errors associated with the transcription of prescriptions.

Conflict of Interest

No conflict of interest

D5. Using media fills to evaluate robotic compounding of sterile preparations

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Background

The Robotic IV Automation robot (RIVA™) has been validated for sterile compounding against all applicable engineering control certification requirements including Canadian Good Manufacturing Practices Guidelines (GMP). RIVA is a primary engineering control that maintains ISO Class 5 conditions under dynamic conditions. In this study, Trypticase-soy (TSB) media fills are used to evaluate sterile compounding in the RIVA™.

Method

A robust media fill protocol test was conducted in a production RIVA™ at Intelligent Hospital Systems (IHS), Winnipeg, Canada in November, 2008. The RIVA cell was operated in an ISO 8 buffer area during compounding. Liquid TSB-2X with colour tracer (Valiteq, VM25C; VM50C, expiry 6/2010) was diluted with sterile saline using RIVA's compounding functions: reconstitution; fluid transfer to syringes or bags; and further dilution in syringes. The TSB has been documented to support growth for 2 years from manufacture. A statistically valid 3000 compounded sterile preparations (CSP) were produced during a 9-day, 9-cycle run with 9 operators loading and unloading the cell. The CSP syringes were capped per RIVA protocol and all CSPs were stored at 25°C. The CSPs were examined at specific intervals for 14 days post compounding for microbial growth. TSB vials, reconstituted during the study to 1X, but only partially used for media fills, were also stored for evaluation.

Results

No CSPs were found to be contaminated during the study period resulting in a contamination rate of less that 0.1% with a 95% confidence level for the 3000 units. No partial vials were contaminated. CSPs and partial vials, stored beyond the 14-day period, showed no growth, which indicates appropriate caps/seals. The TSB was challenged at the 6-month mark and documented tosupport growth, validating the extended shelf life.

Conclusion

The RIVA™ robot effectively compounds sterile preparations with no bacterial contamination even when positioned in a non-ISO 7 environment.

Conflict of interest

Advisory board: L. Power serves on the Scientific Advisory Board for Intelligent Hospital Systems (IHS) financial consideration is not dependent on sales. Other substantive relationships: L. Power is an independent consultant retained by IHS to develop and monitor this protocol. B. Erickson and T. Doherty are employees of IHS.

D6. Bevacizumab eye drops: Assessment of efficacy and safety

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Objective

To establish a standard operating procedure (SOP) for the treatment of corneal neovascularisation (NV) secondary to a variety of corneal diseases with bevacizumab eye drops and evaluate their efficacy and safety.

Method

Bevacizumab eye drops were prepared by the hospital pharmacy following an established SOP. 3 patients with corneal NV not responding to conventional anti-inflammatory therapy were treated with these bevacizumab eye drops for 1-2 months. All patients were monitored for any adverse effects or toxicity. Response to treatment was defined by a decrease in the diameter of the vessels and/or a reduction in the neovascularised area.

Results

According to the SOP, a topical bevacizumab solution 5mg/mL was formulated and prepared aseptically from commercially available intravenous bevacizumab. In a laminar airflow cabinet, we took 1 mL of the commercial bevacizumab 25mg/mL and diluted it with normal saline to 5 mL. We transferred it into a sterile dropper bottle. This process was repeated four times to obtain four bottles of eye drops. These odourless, colourless and clear solutions had a pH of 7 and an osmolarity of 282 mOsm. Stability, according to the bibliography, is three weeks frozen and seven days refrigerated at 4ºC. The patients were instructed to freeze 3 containers and refrigerate the one they are going to use throughout the week. Two patients with corneal NV were treated for two months and the other one for one month. A response was seen within 1-2 months in all patients with no adverse events. Two patients showed a decrease in the dimensions of the vessels and the other one in the neovascularised area.

Conclusions

All patients showed a reduction in the neovascularised area and/or a ecrease in the diameter of the vessels within 1-2 months of start of treatment. Bevacizumab eye drops were well tolerated without obvious corneal side effects and without systemic adverse effects.

Conflict of Interest

No conflict of interest

GROUP E: CLINICAL PHARMACY

E1. The clinical pharmacist as pharmaceutical manager at discharge

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Background and objectives
During hospitalisation, the physician often changes the patient's medicines on admission. These changes are not always communicated properly to the patient and his general practitioner (GP). The aim of this project was to optimise patient compliance by informing him and his GP about the discharge treatment in a standardised way.

Method
The clinical pharmacist (CP) makes an inventory of the medicines on admission. He then analyses the current drug treatment and advises the physician about possible optimisation. Before discharge, the clinical pharmacist gives the patient an overview of his medicines. During this conversation the pharmacist explains the changes in therapy and emphasises the indication, side effects and practical aspects of taking the new medicines.

Setting
Virga Jesse Hospital, a large provincial hospital of 600 beds in Belgium, on the oncology, haematology and abdominal surgery wards.

Results
Over 14 months the clinical pharmacist counselled 785 patients. For these patients, 1096 interventions were recorded, which were divided into 4 categories: 579 suggestions for changes in therapy (53%), 19 suggestions that the therapy be monitored(2%), 45 recommendations for correct use (4%), and 453 corrections of errors in the discharge letter or medicines form (41 %).

Conclusions
These figures show that the medicines check by the clinical pharmacist is very important to be sure that changes are communicated correctly to the patient. The clinical pharmacist plays an import role in counselling the patient at discharge. Correct information given to the patient will improve patient safety and compliance with the treatment.

Conflict of Interest
No conflict of interest

E2. Off-label use of linezolid in outpatients of a general hospital

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Background
Linezolid is an antibiotic indicated for the treatment of complicated skin and subcutaneous tissue infections, community-acquired pneumonia and nosocomial pneumonia caused by Gram-positive bacteria. The recommended length of treatment is 14-28 days. The aim of this study is to evaluate the use of linezolid in off-label uses.

Method
A retrospective observational study carried out from January to September 2009. The patient information was obtained from the outpatients software. Permission had to be requested from the authorities before linezolid was used.

Results
Five patients received linezolid in off-label indications. Linezolid was used in chronic osteomyelitis or prosthetic joint infections. All cases were treated with linezolid 600 milligrams orally twice daily. Microbiological documentation was available in 4 cases. Meticillin-resistant Staphylococcus aureus, penicillin-resistant Enterococcus faecium, Corynebacterium spp and Peptostreptococcus spp were the isolated offending agents. The antibiotic was never used as front line. The duration of treatment was always greater than 28 days. In 4 cases the treatment was discontinued because the patient's condition improved. One patient still continues with the treatment. No adverse effects were observed.

Conclusion
Linezolid was an effective treatment in 5 patients with difficult-to-treat infections, not included in the summary product characteristics, such as osteomyelitis or prosthetic joint infections, with a very good tolerance. All patients received a prolonged course of linezolid therapy (> 28 days), above the duration recommended for this drug

Conflict of Interest
No conflict of interest

E3. Invasive fungal infections in Haematology I Ward of San Giovanni Battista of Turin: the role of the clinical team pharmacist

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Background
This study aimed to evaluate the epidemiology, treatment approach and at assessment of invasive fungal infections (IFI). The Clinical Team Pharmacists (CTPs) have a role in the management of systemic antifungal drugs (SADs) in the Haematology I ward of San Giovanni Battista Hospital.

Methods
CTPs acted as data managers, reviewing the medical records of 189 patients admitted between May 2008 and June 2009 (349 admittances) and of 39 Acute Myeloid Leukemia (AML) patients admitted in 2006-2009 (81 admittances). CTPs analysed the use of SADs in terms of number of Defined Daily Doses (DDDs) and calculated the number needed to treat (NNT) to prevent IFIs for some drugs in subsets with different haematological malignancies

Results
From May 2008 to June 2009, the incidence of probable/proven IFI, according to the EORTC criteria, was 3.15% in the number of hospitalisations and 5.30% in terms of number of patients (11 cases). Analysis of AML patients in the three years 2006-2009 highlighted an incidence of probable/proven IFI of 23.7% (9 cases / 38 patients in induction-phase chemotherapy). From May 2008 to June 2009, SADs were prescribed during 61.6% of hospitalisations. Prophylaxis was widely adopted (90.7% of antifungal treatment); empirical, pre-emptive and target therapy were established during 4.6%, 9.74% and 0.29% of hospitalisations, respectively. Shift to therapy was necessary in 3.6% and 13.8%, respectively, of primary prophylaxis cases. DDD analysis for the three years 2006-2009 confirmed the leading role of fluconazole and moderate use of amphotericin B, voriconazole and posaconazole. NNT of posaconazole to prevent IFI was found to be 7 for AML patients, but it turned out much higher for other subsets.

Conclusions
Different levels of risk were identified according to the underlying haematological malignancies, higher than in the general population, mainly in multiple myeloma and AML patients. Prophylaxis is widely used, but "pre-emptive approach" represents an emerging strategy. CTPs and clinicians will use these data to elaborate differential treatment algorithms.

Conflict of Interest

E4. Effectiveness and safety of abatacept in moderate to severe rheumatoid arthritis

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Background

Abatacept is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have had an insufficient response or intolerance to other disease-modifying anti-rheumatic drugs.

The objective was to analyse the use of abatacept in our hospital and evaluate effectiveness and safety.

Methods

Retrospective study (September 2008 – October 2009) of patients treated with abatacept for at least 6 months.

Clinical records were checked for age, sex, type of RA, previous treatments and cause of withdrawal of the tumour necrosis factor (TNF) inhibitors, dosage of abatacept, side effects and Disease Activity Scope (DAS) value at the start (DAS0) and after 6 months of treatment (DAS6). DAS is a measure of efficacy; a low DAS means effectiveness and when DAS < 1.6, the disease is in remission.

Results

During the 13 months of our study 6 women with moderate to severe RA were treated with abatacept. The mean age was 46 ± 11.8 years old. Withdrawal of the previous TNF inhibitors was due to infusion reactions (67%) or ineffectiveness (33%).

The mean dose administered was 9.9 mg/kg. Following initial administration, abatacept was given after 2 weeks and then every 4 weeks. In 2 patients the administration was delayed due to a mild infection (2) and an episode of neutropenia (4).

Data are shown in the following table:

Patient	1	2	3	4	5	6
Weight (kg)	65	96	85	58	68	60
Diagnosis RA	Severe	Moderate	Moderate	Severe	Severe	Moderate
Previous Treatments	Infliximab, rituximab, etanercept	Infliximab	Infliximab, etanercept	Etanercept, rituximab, infliximab	Infliximab, etanercept, adalimumab, rituximab	Adalimumab, etanercept, rituximab
Abatacept dose (mg)	650	960	750	750	680	650
Efficacy (DAS0 - DAS6)	5.59 - 3.09	4.65 - 3.07	5.15 - 4.39	4.91 - 2.49	5.39 - 3.97	3.74 - 2.24
Side effects	Asthenia	Mild infection	Aseptic inflammation of the coccyx	Infusional reaction, neutropenia	-	Mild arthralgia in hands
Follow up (months)	13	12	7	7	7	6

Conclusions

Since DAS values decreased after 6 months, abatacept was effective in all patients. Disease did not reach remission (DAS6 > 1.6), but these patients were suffering from moderate to severe RA and other treatments had previously failed.

Only one patient (4) suffered a serious adverse reaction which delayed the following infusion. Further studies with more patients are needed to verify and extend our results.

Conflict of Interest

No conflict of interest

E5. Design and consensus of standarized total parenteral nutrition formulas

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Background

To provide an appropriate intravenous nutritional therapy requires daily estimates of energy, protein and electrolyte requirements per patient, and the analysis of compatibility and stability of the parenteral nutrition mixture. This complicates the management of patients with parenteral nutrition at the Centralised Unit of Intravenous Mixtures of Pharmacy Service. Our aim is to assess the energy and protein requirements to allow standardisation of total parenteral nutrition (TPN) in our hospital.

Methods

To assess energy requirements (total kcal) the Harris-Benedict (HB) equation was used, multiplying the result by a stress factor (SF) of between 1 and 2. Protein requirements, expressed as grams of nitrogen (gN) were calculated based on the Spanish Society of Parenteral and Enteral Nutrition guidelines. Given these parameters possible combinations were calculated, according to gender, weight and height, and were grouped by weight. From the overall profile of requirements, five types of TPN were agreed by the Nutrition Committee of our hospital. To calculate the remaining macronutrients the relationship grams of nitrogen/non-protein Kcal (gN / np Kcal) was used recommended by clinical situation.

Results

The combination of energy and protein requirements, grouped by weight ranges are shown in table 1, and the five types of TPN agreed are displayed in table 2.

.	**Table 1. Protein and energy requirements grouped by weight**					
.	Mild Stress		Moderate Stress		Severe Stress	
weight (Kg)	gN	Kcal	gN	Kcal	gN	Kcal
50-60	9.6-11.5	1468-1705	11.2-13.4	1590-1847	15.2-18.2	1712-1989
60-70	11.5-13.4	1605-1930	13.4-15.7	1738-2091	18.2-21.3	1872-2252
70-80	13.4-15.4	1741-2155	15.7-17.9	1887-2334	21.3-24.3	2032-2514

Table 2. Standardised TPN formulas					
	Mild-moderate stress			Severe stress	
Name of TPN	N10	N12	N16	N18	N22
gN	10	12	16	18	22
Glucose (g)	200	250	250	250	300
Fat (g)	50	50	75	80	100
Total Kcal	1528	1778	2116	2214	2705
Np Kcal/gN	128	123	107	98	98
Volume (mL)*	1835	1835	1985	2000	2455

* Includes oigoelements, vitamins and electrolytes of standardised TPN formulas

Conclusions

The design of the five standardised TPN formulas has allowed better management of patients with intravenous nutritional therapy at the Centralised Unit of Intravenous Mixtures of Pharmacy Service. These formulas cover the requirements of most patients without kidney or liver disease.

Conflict of Interest

No conflict of interest

E6. Erythropoiesis-stimulating agents: Is there any difference in haemoglobin levels depending on the care unit where the patient is admitted?

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Background

In 2007 the FDA warned of the risk of cardiovascular and thromboembolic events associated with erythropoiesis-stimulating agents (ESA). It was made known that in order to reduce this risk, the target haemoglobin range should be 10 - 12 g/dL when patients suffering from chronic kidney disease are given these agents.
Our objective was to assess if haemoglobin levels differed depending on the care unit in which the patient was hospitalised.

Methods

A descriptive prospective study was carried out from February to August 2009. Patients with chronic kidney disease treated with ESA and hospitalised in the Nephrology unit were compared to those renal patients admitted to other wards. Haemoglobin levels were recorded once a week while they were in hospital.

Results

We included 89 patients (64% males).
Haemoglobin levels were distributed as follows in the two groups of patients:

Haemoglobin level (g/dL)	Nephrology	ER care units
N	29	60
Mean	10.495	9.850
95% Confidence interval	10.064 - 10.926	9.459 - 10.241
Median	10.140	9.638
First quartile (Q1)	9.675	8.813
Third quartile (Q3)	11.342	10.550
Minimum	8.967	7.200
Maximum	13.100	15.650
Range	4.133	8.450

The mean haemoglobin level was 10.495 g/dL for patients admitted to the Nephrology ward and 9.850 g/dL for patients admitted to other wards. This difference was statistically significant ($p<0.05$).

Conclusions

There was a difference in haemoglobin levels between the two groups. A substantial percentage of patients hospitalised in care units other than Nephrology did not reach the lower limit of the target interval. The haemoglobin level of patients who were treated on the Nephrology ward were more in keeping with the recommendations.
Therefore, the first group would benefit the most from pharmaceutical follow-up to optimise drug therapy.

Conflict of Interest

No conflict of interest

E7. Use of intravenous inmunoglubulins in a tertiary general hospital

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Background

A protocol for the use of intravenous immunoglobulins (IVIGs) was designed in our hospital, in which clinical indications were classified according to their strength of recommendation. Two years later we decided to check the use of IVIGs to review compliance with this protocol.

Method

A longitudinal descriptive study of IVIG prescriptions in our hospital was conducted from December 2008 to February 2009. The following data were collected: patient identification, indication, dosage, duration of treatment and prescribing hospital service.
Indications were classified according to two criteria: the strength of recommendation (A, B, C, D and not determined) and whether they were authorised or not, according to the summary of product information. The strength of recommendation was set in a systematic review of the scientific literature using evidence-based criteria:

- A: evidence obtained from randomised controlled trials or meta-analysis.
- B: evidence obtained from non-randomised controlled trials or quasi-experimental studies.
- C: evidence from non-experimental descriptive studies.
- D: evidence from expert committee reports or review and/or clinical experience of recognised authorities.

Data were analysed using SPSS software.

Results

IVIGs were prescribed to 170 patients (31.2% inpatients and 68.2% outpatients). The hospital departments that prescribed most of the IVIG were: Immunology (44.1%), Oncohaematology (20.5%), Neurology (11.8%) and Paediatrics (3.3%).
There were 23 different indications, 40% were off label.
The indications were: Primary immune deficiency (31.3%), Immune idiopathic thrombocytopenic purpura (15.3%), Secondary hypogammaglobulinaemia (10.2%), Chronic lymphocytic leukaemia (8.5%), Allogeneic bone marrow transplantation (8.0%), Multifocal motor neuropathy(4.5%), Chronic inflammatory demyelinating polyradiculopathy (4.5%), Guillain-Barré Syndrome (2.8%), Recurrent abortion (2.8%), Others (12.1%). The prescriptions were classified according to their strength of recommendation as follows:

- A:41.2%
- B:34.7%
- C:1.8%
- D:2.9%
- Not determined:19.4%

Conclusions

A high percentage of prescriptions (75.9%) had a good strength of recommendation (A or B). However, the great variety of indications, many of them off label, make it necessary to periodically review compliance with the protocol, above all when there is suspicion of misuse.

Conflict of Interest

No conflict of interest

E8. improvement opportunities in parenteral nutrition support process

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Objective

The aim of this study was to identify opportunities to improve the Parenteral Nutrition (PN) support process, describe the strategies implemented and the results obtained.

Method

A systematic search was conducted in MedLine using: Pharmaceutical Care Program (PCP), PN, Nutritional support, and Pharmaceutical Interventions (PI). ASPEN and ESPEN guidelines were reviewed.
Variables analysed over 6 months: number of patients with PN, number of PN units prepared and number of PI. Paediatric patients were excluded. The percentage of patients whose nutrition was adjusted to PN protocols for carbohydrates, proteins and lipids was calculated in two one-month cross-sectional samples, the first in 2008 and the second in 2009. Paediatric and critically ill patients were excluded.
Data was collected with Farmatools and Nutriwin software.

Results
Improvement opportunities identified:
- To update PN protocols.
- To asses the use of new nutrients.
- To standardise the prescription of PN.
- To involve the hospital pharmacist in the clinical and nutritional care of patients receiving PN.

Strategies adopted:
- 14 PN protocols were designed according to patient's weight and metabolic stress level (mild, moderate or severe).
- Lipid emulsions containing omega-3 fatty acids were included in all protocols but supplementation of glutamine only in catabolic stress protocols.
- Computerised prescribing was introduced.
- In context of pharmaceutical care, a hospital pharmacist now monitors nutritional and clinical parameters and records PI daily.

Results obtained:
160 patients were on PN, and 1638 units of PN were prepared.
PI were made in 30.6% of cases (31% and 29% of PI respectively were related to adapting micronutrients and macronutrients to patient needs).
Before the new system was introduced 27.8% of patient nutrition was in accordance with guidelines. Since then the percentage has increased to 56.1%.

Conclusions:
A new system and greater pharmacist involvement in nutritional care has improved nutritional support. Detailed and continuing monitoring of the process is improving nutritional care.

Conflict of Interest
No conflict of interest

E9. Clinical Pharmacists in Clinical Trials? Their contribution to success

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Background
Clinical investigation calls for the establishment of multidisciplinary teams that enable clinical trials to be designed and run efficiently.
In clinical trials run at our hospital, pharmacists are responsible for the drugs from start to finish, including dispensing to the patient with a pharmacist consultation.
The aim of this project was to demonstrate the effect of the clinical pharmacist consultation on adhesion to treatment.

Methods
From our records for the year 2009 (January to September) we extracted a sample to study the impact of the pharmacist consultation on the subject's medication adhesion and drop-out rate.
The percentage therapeutic adhesion was evaluated by counting returned drugs.

Results
The pharmacist consultation depends on the protocol design and on the stage where the patient is at in respect to the protocol. It includes:
- Reviewing the patient's drugs, including clinical trial drugs, in order to check for interactions and exclusion criteria
- Explaining the clinical trial subject's rights and duties
- Explaining what the clinical trial medicine is, precautions and common side effects
- Increasing the patient's awareness of the clinical trial they are enrolled into
- Promoting therapeutic adhesion.

This sample numbered 202 (35.1% female with an average of 66 years old), of the 750 patients currently involved.
- Therapeutic adhesion average – 96.02%
- Drop out rate – 14.36%
  - o Adverse events – 50%
  - o Lost to follow-up – 40%
  - o Death – 10%
  - o Lack of drug compliance – 0%

Conclusions
Most clinical trial protocols do not have a definition of adhesion rate that is considered a drop out. Nevertheless we established a minimum adhesion rate of 90%. These results show that the clinical pharmacist consultation is important for patient's therapeutic compliance, thus providing more accurate data for the clinical trial evaluation and avoiding drop out due to lack of drug compliance

Conflict of Interest
No conflict of interest

E10. Time to treatment failure for antiretroviral therapy regimens. What are the implications for hospital pharmacists?

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Background
The advances made in treating HIV infection have virtually allowed the infection to be considered a chronic disease. Consequently, antiretroviral therapy has become a lifelong treatment. However, for various reasons, prescribed antiretroviral treatments eventually fail. For this reason, it is very important to achieve long-lasting, sustained, treatment.

Objectives
- To measure the sustainability of antiretroviral treatments prescribed in the context of everyday clinical practice.
- To measure the incidence of virological failure.
- To measure the frequency of use of new antiretroviral drugs (darunavir, tipranavir, raltegravir, maraviroc and enfuvirtide) in rescue treatments.

Method
An observational, descriptive and retrospective study. To conduct the study we recorded all antiretroviral treatment changes that occurred during 2008 in a second-level university hospital. In such changes we recorded the median sustainability of failed treatments, understanding it as the time during which it was possible to maintain the prescribed antiretroviral therapy. Similarly we recorded the incidence of virological failure (detectable viral load after at least 24 weeks of treatment) at the time of change and frequency of use of five recently-marketed antiretroviral drugs.

Results
There was a total of 274 antiretroviral treatment changes for the 238 patients studied. The median length of time before which treatment failure led to a change in therapy was 59 weeks. The change was caused by virological failure in 33.21% of cases. Finally, of the most recently marketed antiretroviral drugs, raltegravir and darunavir were the most used, included in 19% and 18.6% respectively of new combinations prescribed.

Conclusions
The median sustainability of antiretroviral treatment is short given the chronic nature of the treatment. Virologic failure is the cause in one third of antiretroviral therapy changes. Raltegravir and darunavir are the new drugs most used. Finally, the pharmacist should help to prolong the sustainability of antiretroviral therapy, optimising adherence, reducing interactions and managing potential adverse effects.

Conflict of Interest
No conflict of interest

E11. Inappropriate prescribing in the elderly: a comparison of the Beers criteria with the French list in elderly hospitalised patients

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Background
The Beers' criteria list is an American tool commonly used in Europe to identify inappropriate prescribing. The French pharmacologists have independently established a list of potentially inappropriate medicines for people aged 75 or older, taking into account French prescribing habits [1].

Objectives
The aim of the study was to assess the prevalence of inappropriate prescribing in a geriatric psychiatric unit for hospitalised elderly people. The second aim was to compare the efficacy of the two tools in identifying inappropriate prescribing.

Methods
A retrospective multicentre study was undertaken in elderly (75 years old and over) patients hospitalised in a geriatric psychiatric unit between 1/07/2007 and 31/12/2008. Prescriptions were collected at discharge. Potentially inappropriate prescribing was evaluated with Beers' criteria and the French list.

Results
Two hundred and ninety patients, aged 82 (±5) years, were enrolled. The number of drugs used at discharge was 7.3 (±2.9). According to Beers' criteria, 31% (n= 89) of patients were prescribed at least one inappropriate medicine (104 inappropriate medicines, mean 1.2 medicines per patient). Hydroxyzine accounted for one third (31%) of inappropriate prescriptions. According to the French list, 73% (n = 211) of patients had been prescribed at least one inappropriate medicine (470 inappropriate medicines, mean 2.2 medicines per patient). Benzodiazepines accounted for half (51%) of inappropriate prescriptions. The French list identified more inappropriate prescriptions than the Beers' criteria.

Conclusion
The rate of inappropriate prescribing according to Beers' criteria is comparable with these identified in a previous study [2]. The rate is higher according the French list. To our knowledge, our study is the first to report a rate of inappropriate prescribing according to the French list. The French list has criteria not contained in the Beers' criteria, when for example criteria such as the diagnosis, or combination therapy, are taken into account. These criteria explain the difference between the two inappropriate prescribing rates.

(1) Rev Med Interne. 2009; 30: 592-01
(2) J Clin Pharm Ther. 2006; 31: 617-26

Conflict of Interest
No conflict of interest

E12. Inappropriate prescribing in the elderly patients: impact of hospitalisation in a geriatric psychiatric unit

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Background
There are few data about inappropriate prescribing in elderly hospitalised patients in a geriatric psychiatric unit.

Objectives
The aim of this study was to assess the prevalence of potentially inappropriate medication in patients aged 75 years or older at admission and at discharge from a geriatric psychiatric unit.

Method
A retrospective multicentric study was undertaken in elderly (≥75 years) patients hospitalised in a geriatric psychiatric unit between 1/07/2007 and 31/12/2008. The prescriptions at admission and at discharge were collected. The potentially inappropriate prescribing rate was evaluated with the Beers criteria.

Results
Two hundred ninety patients, aged 82 (± 5) years, were included. Numbers of drugs used at admission (6.7 ± 2.9) and at discharge (7.3 ±2.9) were significantly different ($p < 0.0001$).
At admission, according to the Beers criteria 32% (n=94) of patients used at least one inappropriate medicine (111 inappropriate medicines, mean 1.2 medicines per patient). Hydroxyzine prescriptions represented a quarter of inappropriate prescriptions. At discharge the prevalence of potentially inappropriate medicines use was 31% (n= 89 patients, 104 inappropriate medicines, mean 1.2 medicines per patient). Hydroxyzine prescriptions represented one third of inappropriate medicines.
The inappropriate prescribing rates at admission and at discharge were not significantly different ($p > 0.05$).

Conclusion
In a geriatric psychiatric unit, the prevalence of inappropriate prescribing was 30%. This rate is close to that of studies in geriatrics [1]. Our study suggests that hospitalisation in a geriatric psychiatric unit does not have any effect on inappropriate prescribing in the elderly, whereas a French study suggests that hospitalisation in geriatric units leads to a reduction in potentially inappropriate medicines use [2].

(1) J Clin Pharm Ther. 2006; 31: 617-26
(2) Drugs Aging. 2006; 23: 49-59

Conflict of Interest
No conflict of interest

E13. TRENDS OF PARENTERAL NUTRITION PRESCRIPTION IN A UNIVERSITY HOSPITAL

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Objective
To describe the use of parenteral nutrition (PN) in a tertiary hospital.

Method
Descriptive observational study in a 300-bed hospital of PN prescription in all patients who received PN over one month (19 January to 18 February 2009). The prescription of PN is standardised into one of 6 pre-defined types, which can be individualised according to the patient's

requirements. Patient data (weight, height, age and sex), data from the ward on which the PN was prescribed, and the type of PN were recorded in an Excel file.

Results
122 patients were included; with a total of 160 units administered (26 patients received more than one type of PN throughout their stay in hospital). Weight and height were only available for 33% and 30% of the patients, respectively. Standard formulas at our hospital include commercially available and "ready to use" formulas (96.2%) as well as mixtures prepared in the pharmacy department from macro and micronutrients (1.9%); non-standard PN is also prepared in the pharmacy department (1.9%). Therefore, in only 3.8% of patients was the PN formula prepared in the pharmacy department. More than half (51.3%) of the prescribed PN was administered into a peripheral vein (PPN), and the other half was divided between the other routes. Formulas were individualised to restrict volume (2 patient) and be without sodium (1 patient). Medical specialties prescribed PN most frequently (39% of occasions) followed by the surgical specialties (33%) and the intensive care unit (28%).

Conclusions
There is a small percentage of patients for whom a commercial formulation of PN is not considered suitable and individualised PN is necessary. Prescriber inertia - it is easier to prescribe commercial presentations of PN available in the hospital, than to individualise formulas - and the increasing number of formulas available to fit patient requirements, explain the high percentage of "ready to use" formulations used. Individualization of PN is limited by the lack of information on the patient's weight and height.

Conflict of Interest
No conflict of interest

E14. Rituximab in Rheumatoid Arthritis:new data of clinical effectiveness and toxicity

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Objective
To evaluate the clinical response and side effects in patients with rheumatoid arthritis (RA), after B-cell depletion with rituximab (RTX).

Method
The clinical pharmacy service together with the rheumatology service of our hospital established a treatment protocol for the use of RTX in RA patients. In order to assess the risk/ benefit ratio among those patients included, the clinical pharmacists conducted a retrospective and non-comparative study. They recorded several disease parameters (visual analogue scale [VAS], DAS-28, C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], rheumatoid factor [RF]), at base line and 6 months post-treatment and any adverse events during treatment. Responders were defined according to the EULAR criteria as good, moderate and non-responders after a single course of therapy.

Results
17 patients with active RA who had had an inadequate response to at least one anti-tumour necrosis factor (anti-TNF) agent (median of 2 previous anti-TNF agents) were included. Patient ages ranged from 25 to 73 years, with a median of 51 years. The majority of patients 14/17(~82%) were female. All patients were given RTX 2 x 1000 mg in combination with MTX (weekly dose 7.5-25 mg). All patients were treated with 100 mg IV methylprednisolone 30 minutes prior to RTX to decrease the rate and severity of acute infusion reactions. At base line the mean DAS-28 score was 6.21. Six months after treatment, our patients were classified according to the EULAR response criteria as good responders 5/17(29.4%), moderate responders 5/17(29.4%) and non-responders 7/17(41.2%). Only two patients(12%) achieved RA remission. RTX was well tolerated in 14(82.3%) patients while 3(17.7%) experienced adverse events (AEs). The most common type of AE was infection, two patients experienced oropharyngeal candidiasis. One patient had an acute infusion-related AE (transient hypotension).

Conclusions
More than fifty percent of our patients (58.8%= good plus moderate responders) improved their RA status after a single course of RTX with 3/17 experiencing mild AEs. So we found RTX a well tolerated and effective treatment in RA.

Conflict of Interest; No conflict of interest

E15. Adherence to NICE recommendations in patients with chronic kidney disease receiving darbepoetin

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Background
NICE guidelines for the treatment of anaemia in chronic kidney disease (CKD) in pre-dialysis patients recommend starting darbepoetin alfa when haemoglobin levels are lower than 11 g/dl, and increase the level to between 11-12 g/dl. The dose must be 0.2-0.4 mcg/Kg/week, the recommended rate of increase of Hb from 1-2 g/dl/month, until the required Hb is reached. Our aim was to analyse adherence to the NICE recommendations for the use of darbepoetin in the treatment of anaemia in CKD in pre-dialysis patients in our hospital.

Method
Retrospective observational study about darbepoetin use in CKD pre-dialysis patients who started treatment during 2008 in our hospital.
Demographic data (sex, age), weight, initial dose of darbepoetin, pre- and pos-treatment Hb values were evaluated. Data were obtained from the clinical histories, outpatients' computer files and laboratory reports.

Results
We included 59 patients (31 men, 28 women), age 66.58 ± 14.75 years old. Average Hb level before starting treatment was 10.6 ± 1.67 g/dl and 42% of patients had Hb levels higher than 11 g/dl.
The first dose prescribed was 0.22 ± 0.17 mcg/Kg/week (n=44). After 75.98± 58.59 days of treatment the rate of Hb increase was 0.73 ± 2.35 g/dl/month and the Hb level reached was 11.53± 1.69 g/dl. Only the 24% of patients had attained the desired Hb level at the moment of the evaluation and 37% of them had Hb values higher than 12g/dl.

Conclusions
A significant percentage of patients did not fulfil the starting Hb criteria or attain the recommended Hb values after starting treatment. The starting doses were appropriate. It therefore seems necessary to establish a protocol for darbepoetin treatment in order to protect this group of patients.

Conflict of Interest
No conflict of interest

E16. In search of biomarkers related to wound healing

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Background
Weekly, the Clinical Nutrition Team consults a selection of in-patients receiving parenteral nutrition. Some of these patients suffer from hard-to-heal wounds that are generally hidden i.e. covered by dressings left in place for several days or by VAC (vacuum assisted closure) devices. As essential and semi-essential substrates are able to improve wound healing, the Clinical Nutrition Team would greatly appreciate having diagnostic data on the wound status. However, no effective non-invasive diagnostic tools currently exist to assess the critical biological activities or impairments within the wound. Thus, there is a need to identify the most reliable non-specific parameters from routine blood tests as a source of information and upon which to base decisions about nutraceutical therapy.

Methods
Before a consultation the patient's clinical records and data sheets from the central chemical laboratory are assessed. Analyses of pO2, total protein, albumin, C-reactive protein, urea, zinc, copper, weight change, energy requirement, the present phase of healing, possibly the microbiology of the exudate and the clinical assessment contribute to assessing the wound and nutritional status and to defining the individual nutritional therapy.

Results
Over a 5-month period, a selection of 14 patients have been receiving special wound care focussing on nutritional treatment. 7 patients suffering from wounds in the inflammatory state and treated by VAC showed a C-reactive protein level of > 100 mg/L, all of them combined with low albumin levels of < 30 g/L, but not all with high urea levels of > 7.7 mmol/L. An additional 3 patients had moderately elevated CRP and normal albumin levels. Zinc blood level, rarely determined, showed no deviation from the reference range. Symptomatic therapy was the treatment of choice, combined with adequate parenteral nutrition. Another 4 patients in more advanced phases of wound healing were diagnosed as malnourished and / or energy deficient. High-energy and arginine, copper, and zinc-enriched drinks were the treatment of choice for these patients.

Conclusions
Non-specific biomarkers of inflammatory status can hardly give more than a confirmation of a clinical assessment. More specific biomarkers, possibly assayed from exudate rather than from plasma would be welcome to assist in determining specific wound healing-focused nutritional treatment. Nitric oxide, intermediates of arginine, ornithine, citrulline and glutamine metabolism, cytokines, growth factors, and enzymes such as nitric oxide synthases or matrix metalloproteinases are expected to be among these specific biomarkers.

Conflict of Interest
No conflict of interest

E17. Pharmaceutical care in out-patients treated with erythropoiesis-stimulating agents
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Objective
The purpose of this study was to evaluate efficacy and safety of erythropoiesis stimulating agents (ESA) in outpatients with chronic renal disease.

Method
A descriptive observational study was undertaken over nine months (January-September 2009) in a general teaching hospital with 717 functioning beds. All outpatients treated with darbepoetin or epoetin alfa were included.
Age, gender, treatment with oral or intravenous iron, haemoglobin (Hb) values within the target range (10-12.5 g/dl), Hb values above the safety limit (>12.5 g/dl) and Hb values under the efficacy limit (<10g/dl) were recorded. The proportion of patients with Hb values within the target range (10-12. 5 g/dl) was calculated.
Drug-related problems (DRPs) were identified and recorded over six months (April-September 2009). DRPs were classified in two categories: safety and efficacy.
During this research ESAs were dispensed monthly for beginners and changes of treatment. Regular appointments were every two months.

Results
94 patients were included in the study (65% women, 35% men), average age of the patients was 73 (26-94). Of these 94 patients, 4 were treated with epoetin alfa and 90 with darbepoetin.
23% of patients had all Hb levels within the target range.
58.5% of all patients were treated with iron (oral or intravenous).
A total of 399 analyses were done. The average number of analyses per patient was 4 (0-15). 55.6% of analyses were into the target range, 32.6% under the efficacy limit and 15% above the safety limit.
22 DRPs were identified and noted from April to September. Of these 22 DRPs, 17 were in the safety category and 5 in the efficacy category.

Conclusions
- Most outpatients with chronic renal disease treated in the hospital presented values out the target range.
- Action must be taken to improve the quality of pharmacotherapy with ESA in patients with chronic renal disease.

Conflict of Interest
No conflict of interest

E18. Effect of hospitalisation on drug prescription in Geriatrics: Focus on psychotropic medicines
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Background
Polymedication in the elderly increases the possibility of harm from the treatment, medical costs and makes treatment compliance difficult. Improving the quality of prescriptions in geriatrics is a public health issue. The aim of this study was to measure the impact of hospitalisation on outpatient prescriptions.

Method
For each patient entering the geriatric emergency ward between March and May 2009, we compared the hospital prescription written in the ward at admission with the outpatient prescription. The types of modification were recorded: discontinuation of a treatment (intentional or unintentional), substitution and addition of a new medicine.

Results
The study was carried out on 74 patients, representing 484 hospital prescription lines. The mean age was 86 (sex ratio 0.85). The average length of hospitalisation was 8.4 days. The average number of drugs prescribed was 6.32 for the outpatient prescriptions versus 6.09 for the hospital prescriptions. 95% of prescriptions were modified on the patient's admission: 37% of outpatient prescription lines were stopped (n=174), 33% of new drugs started (n=155), and 6.4% substituted (n=30). Six treatments were unintentionally stopped (in 4 prescriptions).The main drugs stopped on entry were psychotropics (20.7%: 7.5% antidepressants, 6.9% anxiolytics, 6.3% neuroleptics). 43% of patients had at least one psychotropic drug stopped on admission, in 90.6% of these cases, the discontinuation was maintained until the end of the hospitalisation. The drugs started on admission were antibiotics (27.7%), anticoagulants (20%), analgesics (18.7%), only 4.4% were psychotropics. Substitutions mainly concerned anxiolytics (27.5%), antidepressants (19.9%) and antacids (18.6%).

Conclusion
In geriatrics, psychotropic drugs have a bad reputation for iatrogenesis, especially cardiovascular and neurological. Our results show a reduction in psychotropic prescriptions during hospitalisation, as recommended by the French Health Authority.

Conflict of Interest
No conflict of interest

E19. Evaluation of changing to a biosimilar for treating anaemia
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Background
Recently epoetin zeta (Retacrit), biosimilar of epoetin alfa (Eprex), has been marketed for the treatment of, amongst other indications, anaemia associated with chronic renal failure.
The objectives were to assess the effectiveness of epoetin zeta compared with the reference drug epoetin alfa in patients with chronic renal failure on haemodialysis and assess the financial effect of

replacing epoetin alfa with the biosimilar epoetin zeta.

Method
Descriptive, retrospective study of the use of the biosimilar drug in patients with chronic renal failure undergoing haemodialysis in the Ribera Health Department under treatment with epoetin zeta, previously treated with epoetin alfa. The number of patients that fulfilled these criteria was 26. Drugs were administered by the intravenous route. Haemoglobin (Hb) and weekly doses needed for each patient in treatment with epoetin zeta were examined for three months (March to May 2009), and were compared to Hb and weekly doses for three months (September to November 2008) of each patient treated with epoetin alfa. Three months (December 2008 to February 2009) were excluded from the study to avoid interference. The doses were adjusted to achieve the target value of 11g/dl.
A descriptive analysis (mean and standard deviation) of the two variables was performed, and to compare the variables in each patient the Student T test was used.
The cost of epoetin alfa was calculated during the period prior to the switch (February to November 2008) and was compared with the cost of epoetin zeta during the later period (March to September 2009).

Results
During the treatment with epoetin alfa, the mean dose was 14000±18256 IU and the mean Hb concentration was 12.19 ±1.85g/dl and during the treatment with epoetin zeta the mean dose was 16979.16 ±19685.22 IU and the mean Hb concentration was 11.6538±1.11g/dl.
No statistically significant differences in the comparison of each patient in the mean weekly doses of epoetin zeta and epoetin alfa were observed (p= 0.13). No statistically significant differences in the Hb concentration in each patient under treatment with epoetin zeta and epoetin alfa were found (p=0.196). The cost was reduced from 7075.04±1163€/month to 5419.16±1799€/month, with a difference of 1655€ /month, representing an annual saving of 19870€.
Cost per patient in the period prior to the change was 283€/month and the cost per patient in the later period was 193.54 €/month. This means a saving of 89.46€ per patient per month.
No adverse reactions were reported by the Nephrology Service.

Conclusions
Epoetin zeta appeared similarly effective to epoetin alfa when used to maintain Hb concentrations in patients with CRF-associated anaemia who were successfully switched from epoetin alfa to its biosimilar competitor. Thus epoetin zeta offers a clinical alternative equivalent to epoetin alfa in renal anaemia.
The change to the biosimilar of epoetin alfa reduced costs significantly.

Conflict of Interest
No conflict of interest

E20. Pharmaceutical care in hospitalised patients
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Objective
To assess pharmaceutical care of inpatients and quantify the acceptance level of pharmaceutical care among practitioners.

Method
A prospective observational study of two months duration was undertaken (July-August 2006) in a general hospital with 717 functioning beds. All patients in three hospital units were included in the study, 314 beds in total using the Unit Dose Distribution System from the Cardiology, Heart Surgery and Gastroenterology/Internal Medicine units.
Drug-Related Problems (DRP) were classified into indications, effectiveness and safety.
The rate of therapeutic exchange was calculated according to normalised hospital procedure for therapeutic exchange.
DRP, the degree of acceptance by practitioners and adherence to hospital guidelines on the administration of high-risk drugs were identified on a daily basis by monitoring the pharmacological-therapeutic profile of patients.

Results
4,324 prescriptions were received, 25,074 drug lines were transcribed and validated and 34,283 doses of drug were dispensed.
40% of pharmaceutical interventions were undertaken in Gastroenterology/Internal Medicine, 30% in Cardiology and 30% in Heart Surgery.
A total of 207 DRP were recorded during the study in 141 inpatients, the average age of whom was 73. Of these 207 DRP, 49% were in the indications category, 41% in effectiveness and 10% in safety. Of those, 179 (86.5%) pharmaceutical interventions were accepted and 18 (8.7%) were missed (due to discharges, deaths, transfers).
The rate of therapeutic exchange was 67% and the adherence to guidelines for the administration of high-risk drugs was 98.5%.

Conclusions:
- Pharmaceutical care contributes to the patient's clinical evolution
- Practitioner acceptance of pharmaceutical intervention is high
- The rate of therapeutic exchange is significant
- Physicians adhered to guidelines for the administration of high-risk drugs in nearly all cases. Cases of non-adherence were due to the need for individualized fluid therapy in some cardiology patients.

Conflict of Interest
No conflict of interest

E21. Plerixafor: New drug for peripheral blood stem cells mobilisation for autologous transplantation
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Background
Transplantation of peripheral blood stem cells (PBSC) is a strategy in the treatment of non-Hodgkin's lymphoma and multiple myeloma. Mobilisation strategy is based on the administration of granulocyte colony-stimulating factor (G-CSF) alone or post chemotherapy. However despite this, PBSC fail to mobilise in some patients.
Plerixafor is a PBSC mobiliser that inhibits the CXCR4 chemokine receptor. This mechanism results in leukocytosis and the elevation of circulating blood haematopoietic progenitor cells. In France, Plerixafor hasn't yet got marketing authorisation: a certificate called ATU (temporary use certificate) must be issued by the French Health Product Agency (AFSSAPS) for each patient.

Method
Our study concerns 6 patients, who had failed a prior attempt at mobilisation between December, 2008 and August, 2009. Data were taken from the medical files.
Rescue mobilisation consisted of G-CSF (10µg.kg-1.day-1) on days 1-4 followed by Plerixafor (240µg.kg-1.day-1) on day 4. Plerixafor was administered every day (4 injections maximum) until the goal of 2.106CD34+.kg-1. Apheresis was performed the day after. The pharmacy sent each prescription to AFSSAPS for agreement. All amounts given were nominative and were made every day according to the results of the previous day's cytapheresis.

Results
4 patients had multiple myeloma, 1 Hodgkin's lymphoma, and 1 mantel cell lymphoma. Median age was 58 years (range 22-71). Median number of CD34+ cells collected was 4.97 x 106CD34+ cells/kg-1 (range 3.3-8.12). Median number of apheresis was 1.8 (range 1-3). The most common adverse reactions were gastrointestinal. 11 doses were delivered by the pharmacy for a total cost of 95,443.83 Euros.

Conclusions
The association of Plerixafor and G-CSF was able to successfully mobilise CD34+ cells for patients in whom prior mobilisation with either growth factors or chemotherapy had failed. However, this regimen significantly increases the cost of PBSC autologous transplantation in malignant blood conditions. Inclusion for every patient should be under

multidisciplinary management and should be monitored by the pharmacy.

Conflict of Interest
No conflict of interest

E22. Internal medicine patients: a challenge for clinical pharmacists

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Background
Patients in an internal medicine ward are a challenge for clinical pharmacy due to their age, multiple chronic diseases and consequent use of multiple drug regimens.
Many studies refer to the importance of clinical pharmacists as members of the health care team once drugs play an important role in patients' quality of life, and their safety and necessity became as meaningful as effectiveness.
Among the many assessment tools that become available with pharmaceutical care, pharmacotherapy follow-up optimises the use of prescribed drugs.

Method
A six-month, retrospective, pharmacotherapy follow-up study: evaluation of health problems (HP), pharmacotherapy reviews, drug-related problems (DRPs), identification and classification of pharmacist interventions.

Results
351 patients were included, 181 male and 170 female, with a mean age of 73.6 years and an average hospital stay of 8 days. The major HP were circulatory (60.4%) and respiratory problems (13.7%).
Pharmacists validated 2484 prescriptions, identified 97 DRPs and made 280 interventions.
DRPs were classified according to necessity (7.9%), effectiveness (2.6%) and safety (89.5%); the remaining 173 interventions regarded dosing adjustments based on pharmacokinetics and IV iron administration protocols.
There were interventions for 30 different drugs; antibiotics represented 66.8%, IV iron administration 13.9%, and anti-ulcer drugs 11.8%.

Conclusions
The internal medicine ward assists mainly elderly and poly-medicated patients, with cardiovascular pathology and several co-morbidities. This group particularly needs pharmaceutical care, being especially vulnerable to adverse drug effects and other DRPs.
Our results, in particular those referring to dose-dependent safety problems, confirm the need for pharmacotherapy follow-up on this ward. It would be interesting to extend this experiment to a larger number of drugs and introduce a continuing, systematic, clinical pharmacy service. Such a service allows the clinical pharmacist to work in a multidisciplinary team, helping physicians provide a valuable service to patients.

Conflict of Interest
No conflict of interest

E23. Pharmaceutical care programme for patients with multiple sclerosis

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Background
First-line disease-modifying agents (DMA) for multiple sclerosis (MS), including subcutaneous IFNβ-1b, intramuscular IFNβ-1a and glatiramer acetate, can reduce the rate of clinical attacks and limit disability progression in MS patients. However, common adverse events (AEs) and an impression of lack of efficacy by patients could make them discontinue the treatment. A pharmaceutical care programme training patients on the appropriate injection technique, dose titration and proactive management of AEs can play an important role in optimising adherence and patient benefit.

Method
A literature review enabled us to design protocols and information leaflets about administration, storage requirements and management of AEs. Patients starting with DMA were given an appointment with a pharmacist for a 20-minute start-of-treatment interview. Patients who changed treatment and reported problems managing devices were also given interviews. Within the study period (March - September 2009) clinical histories were reviewed in order to ensure the programme was on track.

Results
93 patients were reviewed, 61,7% women, median age 34.95 years (CI95% 19-50), median treatment duration 34.1 months. 29 patients had an initial interview and 18 changed treatment (12 due to MS progression, 4 because of AEs, 2 problems with administration devices). Most patients (76.34%) were adherent, 13.97% missed a few injections, significant non-compliance (< 65.75% adherence) was apparent in 3 patients. 81.2% of patients had at least one AE: flu-like syndrome (36%), injection site reaction (33%), depression (33%), skin reaction (17%) or asthenia (10%). Management of these AEs included prophylactic administration of NSAIDs, rotation of the injection site, application of ice, monitoring for signs of depression, skin care (hydration and sun protection). In 17% of patients, who reported problems with devices, pharmacists checked whether the reason was a device fault or whether the patient had an inappropriate injection technique.

Conclusion
Increasing numbers of MS patients being treated, a high incidence of AEs and frequent problems with devices justify the continuity and improvement of MS pharmaceutical care programmes.

Conflict of Interest
No conflict of interest

E24. Use of Ustekinumab in patients with psoriasis

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Background
Ustekinumab is a fully human monoclonal antibody that binds with high specificity and affinity to the cytokines interleukin IL-12 and IL-23. It is a new therapy in patients with psoriasis in whom other treatments have failed or are not well tolerated. The aim of this study was evaluate the clinical efficacy and safety profile of ustekinumab.

Method
An observational study was carried out from March to September 2009 in patients treated with ustekinumab. All the cases were compassionate use. The data was taking from the informatics module application and the clinical histories. The information collected was: diagnosis, previous treatments (PUVA, methotrexate, ciclosporin, anti-TNFs), dose, duration of treatment, adverse reactions, efficiency parameters (PASI, BSA, PGA) and EUROQOL values.

Results
Six patients were treated (3 men and 3 women). All the patients received at least three doses (0, 4, 12 weeks). In all of them a reduction of the PASI > 50% at 4th week was observed. In four patients the PASI achieved values of 0 at 12th week of treatment. In two patients PASI increased at 16th week, therefore the frequency of administration was modified to 8 weeks.
The value of PGA was variable from severe or moderated to slight or without symptoms. The itch improved in all patients. EUROQOL values increased from 0-30 to 80-90.

Conclusions: Ustekinumab is a promising new therapy that reduces the extent and severity of psoriasis and is well tolerated. The treatment regimen must be individualised based upon response.

Conflict of Interest
No conflict of interest

E25. Pharmaceutical care programme for paediatric HIV patients

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Objective
To describe a Pharmaceutical Care Programme (PCP) for paediatric HIV patients and analyse preliminary results obtained.

Methods
A search of PubMed/Medline, using as keywords HIV-infected children, pharmaceutical care, adherence, antiretroviral toxicity, metabolic disorders, paediatric as well as the 2008 PENTA guidelines and the Antiretroviral (ART) Product Information, were used to design the PCP.
Variables studied: viral load, percentage CD4, adherence and the metabolic complications of hypercholesterolaemia (≥200 mg/dl), hypertriglyceridaemia (≥170 mg/dl) and hyperinsulinaemia (≥17 µIU/ml).
Adherence was calculated through two indirect methods: the dispensing record and a validated questionnaire. This uses a standardised script to ask the patient/caregiver to report missed doses in the 3 days before the visit.
A cut-off of ≥ 95% compliance was considered as "adherent", as other research has suggested this is sufficient to maintain viral suppression.

Results
The PCP was established in 2008. Every 3 months, follow-up interviews are conducted by the HIV paediatric pharmacist. Pharmaceutical care is divided into three elements:

1. Data is collected including demographic and anthropometric data, % CD4, viral load, antiretroviral drugs, side effects, metabolic disorders and factors associated with low adherence.
2. Oral and written information is provided at key moments (initiation of treatment, changes in treatment and at the patient's request). A leaflet has been designed about ARTs and the drugs most commonly prescribed with them, including indications, dosage, method of administration, special warnings, interactions and side effects.
3. Follow up of clinical and therapeutic adherence.

19 children are presently included in the PCP (68.4% female; 31.6% male). The median age is 13.78 years (0.63-18.71).
78.94% have achieved an undetectable viral load (<20 copies/ml).
73.68% have CD4 cell count ≥ 25%.

Metabolic disorders are shown in the following table.

	n	Median	Prevalence (%)	Prevalence 95% CI
Cholesterol (mg/dL)	19	195.8	36.8	14.8-58.5
Triglycerides (mg/dL)	19	145.1	36.8	14.8-58.5
Insulinaemia (IU/mL)	14	12.2	28.6	4.9-52.3

78.95% of patients were adherent. As of July 2009, 9 patients had taken the questionnaire: 7 reported no missed doses, and the other 2 reports showed that patient had forgotten to take some doses of ART.

Conclusions
Improving the patient's knowledge of HIV infection and ART therapy and close follow-up might be important tools to increase medication compliance and achieve viral suppression.

Conflict of Interest
No conflict of interest

E26. Clinical experince with abatacept: a first-in-class therapy.

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Background
Abatacept is approved in the EU for treatment of moderate to severe rheumatoid arthritis (RA) in adults who have had an insufficient response or intolerance to other drugs, including at least one tumour necrosis factor inhibitor (TNFI). The objective is to review the effectiveness and safety of abatacept in the treatment of adult patients with active RA.

Method
Medical record review and retrospective analysis (from April 2008 to August 2009) of prescriptions recorded in the outpatient pharmacy department (ATHOS-APD drug prescription database) in a general teaching hospital. Previous drug use, progression of radiological joint damage (change score), improvement of physical function (subjective) and tolerance were calculated (SPSS 12.0 for Windows).

Results
A total of 9 patients used abatacept with methotrexate (55.5% - 4 male, 44.5% - 5 female, mean age = 55.75 ± 10 years), 3 (33.3%) of them began using abatacept because of intolerance to TNFI and 6 (66.7%) because of a lack of response to TNFI. All patients with intolerance to TNFI (3) previously received rituximab, 2 (66.7%) of them stopped the anti-CD20 because of side effects, and the third (33.3%) because of low response. All patients with insufficient response to TNFI (6) received at least adalimumab and etanercept in an sequential way, only 3 (50%) patients received infliximab and 2 (33.3%) patients rituximab.
The number of patients who used abatacept for at least 6 months was 6 (66.7%), the mean time on treatment was 7.4 ± 3 months. One patient (11.1%) discontinued the drug due to ineffectiveness. All the individual patient change scores differed from 0 and reflected an improvement in well-being. No one presented an infection related to the drug, but 4 (44.4%) of them presented headache and nausea.

Conclusions
Although longer-term data are required, abatacept caused clinical improvements in the signs and symptoms of RA. Physical function was also improved with abatacept, which demonstrated an acceptable short-term safety and tolerability profile

Conflict of Interest
No conflict of interest

E27. A method for investigating clinical queries: intrathecal colistin for CSF infection with Pseudomonas aeruginosa.

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Background
As hospital pharmacists we are frequently asked to collaborate in treatment-related research. Many queries are incorrectly answered however, due to a lack of skill in formulating questions, crafting effective search strategies and accessing databases. The PICO strategy helps in these characterisations. It enables the best scientific information to be located rapidly. On the other hand, 77% of answers to clinical questions can be obtained from MEDLINE. We present a method we used to approach a clinical question: the case of a patient with evidence of cerebrospinal fluid (CSF) infection by *Pseudomonas aeruginosa*

following insertion of a shunt.

Method
A physician asked “Is the intrathecal use of meropenem possible?” The clinical case was reviewed and the PICO strategy was used to investigate. **P**: Male, 37 years old; cranio-encephalic trauma; ventriculoperitoneal shunt; *Pseudomonas aeruginosa* isolated in CSF, sensitive to ceftazidime (moderate), meropenem (moderate), amikacin, colistin. Previous anti-infective IV treatment had been ineffective; **I, C**: intraventricular amikacin, colistin; **O**: Sterile CSF. A search was performed on PubMed using medical subject headings: "Pseudomonas aeruginosa"; "Central Nervous System bacterial infections"; “injections, intraventricular"; "injections, spinal"; "colistin"; "amikacin". Literature was evaluated using the Critical Appraisal Skills Programme method. Feedback was obtained to evaluate the quality and results of our assistance.

Results
The search revealed the possibility of using amikacin or colistin intrathecally for this problem. Preservatives in amikacin formulations eliminated this strategy. A regimen with intrathecal colistin was agreed: a dose of 5 mg administered at once, and then 10 mg once a day thereafter. CSF cultures were negative on day 7. The patient completed a 20-day regimen.
The physician considered the help provided was complete, accurate, applicable to clinical case and extremely significant to the results, which means it potentially contributed to saving the patient’s life.

Conclusions
Effective searching requires a series of steps to lead the pharmacist from a clinical question to evidence-based answers that are applicable to practice. The methodology we use allows us to obtain rapid, accurate and applicable answers in most cases.

Conflict of Interest
No conflict of interest

E28. The effect of zinc supplementation on serum copper levels and nutritional status in chronic hemodialysis patients

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Background
Insufficient macronutrients and micronutrients (malnutrition) is a common cause of morbidity in chronic haemodialysis patients. Some studies describe an interaction on absorption between divalent cations. The aim of this study is to evaluate the effect of zinc supplementation on nutritional status and seek a correlation between serum zinc and copper in this population

Methods
39 haemodialysis patients were enrolled in this randomised, placebo-controlled study. Patients received a daily supplement of 100 mg elemental zinc or placebo for 60 days. Patients completed 2-day food records at day 0 and day 60, which included 1 dialysis day and 1 non-dialysis day. Fasting, pre-dialysis serum samples were collected at baseline and day 60 to determine serum zinc and copper by atomic absorption spectroscopy. Body compositions were assessed by bioelectric impedance analyser. Nutritional status was assessed by questionnaires for each patient on the same days.

Results
After supplementation, subjects in the zinc-supplemented group showed significant increases in serum zinc concentrations as expected. No significant alterations in serum copper levels were detected in either group or between two groups. Also no significant correlations could be detected between serum zinc and copper levels.
Body Mass Index (BMI), Body composition, bad taste in the mouth, mean dietary protein intake and mean energy intake did not show statistically significant alterations with zinc supplementation.
Xerostomia (dry mouth) was reduced after zinc supplementation from 52.4% to 9.5%.Although perception of pleasant food smells was increased from 38.1% to 71.4%, no reduction of nausea was reported in this population.

Conclusions
This study could not detect any interaction between zinc supplementation and serum copper level. Although nutritional status did not improve significantly in haemodialysis patients, some complications such as xerostomia and hyposmia responded dramatically.

Conflict of Interest
No conflict of interest

E29. Can written recommendations from pharmacists be used in electronic patients’ records?

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Objective
The aim was to demonstrate that written remarks from the pharmacist can be used in the electronic patient record and thereby reduce medication errors at the hospital and increase patient safety.

Background
Hospital admission and discharge involve a high risk of medication errors, caused by unclear division of responsibilities, lack of communication, frequent change of synonyms and analogues, drugs, polypharmacy, compliance issues as well as insufficient staff education and training.
The department has worked with the national campaign Operation Life, dealing with medication reconciliation.
The pharmacist has been checking patients’ medicines in the electronic patient records since 2008. The pharmacist writes the recommendations in the electronic patient record after admission to the medical ward.

Method
For 1 month all of the pharmacist’s recommendations were recorded. 3 days after making the recommendations the pharmacist recorded the physician follow up. The recommendations were arranged in 13 categories. The recommendations were recorded as accepted, not accepted or no comment.

Results
The pharmacist checked the records of 95 patients, who had a total of 872 prescriptions.
The pharmacist wrote 83 recommendations, corresponding to 10% of the prescriptions.
The recommendations were made for 51 patients, corresponding to 53% of records checked.
The majority of the recommendations dealt with medication reconciliation (33%), adverse effects of the medicine (24%) and additional treatment was suggested in 12% of the recommendations. 10% of the remarks dealt with dosage and another 10% with technical problems as regards using the electronic patient record. 6% of recommendations concerned interactions.
Physicians agreed to 53% of the recommendations and the medicine was changed. 8% of the suggestions were refused. 39% of the recommendations involved no direct action by the physicians and no change in the patient’s medicines was seen
The physician followed up recommendations if the notes were about synonyms and dosage time (100%). The follow up of remarks regarding the electronic patient records was 75%. Suggested clinical treatment was followed up in 70% of the recommendations.

Conclusions
Written remarks from pharmacists can be used in the assessment of patients’ medication in order to increase the general quality. The pharmacist had many different recommendations which had a

different focus from the physician. The pharmacist was most focussed on medication reconciliation, while physicians prioritized following up of remarks about things in the electronic patient records, remarks about synonyms, and suggested clinical treatment.

Conflict of Interest
No conflict of interest

E30. Medicines reconciliation upon admission to hospital
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Background
Discrepancies in prescribed medicines can occur when patients are admitted from the community into hospital. Medicines reconciliation is a process that compares what the hospital physician prescribes versus what the patient was taking in the community.
Provision and maintenance of an accurate and up-to-date record and correction of unintended differences are the goals of medicines reconciliation.
We conducted a study to identify the type and frequency of discrepancies between medicines in the hospital and the drug histories when medicines reconciliation was carried out by a pharmacist.

Method
A prospective study was conducted for four months. The medicines were reconciled by a pharmacist who assembled the complete list of current prescriptions (within 24 hours of admission) and checked this list against the medicines taken before admission. The reconciliation form was made easily accessible to the clinicians. The prescriptions written were compared by the pharmacist with the list provided.
The study was done on a surgical ward, Vascular Surgery and a medical ward, Internal Medicine.
The medicines errors were classified using Delgado's system.

Results
40 patients were included. The mean age was 78.3±6.9, with 8.3±2.8 drugs per patient. 332 drugs were compared.
Discrepancies were found in the medicines of 95% (38) patients which involved 30.7% (102) prescribed drugs. Only in 27.5% (11) patients had a medicines error been made, which involved a total of 5.1% (17) of the drugs checked. The mean was 0.5 errors per patient. The errors were classified as: 63.7% (11) missing medicine, 29.4% (5) different dose, route or frequency and 5.9% (1) incomplete prescription.

Conclusion
Discrepancies between previous and current medicines were frequent in the medical records of elderly patients upon admission to hospital, despite the use of home medicines lists. Omissions and incomplete prescription accounted for the majority of medicines discrepancies.

Conflict of Interest
No conflict of interest

E31. Study into the clinical use and effectiveness of granulocyte colony-stimulating factor
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Background
Febrile neutropenia (FN) is one of the most serious treatment-related toxicities of cancer chemotherapy and can be prevented and treated with colony stimulating factors (CSFs). Given the high costs of the consequences of FN, and also of the CSFs themselves, CSFs need to be used correctly and optimally.

Methods
Descriptive and retrospective study designed in the form of a therapeutic audit, from May to July 2008.
The main objective was to evaluate the clinical use of granulocyte colony-stimulating factor (G-CFS; filgrastim) and to assess the degree to which the criteria of the American Society of Clinical Oncology (ASCO) were obeyed. The second objective was to determine the effectiveness of the G-CSF treatment.
Records were obtained from pharmacy dispensing of filgrastim. The following data was collected: age, gender, diagnosis, G-CSF indication, chemotherapy regimens and effectiveness.
Data is presented with its relative frequency and 95% confidence interval.

Results
A total of 245 treatments were assessed. The average age was 48.7 (range:11-81); 68.1 % were women, the principal diagnosis was solid tumour at 63.6%, the most frequent indication being breast cancer with 33.9%.
The principal indication was prophylaxis for chemotherapy with 77.2% of the cases (CI95%:72 to 82.4%). 60.3% of patients were at high or intermediate risk of febrile neutropenia (CI95%: 53.4 to 67.2%).
Other indications were: febrile or afebrile neutropenia (16.3%; CI95%:11.7 to 20.9%) and mobilisation of peripheral blood progenitor cells (5.7%; CI95%:2.8 to 8.6%). The percentage adherence to the ASCO criteria was 73.9% (CI95%: 68.4 to 79.4%) and the global effectiveness was 87.7% (CI95%: 83.6 to 91.8 %).

Conclusions
The use of filgrastim follows ASCO recommendations in our hospital and it is an effective treatment. The principal indication was prophylaxis for chemotherapy in solid tumours, although this could have been given better in cycles with a low risk of febrile neutropenia.

Conflict of Interest
No conflict of interest

E32. A pharmacy-led interdisciplinary project to optimize the use of analgesics
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Background
During routine clinical pharmacy on the orthopaedic wards of a large Austrian general hospital the use of pain medicine was identified as needing improvement in order to increase drug safety and improve patient care. An interdisciplinary project (pharmacy, orthopaedics, pain clinic) was started to analyse current analgesic drug usage and to develop and implement guidelines for postoperative pain medication in adult orthopaedic patients.

Methods
Pain medicine was assessed retrospectively using a newly-designed recording form after interdisciplinary agreement about the data to be collected. Interdisciplinary guidelines were developed and introduced for post-operative pain medicines for adults as specified for orthopaedic indications. After implementing the guidelines, pain medication was prospectively assessed using the same data collection form.

Results
The main analgesics-related problems found in the retrospective assessment of 200 patients were the excessive use of analgesics as "as-needed doses" (71%), under- or overdosing (33%), the combination of two or more NSAIDs at the same time (47%), the combination of a weak and a strong opioid at the same time (6%), the inappropriate use of drugs due to organ status (39%) and potential drug interactions with analgesics (9%). After the guideline had been introduced the assessment of 110 patients showed that the percentage of patients with "as-needed doses" was reduced to 38%, inappropriate doses to 26%, combination of NSAIDs to 8% and combination of weak and strong opioids to 5%. Unfortunately the percentage of patients who received analgesics regardless of their organ status was still 38% and 7% of patients were still at risk of drug interactions.

Conclusions
The project demonstrated that our interdisciplinary effort to optimise the use of analgesics was successful and resulted in improvements in drug

safety and patient care. The findings also suggest that more work needs to be done to further promote the appropriate use of medicines - an opportunity for clinical pharmacy.

Conflict of Interest
No conflict of interest

E33. Standard treatment protocol in the Electronic Patient Medications Module

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Objective
The aim was to use the function "standard treatment protocol" in the Electronic Patient Medications Module (EPM) when prescribing. The benefits of using the standard treatment protocol are that the doctor saves time when prescribing; the IV treatment is prescribed as solutions; the nurses can see how to prepare the IV treatment and there is a discontinuation date, to make sure that the prescription does not continue indefinitely. Furthermore the use of standard treatment protocols ensures that the department's treatment guidelines are followed and the patients therefore receive the correct treatment regardless of the prescribing doctor. All the aspects mentioned increase patient safety.
At the request from the prescribing doctors, pharmacists in the hospital pharmacy set up admixtures for IV treatment with the right infusion solutions in the EPM setting module. Pharmacists ensured that the allowed admixtures were stable and compatible.
For the last couple of years, two departments from The Heart Centre at the Copenhagen University Hospital have worked with the standard treatment protocol.

Method
A doctor with rights to work in the EPM setting module sets up the standard treatment protocol and pharmacists stand by as consultants.

Results
At present the EPM includes about 1250 admixtures and this number is expanding. The department of Cardiology and the department of Thoracic Anaesthesiology have at present set up 95 standard treatment protocols.

Conclusions
The two departments have taken the standard treatment protocols into practice and they are used routinely. Every day the doctors and nurses experience the benefits of using the standard treatment protocol as part of the EPM.

Conflict of Interest
No conflict of interest

E34. Analysis of pharmacist intervention supports used for drug therapy recommendations

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Background
Clinical pharmacists can improve patient outcomes through central or ward activities. Drug-related problems, and consequently pharmacist clinical interventions, are transmitted to prescribers in a written form. The aim of this study was to assess the understanding of these interventions transmitted to the medical team.

Method
All interventions written by the five pharmacists of team, between 1 January and 31 May 2009, were classified into 5 groups (one group for each pharmacist). 20 reports were chosen randomly from each group. The total of 100 reports was then examined by a clinical pharmacist from another hospital and by a physician not working on the medical wards involved in the study. We wanted to assess the understanding of the report (drug-related problems, risks, interventions) by comparing medical and pharmaceutical vision.

Results
110 pharmaceutical interventions were assessed (7 reports described several interventions). The drug-related problems were more difficult to understand than the other interventions, for the prescriber and for the pharmacist. The interventions were well understood by the prescriber (80%) and by the pharmacist (74%). The items less understood by the prescriber were the totality of the intervention (55%) and the drug-related problem (54%) and risk (46%) for the pharmacist. Lack of understanding was related to problems of form and content. More details about interventions (76%) and drug-related problems (28%) were wanted by the pharmacist for a better overall understanding. The physician also wanted more details about the risk to the patient (83%) in cases of drug problems.

Conclusions
The pharmaceutical team will now state the risk to the patient in more specific terms and describe any drug-related problems and interventions in more detail (using the French Society of Clinical Pharmacists classification). The model used in our hospital will be improved in order to meet this objective. Finally, training in written communication will be suggested to pharmacists to improve the transmission of information between health professionals.

Conflict of Interest
No conflict of interest

E35. Quality assessment of pharmaceutical records used for inpatients in a general hospital

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Background
Since October 2004, a pharmaceutical file has been created for each patient admitted to our hospital. The different wards are on a unit dose system for collecting patient data and for interventions made for the patients. The aim of this study was to evaluate the quality of the records used for these inpatients.

Method
On a given day, all pharmaceutical records from each unit were evaluated by two pharmacists not associated with the unit. The following data were analysed: patient characteristics, medication history, critical biological data and therapeutic monitoring. The evaluation was looking for missing data, quality of understanding, and facilitation of the pharmaceutical validation of prescriptions. The explanations and consequences of lack of information were discussed with each ward pharmacist.

Results
107 pharmaceutical records were analysed. Patient characteristics were complete for only 7% of records. The most frequently data missing were patient weight or height (74%), knowledge of allergy (66%) and clinical data (42%). Medication history was complete for only 15% of records. Therapeutic follow up was complete for 31% of patients, justification of treatment were missing for 47%. The principal explanations were the lack of information in the patient file (25%), failures of transmission (lapses) (24%), lack of time (18%), recent admission of the patient (15%), absence of the referring pharmacist (5%). No consequences were seen in 50% of cases, but in 39% of records, the pharmaceutical interventions were delayed and in 3%, were not appropriate.

Conclusions
Quality can be improved, mainly in collection of patient data (weight, size, allergy), drug history and notification of pharmaceutical interventions. Our records have been modified with the agreement of the team of pharmacists. Otherwise, computerisation of patient files could enable more information to be exchanged.

Conflict of Interest
No conflict of interest

E36. Comparative study of compliance, clinical events and quality of life, in renal transplant patients treated with tacrolimus and sirolimus.

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Background
Tacrolimus (FK) and Sirolimus (SRL) are immunosuppressives used in renal transplantation with different characteristics, namely mechanism of action, daily dosage and adverse effects, which may cause differences in compliance, clinical events and quality of life (QoL).

Objective
To compare patients from the two groups (FK/SRL) regarding treatment compliance using "compliance self-reporting" (CSR); clinical events potentially attributed to non-compliance and self-perceived QoL.

Method
Observational, prospective study of 49 patients (SRL:31; FK:18), taking the medicine for a comparable length of time (FK: 125±20days; SRL:140±32days). We adapted the "Brief Medication Questionnaire" to assess self-reported compliance (Adherent patients: self-reported absence of non-compliance). We used patient interviews, prescriptions review and medical records to identify clinical events. To evaluate self-perceived QoL, we used the "End-Stage Renal Disease Symptom Checklist – Transplantation Module" (ESRD-SCL), at the end of the study (self administered). SPSS 11.5 was used for data processing: comparison of groups by Student's t test or Mann-Whitney U test, and χ^2 test or Fisher's exact test. Statistical significance threshold $p < 0.05$.

Results
Group baseline characteristics were essentially similar, males predominating and age comparable (mean: 47 years). Baseline immunosuppression was primarily triple (77.8% patients with FK and 87.1% with SRL), mostly of the (SRL/FK) + Mycophenolate Mofetil + Prednisone type.
When measuring compliance, FK and SRL groups were comparable: FK–94.4% adherents; SRL–93.5% adherents. SRL and FK groups were comparable regarding clinical events, except side effects potentially due to the studied drugs, which were experienced by more patients in the SRL group (71.0% versus 33.3%; p=0.010). Six-scales and global scores of QoL questionnaire were comparable (global: FK–1.012±0.683; SRL–1.029±0.499).

Conclusions
Although the groups used different immunosuppressives, neither compliance results, nor clinical events, were related specifically to one or other studied drug. A high percentage of adherence was found except due to side effects, or QoL. The low global QoL score showed that the effect of disease and treatment on the patient's life was self-perceived as not so negative.

Conflict of Interest
No conflict of interest

E37. Pharmaceutical care at a thoracic and abdominal surgical ward

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Background
The identification of at-risk patients and accurate management of their drug treatment are important challenges to avoid serious clinical consequences caused by drug-related problems (DRPs).

Method
All patients of a thoracic and abdominal surgical ward of a university hospital with a total of 30 beds were evaluated in a prospective single-centre study design over a twelve-month period. The time spent by pharmacy staff was max. 90 min every working day. Clinical pharmacy review of pharmacotherapy on ward rounds and from case notes were documented and DRPs identified were classified using a modified Pharmaceutical Care Network Europe (PCN) system version 5.01 German Edition.

Results:
In the study period 4013 drug prescription records were reviewed for a total of 29131 prescriptions. 1148 interventions were made regarding 697 documented DRPs (2.4% of prescriptions). 548 (78.6%) of the DRPs were considered as completely solved and 26 (3.7%) as partially solved. The outcome of the intervention was not known in 86 (12.3%) of the cases. 315 (45.2%) DRPs were related to changes due to the unavailability of the patient's home medicines in the hospital formulary (P6). Other main causes of DRPs were dosing problems (196; 28.1%, P3) and drug choice problems (157; 22.5%, P2).

Conclusion
The involvement of a pharmacist as part of the multidisciplinary team on the surgical unit can improve patient safety and support the choice of drug therapy by the physician.

Conflict of Interest
No conflict of interest

E38. Global evaluation of treatment with monoclonal antibodies and anti-tumour necrosis factor in rheumatoid arthritis, Crohn's disease and psoriasis

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Background
The introduction of biological response modifiers (BMRs) obtained by recombinant technology has changed the treatment of autoimmune diseases. Some unexpected and severe adverse reactions occur and strict pharmacovigilance is needed for their use. In our study we aimed to monitor the use of these drugs in a central general hospital.

Method
Retrospective observational study of patients treated with BMRs (adalimumab, infliximab, efalizumab and etanercept) in outpatient clinics between January 2004 and December 2008. Data were obtained on previously structured forms, processed using a statistical analysis programme.

Results
20 patients included, average age 45.5 years (range: 28-66), 11 male (M), 9 female (F) Diagnosis: Psoriasis 10, (5 M, 5 F); Crohn's disease 7 (5M, 2F); other diseases: 3. Drugs used: etanercept: 11; infliximab: 6; efalizumab: 2; adalimumab: 1.
We recorded side effects in 3 patients: 2 on infliximab (fever; inflammation at the injection site); 1 on etanercept had a rise of hepatic enzymes (AST, ALT).
Infections were noted in 4 patients: 2 pulmonary tuberculosis (1 on infliximab; 1 on efalizumab), 1 cellulitis and 1 lower respiratory infection that needed intensive care (both on etanercept). In 12 of 20 patients the biological response modifying drug prescribed initially was stopped because: efalizumab in 2 after FDA drug alert; tolerance developed leading to interruption of the medicine in 4 patients on etanercept and 1 on infliximab.

Conclusions:
Despite some limitations of this work, especially due to the small sample size, difficulties in the subjective and objective evaluation of the state and evolution of the disease, the centralization of distribution by pharmaceutical services has enabled us to improve monitoring and

follow up patients better.

Conflict of Interest: No conflict of interest

E39. Introducing a Department of Cardiology to patient-specific clinical pharmacy

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Background
In recent years there has been an increasing focus on the value of clinical pharmacists in improving patient safety and optimising drug therapy. At several hospitals in Denmark clinical pharmaceutical services including medicines reviews performed by clinical pharmacists have been successfully implemented. However, at Aarhus University hospital, Skejby, Denmark the benefits of patient-specific clinical pharmacy have not yet been recognised.
In this pilot study we offered the Department of Cardiology medicines reviews performed by an experienced clinical pharmacist for one month free of charge. The aim was to introduce the department to patient-specific clinical pharmacy.

Methods
For one month a clinical pharmacist conducted medicines reviews on patients admitted to B2, a ward at the Department of Cardiology. The pharmacist identified drug-related problems, and the recommended changes to medicines were presented directly to the attending physician. The following day the pharmacist checked if the intervention had been accepted and implemented. At the end of the period the results were analysed and presented to the physicians.

Results
The pharmacist reviewed the medication of 118 patients. In one out of two patients (49 %) changes to the medicine were recommended. Sixty-nine percent of the recommendations were accepted and implemented. The physicians thought that the dialogue with the clinical pharmacist during the study period had been valuable and they expressed a need for further co-operation.

Conclusion
The department has been introduced to patient-specific clinical pharmacy and has recognised the value. The project was successful. We therefore suggest that this is a way to increase the knowledge of, and demand for, patient-specific clinical pharmacy.

Conflict of Interest
No conflict of interest

E40. Pharmaceutical care to inpatients with impaired renal function under antimicrobial treatment

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Background
Inappropriate use of drugs in patients with renal impairment may be harmful. Most antimicrobial drugs must be dosed based on estimated glomerular renal filtration.

Objective
To monitor individually inpatients with renal impairment taking antibiotics to detect antibiotic-related problems (ARPs).

Methods
Prospective and descriptive 4-month study in a general university hospital. Inpatients over 16 years with at least one estimated clearance value below 50 ml/min and intravenous antibiotics were selected. Critical and onco-haematological patients were excluded. All included patients were monitored daily by a pharmacist. If any ARPs were detected, a recommendation was made to the prescriber. Patients were evaluated until discharge. Data were analysed by SPSS.
Demographic data (age, sex, comorbidities and renal impairment according to the Spanish Society of Nephrology), hospital ward, type of infection(s) and antibiotics were recorded. ARPs were classified by category, type of problem, cause of problem and severity of problem.

Results
78 patients (28 women, median age =81and comorbidities = 4, renal impairment = 50% mild, 48% moderate, 2% severe). Most were hospitalised in Internal Medicine and Geriatric wards (30% and 47% respectively). The antibiotics most commonly involved were beta lactams (54%) and the most frequent type of infection was community-acquired pneumonia (50%).
53 patients had at least one ARP (total 79 ARPs) and 71 recommendations were made (83% were accepted). Category of ARP: indication 14% (11), efficacy 39% (11) and safety 47% (37). Type of problem: additional antibiotic needed 4% (3),antibiotic was unnecessary 10% (8) or inappropriate 30% (24), sub-therapeutic dose 8% (7), adverse event 23% (18), and excessive dose 25% (19). Common causes: inappropriate dosage/interval 34% (26) and administration via 26% (21). Nearly 50% patients needed a change of antibiotic or increased monitoring.

Conclusions
The number and seriousness of antibiotic-related problems detected in patients with renal impairment showed the importance of this area of pharmaceutical care. Recommendations were well accepted.

Conflict of Interest
No conflict of interest

E41. analysis of prescriptions and impact of pharmacists' interventions in medical post emergency unit

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Objective
In order to make the sequence of prescribing, dispensing and administration safer, a daily pharmaceutical validation was initiated in a medical post-emergency unit (PME). The aim of this study was to evaluate the pharmaceutical interventions carried out. This analysis aimed at bringing the pharmaceutical and medical teams closer by means of regular activity on site.

Method
Since May 2009, every week, from Monday to Friday, on site at the PME unit, a pharmacist has validated all inpatient prescriptions and recorded all recommended interventions on them. All the interventions are examined according to the "pharmaceutical intervention card" suggested by a working group of the French Clinical Pharmacy Society: drug problem, intervention, drug family (according to ATC classification), physician's decision.

Results
From May to September 2009, 954 prescriptions were validated with a daily average number of inpatients equal to 13. 140 prescriptions (15%) gave rise to an intervention. The main errors found concerned non-standard choice of drug (32.8%), inappropriate route and/or administration (22.1%), drug interactions (18.5%) and dosage errors (15.7%). The pharmacist intervened by proposing a therapeutic or generic alternative (34.2%), by optimising the methods of administration (20.7%), by adding or stopping treatment (15.7%), by reinforcing therapeutic follow-up (15%) and by changing the dosage (14.3%). The principal therapeutic families concerned were: Digestive tract and metabolism (28.6%), Nervous system (21.4%), Cardiovascular system (18.6%), and Anti-infectious agent (13.6%). Almost all of the suggested interventions were acted on by a physician (82.9%). Some drug interactions were not considered important by the physician, but they were always justified.

Conclusion

We underline that a significant number of interventions improved the way the medicines were used. Moreover, a pharmaceutical presence on site allows rapid interventions with the medical team which is able to consider the remarks and act accordingly. With the pharmaceutical team on site, the medical staff is better acquainted with the role of the pharmacist.

Conflict of Interest
No conflict of interest

E42. Evaluation of a computerised decision support system for drug switching at the interface between primary and tertiary care

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Background
On hospital admission patients' medicines frequently need to be switched to alternative drugs due to restricted hospital drug formularies (HDF). This substitution process is complex, error-prone and also time-consuming as it is performed in German hospitals over a hundred million times each year. Thus, a sophisticated computerised decision support system (CDSS) would be an elegant way to solve this common problem.

Methods
Based on a multi-step interchange algorithm [1] we developed and implemented a CDSS for drug switching as part of a computerised physician order entry (CPOE). To evaluate its functionality we switched the medication of 174 consecutive patients admitted to surgical wards (1176 drugs) and compared the results with those of manual switching by clinical pharmacists (CPs) in daily routine. Recommendations that disagreed were reviewed by an experienced CP who was blinded for the origin of the suggestion.

Results
Of 1176 drugs 828 (70.4%) drugs were substituted similarly by CPs and CDSS, i.e. identical drugs and dosage regimen were suggested. In 348 (29.6%) cases a different drug or a different dosage regimen resulted from automatic and manual switching. Revision of these differences revealed that in 38.2 % both suggestions were appropriate, in 28.5 % the CDSS result, and in 33.3 % the initial switch by a CP was assessed as superior. Hence, ultimately in 1060 cases (90.1%) the suggestions issued by the CDSS were appropriate. For 116 drugs (9.86%) the CDSS had no suggestion or was not able to suggest an adequate dosage regimen. No (0%) incorrect drug switch, e.g. with potential to harm patients, was suggested by the CDSS.

Conclusions
The results demonstrate that switching drugs automatically at hospital admission is possible for a large majority of cases (>90%).
Consequently CDSS for switching drugs can help save time and reduce the work load of healthcare professionals.

(1) Walk SU, Bertsche T, Kaltschmidt J, Pruszydlo MG, Walter-Sack I, Haefeli WE. Rule-based standardised switching of drugs at the interface between primary and tertiary care. Eur J Clin Pharmacol 2008; 64:319-27.

Conflict of Interest
No conflict of interest

GROUP F: DRUG INFORMATION

F1. Use of anidulafungin in a reference hospital

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Background
Anidulafungin is an antifungal introduced into our hospital to treat invasive candidiasis in critically neutropenic patients with other health problems (immunosuppression, renal or hepatic impairment) and for triazole-resistant strains. The recommended dose is 200mg IV on day 1, followed by 100 mg IV/day, continuing for at least 14 days after the last positive culture. The objective was to analyse the conditions of use in a reference hospital and check that the pharmacy's protocol for use was being followed.

Method
Retrospective descriptive study of patients treated with anidulafungin from January 2009 to October 2009. Data collected: age, ward, neutropenic state, fungus isolated, renal/hepatic impairment, previous antifungal treatments, indication, treatment duration and clinical outcomes.

Results
11 patients were treated with anidulafungin. Average age was 63.1 years. The wards with most prescriptions were the infectious diseases ward and general surgery. All patients were neutropenic and 8 (72.8%) had renal and/or hepatic impairment.
Microbiological test results: C. albicans (4), C. parapsilosis (2), C. glabrata (2),C. tropicalis (2) and 1 negative blood culture. 6 patients (54.54%) had received no previous antifungal treatment, 4 (36.3%) had been treated with fluconazole previously and 1 patient (9%) with fluconazole and caspofungin. Average length of treatment was 6.8 days, in 91% of cases under 14 days and 7 patients (63.6%) received a loading dose. The agent was authorized for patients with renal and/or hepatic insufficiency (7), critical patients (2) and fluconazole-resistant (2). 6 patients (54.54%) had a good response (afebrile), 4 (36.3%) died and 1 patient (9%) didn't respond.

Conclusions
1. All patients received an appropriate dose, although 4 patients didn't received a loading dose.
2. Treatment duration was shorter than the recommended time.
3. Prescribing adhered to the hospital protocol in all cases.
4. Pharmaceutical monitoring would be advisable to improve the use.

Conflict of Interest
No conflict of interest

F2. Appropriateness of off-label uses of human intravenous immunoglobulin

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Background
The indications authorised in Italy for human intravenous immunoglobulin (IVIG) are continually being revised by the Italian Medicines Agency. By comparing the first half of 2009 with 2008 it is clear that the use of IVIG replacement therapy in primary and secondary immunodeficiency and in allogeneic transplant has not changed. As for the treatment of autoimmune diseases, the only diseases for which IVIG treatment was retained were idiopathic thrombocytopenic purpura and Guillain-Barré syndrome. In the treatment of myasthenia gravis, multifocal motor neuropathy, chronic inflammatory polyneuropathy and mixed connective tissue disease unresponsive to traditional treatment, the use of IVIG changed, becoming off label in 2009.

Methods
From January to June 2009 prescriptions for and consumption of IVIG were monitored. The aim was to focus on those departments most involved in off-label treatments, for example neurology, kidney dialysis and transplant, rheumatology.

Results
The total consumption of IVIG in the first quarter of 2009 was 7446 units, 2979 (40%) of which was off label. The departments involved in using IVIG outside of authorised indications were the following: neurology, with 2680 units (27%), rheumatology, requiring 12 units (0.2%) from the pharmacy, and nephrology which required 97 units (1.3%). On 15 May 2009, the internal pharmaceutical board, a business group assigned to evaluate off-label use, approved the use by the department of nephrology and dialysis of IVIG in kidney transplant patients. Further requests for approval of off-label use from other departments are awaiting assessment by the board.

Conclusions
The use of IVIG for many diseases still remains a controversial issue due to the continuous evolution of authorised indications. Further knowledge of disease mechanisms and mode of action of immunoglobulins in various diseases will probably allow more rational clinical use.

Conflict of Interest
No conflict of interest

F3. Evaluation of vitamin supplements marketed in Spain

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Background
A balanced and varied diet usually supplies the body's requirement for vitamins. The use of vitamin supplements (VS) should be restricted to the treatment of specific nutritional deficiencies and also to the prevention of these deficiencies in risk groups. The fact that these drugs are self-prescribed and the wide variety of different compositions available may lead to the toxic accumulation of lipophilic vitamins A and D. Megadoses of hydrophilic vitamins are not scientifically justified and may cause adverse effects.

Objective
To analyse VS marketed in Spain as pharmaceutical specialities, to check if different formulations are equivalent and whether they achieve the Recommended Daily Allowance (RDA).

Methods
- The composition was checked of the main VS marketed (2009) in Spain that belong to the therapeutic groups A11A (multivitamins preparations, mineral combinations), A11JA (vitamin combinations) and A11JC (other vitamin combinations).
- The quantity of vitamins that each speciality provided in relation to the RDA was checked. We did not investigate the quantity of minerals provided by each preparation because they were low in relation to the RDA.
- Preparations that we considered incomplete were excluded from the study.
- In order to compare the different VS, we took each chemical separately.
-

Results
From the 17 preparations registered, 8 were analysed and 6 exceeded RDA. Dosing range; 1-4 units/day.
The following table describes the quantity of vitamins that each VS provides in terms of the RDA (%);

Vitamin (%)	Dayamineral	Elevit	Hidropolivit A mineral	Pharmaton complex	Redoxon complex	Vitagama fluor	Protovit	Forcemil
A	93.8	72.9	93.8	30.4	30.4	151.9	60.8	48.9
D	500.0	250.0	250.0	100.0	200.0	100.0	450.0	200.0
B_1	736.4	109.1	181.8	145.5	145.5	81.8	145.5	109.1
B_6	85.7	185.7	66.7	57.1	142.9	57.1	114.3	114.3
B_9	125.0	-	50.0	-	-	-	-	200.0
B_{12}	200.0	160.0	80.0	40.0	200.0	-	-	240.0
C	187.5	125.0	50.0	75.0	125.0	62.5	100.0	75.0

Conclusions
- No VS match the RDA.
- Self-prescription of VS should be avoided because most of them provide too large a quantity, which is not safe.
- The use of VS should be checked by a health professional as their composition varies.

Conflict of Interest
No conflict of interest

F4. Effectiveness and safety of rituximab for idiopathic thrombocytopenic purpura

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Objective
To measure the effectiveness and safety of use of rituximab (RTX) in patients with idiopathic thrombocytopenic purpura (ITP).

Method
Observational retrospective study of the use of RTX at a dose of 375mg/m2 weekly (4 doses) in patients diagnosed with ITP (except one patient who was administered 1g/15 days).The variables recorded were: age on diagnosis, sex, cause of the ITP, mean time from diagnosis to the first dose, previous treatments and treatment cost. To evaluate the effectiveness we measured platelet count, defining full recovery as > 100,000 PLT/µL, partial recovery 50-100,000 PLT/µL and minimum recovery < 50,000 PLT/µL. We measured levels prior to treatment, after 4 doses and at 6 months. As a safety measure we determined the most frequent adverse secondary effects observed.

Results
We studied 7 patients, 3 men and 4 women with a mean age of 38 years (2-77). The causes that had triggered ITP were immune system disorders (43%), infections (28.6%) and unknown causes (28.4%). All the patients had failed to respond to previous treatments, including immunoglobulins (85.7%), corticoids (85.7%), splenectomy (42.8%), danazol (17alpha-ethinyl testosterone) (28.5%), gamma globulin anti D (14.2%), vincristine (28.5%) and desmopressin (14.2%).The mean time from diagnosis was 45 years (10-77). All the requests for medication were handled as compassionate use. The mean number of previous treatments was 3.
The mean platelet count before start of treatment was 39,000 PLT/µL (4,000-82,000).After one cycle, 4 patients recovered fully (57.1%) and 3 did not respond (42.8%). At six months, 3 patients had recovered fully (60%), 1 had partial recovery (20%), and 1 minimum recovery (20%).Only 2 patients (28.5%) showed adverse secondary effects (related to the infusion and gastric repletion).The mean treatment cost was 6,091 €.

Conclusion
RTX is a therapeutic alternative in patients with ITP that is resistant to other treatments. A full recovery was demonstrated in 57.1% of patients after 4 doses and in 60% after 6 months of treatment. It is a well tolerated drug with 71.5% of patients not suffering adverse secondary effects.

Conflict of Interest
No conflict of interest

F5. Quality assurance in a newly established Question & Answer Medicines Information Centre

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Background
In March 2009 a Question and Answer Medicines Information Centre "MedicinInfo" run by clinical pharmacologists, pharmacists and pharmacy technicians was established in the Capital Region of Denmark. Pharmacologists, pharmacists and pharmacy technicians are all following a new common standard operating procedure (SOP) for the quality assurance of each query, depending on its complexity and category. To ensure uniformity in data collection, a common registration form was developed. The form is used to record quality parameters that are used in the quality assurance and quality control system. Parallel to this all questions and answers are recorded in databases for documentation and statistics.

Methods
Incoming questions are recorded on the common registration form. The form provides information about the date and time of the query, and a deadline for the answer. When answering, the actual time is recorded. The aim is to answer within 24 hours or alternatively within the time limit stated by the questioner. A group of experienced employees performs audits. Samples of queries from the databases are reviewed to assure that the SOP is followed and both pharmaceutical and clinical aspects have been considered. The quality of the answers is assessed in terms of response time, relevant sparring, scope and level of professionalism.

Results
Audit was performed three times during the first six months. 64 cases out of a total of 1580 queries were reviewed. The quality criteria were met as follows:

Criteria	Result (%)	Aim (%)
Response time <24h	77	80
Response time < time limit stated by the questioner	94	100
Relevant sparring	100	100
Scope	89	100
Level of professionalism	95	100

This shows that the common SOP is being followed and quality is good. The audit process is still under evaluation. The presentation will provide updated data based on the first 10 months with MedicinInfo.

Conclusions
Audits show that quality is good, though sample size is small. The common SOP is followed and response times lie within acceptable limits.

Conflict of Interest
No conflict of interest

F6. Bendamustine in the treatment of relapsed B-cell non-Hodgkin's lymphoma (NHL): Revision of the therapeutic strategies in a case report

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Background
Bendamustine is an alkylating agent, approved by the US Food and Drug Administration (FDA) on October 2008 to be used in combination with other chemotherapy in the treatment of chronic lymphocytic leukaemia (CLL) and in progressed indolent B-cell non-Hodgkin's lymphoma (NHL). The aim of the study was to describe the use, effectiveness and safety of this drug.

Methods
The subject of this study was a 67-year-old man with B-cell NHL. Data obtained from the medical report and pharmacy database were: age, sex, diagnosis and previous pharmacological therapy. The use of bendamustine was evaluated for adherence to labelled indications. Effectiveness was measure by radiological progression. Safety was checked based on reported adverse drug reactions.

Results
In 2002 the patient was diagnosed with B-cell NHL and was given the CHOP-R regimen (cyclophosphamide + doxorubicin + vincristine + rituximab) for 8 cycles, without achieving complete remission. After relapse in 2007, fludarabine 25 mg/m2 + cyclophosphamide 1000 mg/m2 + rituximab 375 mg/m2 were scheduled for 6 cycles. In May 2009 there was an increase in the size and number of lymphadenopathies (scanned with computerised axial tomography) and he was diagnosed with relapsed B-cell NHL. He was prescribed rituximab 375 mg/m2 on day 1 + bendamustine 90 mg/m2 intravenously on days 2 and 3, every 28 days for up to 6 cycles. Rituximab infusion was also administered 7 days before the first cycle. At the moment he has received 5 cycles of chemotherapy. At his last check up (September 2009), there was radiological improvement with a reduction in lymphadenopathies. Grade 3/4 myelosuppression was reported, but it was not necessary to suspend treatment.

Conclusions
In our case, bendamustine was used according to the labelled indications. For the treatment of relapsed B-cell NHL bendamustine-based treatment was safe and effective. However, the patient needs to be followed up to evaluate long-term outcomes and adverse reactions.

Conflict of Interest
No conflict of interest

F7. Treatment of basal cell carcinoma with intralesional interferon alpha

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Background
Basal cell carcinoma (BCC) is the most common skin cancer. The first-line treatment is usually surgical excision, but these tumours appear on the face and the cosmetic result is often important. Cell-mediated immunity appears to be important in the pathogenesis of BBC and the immune system may contribute to protection in this disease.

Method
Retrospective study in a tertiary hospital in Spain. All patients treated with intralesional IFN-alpha-2b were recruited. The following information was collected from the clinical histories: location and size of the tumour, dose and number of cycles with interferon and previous treatment with other alternatives. Treatment consisted of a course of 9 intralesional injections of interferon alpha-2b 3 days each week for 3 weeks. Each injection contained 1.5 or 3 million units dissolved in 0.2-0.5 ml water.
The response was classified as cure /reduced tumour size /enlarged tumour and recurrence. After treatment subjects were reviewed every 3 months and some patients are currently under review. Side effects were recorded.

Results
Thirty-nine patients were recruited (21 males and 18 females). The median age was 62 years old (range 30-76). The tumour site was nasal in 29 (74.3%) patients, ocular in 6 (15.3%), back of hand in 1 (2.5%) and ear in 3 (7.7%). After treatment the tumour was cured in 26 (66.7%) patients, size reduced in 2 (5.1%) and enlarged in 11 (28.2%). At the 3rd review, the tumour was cured in one more patient (2.5%) but it reappeared in 2 (5.1%). The total of patients with recurrence at 6 months was 8. The median follow-up time was 24 months (range: 3-108 months). The tumour has currently disappeared in 17 (43.5%) patients, a new basocellular carcinoma has appeared in 5 (12.8%) patients and surgery has been performed in 16 (41.0%). Side effects were mild.

Conclusion
IFN-alpha-2b is a useful agent for treating BCC in selected patients. Its non-surgical approach and excellent cosmetic results make IFN-alpha-2b an attractive option for patients when other treatment is impractical or contraindicated and it is not expensive.

Conflict of Interest: No conflict of interest

F8. Analysis of body weight gain in patients treated with the second-generation antipsychotic drugs in Tokushima University Hospital

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Background
The Tokushima prefecture in Japan has been reported as having a high prevalence of type 2 diabetes and obesity; therefore, adverse drug reactions, such as overeating and body weight gain are more important determinants of poor adherence to antipsychotic treatment. In the present study, we examined the incidence of body weight gain caused by their drugs in Tokushima University Hospital.

Method
Inpatients treated with the second-generation antipsychotic drugs (aripiprazole: n=20, olanzapine: n=30, quetiapine: n=36 and risperidone: n=42) were monitored retrospectively between January 2008 and September 2009. Body weight was measured once a week until 12 weeks after the start of the treatment. Clinical risk factors (age, gender, baseline Body Mass Index (BMI), drug dosage and type of disease) were tested for their association with body weight gain.

Results
The absolute and percentage average weight gains were significantly higher for the olanzapine group than for other groups. The percentage of patients who gained at least 7% of their baseline body weight with olanzapine in 12 weeks was about 50%, which is much higher than data on the attached document for olanzapine. In addition, higher rate of body weight gain by olanzapine was significantly observed in female compared to male, and the degree of body weight gain was negatively correlated to age and baseline BMI. On the other hand, there was no significant relationship between body weight gain and dosage of olanzapine.

Conclusions
Because adverse events such as body weight gain are attributed to not only antipsychotic drugs but also genetic and environmental factors, it could be helpful for pharmacists to evaluate the frequency and predicted severity of adverse events in an individual hospital. The local data based on the actual measurements must be more useful for the decision on pharmacotherapy and the improvement of adherence to treatment.

Conflict of Interest
No conflict of interest

F9. entecavir in patients with chronic hepatitis B virus (HBV) infection: effectiveness and safety of treatment after 24 weeks of treatment

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Aim
To evaluate the effectiveness and safety of treatment with entecavir in patients with chronic hepatitis B virus (HBV) infection, after 24 weeks of treatment.

Material and methods
1. An observational retrospective study of patients being treated with entecavir in our health area. Data was collected from:
2. Database from the out-patient prescription program.
3. Laboratory tests: HBV DNA, transaminases, albumin, bilirubin, and platelets.
4. Revision of the clinical histories.

Results
During the follow-up period we evaluated 4 patients (2 men and 2 women) with a mean age of 57.7 years. All the patients received 0.5 mg of entecavir every 24 hours, with the mean duration of treatment being 10.5 months (range 8-15).
Quantification of HBV DNA was carried out for all patients using PCR before starting treatment and at 24 weeks, with a clear reduction in the viral load being observed in all cases.
The biochemical data was as follows:
The transaminases values normalized in all four patients. Alterations in the albumin levels were not observed. Total bilirubin was increased in one case. Platelet counts were maintained within the normal range, except in one patient who started treatment with low levels and in whose case the counts increased within the study period but did not reach normal levels.

Conclusions
After 24 hours of treatment, entecavir has proven to be an efficient and safe drug, on observing clear reductions of viral DNA in all patients and without identifying relevant alterations in the biochemical parameters measured.

Conflict of Interest
No conflict of interest

F10. consumption of drugs with low therapeutic utility in a geriatric health and welfare center
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Objective
To describe the evolution of prescriptions of low therapeutic utility (LTU) in a geriatric health and welfare centre (GHWC) after the introduction of a pharmaceutical care (PC) programme. To evaluate the interventions made by pharmacists, clinical implications, financial evaluation.

Methods
LTU medicines were identified in the pharmacology guide (PG). 100% of LTU prescriptions were reviewed through the medical records prior to the PC starting and after one year. A database was set up to record interventions regarding LTU drugs. Medical records were examined to assess the effect on the patient. The economic impact of LTU drugs compared with overall drug expenditure was also assessed.

Results
LTU prescriptions included in PG: acetylcysteine (not associated with an antibiotic and non-COPD), betahistine, citicoline, pentoxifylline and topical piketoprofen and diclofenac. They represented 1.86% of all drugs included in the PG. Of the 125 patients admitted to the GNWC during the study period (November 2008 - September 2009) 35.2% had LTU prescriptions at baseline (25.45% analeptics (NO6D); 23.67% antivertigo (N07CA); 18.18% topical NSAIDs and antirheumatic preparations (M02AA); 16.35% protective capillaries and peripheral vasodilators and 16.35% others). Per year: 19.2% patients (N06D: 44.82%; N07CA: 41.38%; M02AA: 6.9% and 6.9%).

During the study period, 42 interventions were performed regarding LTU drugs, with a degree of acceptance of 90.5%. 32 led to the withdrawal of the LTU drug and 4 to substitution of a LTU medicine. There were no reintroductions of LTU drugs previously withdrawn, nor was it necessary to add new drugs to replace them. LTU drugs consumed during the study period accounted for 9.70% of the drugs expenditure of GHWC, citicoline being responsible for the 83.60% of that figure.

Conclusions
The treatment group most prescribed was N06D: 44.82%.
The incorporation of a pharmacist decreased the prescription of LTU drugs in GHWC. Unless a review of the current scientific evidence for citicoline can justify its use it should be removed from the PG.

Conflict of Interest: No conflict of interest

F11. Analysis of pharmacist`s opinions and experiences of generic substitution and generic drugs in the Czech Republic
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Background
Generic substitution is a common element of health care systems. Generic substitution was established in the Czech Republic by law in January 2008. The aim of this study was to examine pharmacists' opinions and experiences of generic substitution and generic drugs after the first year of the new law in the Czech health care system.

Method
Data for the prospective study were collected by questionnaire. The questionnaire was sent to 7450 members of Czech Chamber of Pharmacists as a component of the pharmacy journal in December 2008. Demographic characteristics of the pharmacists were recorded in the first part of the questionnaire. The second part of the survey focused on the general principles of generic drugs and generic substitutions. In the third part, respondents were asked their opinions of, and experiences with, generic substitution. Data were evaluated by SPSS statistical software.

Results
Questionnaires from 615 respondents were received and evaluated. Basic characteristics of the respondents: mean age 37.5 years; 429 were qualified to first grade of attestation in pharmacy; 345 pharmacists (56.1%) had already been taught about generic drugs as undergraduates. 71 pharmacists (11.5%) were able to select correctly the essential conditions for generic substitution. A generic drug was bioequivalent to a branded medicine according to 378 (61.1%) respondents. More than 75.0% of respondents needed more information on how bioequivalent tests are conducted for generic drugs. Reduced costs and increased pharmacist status were mentioned as the most important benefits of generic substitution. Correlation between respondent characteristics and experiences or opinions of generic drus and generic substitution will be presented.

Conclusions
On the basis of these relevant and exclusive data it is necessary to discuss generic drugs and generic substitution and to support effective cooperation between physicians, pharmacists and patients.

Conflict of Interest
No conflict of interest

F12. Use of protein-tyrosine kinase inhibitors
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Background
Study of the use of protein tyrosine kinase inhibitors (PTKI) in a tertiary hospital (January 04 - August 09).

Method
Descriptive and retrospective study based on the review of clinical histories of patients treated with PTKIs who were treated in our outpatient department. Information obtained: patient number, diagnosis,

treatment, dosage, adverse drug reactions (ADRs), evolution and cost.

Results
37 patients were evaluated.
Diagnosis: 83.8% Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+CML), 13.5% Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ALL) and 2.7% Hypereosinophilic Syndrome (HES).
Ph+CML patients: 100% used imatinib 400 mg/day, 25.8% of them needed an increase of dose. 67.7% continued imatinib treatment and 38.9% of them obtained a complete response. 32.3% of the patients stopped imatinib treatment: 20% died, 10% of ADRs and 70% due to lack of response, 42.8% of whom used dasatinib and 57.2% nilotinib as an alternative. 28.5% needed a second change of treatment due to lack of response.
Ph+ALL patients: 100% used imatinib 400 mg/day associated with chemotherapy. 40% of the patients continue with imatinib, being all in complete remission. 10% died and 50% needed change to dasatinib treatment for lack of response.
The HES patient was first treated with 100 mg/day imatinib, the dose was increased to 400mg/day, finally treatment was stopped for lack of response.
The most frequent ADRs described were gastrointestinal disorders 13.5%, skin disorders 13.5%, blood disorders 10.8% and muscular pain 8.1% for imatinib. Pleural effusion 28.6%, blood disorders 28.6% for dasatinib and blood disorders 40% for nilotinib.
Patients treated with PTKI represent 2.2% of the patients attending our ambulatory patient unit care and they are responsible for 7.9% of the total cost of this area.
At the moment 29 patients are being treated, 62.5%, with imatinib, 10.8% dasatinib and 5.4% nilotinib.

Conclusions
Our patients use PTKI according to the product information. Imatinib is always the first option. Dasatinib or nilotinib are only used when there is imatinib resistance/intolerance.
Monitoring these patients is necessary to improve the safety and quality of health care.

Conflict of Interest
No conflict of interest

F14. Development of a multidimensional system for classification and management of health information. Applying to clinical information.

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Introduction
The widespread use of information in the medical field creates management problems, requiring systematic methods for classification, filing and retrieval, integrating authorised biomedical terminologies and desirable characteristics oriented to structure, content and clinical results. The objective was to describe a multidimensional system for the classification and management of clinical information queries and test its applicability and capacity for retrieval.

Method
Three hundred questions were selected by a random electronic method (www.randomizer.org), from a six-year period. They were characterized according to the system and evaluated for applicability by the quantity classified and the need to alter the system. Retrieval was tested searching for information in one dimension or between dimensions.

Results
The system could be consulted by independent dimensions: type, scope, object, area and subject, defined by hierarchical concepts. Meaningless codes were created or other internationally accepted codes were adopted, incorporated by linking to external dimensions (i.e. ICD-10). The ontological relations help to retrieve clinical results, generating inferences to support clinical decisions.
All questions were classified: 53% were clinical cases concerning the genitourinary system; metabolic, nutritional and endocrine disease; cancer; infections and the nervous system. In 81%, the object was a drug, mostly anti-infectious and anti-neoplastic agents. The therapeutic and safety areas were the most requested. As to applicability, it was necessary to add some concepts and alter some hierarchical groups, but that did not modify the basic structure, or interfere with the desirable characteristics. Limitations were related to external classification systems. With the search between dimensions it was possible to retrieve information from any one of the levels of the hierarchy, from the most general to the most specific and even from external dimensions.

Conclusions
The use of the system in this sample showed its applicability in clinical information classification and filing, retrieval capacity and flexibility, supporting modifications without interfering with desirable characteristics. This tool allows retrieval of patient-oriented evidence.

Conflict of Interest
No conflict of interest

F13. Cost/utility analysis of information sources to answer clinical questions in a random sample of 2500 queries.

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Background
The policy of acquiring the use of medicines information resources is based on the analysis of frequently asked medicines questions by healthcare professionals and on the cost/utility relationship. The value of an information source has been defined as its utility relative to its cost. Utility is determined by evaluating the extent to which the source meets the need for information. Cost includes the purchase price, the time taken to access the source (availability), the time required to gather information (ease of use) and time spent in preparing a response.
The objective of this study is to evaluate the cost/utility relation of information resources.

Methods
A sample of 2500 questions was selected by a random electronic method (www.randomizer.org). They were classified, main subjects were identified and we calculated for how many of these subjects the resources provided answers. Cost was presented as a percentage of the total expenditure on resources. Utility was considered the degree to which it provided answers and cost based on purchase price.

Results
We identified 17 major subjects of clinical questions. Results shows that Micromedex contained the information needed to answer 13 subjects (47%), with average cost representing 21.86% of acquisition value. Equivalent results were also found for primary sources with full-text online access, which although representing the largest percentage of the total value of acquisitions (34.25%), contained information to answer 15 subjects (88.24%).
These results were obtained for all sources evaluated, with the exception of specialised sources, such as those used for special populations - pregnancy, geriatrics, paediatrics or poisoning. In these cases, although only containing information for a specific subject, their utility outweighs their cost.

Conclusions
The results will form the basis for selecting library resources, developing research strategies, evaluating users' information needs and planning the development of active information.

Conflict of Interest
No conflict of interest

F15. Physicochemical and biological comparability of a new biosimilar granulocyte-colony stimulating factor with its reference product

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Background
Development of biosimilars requires physicochemical and biological characterisation to show comparability with a reference product. Zarzio (filgrastim) is a recently approved recombinant human granulocyte-colony stimulating factor (rhG-CSF) which uses Neupogen as its reference product. A broad range of standard and advanced analytical methods was used to compare drug identity, purity and bioactivity of Zarzio (300 and 480 µg/0.5 ml solution) with Neupogen.

Methods
Peptide mapping with UV detection and mass determination, circular dichroism (CD) spectroscopy, NMR spectroscopy, matrix-assisted laser desorption/ionisation-time of flight (MALDI-TOF) mass spectrometry and liquid chromatography electrospray ionisation (LC-ESI) mass spectrometry were among the analyses used to compare primary and higher-order protein structure. Gel isoelectric focussing (IEF), cation and anion-exchange chromatography, capillary zone electrophoresis (CZE), and reverse-phase high performance liquid chromatography (HPLC) were used to compare polarity and charge. Biological characterisation included comparison of G-CSF receptor binding affinity by surface plasmon resonance spectroscopy, an *in vitro* cell proliferation assay, and Western blot immunological binding.

Results
The primary structures of Zarzioand Neupogen were shown to be identical by peptide mapping and other tests. CD and NMR spectroscopy demonstrated that both products have comparable secondary and tertiary structures. HPLC, CZE, IEF and other methods showed that both products had a similar impurity profile. Comparable affinity with the G-CSF receptor GCSFR/CD114 was obtained using surface plasmon resonance spectroscopy, and comparable *in vitro* bioactivity was shown in a cell proliferation assay. Similar affinity to anti-G-CSF antibodies were shown on a Western blot.
Conclusion
These results show the physicochemical and biological comparability of Zarzio and its reference product Neupogen.

Conflict of Interest
Yes: Other substantive relationships: Independent consultant pharmacologist involved in clinical development of Zarzio with Sandoz.

F16. Clinical development of a new biosimilar granulocyte colony-stimulating factor

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Background
Granulocyte colony-stimulating factor (G-CSF) is used to reduce the duration and severity of neutropenia in patients undergoing myelosuppressive chemotherapy and to mobilise peripheral blood progenitor cells. Zarzio (filgrastim) is a new approved recombinant human (rh) G-CSF biosimilar developed using Neupogen as the reference product. The pharmacodynamic (PD) and pharmacokinetic (PK) bioequivalence of Zarzio with Neupogen was evaluated in phase I studies. Efficacy and safety were assessed in a phase III trial in patients with cancer.

Methods
In four double-blind, randomised, two-period crossover phase I studies, 146 healthy volunteers received Zarzio and Neupogen as single or multiple-dose subcutaneous (SC) injections of 1 µg/kg (n=24), 2.5 µg/kg (n=28), 5 µg/kg (n=28) or 10 µg/kg (n=40) or as a single intravenous 5 µg/kg dose infusion (n=26). PD parameters evaluated were absolute neutrophil count (ANC) and CD34+ cell count. Filgrastim serum concentrations were measured and PK parameters analysed at predetermined time points. Supportive efficacy and safety data were obtained from a single-arm open-label phase III study in which 170 patients with breast cancer undergoing four cycles of doxorubicin and docetaxel chemotherapy received SC Zarzio(300 or 480 µg daily depending on whether body weight < or =>60 kg) from day 2 of each chemotherapy cycle.

Results
Zarzio and Neupogen had comparable effects on ANC and CD34+ count with confidence intervals within predefined equivalence boundaries. PK parameters also showed bioequivalence. In the phase III study, Zarzio was effective and well tolerated. None of the 316 subjects treated with Zarzio in these studies developed anti-rhG-CSF binding antibodies.

Conclusions
These phase I data confirm the comparability of Zarzio and its reference product Neupogen with respect to PD and PK profiles. The efficacy and safety of Zarzio was further confirmed in neutropenic patients with breast cancer receiving myelosuppressive chemotherapy.

Conflict of Interest
Yes: Other substantive relationships: Independent consultant pharmacologist involved in clinical development of Zarzio with Sandoz.

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17. First experiences with "MedicinInfo" - a Question and Answer Medicines Information Centre run by pharmacologists, pharmacists and pharmacy technicians

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Background
In March 2009 a Question and Answer Medicines Information Centre "MedicinInfo" run by pharmacologists, pharmacists and pharmacy technicians was established in the Capital region of Denmark. The overall aim was to provide hospital healthcare professionals in the region with highly specialised knowledge regarding medicines and clinical problems, benefiting from the unique synergism of the interdisciplinary competences.
MedicinInfo receives questions by telephone, e-mail, fax or personal application.
The questions are pre-classified into three groups: pharmaceutical questions, medical/clinical questions and mixed questions. The questions are then divided into simple or complex cases and recorded in databases.

Method
The poster schematically shows the working process of MedicinInfo.
Statistics are drawn from the databases, to determine quantity, users' professional background, the most common categories and the time taken for the answers.
The working process is evaluated at monthly meetings.

Results
Since the establishment of MedicinInfo, the three professions have been working together to answer questions mainly from physicians and pharmacy technicians.

Answers from 511 complex and 708 simple questions were given during the first approximately five months. The most common categories were "Dosage and administration" and "Storage and stability".
80% of the answers were given within 24 hours. 87% of the answers were given within the agreed time.
The overall impression is that pharmacologists, pharmacists and pharmacy technicians are satisfied and that synergy between the professions is an important tool in optimising the answers.
The poster will present updated data based on the first year with MedicinInfo.

Conclusions
1219 answers were given during the first five months with MedicinInfo and 87% were given within the agreed time. Interdisciplinary synergy has been achieved.

Conflict of Interest
No conflict of interest

F18. Tolerance and efficacy of sodium oxybate (oral solution) in treatment of narcolepsy in adults with cataplexy
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Background
Narcolepsy is a rare neurological disease that affects the organization of sleep and wakefulness. Drug treatment consists primarily of central nervous system (CNS) psychostimulants such as modafinil and amphetamine-related drugs, methylphenidate. These drugs improve alertness and daytime performance but the patient does not reach a normal level of alertness. In addition, modafinil provides no benefit for cataplexy and adverse events are common with methylphenidate. Sodium oxybate (Xyrem) is a CNS agent commercially available in oral solution for 3rd-line treatment of cataplexy in narcoleptic patients. The aim of this study was to determine the efficacy and tolerance of sodium oxybate oral solution in patients suffering from narcolepsy with cataplexy.

Method
Retrospective study from July 2006 to June 2008 (Department of Pharmacy in Hotel Dieu Hospital, Paris, France) in narcoleptic outpatients suffering from cataplexy and treated with sodium oxybate oral solution The efficacy was assessed by onset of narcolepsy, dose modification and associated drugs. The safety profile was evaluated by type of side effects.

Results
Eight patients (6 females, median age 42.6 ± 10.0) were included. The starting dose was 2 g bid. Each patient received modafinil, associated with methylphenidate for 6 of them. Two patients had an antidepressant in addition. There was no modification of concurrent treatment throughout the study. According to the patients, onset of cataplexy decreased by 50% after 5 months of treatment at a median dose of 6 g divided into two daily doses. During the first month, 5 patients out of 8 had side effects. The most frequent adverse events were fatigue (5 patients), nausea (3), sweating (3), dizziness (2) and delayed nocturnal sleep (1). Dizziness was related to insufficient dosage and disappeared after the dose was increased to 4g bid. Apart from this side effect, the tolerance improved throughout the treatment without dose modification and these clinical effects disappeared after 4 months (median duration of treatment). No adverse events altered the self-reported treatment adherence except for the solitary patient who experienced delayed nocturnal sleep. This patient interrupted sodium oxybate after 2 months of treatment.

Conclusion
This study supports the efficacy of sodium oxybate in improving excessive daytime sleepiness in narcolepsy. All of the adverse events are described as frequent in the summary of product characteristics and the tolerance improved throughout the treatment. The efficacy of sodium oxybate for the treatment of cataplexy depends on duration of treatment and the daily dose.

Conflict of Interest
Conflict of interest

F19. Revived interest on thalidomide: current use in a Spanish hospital
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Background
Thalidomide was introduced as a non-toxic sleeping pill, but soon the link between congenital limb defects and its use in pregnancy was proven, resulting in its withdrawal.
In vitro, thalidomide has immunoregulatory properties and it is administered in many immunological diseases. In 1964 it was discovered that thalidomide was effective against erythema nodosum leprosum, aphthous stomatitis and Behçet's disease. Thalidomide also has been studied as a possible anticancer drug and its current therapeutic indication, in combination with melphalan and prednisone, is as first line treatment of untreated multiple myeloma; now thalidomide is viewed as a potentially life-saving drug. Considering this revived interest on thalidomide, we evaluated the use of this drug in our hospital.

Method
Retrospective study over the period 2004-2009, to determine the number of patients treated with thalidomide in our hospital and classify them according to diagnosis, specialities and cost. Data were obtained from an individualised register of patients undergoing thalidomide treatment.

Results
14 patients were identified (33-78 years). By gender there were 4 men (28.6%, 48-68 years), and 10 women (71.4%, 33-78 years). By speciality there were 6 haematology patients (42.8%), 8 dermatology patients (57.2%). By diagnosis: 5 multiple myeloma patients (35.71%); 3 with relapsing aphthous stomatitis (21.42%); 2 Behçet's disease (14.28%); 2 cutaneous lupus erythematosus (14.28%); 1 prurigo nodularis (7.14%);1 myelodysplastic syndrome with medullar fibrosis (7.14%).
The total cost was 72.552 euros, i.e. an average of 12.092 euros/year.

Conclusions
Thalidomide is a valuable treatment for a number of medical conditions and it is being prescribed again, especially for dermatological and haematological diseases such as multiple myeloma. Results show that these serious or rare medical conditions, and the lack of alternative treatments, have resulted in fresh efforts to identify new indications for older medicines, such as thalidomide.

Conflict of Interest
No conflict of interest

G1. Potential drug - drug interactions in the pharmaceutical care of multi-injured patients in a general hospital

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Background

Whenever two or more drugs are taken concurrently, there is a chance that there will be an interaction between the drugs. The interaction may increase or decrease the effectiveness and/or the side effects of the drugs The drug interactions correspond to 3-5% of the side effects in hospitals and increase hospital visits and admissions. The frequency of interaction increases a lot when more than 4 drugs are used, depending on the type of drug.

Objective

To examine potential drug-drug interactions in the pharmaceutical treatment of multi-injured patients who are at risk because of major organ impairment and decreased organ function.

Method

Information from prescriptions such as number of drugs given, number and severity of potential interactions, were examined for the pharmaceutical treatment of multi-injured patients in the surgical sector during one month (May 2009). The dose of given drugs was for two days.

The MEDSCAPE data base was used for the study. The programme uses two severity rating scales simultaneously to determine the level of severity of a particular drug-drug interaction. The severity of interaction is determined by the description of the measure as mild /moderate/severe/no interaction and in the form of numbers (classes) ranging from 1 to 5 determining their level of severity in terms of clinical significance.

Rating from 1 to 4	Severity rating of DI	Description of severity rating
1	Severe interaction and classes 1 and 2	Avoid administration of combination
2	Moderate interaction and class 3	Avoid administration unless it is determined that the benefit of coadministration outweighs the risk to the patient
3	Mild interaction and class 4	Minimise risk by considering alternative agents or change dosage or route of administration No action needed - risk of adverse outcomes appears small
4	No interaction and class 5	No interaction - evidence suggests no interaction

Results

Number of prescriptions examined: 127
Number of prescriptions with potential interactions 34
Number of prescriptions with potential interactions with more than 4 drugs: 34
Number of potential interactions: 54, of which 22 (40.74%) were classed as potentially severe interactions and 32 (59.25%) were classed as potentially moderate interactions.
Examples of combinations/interactions found:
Aminoglycosides/loop diuretics:18.51%. Class 2 severe interaction, rapid onset of eighth nerve ototoxicity may be observed. Hydantoins/omeprazole: 11.11%. Class 3 moderate interaction, omeprazole may inhibit the metabolism of hydantoins .
Corticosteroids/hydantoins:11 11% Class 3 moderate interaction, decreased pharmacological effectiveness of corticosteroids.
Quinolone/corticosteroids: 9.25%. Class 2 severe interaction, quinolone-induced arthropathy

Conclusion

The serious situations of the patients treated required multi-drug treatment and consequently the risk of potential interactions increased with length of hospital stay. The study shows the important role of hospital pharmacists in the drug treatment. Constructive cooperation between physicians, pharmacists and nurses optimises pharmaceutical care and reduces length of stay in hospital.

Conflict of Interest

No conflict of interest

G2. Wound oozing with dalteparin and rivaroxaban after orthopaedic surgery

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Background

Studies have been conducted comparing oral rivaroxaban 10mg daily with subcutaneous enoxaparin at the high-thromboprophylaxis risk dose of 40mg daily. We wanted to determine how rivaroxaban was tolerated compared with dalteparin. Our usual practice is to use dalteparin at the moderate-thromboprophylaxis risk dose of 2,500 units daily in elective hip and knee replacement patients.

Method

For 5 weeks our usual practice with dalteparin 2,500 units, commenced 30 to 36 hours postoperatively, was continued. This was followed by six weeks where the dalteparin was replaced with rivaroxaban, commenced 6 to 15 hours postoperatively. A venous thromboembolism risk assessment form was completed for each patient. Following the operation nurses completed a wound oozing score for up to 5 days or hospital discharge if earlier. Points for wound oozing were given as follows: 0=no bleeding, 1=less than 50p size spotting, 2=dressing pad covered, 3=leaks through dressing. The length of hospital stay (LOS) was also recorded for all patients as it is local policy not to discharge patients unless the wound is dry.

Results

Eighty-one patients underwent knee replacements (37 dalteparin, 44 rivaroxaban) and 71 underwent hip replacement (24 dalteparin, 47 rivaroxaban). By day 3 the average wound oozing scores for knee replacements were between 0.42-0.59 for rivaroxaban and 0.23-0.61 for dalteparin. For hip replacements the average scores were 0.74-0.64 for rivaroxaban and 0.74 and 0.53 for dalteparin. The average LOS for hip replacement patients with rivaroxaban and dalteparin was 6.1 days and 6.0 days respectively. For knee replacement patients the average LOS with rivaroxaban and dalteparin was 6.1 days and 6.4 days respectively.

Conclusion

Rivaroxaban 10 mg daily and dalteparin 2,500 units daily caused minimal and similar amounts of wound oozing. This was supported by the average LOS being 6 days for hip and knee replacement patients whether they received rivaroxaban or dalteparin for thromboprophylaxis.

Conflict of Interest

Yes: Other substantive relationships: S.Bhandal - Small honoraria to speak at thrombosis meetings from Bayer and sponsorship to attend international conferences from Boeringer-Ingelheim and Pfizer.

G3. Identification of the Need for Dosage Calculation Tools for Injectable Drugs

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Background

Research indicates that the incidence of errors in prescribing, preparing and administering injectable drugs is higher than for other forms of drugs (1). The NPSA recommend the provision of calculation and training tools to improve safety, particularly targeting high-risk injectable drugs.

Objectives
To identify high-risk injectable drugs in the Mater Misericordiae UniversityHospital (MMUH). To identify injectable drugs requiring a dosage calculation.

Method
Medication incident reports in MMUH were reviewed (2005 to 2007).
Data from hospital in-patients was collated for all injectable drugs requiring a dosage calculation.

Results
Medication Variance Reports Review
A range of 32 – 48% of MMUH medication incidents involved injectable drugs over the three years reviewed.
Collectively anticoagulants had the highest number of medication variances by drug category in each year.

Data Collection
One-day, cross-sectional review of **567** in-patient drug charts in the hospital.
38 prescriptions for injectable drugs prescribed required a dosage calculation.
35 (92%) of prescriptions requiring a calculation were for therapeutic LMWHs.
17 (44.5%) of prescriptions requiring a calculation were for tinzaparin 175 units/kg once daily on **12** different wards (n=26).
1 prescription each was for liposomal amphotericin, Foscavir and rasburicase.

Conclusions
Anticoagulants are one of the classes of drugs most frequently identified as causing preventable harm (2). Despite ongoing safety initiatives, anticoagulants and LMWHs continue to have high rates of reported medication incidents in the MMUH.
Data collection indicated that 38 injectable drug prescriptions did not have a dose specified, and required a calculation prior to administration. Tinzaparin prescriptions require nurses to make complicated calculations prior to preparation and administration. A tinzaparin dosage and administration calculation tool has been developed. The introduction of this tinzaparin calculation tool will eliminate the need for difficult calculations for doses and volumes, and will indicate the appropriate strength syringe to use. Different formats (poster, bookmark, intranet) for the calculation tool will be used to ensure that this will be readily available at the point of use for prescribers and nurses.
The need to develop dosage calculation tools for specialist drugs (for example co-trimoxazole, rasburicase) is currently under review.

References
(1) NPSA Patient Safety Alert 20. Promoting the Safer Use of Injectable Medications. 28 March 2007
(2) NPSA Patient Safety Alert 18. Actions that make Anticoagulant Therapy Safer. 28 March 2007

Conflict of Interest
No conflict of interest

G4. Branded vs. generic oxiplatin: changes in ADR over the year 2008 in the Mondovi hospital
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Background
The reporting of an Adverse Drug Reaction is a way of announcing that an adverse reaction is suspected of having occurred after a drug has been taken. It is a simple, practical, economical method of warning, applicable to all types of patients, all drugs and can indicate potential warning signs. During the year 2008 in the Mondovi hospital branded oxaliplatin was replaced by a generic version and a considerable increase in ADRs was seen. So we decided to evaluate whether this trend was localised exclusively in our Local Health Unit or if it was spread over the rest of Piedmont.

Methods
We examined the Italian National Register of pharmacovigilance; here we have extrapolated the data of adverse reactions related to oxaliplatin in 2007/2008. These data are data comparing the branded drug versus unbranded drug. We then used the SFERA Hospital database to determine the consumption of the two versions of the drug over the years.

Results
From the results we can see how reports of ADRs increased through the year 2007 to 2008, both for the brand and for the unbranded. In the analysis of the ADR/consumption (‰) we can see that in 2008 there was a greater number of records relating to the unbranded drug vs. the branded drug (6.15 vs. 1.30 in Piedmont and 33.33 vs. 0 in Mondovi hospital).

Conclusions
From the data analysis we can see an increase in reports of ADRs during 2008, perhaps due to a greater awareness of the drug by the medical profession. It was noted however, that the ADRs were ascribed to the unbranded drug, resulting in greater proportion of ADRs per units of drug used. The increase in ADRs was recorded for the gastrointestinal system (26.8% in 2007 vs. 28.2% in 2008), the nervous system (15.2% in 2007 vs. 27.3% in 2008) and an increase in respiratory, thoracic and mediastinal disease (12.5% in 2008 vs. 14.4% in 2007). It will therefore be important to assess whether in future ADRs will be ascribed to the unbranded drug in the same way when switches are made. If this situation occurs our study will be extended to other drugs.

Conflict of Interest
No conflict of interest

G5. Evaluation of the pharmacokinetic effect of the interaction between valproate and meropenem in critically ill patients
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Background
Previous studies have described an interaction between valproate (VPA) and meropenem (MER) in hospitalised patients. Little is known about the pharmacokinetic effect of the interaction in critically ill patients. The effect of starting MER on the VPA plasma levels was assessed in this patient population.

Methods
In a retrospective cohort study patients admitted to the ICU who were treated simultaneously with VPA and MER between December 2003 and March 2009 were identified. Patients were included in the study if MER was added to ongoing treatment with VPA and if plasma monitoring of VPA was available during the first 48h of concomitant treatment.
Demographic data, route of VPA administration, indication for VPA and MER treatment, VPA plasma levels and dose adjustments were retrieved from the patient file. The change (%) in VPA levels after initiation of MER was calculated after 24 and 48h.

Results
50 episodes were identified in which 43 different patients were treated with VPA and MER. 23 episodes were included in this analysis. In the other episodes PA was added to MER treatment (n=4), MER and VPA were initiated at the same time (n=7) or insufficient PK data were available (n=16).
In the 23 episodes MER was added for the treatment of pneumonia (56.6%), empirical treatment for septic shock (13.3%), meningitis (8.6%), urinary tract infection (8.6%), infected burn wounds (4.3%), ventriculitis (4.3%) or intra-abdominal infection (4.3%).
In 22 episodes VAP was administered intravenously, in 1 orally. The mean age was 55.7 years and the ratio male/female was 17/6.

In 21 of the episodes a decrease in the VPA level of 56.5% was identified after 24h. In one episode there was an increase of 36.7%. VPA levels after 48h were available in 15 episodes. In all 15 episodes the VPA level dropped by an average of 63.0%.

Conclusion
This study shows that the pharmacokinetic effect of the initiation of MER on the plasma levels of VPA in critically ill patients is important. Based on this data concomitant therapy of MER and VAL should be avoided.

Conflict of Interest
No conflict of interest

G6. use and safety of vorinostat in a cutaneous T cell lymphoma: a case report

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Background
Mycosis fungoides (MF) is a type of Cutaneous T-Cell Lymphoma (CTCL). Vorinostat is indicated for the treatment of CTCL in patients who have progressive, persistent or recurrent disease on, or following, two systemic therapies. Vorinostat is a histone deacetylase inhibitor that induces cell-cycle arrest and apoptosis in some transformed cells. EMEA considers that information is insufficient to evaluate the risk/benefit of Vorinostat. The objective was to analyse the use and safety of Vorinostat in one patient diagnosed with MF.

Method
A retrospective study of a patient with recurrent MF. Information was collected from the clinical and pharmacotherapeutic history. The product information and literature about vorinostat was reviewed.

Results
A 49-year-old woman was diagnosed with MF by Dermatology in 2005. Firstly she was treated with topical and oral corticosteroids, antihistamines and oral bexarotene for two years, with clinical improvement. Second line treatment was 19 sessions of Skin Electron Beam radiation, which did not achieve a response. Third line treatment was chemotherapy (6 cycles of CHOP + methotrexate). Fourth line treatment was with interferon alfa 2b in increasing doses and finally vorinostat 400 mg/day for 41 days. Cutaneous damage improved, the skin became dry in the first week. It was suspended due to adverse events (AE): hyperglycaemia (maximum of 156 mg/dl), severe thrombocytopenia (60 x 10 9 platelets/L) controlled by platelet transfusions, haemoglobin decreased to 9 g/dl and red blood cell count to 2.97x 1012/L. An electrocardiogram showed sinusal tachycardia (156 beats per minute). Other AE: severe mucositis, fatigue, dizziness.

Conclusions
Adverse effects forced the interruption of vorinostat treatment. All AE were described in the product information document. The duration of treatment was less than the time required to evaluate the results. More studies are necessary to define the risk/benefit status of vorinostat.

Conflict of Interest
No conflict of interest

G7. Strategies on safety in use of excipients

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Background
Excipients are involved in medicines-related problems, especially in safety issues that affect many patients due to their age (neonates, pregnant women), presence of chronic disease (metabolic disorders, epilepsy), or idiosyncratic reactions (allergies, intolerances). The objective of this study was to review the composition of notifiable excipients in proprietary medicines admitted to the hospital's Drug Therapy Guide (DTG), in order to develop a prescribing tool and avoid potential risks.

Method
A systematic review was conducted of the composition of the notifiable excipients of 1137 medicines included in the hospital's DTG. We used pharmacy management software and the General Council Official College of Pharmacists database (BOT PLUS -April 2009 version).We included all routes of administration (parenteral, oral, topical, rectal, ophthalmic, otic) and excluded fluid therapy, dialysis solutions, prepared nutrition and foreign drugs. According to Spanish legislation, some excipients are only notifiable depending on the quantitative composition, which could be a limitation in the information collected.

Results
48.99% (557) of the drugs reviewed (1137) contained notifiable excipients. 54 different excipients were involved. Percentages for some notifiable excipients were: aspartame (3.23%), benzalkonium chloride (1.97%), benzoic acid/ benzoates (8.44%), benzyl alcohol (2.89%), borates (1.07%), castor oil (2.15%), chlorobutanol (0.89%), ethanol (7.71%), fructose (0.54%) , glucose (1.43%), glycerol (8.25%), lactose (35.91%), mannitol (14.90%), phenylmercuric salts (0.54%), potassium salts (1.07%), propylene glycol (5.03%), starch (10.41%). Gluten was present in 12.06%, sodium salts (6.28%), sorbitol and derivatives (8.07%), soybean oil (0.72%), sucrose(13.1%), sulfites/ metabisulfites (6.10%), thiomersal (0.89%), etc.
Tables of medicines were created and classified by pharmaceutical-therapeutic group. They were then used to update the drug master files used by the electronic prescription program.

Conclusions
Knowledge of excipients and their incorporation into the hospital's drugs database provided the necessary support for the introduction of safety strategies in the use of drugs in selected clinical units.

Conflict of Interest
No conflict of interest

G8. Intranet- based medication errors reporting system in a tertiary hospital

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Background
Medication errors (MEs) are responsible for morbidity and mortality in health care facilities. A knowledge of MEs in every hospital would lead to an improved pharmacotherapy process and improve patient safety. The aim of this study was to describe and analyse MEs reported in our hospital and the utility of the internet-based ME reporting system.

Method
On the intranet of our 650-bed tertiary teaching hospital, we placed an application of our own design to report MEs detected in hospitalised patients and outpatients. The report, which could be anonymous, included: date, time, patient characteristics (sex, age, and weight), location, medicine involved, description of the event, patient consequences, professional health worker involved and suggestions to avoid recurrence. Database reports were analysed from January to September 2009.

Results
During the study period 282 MEs were reported (1.04 ME per day) affecting 281 patients (118 females (65%); mean age 61.67 years (range 1 month - 93 years)). 354 drugs were involved in the ME reports. The main pharmacological classes involved were systemic anti-infective agents (29.94%), metabolic and digestive tract agents (13.27%), central nervous system agents (12.42%) and cardiovascular agents (11.58%). The most frequent types of ME were duplicated treatment (15.60%), wrong schedule (13.47%), overdose (12.76%) and transcription error (9.57%). 47 MEs reached the patient (16.66%) and 18 (6.38%) resulted in patient harm. Clinical pharmacists were the health professionals who reported the most MEs (94.68% of reports). More than 15% of ME reports were related to high-risk drugs as defined by the Institute for Safe Medication Practices.

Conclusions
An internet-based medication errors reporting system is a helpful tool to improve knowledge of MEs. Approximately 1 ME was reported per day and more than 16% reached the patient.

Conflict of Interest
No conflict of interest

G9. Transposing safety guidelines across national borders: Introducing UK NPSA guidelines to Ireland.
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Background
Inadvertent administration of oral medicines intravenously was a serious incident reported twice in 3 years in the MMUH, an Irish hospital. In the UK 33 such incidents over 17 months prompted the National Patient Safety Agency (NPSA) to produce advice in 2007 to improve safety in this area. The MMUH adopted these UK guidelines and implemented them in an Irish context.

Method
NPSA advice:
1. Use labelled oral/enteral syringes, in a 'judicious colour', which do not connect to IV ports.
2. Use labelled enteral giving sets to which IV equipment cannot be attached.
3. Review organizational procedures, training and audit.

MMUH actions:
1. A syringe supplier with a guaranteed supply chain and the colour purple were chosen, based on availability on the Irish market
2. Irish suppliers were asked to upgrade enteral sets to comply with NPSA standards.
3. An MMUH educational campaign on safe oral medicines administration was launched to raise awareness with an Irish audience. MMUH incidents were used to reinforce relevance. An NPSA audit tool facilitated a compliance check 6 months later.

Results
In 2009 NPSA-compliant safer enteral systems were introduced in the MMUH. A follow-up audit showed that:
- Risks of wrong route errors with oral medicines are now identified in MMUH medicines management policies
- Oral/enteral syringes (purple) are available in all clinical and dispensing areas
- Staff training emphasises the need to use safe devices when using

Conclusion:
Using lessons learned in the UK an Irish hospital has implemented NPSA advice to improve patient safety. There have been no further reports of oral medicine administration intravenously. A follow-up audit showed hospital-wide compliance with NPSA guidelines. Further audits will determine the long-term success of this system-change approach to medicines incidents, using the lessons learned at home and in other countries.
Conflict of Interest
No conflict of interest

G10. Assessment of tolerance and effectiveness of sodium oxybate
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Introduction
Narcolepsy is a neurological disorder characterised by an alteration in the management of all three natural states of consciousness (wakefulness, non-REM sleep, REM sleep). It is a rare disease (25-50 cases/100,000 population) characterized by daytime sleepiness, cataplexy, hypnagogic hallucinations and sleep paralysis. Sodium oxybate is an orphan drug.

Objective
To evaluate the effectiveness, tolerance and adverse effects of the use of sodium oxybate in patients diagnosed with narcolepsy.

Method
A retrospective observational study was performed of patients treated with sodium oxybate, diagnosed with narcolepsy in our hospital. We have also reviewed the medical histories and conducted a personal interview in which we assessed the effectiveness of, and tolerance to, treatment.

Results
We evaluated seven patients (5 women and 2 men), with a mean age of 39 years, treated with sodium oxybate for an average period of 5 months. From the start of treatment all patients suffered some side effects incompatible with daily activity (nausea, anorexia, anxiety and feeling drunk). In four of these cases, these side effects caused the withdrawal of the treatment. A further resignation was due to lack of information about the drug to the patient.
Currently, 2 patients are continuing with the treatment, showing a clear improvement in their symptoms.

Conclusions
From the results, despite our limited experience, we can say that sodium oxybate is a poorly tolerated drug in a high percentage of cases, frequently being the cause of treatment failure.
The effectiveness could not be assessed due to early discontinuation of the treatment by the patients.

Conflict of Interest
No conflict of interest

G11. Errors produced during filling of medicines cassettes in a hospital pharmacy service
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Background
Dispensing by a unit dose drug-dispensing system (UDDDS) has improved the quality of pharmaceutical care. However, it is a potential source of medicines errors and adverse drug events (ADEs). The detection of errors in the medicines provides an opportunity to identify system problems and to establish corrective measures.
The purpose of this study was to determine the rate of dispensing errors made by a manual UDDDS and to suggest preventive actions.

Method
Prospective study through direct observation carried out from January to September 2009. Pharmacists and pharmacy technicians checked medicines cassettes prepared manually with the help of filling listings generated by the software unit dose available in our hospital. The main types of dispensing errors recorded were: dose omission (DO), wrong dose (WD), spare dose (SD), wrong medicine (WM), wrong pharmaceutical form (WPF), wrong patient name (WPN) and deteriorated medicines (DM). The dispensing error rate was obtained by dividing the number of errors by the total dispensed doses.

Results
Among the 739,636 total dispensed doses, 5643 errors were detected (0.76%). There was an average of 609 errors/month. The most frequent type of error was dose omission (42.10%). The day and month in which more errors were produced were Tuesday and January, respectively. Pharmaceutical specialities involved in a higher rate of errors were Cesplon, Clexane, oral Anagastra and oral Seguril.

	DO	WD	SD	WM	WPF	WPN	DM	Others
% error	42.05	10.14	14.30	11.41	4.52	14.00	0.55	3.03

Conclusions
- The DE rate was lower than those reported in other studies, probably due to the experienced pharmacy technicians in our hospital.
- Despite this low value, the large number of errors detected every month indicates the need to check medicines cassettes after they have been filled in order to prevent ADEs.
- New technologies, such as bar-code medicines systems and automated medicines dispensing would be important tools to reduce our significant dose omission rates.

Conflict of Interest
No conflict of interest

G12. Pharmacovigilance of intravenous chemotherapy in a day-hospital unit

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Objective
To make a quantitative and qualitative analysis of the adverse drug reactions (ADRs) caused by intravenous chemotherapy in our day-hospital unit.

Method
A prospective observational study was conducted for 2 months (March-April 2009). The ADRs were collected by monitoring the pharmacotherapy by means of drug alerts, dose reductions and treatment discontinuations.

Results
In that period, 73 ADRs were detected from a total of 687 preparations of cytostatics (10.6%). Of the total number of patients, 79.5% were oncology patients and the rest were haematology.
Cytotoxic drugs that were involved in a higher number of ADRs were oxaliplatin 13 (17.8%), cisplatin 9 (12.3%), etoposide 6 (8.2%), paclitaxel 5 (6.8%), gemcitabine 5 (6.8%), carboplatin 4 (5.5%) and irinotecan 4 (5.5%). Many other drugs appeared to be involved in lower percentages, such as fluorouracil, trastuzumab, cyclophosphamide, bortezomib, azacitidine, fludarabine and doxorubicin.
The most frequent adverse reactions were minor-to-moderate nephrotoxicity 15 (20.5%), neutropenia 12 (16.4%), peripheral neuropathy 12 (16.4%), anaemia 6 (8.2%) and diarrhoea 6 (8.2%). Other reactions occurred in small numbers, for example tachycardia with nausea and vomiting, stomatitis, jaundice, nausea and vomiting, rash and fatigue. In order to prevent future ADRs treatment was discontinued in 10 cases and the dose was reduced in the rest of cases.

Conclusions
Onco-haematology treatment caused a high incidence of ADRs in the day-hospital unit. The existence of an active pharmacovigilance programme allowed us to detect the ADRs, to improve our knowledge of them and to establish strategies to reduce them. On the other hand, patients and staff became better informed, developing a better understanding of intravenous chemotherapy.
Conflict of Interest
No conflict of interest

G13. Transition from one level of care to another: reconciliation errors

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Background
Adverse drug effects and medication errors constitute 20 - 72% of the adverse events that occur during hospitalisation and 7-12% of all deaths and permanent disabilities occur as a result of adverse events.

Objective
To identify reconciliation errors occurring during the transition from primary to specialised health care and their seriousness.

Methods
Descriptive observational study. Patients admitted to the traumatology department in a general hospital for three months (April - June 2009) were included.
48-72 hours after admission, the drug history was obtained by interviewing the patient and/or carer, with the help of the electronic patient record and was compared with the treatment prescribed in the hospital. When a discrepancy was identified, the doctor was consulted to find out if it was deliberate or not. An internist evaluated the seriousness of non-deliberate differences.
Dependent variables were:% discrepancies, the seriousness of the discrepancies. Independent variables were: gender, number of prescribed medicines before admission, type of admission, age, therapeutic group, person interviewed, information sources.

Results
38 patients were included (average age: 65±17.86), of which 55.3% were women. In 65% of patients the admission to hospital was urgent. The average number of medicines before admission was 4.95 ±3.68. The number of discrepancies identified was 280, or 25%. Of these 88% were not justified, occurring because of one drug had been omitted. Of the unjustified discrepancies, 53% was classified as “low seriousness” and 22.4% “moderate seriousness”. The average total number of discrepancies per patient was 7.37±2.38 and the average non-deliberate discrepancies per patient was 1.84±1.24.

Conclusions
Medicines errors occur in the transition of patients from primary to specialised health care.
To prevent these errors from happening medicines reconciliation by pharmaceutical intervention is necessary.

Conflict of Interest
No conflict of interest

G14. the use of serotonergic antidepressants and changes in blood pressure

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Background
Selective serotonin reuptake inhibitors (SSRIs) have been associated with an increase in blood pressure but evidence is scarce. As blood pressure is closely monitored during anaesthesia, we considered that routine intraoperative haemodynamic data could be used as a marker for a potential effect. Normally, side effects of anaesthetics result in a decrease in blood pressure. This study aimed to associate the use of SSRIs and changes in blood pressure by measuring the occurrence of intra-operative hyper- and hypotension.

Methods
We conducted a retrospective cohort study among patients who underwent elective primary Total Hip Arthroplasty (THA) in the period 1 July 2004 to 1 July 2008. The target group included all users of both serotonergic and non-serotonergic antidepressants. The reference group included a random sample (ratio 1:3) of non-users. The outcome was an episode of decreased or increased blood pressure defined as a change in blood pressure of 30% or more compared to baseline. Number, mean duration, total duration and area under the curve (AUC)

of these episodes were recorded.

Results
The target group consisted of 22 users of SSRIs and 15 users of non-serotonergic antidepressants. The reference group contained 111 patients. After adjustment for confounding factors, users of SSRIs showed fewer hypotensive episodes, a shorter mean and total duration of these episodes and a smaller AUC when compared to the reference group. These effects were statistically significant for the number of episodes (mean difference of 1.1, 95% CI: 0.01-2.19) and total duration (mean difference of 28.8 minutes, 95% CI: 10.0-47.5). This effect was not observed in users of non-serotonergic antidepressants. The occurrence of hypertensive episodes did not differ between groups.

Conclusions
The use of SSRIs was associated with an increase in blood pressure, evidenced by a significantly decreased number and total duration of intraoperative hypotensive episodes.

Conflict of Interest
No conflict of interest

G15. the use of serotonergic antidepressants and bleeding risk in orthopedic patients

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Background
Selective serotonin reuptake inhibitors (SSRIs) have been associated with an increased tendency to bleed. Literature on the effect of possibly impaired haemostasis associated with the perioperative use of SSRIs is limited. This study aimed to determine the association between the perioperative use of SSRIs and the amount of blood lost during surgery as well as perioperative transfusion requirements.

Method
We conducted a retrospective cohort study among patients who underwent elective primary Total Hip Arthroplasty (THA) in two hospitals in the period 1 July 2004 to 1 July 2008. The target group consisted of all users of both serotonergic and non-serotonergic antidepressants. The reference group consisted of a random sample (ratio 1:3) of non-users. The primary outcome was the amount of blood lost intraoperatively. The requirement for blood transfusion was a secondary outcome. The outcomes were adjusted for confounding factors (co-morbidity, co-medication) using regression techniques.

Results
The target group contained 66 users of serotonergic and 29 users of non-serotonergic antidepressants, the reference group consisted of 285 patients. After adjustment for confounding factors, mean blood loss during surgery was significantly higher in users of SSRIs when compared to the reference group: 95 mL more blood was lost per person (95% CI: 9 to 181). Mean blood loss in the users of non-serotonergic antidepressants did not differ from the reference group. Users of antidepressants did not have a higher risk of transfusion.

Conclusions
Patients undergoing THA who continue the use of SSRIs show a significantly increased intraoperative blood loss without an increase in transfusion requirements.

Conflict of Interest
No conflict of interest

G16. Risk of unintended intrathecal application of Vincristine in German University Hospitals? status quo and proposals for risk reduction strategies

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Background
Vincristine (VCR) is an antineoplastic drug often used in combination with methotrexate (MTX) in several therapeutic schemes for leukaemia. If metastatic tumour growth is found in the subarachnoid space MTX has to be given intrathecally (ith). By contrast, ith VCR instillation is a fatal error, causes progressive neurotoxicity and paralysis and has a fatal outcome in almost every case. WHO states that 55 cases of unintended ith VCR administration have occurred worldwide since 1968.

Objective
We compared existing guidelines for VCR/MTX combination therapies with the current situation in German university hospitals. To do this we a surveyed university pharmacy departments (n=33). The aim of the survey was to collect information about the general awareness of the problem, the frequency of incidents and the measures undertaken to prevent inadvertent ith administration of VCR. The results were described and as a consequence suggestions have been made for a national guideline.

Results
The response rate was 76% (25/33). There are several antineoplastic protocols in response to the risk of unintended ith administration of VCR due to the fact that IV VCR and ith MTX have to be administered on the same day. The so-called Hoelzer Protocol is most frequently used in adults and children (3719/3418). 3 incidents of inadvertent German administration of ith VCR have been documented in the literature. Responders stated they were aware of 2 cases (average, max. 4, 5 responders were not aware of any cases) that happened in Germany. As cytotoxic reconstitution can affect risk and safety, we asked for information regarding this process. More than 40% of reconstitutions were prepared as 1-3 ml bolus syringes with the high risk of unintended ith application. 20% of respondents did not use a special label for VCR applications (additional 20%: no answer). There was little knowledge of clinical guidelines regarding application on the same day or staff training procedures, indicating that the involvement of hospital pharmacists in clinical pathways is low in this field.

Conclusions
In order to prevent future incidents of unintended ith VCR administration we recommend a national guideline following NPSA and WHO guidelines even if those guidelines can hardly prove a reduction in risk due to the small number of incidents. These guidelines should include instructions on administration (e.g. VCR in 50 ml minibag), spinal needles incompatible with the Luer-lock system, labels (positive: e.g. IV route only), special training for staff, and prohibition of IV VCR administration on the same day as ith MTX administration.

Conflict of Interest
No conflict of interest

G17. Development of an activity based interaction guidance regarding phenprocoumon

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Background
Different factors influence dosing of the Vitamin K antagonist phenprocoumon e.g. age, nutrition, comorbidities and comedication. Drug interactions with coumarins are well documented, but many of interactions recorded are of theoretical rather than practical importance. Commonly used databases describe the type and mechanism of interaction, but information about the proper prospective from which to handle the potential interaction is lacking. The purpose of our work was to establish a database of potential drug interactions during

phenprocoumon therapy and to define actions to be taken.

Method
An intensive literature research was used to generate a comparative table including any potential interaction partner of phenprocoumon mentioned either in Drugdex, Abda Datenbank, Marcoumar Product information, coumarin interaction information from the Federatie van Nederlandse Trombosediensten or in a literature review of warfarin interactions (2005). The comparative table was examined by an expert team of two pharmacists and a specialist in *haemostasis* to assess the information. Three parameters were defined: degree of severity, clinical relevance (both graded from 0 to 4) and recommended measure.

Results
The database lists 381 potential interaction partners of phenprocoumon. Information varied significantly between the sources, which sometimes made it difficult for the expert team to agree. Almost 50% of the possible interactions were only of theoretical relevance and no action was necessary. Alternatives were suggested for the few drugs that are considered to be contraindicated. In remaining cases the expert team recommended the steps to be taken to minimise the risk of INR variation caused by the interaction.

Conclusion
Based on a systematic reassessment of known interaction data we developed a new phenprocoumon interaction guide restricted to relevant interaction partners of the agent. The database will be used as background information in drawing up an algorithm to adjust the dose of phenprocoumon prospectively when an interacting drug is newly prescribed.

Conflict of Interest
No conflict of interest

G18. Imatinib associated with cardiotoxicity
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Background
In October 2006, the FDA published a safety alert for imatinib (Gleevec) warning of the risk of adverse cardiac effects. The last EMEA post-authorisation review for imatinib (Glivec), November 2007, concluded that: *"Concerning imatinib's safety profile[…], it did not differ substantially from that previously described […] There was one case of a cardiac adverse event…related to imatinib, which could suggest additional monitoring in this patient population".*

Method
Imatinib's adverse effects were researched using Micromedex, Up To Date, Lexi Drugs and by a free search on Medline (PubMed) for: imatinib cardiotoxicity OR heart failure, Field: Title/Abstract, Limits: Humans. The Karch-Lasagna algorithm was used in the following case: a 64-year-old woman diagnosed with chronic myeloid leukaemia 5 years ago was being treated with imatinib 400 mg/day. The patient was admitted to hospital following chest pain of 5 hours that had started at rest, which increased with breathing and movement. No risk factors or prior cardiac disease were present. The electrocardiogram and echocardiogram showed no abnormalities and laboratory values were within normal limits. Nitroglycerin perfusion was started without pain improvement. Intravenous analgesics were administered until pain resolution. The patient was discharged without the cause of the chest pain being determined.

Results
All databases consulted described adverse cardiovascular effects for imatinib with an incidence from 0.1% for severe adverse effects up to 86.1% for oedema. The risk of chest pain was between 7 and 11%. PubMed results were contradictory: four articles warned about the frequent risk of cardiotoxicity associated with imatinib whereas another five considered it a side effect but cited no evidence.
Causality was considered to be likely, and was communicated to the Pharmacovigilance Centre.

Conclusion
Imatinib-associated cardiotoxicity appears to be an adverse effect to consider, especially in patients with prior heart disease. Notification of cases will provide more information about an effect that has not been suitably detected in approval studies.

Conflict of Interest
No conflict of interest

G19. Identification of patients with high risk of drug relation problems according to beers criteria
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Objective
To estimate the prevalence of inappropriate drug prescribing based on Beers' criteria in hospitalised older adults (65 years and over) at Nuestra Señora de Sonsoles Hospital in Avila as a cause of drug-related problems and its effect on patient safety.

Methods
Descriptive, observational before-and-after study divided into two periods, each lasting 28 days, between which Beers' criteria were introduced: a clinical session and information triptych.
Patients > 65 years old admitted to wards with Unit Dose drug Delivery System (UDDS) during the study period were included.
Study variables: number of patients > 65 years old admitted to UDDS wards, gender, age, dates of admission and discharge. Patients were selected if they received inappropriate medication with at least one potentially inappropriate drug.
The data were examined and a comparative analysis made of how many patients had at least one DRP.

Results
Hospitalised patients > 65 years numbered1276: (A=707; B= 569), of which 21.7% had at least one DRPs (21% in A and 22.6 % in B). There was no statistically significant difference between these percentages (c2=0.56;p=0.454).
328 DRPs were detected in 277 patients (184 in period A: 45% safety and 55% treatment indication, and 144 in B : 49.3% safety and 50.7% treatment indication).
70% of identified DRPs related to 4 drugs:(oral iron sulfate, digoxin, pethidine and doxazosin). Differences between the periods, age (79.7 in A vs. 78.8 in B) and gender distribution were not statistically significant.

Conclusions
The prevalence of elderly patients with potential DRPs was similar to that described by other authors.
The similar prescription profile between the two periods suggests that an improvement in prescribing may need action by pharmacists to identify and / or prevent DRPs if patient safety is to improve.

Conflict of Interest: No conflict of interest

G20. Prevention of injectable drugs incompatibilities in Y site administration
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Background
Pharmacological treatment in hospital settings is increasingly complex and patients often receive several drugs intravenously. Frequently, for practical reasons, physicians and nurses administer two or more drugs through the same infusion line. Data concerning the compatibility of injectable drugs are insufficient and difficult to use. Furthermore the clinical consequences of drug incompatibilities are of primary concern. In order to assist clinical practitioners in our Cardiology Unit in preventing incompatibilities during Y site administration, we created two

linked electronic tables, based on bibliographic and empirical data concerning the physical stability of cardiology drug admixtures.

Methods
First we selected 20 of the drugs used most in the cardiology unit. Then we looked for bibliographic data regarding the physical compatibility of all 190 binary combinations. We verified the result by visual inspection with reference to admixtures judged compatible, based on literature evidence. Conversely, in the presence of negative outcome studies, drugs were considered incompatible without performing an empirical evaluation. We also tested several admixtures of unknown stability. Visual inspection was performed according to standard methods. Results were presented in an easy format with the aid of two tables based on a colour code and concise instructions.

Results
Visual inspections substantially confirmed literature evidence. By integrating bibliographic and empirical data we found that 90 (48%) combinations were of compatible drugs and 37 (20%) were incompatible. With regard to 32% of drug pairs we could not find bibliographic or empirical information on the compatibility , so we couldn't make any recommendations.

Conclusions
Results show that 20% of binary combinations are of potentially incompatible drugs. Thus theoretically, assuming that no compatibility data are consulted, one fifth of Y site administrations can be harmful to patients. We hope our study will make intravenous administration safer by reducing the risk of giving unstable admixtures.

Conflict of Interest
No conflict of interest

G21. Safety in the treatment with digoxin in patients over 65 years
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Objective
To evaluate the characteristics of the population over age 65 who have suffered digitalis toxicity.

Method
A retrospective observational study of a two-year period (2007-2008). Includes all patients over 65 years who had digoxin levels greater than 2 ng/mL. We collected data: age, gender, renal function, left ventricular ejection fraction (LVEF) and left atrial diameter, associated illnesses and concomitant therapy.

Results
In total 67 patients suffered digitalis toxicity during this period, 57 women (85.07%) and 10 men (14.93%) with a mean plasma digoxin level of 2.96 (2.03-6.46).A total of 491 patients were monitored for plasma digoxin. The median age of men was 80 years (66-91) and women 83 years (70-98).
The main symptoms in adversely-affected patients were alteration of cardiac function, atrial fibrillation with a dilated left atrium in 74.5% of cases and with poor left ventricular systolic function (LVEF <50%) in 62.8% of these patients. 70.6% of cases also had renal impairment with serum creatinine values > 1.2 mg/dL.
Note that 100% of patients with digitalis toxicity had at least three diseases associated with chronic atrial fibrillation or heart failure, predominantly hypertension, chronic respiratory disorders and diabetes mellitus.
The majority of regimens were 0.25mg/24h every day (37.3%) 0.25mg/24h six days a week (32.8%) 0.25mg/24h five days a week (27.8%).
These patients had an average of eight prescription drugs each. The 54.9% of patients with digitalis toxicity were also prescribed other antiarrhythmics in the therapeutic regimen. Such combinations have produced frequent and severe ADRs in geriatric patients.

Conclusions
The need for adequate monitoring and dosing of patients over 65 years on treatment with digoxin is highlighted. Monitoring such parameters alerts to the safe use of digoxin, in which the risk of cardiac toxicity does not exceed the clinical benefit.

Conflict of Interest
No conflict of interest

G22. Prescription of drugs with potential for interaction with proton pump inhibitors in the emergency department of a general hospital.
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Background
Although proton pump inhibitors (PPIs) are considered safe drugs, they show potential for interaction with other drugs. The incidence of interactions of clinical significance increases with the number of drugs and patient age. There is a high consumption of PPIs (esomeprazole) in the emergency department. The objective is to study the frequency of prescription of PPI injections associated with drugs with potential for interaction and to investigate the risk described in the literature.

Method
To review patient medical records from emergency episodes to whom PPIs were prescribed during February 2008. To search for potentially interacting drugs on Micromedex, Clinical Pharmacology (CP) and Lexi-Comp ONLINE (LCO).

Results
PPI injections were prescribed to 317 patients, with average age 63.59 (SD=20.80). The average number of drugs prescribed concomitantly was 2.97. Five or more medicines were prescribed to 78 patients. Drugs potentially interacting with PPIs were concomitantly prescribed to 55 patients with an average age of 64.45 and 18 of them were prescribed 5 or more drugs. Eleven different drugs with the potential to interact with esomeprazole were prescribed: Information about an interaction was found for 10 drugs on CP, 3 on Micromedex and 6 on LCO. The most commonly prescribed drugs with a potential for interaction with esomeprazole were diazepam (29 prescriptions) and clopidogrel (10). Diazepam is described in CP as having a moderately severe interaction; it was not included in Micromedex and LCO as moderate. Clopidogrel was described in CP as moderate severity, in Micromedex and LCO as major.

Conclusions
Medicines potentially interacting with PPIs were prescribed concomitantly in 17% of patients. Since these are older, polymedicated patients, the risk of clinically significant drug interactions might be increased. There was no consensus of information between the databases searched. This, together with high PPI consumption, polypharmacy and the population characteristics, reveals the need for further studies to evaluate the clinical significance of these interactions.

Conflict of Interest
No conflict of interest

G23. Calcium and phosphate metabolism disorders after only one month of Imatinib treatment
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Background
The tyrosine kinase inhibitor imatinib mesylate has an established role in the management of chronic myeloid leukaemia by inhibiting the Bcr/Abl fusion protein. Several studies, included ours, have

demonstrated that imatinib therapy causes abnormalities in calcium and phosphate metabolism, such as hypocalcaemia, hypophosphataemia and hyperparathyroidism. We assessed at what point in the treatment the stated alterations appear.

Method
Prospective study of CML patients treated with imatinib from July 2006 to September 2009: 10 patients (5 male, 50%), with a median age of 60 years (29-83), in treatment with a daily imatinib dose of 400 mg. Serum levels of calcium, phosphate and parathyroid hormone were determined before the start of imatinib treatment, and then monthly until a significant difference was observed with regard to the initial determinations. The statistical analysis of the results was performed by the Wilcoxon test.

Results
Significant differences were detected for all the parameters measured after one month of treatment with imatinib: calcium (8.76 vs. 9.56 mg/dl; p= 0.005; mean decrease of 8%), phosphate (2.80 vs. 3.85 mg/dl; p=0.007; mean decrease of 26%) and parathyroid hormone (112.74 vs. 53.97 pg/ml; p= 0,005; mean increment of 153%).

Conclusion
Disorders of calcium and phosphate metabolism appear early after starting imatinib therapy. We note that these analytical changes turn up as soon as after one month of treatment.

Conflict of Interest
No conflict of interest

G24. Detecting relevant drug interactions through an application integrated into a computerised medical history

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Background
Drug interactions may make treatment ineffective and may cause morbidity and mortality. Computerised medical records may be useful to provide easy-access information to hospital practitioners. Integrated applications may facilitate the detection of drug-related problems (DRP), including interactions and pharmacist interventions on pharmacotherapy.

Objective
To describe drug interactions detected through an integrated application in the computerised medical history and to predict which pharmacist interventions will be accepted.

Method
Prospective study from January to April 2009 in a 450-bed university hospital with computerised physician order entry. Our pharmacy department developed an integrated application to detect DRPs, including relevant drug interactions, in the computerised medical history. Pharmacist interventions were included in the computerised medical records in real time. Data collected: demographics, type of patient, drugs, type of interaction and acceptance. Drug interactions was classified as severe, moderate or minor. Statistical analysis was performed with SPSS (ver.13.0).

Results
Admissions: 7444 patients, patients with drug interactions: 155 (2.1%), male: 71 (45.8%), median age: 66.7, medical/surgical: 112/43, number of interactions: 187, number per patient: 1.2. Drugs involved in interactions: 86, main drugs: levothyroxine 29 (7.6%), amiodarone 26 (6.8%), tramadol 24(6.3%). Type of interaction: bioavailability alteration 73 (39.0%), additive toxicity 57 (30.5%), induction-inhibition 54 (28.0%), antagonistic effect 3 (1.6%). Severity of the interaction: severe 90 (48.1%), moderate 78.(41 .7%) and minor 19 (10.1%). Global acceptance/non-acceptance 152 (81.3%) / 35 (18.7%). No differences were found in acceptance by severity. Interventions in drug-bioavailability interactions were the most accepted (72/73 vs. 80/114; p<0.001; OR: 30.6) while induction/inhibition interactions were the least accepted (33/54 vs. 119/133; p<0.001 OR: 0.2).

Conclusions
Many drugs were involved in interactions. The most frequently detected were interactions that altered bioavailability, additive toxicity and induction-inhibition and were of severe or moderate relevance. Medical acceptance of pharmacist interventions was high. Interactions involving bioavailability were a predictor of acceptance.
An integrated application in the computerised medical history was an efficient tool for detecting drug interactions.

Conflict of Interest
No conflict of interest

G25. Review of the adverse haematologic reactions of linezolid: experience of five years

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Background
Adverse haematological reactions (HR) to linezolid (LZD) treatment such as anaemia, thrombocytopenia, leukopenia and granulocytopenia have been related to more than two weeks of treatment. Therefore the FDA and EMEA do not recommend more than 28 days of treatment with LZD.
The aim was to evaluate HR in patients who received LZD more than 28 days according to the hospital protocol for osteomyelitis caused by MRSA or Staphylococcus epidermidis.

Methods
Retrospective study from January 2004 to December 2008 in a 500-bed Spanish university hospital.
Data collected included demographics, days of treatment, initial and final haematological values (concentration of haemoglobin, platelets, leukocytes, monocytes, lymphocyte and granulocytes).
Descriptive statistics were performed by means of parametric tests (t-Student) .

Results
During the last five years we recorded the data of 39 patients, whose haematological values were analysed before, and at the end of, treatment.
LZD was administered for an average of 44 days (7-125). The length of treatment was > 28 consecutive days in 21 patients and it was ≤ 28 days in 18 patients.

	≤ 28 days of LZD		> 28 days of LZD	
	Mean	**p**	**Mean**	**p**
Haemoglobin (13-16 g/dL)	10.66-10.02	0.211	10.30-12.01	0.001
Platelets (150-440x10^9/L)	307.91-278.57	0.369	263.70-267.81	0.900
Leukocytes (4.1-10x10^9/L)	7.09-7.17	0.909	7.47-6.70	0.289
Monocytes (3.1-8%)	7.08-8.43	0.151	6.58-7.76	0.147
Lymphocytes (36-56%)	23.96-24.16	0.929	25.88-29.97	0.181
Neutrophils (50-75%)	63.87-64.41	0.829	62.78-59.99	0.424
Eosinophils (0.2-8.4%)	3.34-2.91	0.440	3.39-2.45	0.048
Basophils (0.2-1.8%)	0.53-0.42	0.397	1.10-0.39	0.281

Mean haematological values before and at the end of LZD treatment and p value with 95% confidence interval.

Conclusions
Haematological values were constant in patients treated with LZD for 28 days or less.
Patients who were treated for more than 28 days with LZD only developed granulocytopenia.
It seems that safety of LZD depends on length of treatment. When administration extends beyond 28 days, it will be necessary do a weekly blood test, with special attention to granulocyte values.

Conflict of Interest
No conflict of interest

GROUP H: INFECTIOUS DISEASES

H1. New antiretroviral drugs: a study of their use

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Background
Rescue therapy with new antiretroviral drugs in HIV/AIDS patients is essential due to therapeutic failure, toxicity and drug interactions. This aim of this study was to evaluate the use and associated costs of the newer antiretroviral drugs darunavir, raltegravir and etravirine.

Method
Retrospective observational study of all HIV/AIDS patients who started treatment with at least one of the new drugs mentioned, between October 2007 and September 2009.

Results
Of a total of 1335 patients on active antiretroviral therapy in September 2009, 28 were on a regimen that included at least one of the three drugs being evaluated. Their average age was 43.9 years old and 21 (75.0%) were male. Eighteen (64.9%) started antiretroviral therapy more than 10 years ago. In the patients studied, 21 different treatment regimens were found, the most common being darunavir/ritonavir + raltegravir + tenofovir / emtricitabine (n=5). Of the patients studied, 2 had darunavir, raltegravir and etravirine included in their regimen, 21 patients only had 2 of these drugs and 5 patients only one. The average cost per year of treatment with these new regimens was 22,217 € [14,189 € to 28,099 €] which is higher when more recent drugs are involved. The average cost per year of treatment of a conventional scheme (without new drugs) was 9,251 €, implying that the introduction of at least one of the new drugs leads to the annual cost per patient increasing by 2.4 times.

Conclusion
The economic impact of treatment failure of conventional schemes is high, since the annual cost of treatment per patient more than doubled with the new drugs. It is essential to develop strategies to prevent the failure of conventional therapies and avoid the need for rescue therapy. The savings associated will allow substantial investment in human resources and technology necessary to implement these strategies, which might include pharmaceutical expertise.

Conflict of Interest
No conflict of interest

H2. Treatment adherence in HIV patients starting rescue antiretroviral therapy

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Background
Adherence to HIV treatment is considered to be implicated in the development of drug-resistant HIV. We analysed the adherence of treatment-experienced patients before starting rescue antiretroviral therapy (RART) and during this treatment.

Methods
Retrospective-observational study from April 2008 to April 2009, including patients registered in the pharmacy outpatient database and treated with one of the new antiretroviral agents raltegravir and/or maraviroc. Adherence was measured 6 months before starting RART and during the first 6 months of this treatment using the indirect method of dispensing records. Values of 95% or more were considered adherent. Lower values were considered non adherent.

Results
Eligible patients: 30 (22 men, average age: 43.6 years), 2.8% of total patients with antiretroviral treatment (1086 patients). All patients had previously been treated with an average of 6.7 different treatment lines. The current treatment consisted of 3 drugs for 23 patients (76.7%), 4 drugs for 2 patients (6.7%), 5 drugs for 4 patients (13.3%) and 6 drugs for 1 patient (3.3%). All patients had a twice daily schedule with an average of 9 dosage forms per day.
Adherent patients 6 months before RART: 20 (66.7%), average adherence rate (AAR): 99%. Non-adherents: 10 (33.3%, AAR: 84.5%)
Adherent patients during first 6 months of RART: 24 (80%, AAR: 100%). Non-adherents: 6 (20%, AAR: 86.7%) Six patients (60% of previous non-adherents) improved their adherence in RART, 2 became non-adherent and 4 continued being non-adherent as in previous regimes.

Conclusions
Adherence is only one of the several factors involved in the development of drug-resistant HIV (the percentage of non-adherents among all patients starting a RART was 33.3%). There was a significant improvement in adherence in RART as a result of the pharmacotherapy follow-up performed by the pharmacy department.

Conflict of Interest
No conflict of interest

H3. Naïve HIV patients: immunological conditions and antiretroviral theraphy

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Background
To determine the number of HIV patients who start antiretroviral therapy (ART) in our hospital, to record their immunological and virological status, the ART used and its agreement with present Spanish guidelines.

Method
Retrospective study from 01/03/2008 to 30/09/2009. Data source: Clinical history and pharmacy department database. Data recorded: age, gender, clinical follow up before treatment, antiretroviral therapy (ART), CD4 counts, viral load, HBV and/or HCV co-infection, percentage of CD4 cells.

Results
ART was started in 135 patients: 14 were transfers from other institutions, 6 post-exposure prophylaxis and 7 pregnant HIV-infected women. 108 patients were treatment-naïve, 70.4% men, average age 39.6 ±9.6 years, 72.2% with previous clinical follow up. The patients studied were grouped according to the CD4 count: ≤ 350 cells/µL (88.5% of patients), 351-500 cells/µL (10.5%) and > 500 cells/µL (1%). Regarding the patients with CD4 count 351-500 cells/µL: the average viral load was 110,993 copies/mL (1,016-603,098), HIV RNA >100,000, (27.3% of patients) and all had fewer than 14% CD4 cells, 27.3% had HBV and/or HCV co-infection and 9.1% were over 55 years old. Only one patient had 530 CD4 cells/µL at the beginning, although he had had CD4 <350 cells/µL in previous reviews. The ART included protease inhibitors in 43.5% of patients and non-nucleoside reverse transcriptase inhibitors (NNRTI) in 56.5% of patients. Of the nucleoside reverse transcriptase inhibitor prescriptions, tenofovir was used in 88.0% and abacavir in 11.1% of cases. A significantly greater percentage of patients had CD4 counts <200 cells/ µL in the group without previous clinical follow-up versus the group with previous follow-up (73.3% vs. 24.4%, p<0.01).

Conclusions
The treatment complied with the present Spanish recommendations. Most patients (88%) began with CD4 ≤350 cells/µL. ART mainly included tenofovir and a NNRTI (48.1% efavirenz). The CD4 counts at start of treatment were worse in patients new to the hospital than patients who were known already to the hospital.

Conflict of Interest
No conflict of interest

H4. Antibiotic consumption from 2004-2008 in a teaching hospital pharmacy

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Background
The correct use of drugs is one of the most important objectives for health care professionals. To achieve this, usage patterns and consumption should be studied. Antibiotic resistance is increasing worldwide as well as their cost, which represents a significant part of the hospital budget.

Method
Retrospective study. The consumption of antibiotics was monitored from 2004 to 2008 from the data system used in our pharmacy department. Intravenous (IV) amoxicillin-clavulanic acid, piperacillin-tazobactam, cefotaxime, ceftriaxone, imipenem-cilastatin, IV ciprofloxacin and IV levofloxacin were studied with particular attention because the infections committee was conducting an epidemiological survey. The results were expressed by defined daily dose (DDD)/100 bed days.

Results
Antibiotic costs represented 16.7% of the overall drug expenditure in the hospital (DE 2.75) (04-08: 16.9-21.1-15.9-13.7-15.6%).
The table shows the DDD consumption of the selected antibiotics during the period and the antifungal DDD:

	Amoxicillin-Clavulanic	Piperacillin-Tazobactam	Cefotaxime	Imipenem-Cilastatin	Ceftriaxone	Levofloxacin	Ciprofloxacin	DDD antifungals
2004	5.03	1.17	5.78	1.82	1.10	0.51	1.54	62.37
2005	5.60	1.06	6.18	1.39	0.70	0.84	1.61	61.59
2006	6.64	0.87	6.19	2.97	0.60	1.09	1.68	67.48
2007	7.06	1.15	5.83	2.70	1.03	1.07	1.60	62.03
2008	6.24	2.39	5.06	2.56	4.51	2.58	1.72	63.28
% Change 04-08	24.04	103.24	-12.48	40.80	311.61	406.68	11,47	1,46

Consumption of piperacillin-tazobactam, levofloxacin and ceftriaxone increased significantly during 2008.
A constant monthly pattern was not observed for every antibiotic during the period studied. Only levofloxacin and amoxicillin-clavulanic acid IV were used more often in winter.

Conclusions
Our average consumption of antibiotics and antifungals expressed in DDD was stable during the period 2004-2008, while other studies in Europe showed increases of 14-24% during a similar period.
Levofloxacin and piperacillin-tazobactam were gradually used more frequently. Ceftriaxone consumption increased over the last year and DDD of cefotaxime decreased.
The cost of antibiotics compared to the overall cost of drugs in the hospital was stable during 2004-2008.

Conflict of Interest
No conflict of interest

H5. Haematological safety of ambulatory treatment with oral linezolid

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Background
Linezolid is an antibiotic used in severe infections caused by Gram-positive bacteria that are resistant to several other antibiotics. According to the product information, its safety has not been established when the treatment duration is longer than 28 days and it is recommended to do haematological analyses weekly during this treatment.
In this study we analysed the use and the haematological adverse effects of ambulatory treatment with oral linezolid.

Method
Retrospective, descriptive study of outpatients treated with oral linezolid between January 2007-September 2009 attended in a Pharmaceutical Care consulting room.
Data collected: sex, age, diagnosis, length of treatment, microbiological test results and data from blood tests (haemoglobin, neutrophils and platelets).

Results
We recorded 22 patients (9 men), median age: 65 years, median treatment duration: 26.41 days. 6 patients were treated for more than 28 days.
Diagnosis: nosocomial/community-acquired pneumonia (n=3), complicated skin and soft tissue infection (n=14), and osteoarticular infection, an indication not approved in the official product information (n=5).
A microbiological test was only ordered for 12 patients before starting linezolid. Infectious agents identified in the test: Meticillin-resistant *Staphylococcus aureus* (n=6),coagulase-negative *Staphylococcus* (n=3),penicillin-resistant *Staphylococcus aureus* S (n=3).
Haematological analyses were carried out in 16 patients before and after treatment , but none of the patients had weekly blood tests.
Haematological effects observed in 8 patients at the end of the treatment: anaemia (4), decreased number of platelets (2) and both (2). None presented neutropenia. Only 2 of them were treated for more than 28 days.

Conclusions
Thrombocytopenia and anaemia were evident with linezolid treatment. These results indicate that haematological monitoring is required weekly.
The rationality and safety in use of oral linezolid can be improved with the implementation of a monitoring programme in the pharmaceutical care consulting room. The pharmacist should promote patient safety practices, such as ensuring compliance with the recommendations and conditions stated in the official summary of product characteristics.

Conflict of Interest
No conflict of interest

H6. Parmacist interventions on antibiotic dosage performed on antibiotic dosage performed through two different computer programmes

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Background
Insufficient dosage of antibiotics may produce an increase in antimicrobial resistance, treatment failures and adverse effects. Computer Prescriber Order Entry Systems (CPOES) can be useful tools in order to avoid ID.

Objectives
- To compare clinical and microbiological features between patients with a pharmacist intervention on antimicrobial dosage adjustment performed through an old and a new CPOES.
- To assess the utility of a new CPOES in detecting inadequate dosage.

Method
Six-month retrospective study in a 450-bed university hospital including all patients with antimicrobial interventions made through an old CPOES1 (without real time alerts) and after the implementation of a new CPOES2 (with real time alerts appearing on the computer screen). CPOES1: January-March 2006, CPOES2: June-August 2008.
An insufficient dose was considered when the dose of antibiotic was not adjusted to patient characteristics or infectious foci.
Data collected: demographics, simplified acute physiology score (SAPS-II) at admission, type of admission, medical ward, length of hospital stay, crude mortality, MDRD estimate of creatinine clearance (CrCl),

type of dose adjustment intervention, type of antibiotic, number of microorganisms related to infection isolated, site of infection and intervention acceptance. These variables were compared between CPOES1 and CPOES2.

Statistical analysis: Chi-square and t-student tests.

Results

	CPOES1	CPOES2	p
Total interventions	98	175	
Patients with antibiotic interventions	22	89	
Clinical/microbiological features:			
-SAPS-II	26.1 (CI95%:	31.8	0.010
-CrCl <30 ml/min/1.73m^2	23-29.2)	(CI95%:29.9-33.8)	0.013
- Urinary tract infection	5 (22.7%)		0.041
	1 (4.5%)	50 (52.1%)	0.020
- Empirical therapy	8 (36.4%)	24 (25%)	
		61 (63.5%)	
Antimicrobial dosage adjustment intervention	22 (22.4%)	96 (54.9%)	<0.001
-According to CrCl	3 (13.6%)	55 (57.3%)	<0.001

No differences were observed in the remaining variables, including intervention acceptance.

Conclusions
Patients severely ill at admission, those with urinary tract infections and having empirical antimicrobial therapy have more dose adjustment interventions with the new CPOES2. The new CPOES2 allows a higher number of antibiotic adjustment interventions than the old CPOES1. As a consequence of real time warnings of CrCl reduction, most interventions are related to dosage adjustment in patients with severe renal impairment.

Conflict of Interest
No conflict of interest

H8. Analysis of the prescription of antiretroviral in a local hospital
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Objective
To examine the profile of antiretroviral drug prescriptions to outpatients in order to identify patterns of use, their economic impact and analyse the evolution over the past two years.

Method
A retrospective study analysing antiretroviral drugs dispensed in the outpatient clinic during the period September 2007 to August 2008 (1st period) and September 2008 to August 2009 (2nd period). We identified the combination of antiretroviral drugs for each patient and determined the number and proportion of patients for each pattern, each type of therapy (double, triple, etc.) and every kind of combination for families (nucleoside reverse transcriptase inhibitors or NRTIs, non-nucleoside reverse transcriptase inhibitors NNRTIs, protease inhibitors or IP). In addition we determined the cost of each combination, a financial analysis in both periods.

Results
The number of patients was 33 (which generated 226 views) in the 1st period and 40 patients during the 2nd period (281 appointments). The most widely used treatment in both periods was the triple therapy (69%,65% respectively), coinciding in both periods more combinations of families required: 2ITIAN/1ITINN (49%,53%) and 2ITIAN/1IP (36% ,35%).

It highlights the increasing prevalence of once-daily (QD) treatment, mainly due to the appearance on the market of combinations (tenofovir-emtricitabine-efavirenz). These accounted for 38% of prescriptions in the 2nd period.

The financial analysis on the requirements in both periods shows that the total cost has increased 30% in the 2nd period. Of this increase, 20% would be for the increase in the number of patients seen and 10% of the increase in the average cost of therapy (greater complexity of the prescription).

Conclusions
- Increased quality guidelines to promote patient adherence to antiretroviral therapy.
- The increased spending was due primarily to the increase in the number of patients treated, 21% more than in the previous period.

Conflict of Interest: No conflict of interest

H7. Pharmacotherapeutic profile in chronic HBV in a local hospital
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Background
Chronic infection by the hepatitis B virus (HBV) may eventually trigger serious complications such as cirrhosis, hepatocellular carcinoma and terminal liver disease.

Method
The aim of this study is to describe the profile pharmacotherapy and virological response in patients being treated for chronic hepatitis B.
We examined a cross section of patients in drug treatment for HBV in the third quarter of 2009. Demographic data, drugs, treatment duration and viral load were collected. Response to antiviral therapy, or virological response, was indicated by a decrease in viral load to undetectable levels (<2000 copies/ml).

Results
At the time of the study in our centre 18 patients were being treated for HBV (72.3% men and 27.7% women), 9 as treatment-naive patients (50%) and 9 as non-treatment naive. The median age was 50±11.5 years and average treatment time was 37.6 months (range: 2.8 months).
The predominant regimen was 77.7% monotherapy vs. 22.3% combination therapy. The distribution of treatment was as follows:
- Lamivudine: 3 patients (16.5%)
- Adefovir: 5 patients (28%)
- Entecavir: 5 patients (28%)
- Tenofovir: 1 patient (5.5%)
  Lamivudine+Adefovir: 3 patients (16.5%)
- Entecavir+Adefovir: 1 patient (5.5%)

Virological response was achieved in 13 patients (72.2%), of which 4 were taking entecavir, 3 adefovir, 3 lamivudine+adefovir, 2 lamivudine and 1 tenofovir. The other 5 patients (27.8%) still had a detectable viral load.

Conclusions
1. The profile of the majority was monotherapy with adefovir or entecavir
2. Entecavir represented 28% of the active treatments, achieving viral load suppression in 80% of them, becoming a preferred option for both treatment-naive patients and those resistant to lamivudine and/or adefovir.
3. The introduction of drugs such as entecavir and tenofovir for the treatment of chronic HBV in adults with compensated liver disease, evidence of viral replication and biochemical involvement represents a change in the treatment algorithm of this disease.

Conflict of Interest: No conflict of interest

H9. Comparative analysis of empiric antibiotic therapy for community acquired pneumonia

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Background

Community-acquired pneumonia (CAP) is one of the most common respiratory tract infections. The protocol for empirical antibiotic therapy (EAT) for CAP in our hospital is levofloxacin or beta-lactam antibiotics alone or with macrolides.

The aim of the study was to assess the effectiveness of the EAT in CAP.

Method

Retrospective, observational study conducted from 1 April to 30 June 2009 in a secondary-care hospital with 260 beds. All patients admitted with CAP were included.

The following variables were recorded from the hospital database: age, sex, EAT (levofloxacin or ß lactam+/-macrolide), microbiological culture results, change of empiric treatment after microbiologic results, total duration of antibiotic therapy and length of hospital stay.

We checked whether patients treated with levofloxacin met the criteria for use: beta-lactam allergy, prior treatment with beta-lactam antibiotics, readmission or institutionalized patients.

Statistical analysis was performed using SPSSv15 (χ^2test and T-student) to compare the variables length and change of antibiotic treatment and hospital stay of the two groups (levofloxacin and ß lactam+/-macrolide).

Results

Sixty patients were included (33men/27women) with a mean age of 73 years (19-101).

Table 1 shows the antibiotics prescribed.

27%(n=10) of levofloxacin-treated patients met one or more of the prescription criteria.

Mortality rate was 6.66%(n=4), and all of whom had been treated with levofloxacin.

Statistical analysis showed no significant differences in length of antibiotic treatment or change of treatment between patients treated with levofloxacin ß lactam+/-macrolide (Table 2).

Hospital stay was longer in patients treated with levofloxacin (p=0.045-IC95% 0.085-6.958).

Table 1

	n	%
Levofloxacin	37	61
ß lactam	14	23
ß lactam + macrolide	9	15

Table 2

	Levofloxacin (n=33)	ß lactam +/- macrolide (n=23)	
Length of antibiotic treatment: days	Mean=13.97 (SD=6.302)	Mean=12.52 (SD=5.151)	p=0.350 IC95%:-1.632-4.528
treatment change: Yes/No	9/26	9/14	p=0.214

Conclusion

No difference was found in efficacy (length or change of antibiotic treatment) between levofloxacin and ß lactam +/- macrolide used in EAT for CAP.

The longer stay in hospital and greater mortality rate in patients treated with levofloxacin may have been associated with the worse clinical status of these patients.

Conflict of Interest

No conflict of interest

H10. Telbivudine in chronic hepatitis B

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Objective

Telbivudine (LdT) is a nucleoside analogue antiviral, indicated for the treatment of chronic hepatitis B (CHB). The aim of this work is to evaluate its effectiveness.

Method

Retrospective observational study of patients with CHB treated with LdT from September 2008 to September 2009 in our hospital. The information was obtained from the computerised clinical history and the outpatient dispensing program, recording the following parameters: age, sex, diagnosis, previous treatments, current treatment, dose, biochemical parameters: alanine aminotransferase (ALT), presence of hepatitis B e antigen (HBeAg), surface antigen (HBsAg), Anti-HBs and anti-HBe antibodies, as well as viral load (HBV DNA).

Success of the treatment was defined by two criteria: biochemical response (normalisation of ALT levels (7-35 U/L)) and virological response (undetectable HBV DNA). In HBeAg+ patients we evaluated the neutralisation of HBeAg and the appearance of anti-HBe antibodies.

Results

The study population consisted of 9 patients (7 men) with a mean age of 43.6 years (30-60). There were 4 treatment-naive patients, 3 of whom were included in a clinical trial of LdT. The other 5 patients had received previous treatment including lamivudine, adefovir and interferon.

	HBeAg+ (number of patients)	HBeAg- (number of patients)	Total
Monotherapy	1	3	4
Combined	2	3	5

The combination therapy included either adefovir or tenofovir.

The average duration of treatment with LdT in monotherapy was 7.36 months (2.6-16.4) and 10.73 months (5.4-16.2) in combination therapy. 100% of patients became HBV DNA seronegative. Transaminase decreased in 88.8% of the patients and in 66.7% reached normal values. In none of the 3 HBeAg+ patients were neutralisation of antigen or the appearance of anti-HB antibodies observed.

Conclusions

LdT is an effective antiviral treatment of patients with CHB.

Treatment response was faster in treatment-naive patients who received LdT in monotherapy than in those previously treated with combination therapy.

Conflict of Interest

No conflict of interest

H11. Analysis of tigecycline prescriptions in a general hospital

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Background

Tigecycline is a broad spectrum tetracycline that is included in the hospital formulary as a restricted antibiotic, under the antibiotics policy. Restricted antibiotics must be ordered on a special application form on which doctors justify their prescriptions. The aim of this study is to evaluate if the application form was completed correctly and the suitability of the prescription.

Method

A retrospective study was made in a 550-bed general hospital. Tigecycline prescriptions received at the hospital pharmacy from October 2008 until September 2009 were examined. Age, clinical

department, indication, microbiological culture sample origin, microorganism isolated and antibiogram results were collected from patients' clinical records. Prescription suitability was evaluated according to EMEA-approved tigecycline indications for use, severity of the infectious disease and underlying pathology.

Results
25 patients were included in the study group. Mean age was 52 (25-79). Most of prescriptions were written by Surgery (15, 60%) and Intensive Care (6, 24%). The application form was filled in correctly in 18 cases (72%) but complete information was lacking in 7 forms (28%). The indication was considered suitable in most cases (96%); of these, 18 (75%) corresponded to EMEA-approved tigecycline indications (6 complicated skin and soft tissue infections, 12 complicated intra-abdominal infections), and 6 (25%) corresponded to off-label indications (infections caused by Acinetobacter baumannii). Treatment was prescribed empirically, except in infections due to Acinetobacter. 8 patients had previously been treated with other antibiotics, 4 were allergic to beta lactams and 3 had renal impairment. Microorganisms were isolated in 21 patients. Inappropriate treatment was confirmed in 2 patients, in whose culture samples Candida albicans and Aeromonas hydrophila were isolated.

Conclusion
In most cases tigecycline was used appropriately. However the application form was filled in unsatisfactorily in a quarter of the total prescriptions, so a new design of application form is needed to make it easier to fill in.

Conflict of Interest
No conflict of interest

H12. Microcalorimetry: an early identification method for bacterial growth

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Introduction
Early diagnostic methods allow early treatment and improved treatment outcomes in infectious processes.
Bacteria in culture medium convert part of the energy from the C supplied into ATP, freeing the rest as heat.

Objective
To evaluate the use of microcalorimetry as a method of identifying bacterial growth.

Methods and materials
We used a Calvet microcalorimeter, inside which two Teflon screw-capped stainless steel cells are located (sample and reference). The caps are perforated through their centres so that a needle connected to a syringe can pass through. A constant temperature of 37ºC is maintained within the microcalorimeter.
We started with S. aureus (ATCC 20203) stock, with its concentration adjusted to a turbidity of 0.5 on the McFarland scale (Densichek calorimeter), and diluted it with physiological saline solution to obtain final concentrations of 106,105,103, and 10 CFU/mL. Digested liquid soy-casein medium was used.
In the Calvet microcalorimeter, 7 mL of culture medium and 1 mL of physiological saline solution were injected into the reference cell and 7 mL of culture medium into the sample cell. Both cells were then left in the microcalorimeter and allowed to stabilise for an hour and a half. After stabilisation 1mL of test solution was injected into the test cell at the aforementioned concentrations.

Results
Plotting the difference in calorific potential over time we obtained growth charts for S. aureus at various concentrations, in which the lag, exponential, stationary and death phases could be identified. At high concentrations (106,105,and 103 CFU/mL), maximum growth was observed before 5 hours, whilst in the10 CFU/mL sample maximum growth was observed after 10 hours.

Conclusions
Microcalorimetry allows us to measure bacterial growth from the heat liberated during microbial metabolism and can identify if a sample is contaminated in a few hours.

Agreement:
We thank María Perfecta Salgado González and Sofia Baz Rodríguez for their collaboration with the technical measures

Conflict of Interest
No conflict of interest

H13. experience of use of peginterferon plus ribavirin against hepatitis C virus

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Background
We examined the effectiveness of peginterferon plus ribavirin in chronic hepatitis C patients in a health area of 371,000 inhabitants, measured as sustained viral response (SVR) 24 weeks after treatment end. We also tried to relate genotype with SVR and known safety data.

Method
Observational, descriptive and retrospective study of 100 patients infected with HCV who started treatment between 02/2006-07/2008. Patients co-infected with HIV-HBV were excluded.
The variables analysed included age, sex, genotype, duration of treatment, response at end of treatment (ETR), SVR, relapse, breakdown of response, no primary response, adverse reactions (AR).

Results
We analysed 100 patients (72 men) of which only 75 could be evaluated: 24 were still receiving treatment and one was lost to follow up. Mean age was 44.28±11.2 years. The most frequent genotype was type 1 (63 patients), then type 3 (26).
Treatment was adhered to in 95% and there was no relationship between gender and withdrawal from treatment.
Regarding efficacy, 49 patients showed ETR, 25 no primary response and 1 breakdown of response. Of those who showed ETR, 25 achieved SVR (42.3%), 8 experienced relapse (13.6%) and 16 were awaiting review (not included in analysis).
There was a significant relationship between genotype and SVR: 37.1% of genotype-1 patients achieved SVR, and 73.3% of genotype 3 ($p < 0.02$).

Treatment was discontinued because of AR in 13%:
- 6% for haematological disorders: it was necessary to reduce the dose of peginterferon because of neutropenia in 12% and the dose of ribavirin because of anaemia in 17%. By Somer's delta coefficient, we found that patients were 16% less likely to achieve SVR when the dose of peginterferon was reduced, and 33% with ribavirin reductions.
- 4% for depression: equally common in males and females.
- 3% for malaise, loss of weight: more frequent in females, but without significant differences.

Conclusions
In our environment these therapies are able to achieve around 42% SVR, significantly higher in genotype-3. These findings were consistent with the reviewed literature.
Our findings seemed to show that reducing the dose of both drugs decreased the chance of achieving SVR.

Conflict of Interest:
No conflict of interest

H14. Stability of dicloxacillin sodium in elastomeric infusion pumps

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Background
The Department of Orthopaedic Surgery at Aarhus University Hospital is interested in using dicloxacillin sodium for home therapy for a patient group that requires prolonged anti-microbiological intravenous therapy. Using home therapy has several advantages: a decrease in admission days reduces the cost and increased mobility presumably increases quality of life for most patients. Preparation at the pharmacy under aseptic conditions might prevent nosocomial infections.
Therefore a study was initiated to investigate the stability profile of dicloxacillin sodium 10 mg/mL in sodium chloride 0.9% in elastomeric infusion pumps.

Method
The dicloxacillin sodium 10 mg/mL in sodium chloride 0.9% solution in elastomeric infusion pumps was prepared at the Hospital Pharmacy, Aarhus University Hospital, Skejby.
The dicloxacillin concentration was assayed by HPLC. Furthermore, pH and particle content were measured. The microbiological status was examined by *Test for Sterility* and *Container Closure Integrity Test*.
The quantitative content was measured after 0, 22, 70, 94 and 167 hours of storage at 4 ˚C. The samples were kept at room temperature for at least one hour before they were analysed.

Results
The content of dicloxacillin remained practically stable during the 167 hours. There was a pH drop from 5.7 to 5.1 during the test period. A few samples were slightly over the limit for 10 µm particles. This is most likely due to the sampling method and analysis insecurity.
No growth of micro-organisms occurred.

Conclusion
Dicloxacillin sodium 10 mg/mL in sodium chloride 0.9% in elastomeric infusion pumps remained stable for 167 hours at 2-8 ˚C followed by 1 hour at room temperature protected from direct sunlight.

Conflict of Interest
No conflict of interest

H15. Study of use of linezolid in a general hospital

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Background
To describe the use of linezolid after the introduction of a protocol to restrict the use of antibiotics recently included in our pharmacotherapeutic guide.

Method
We did a retrospective descriptive study of all patients who started linezolid treatment from February 2008 to September 2009. A form has to be filled in in order to request the use of linezolid according to the protocol. We reviewed those forms which record: patient demographic data, posology, duration, kind of treatment: (empirical or microbiological diagnosis) and type of infection. All data were collected in an Excel database.

Results
In this 18-month period, 126 patients were prescribed linezolid (55% men). In all cases the posology was 600mg/ 12h, mean duration of treatment was 11.07 days (SD: 3.97), but in 48 patients (38%) we did not get data about duration of treatment because there were mistakes in the forms. Some of them were incorrectly filled in and in other cases physicians did not record this information.

Linezolid was used in the following departments: ICU (54%), Haematology (15%), Surgery (7%) Internal Medicine (5.5%), Traumatology (3%) and other several wards (12%)

Linezolid treatment was started empirically in 80 patients (63% of the total). In some of these, 46%, it was used due to the suspicion of mechanical ventilation-associated nosocomial pneumonia caused by meticillin-resistant Gram-positive cocci, and in 35% due to septic shock and renal insufficiency.
Microbiological diagnosis (meticillin-resistant Staphylococcus aureus infection) was the reason for linezolid treatment in 43 patients (34%). Of these, 37% of patients had a vancomycin-resistant infection, and 42% were intolerant to vancomycin or treatment had failed.
Physicians did not justify the use of linezolid according to the protocol in 21% of patients.

Conclusion
In spite of introducing the protocol for the correct use of linezolid, we observed several protocol deviations that we have to improve. It is necessary to monitor carefully and to improve our active communication with the main wards, such as ICU, physicians and the infection committee in order to promote the rational use of antibiotics.

Conflict of Interest
No conflict of interest

H16. Antiretroviral treatment in patients infected wtih the human immunodeficiency virus: causes and profile of treatment modifications

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Background
Antiretroviral treatment (ART) is a chronic treatment and as such it is subject to changes with the objective of improving adherence or minimising side effects. The aim of this study is to analyse the causes and profile of modifications to antiretroviral treatment (ART) in patients infected with the human immunodeficiency virus (HIV).

Methods
Cross-sectional and retrospective descriptive study of changes in the antiretroviral treatment of patients seen in the hospital between July 2008 and September 2009. Variables were gathered from the review of clinical histories and the outpatient computer system. Simplification, side effects, resistance and unknown causes were classified as reasons for treatment modification.

Results
Of the 238 patients receiving ART treatment, 51 (21.43%) required treatment modification and 5 of these required a second modification due to side effects. A total of 56 modifications was made. 46.43% of changes (26 patients) corresponded to treatment simplification, 28.57% (16) to side effects, 17.86% to resistance and 7.14% to other causes.
84.62% (22) of simplifications corresponded to a change to the single dose presentation of emtricitabine, tenofovir and efavirenz (Atripla). Modifications due to side effects were primarily a result of the onset of lipoatrophy caused by thymidine analogue NRTIs.

Conclusions
The modifications performed in antiretroviral treatment are mainly due to simplification with the objective of reducing the number of daily tablets to be taken. More studies should be conducted to determine if a decreased number of tablets correlates with higher adherence.

Conflict of Interest
No conflict of interest

H17. Antiretroviral treatment in treatment-naive patients: compliance with clinical practice guidelines

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Background

Spanish guidelines (2008) recommend starting antiretroviral treatment (ART) in treatment-naive patients infected by human immunodeficiency virus (HIV) when the CD4 count falls below 200 cells/μL. In most cases, patients with a CD4 count between 200 and 350 cells/μL should also start treatment. The recommended initial treatment should include the combination of two nucleoside analogue reverse transcriptase inhibitors (NRTI) with either a non-analogue reverse transcriptase inhibitor (NNRTI), preferably efavirenz (EFV) or a boosted protease inhibitor (PI). The aim of the present study was to analyse compliance with Spanish clinical practice guidelines in treatment-naïve patients who started ART in 2008.

Methods

Review of the medical records of treatment-naïve patients who started ART in a community hospital in 2008. The following data was recorded: CD4 count and viral load at the beginning of treatment and a follow up at 3 and 6 months. The initial ART was also recorded.

Results

Fifteen patients started ART during 2008. All but one received one of the regimens advocated by the guidelines. Seven of them received the 2NRTI+EFV combination and the remaining seven were treated with 2NRTI+PI. Changes in CD4 count and viral load are summarized in the following table:

	CD4 (cells/μL)	Viral load (cop
Baseline (n=15)	154 (5-287)	314.773 (2176-1.763.6
3 months (n=15)	280 (14-610)	<40 in 50% of patients
6 months (n=11)	276 (90-592)	<40 in 66% of patients

Conclusions

The initial ART administered in our hospital complies in nearly all cases with current national guidelines in Spain.

The majority of patients started ART with a CD4 count below 200 cells/ μL. Taking into account that the latest guideline reviews recommend starting treatment at a higher CD4 count, physicians should consider starting treatment when the CD4 count falls below 350 cells/ μL or when it is lower than 500 cells/ μL if comorbidities are present.

Conflict of Interest

No conflict of interest

H18. Evaluation of antifungal prophylaxis with posaconazole in haematooncological patients

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Objective

To evaluate antifungal prophylaxis with posaconazole in haemato-oncological patients treated with chemotherapy.

Method

Retrospective study performed over one year (March 2008 to March 2009) in a 500-bed general hospital with twelve haemato-oncological beds in which approximately 30% of all haemato-oncological patients receive antifungal prophylaxis with posaconazole. Haemato-oncological patients were selected using a database that included the duration and evolution of posaconazole prophylactic treatment (PPT) from admission. This was supported by patient clinical histories and lab values.

The records of all patients prescribed PPT were examined to determine if they met the indication criteria according to the summary of product characteristics.

Low baseline neutrophil levels were considered a risk factor for invasive fungal infections (IFI).

The length, tolerability, and any changes in the PPT were characterised and the antifungal treatment (AFT) required was specified.

Results

Initially 38 patients were recorded as receiving PPT, but in ten of these the prophylactic treatment was changed upon admission. Therefore, 28 events kept the prophylaxis treatment just with posaconazole. These episodes corresponded to 16 patients (63% men) with a mean age of 30 years (16-74).

Medical diagnosis requiring PPT was satisfied by 23 (82%) cases, of which 21 presented with acute myeloid leukaemia and two corresponded to myelodysplastic syndrome. The five remaining cases were unrelated and due to a diagnosis of acute lymphoblastic leukaemia.

Baseline neutrophil levels of PPT and incidence of IFI are listed in the following table.

Neutrophil levels	IFI
Normal (1.8-7.2·10^9/L) = 8 (29%)	1
Low = 17 (61%)	8
High = 3 (10%)	0

The mean length of PPT was 20 days (4-48).

No adverse reactions were recorded related to posaconazole treatment.

AFT was not required in 19 (68%) cases, meanwhile in nine (32%) cases it was required despite PPT.

Amphotericin B lipid complex was prescribed for six (67%) of the infected patients. The other patients were treated with caspofungin, fluconazole or liposomal amphotericin B.

Conclusions

PPT was safe and effective in haematological patients at high risk of infection.

In the end, nine (32%) patients developed an IFI, eight (89%) of the infected episodes occurring in patients with low baseline neutrophil levels.

Conflict of Interest

No conflict of interest

GROUP I: ONCOLOGY

I1. Neutropenia: Pemetrexed vs Docetaxel

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Background

In the head-to-head phase III trial that compared pemetrexed to docetaxel in second-line treatment of non-small cell lung cancer (NSCLC), all histologies included, pemetrexed showed clinical equivalent efficacy, but had a statistically significant lower rate of neutropenia, febrile neutropenia, and neutropenia with infections. In this trial, only 2.6% of the patients in the pemetrexed arm needed treatment/prophylaxis with granulocyte colony stimulating factors (G-CSFs), compared with 19.2% in the docetaxel arm. The aim of our study was to evaluate, in real practice, the use of G-CSFs in NSCLC patients treated with pemetrexed or docetaxel.

Method

Retrospective study of the use of filgrastim or pegfilgrastim, in all NSCLC patients treated with pemetrexed or docetaxel, from January 2008 to September 2009, based on the pharmacy records.

Results

During the study period, 44 patients were evaluated (16 treated with pemetrexed and 28 with docetaxel). The pemetrexed group had 13 males and a median age of 59.81 ±10.76 years [49-77 years]. In the docetaxel group there were 26 males and a median age of 62.39±9.26 years [42-77 years].
Sixty pemetrexed cycles were given: 3.75 cycles/patient [range 1-6]. Five of the 16 pemetrexed group patients (31.25%) received G-CSFs [filgrastim (n=4) or pegfilgrastim (n=1)]. 105 cycles of docetaxel were given: 3.75 cycles/patient [range 1-6]. Twelve of the 26 docetaxel group of patients (42.80%) were given G-CSFs [filgrastim (n=11) or pegfilgrastim (n=1)]. The median number of filgrastim administrations were 2.8 per cycle, for both groups.

Conclusions

The need to use G-CSFs was much higher than that described in the comparative trial for both drugs we examined, remaining more frequent for the docetaxel group. In real practice, it seems that the differences between neutropenic events caused by pemetrexed and docetaxel treatment are smaller than expected.

Conflict of Interest

No conflict of interest

I2. Use of palonosetron in 4 oncology patients in the control of nausea and vomiting induced by chemotherapy

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Objective

To analyse the use of palonosetron after its introduction in the hospital as drug with restricted use.

Method

Data were collected in a retrospective study of palonosetron use since April 2008. Data, which were collected from a computerised multidisciplinary application, were: sex, age, diagnosis, chemotherapy regimens and antiemetic treatment. Efficacy was measured as the absence of emetic episodes and no use of rescue therapy.

Results

4 patients (3 female, 1 male; mean age 55 (SD: 17) years) were treated with palonosetron. In three the diagnosis were non-small cell lung cancer, in one was colon cancer. This drug was prescribed in a total of 16 chemotherapy cycles. According to Hesketh's algorithm, all the patients were treated with highly emetogenic regimens; three included cisplatin ≥50 mg/m2 and one oxaliplatin ≥75 mg/m2 plus 5-fluorouracil. The antiemetic treatment used as first line in three patients was: aprepitant 125mg, intravenous ondansetron 8mg and dexamethasone 12mg before chemotherapy, plus oral aprepitant 80mg on days 2-3 and dexamethasone 8mg on days 2-4. In the other patient intravenous ondansetron 8mg, dexamethasone 12mg before chemotherapy, oral dexamethasone 8mg, metoclopramide 60mg and lorazepam 2mg were given on days 2-4. The antiemetic treatment was changed due to poor antiemetic control, so the use of ondansetron was discontinued and intravenous palonosetron 250mcg was introduced on day 1. After inclusion of palonosetron, no emetic episodes were observed independently of the line of treatment used. Constipation and headaches were related adverse effects.

Conclusions

Palonosetron showed to be effective and safe in the control of highly emetogenic chemotherapy-induced nausea and vomiting in 4 patients who were suffering these adverse effects despite the adequate control of them in previous cycles.
Pharmacists should work with the oncology service to improve the quality of life of these patients and ensure the appropriate use of antiemetics in the control of the refractory nausea and vomiting.

Conflict of Interest

No conflict of interest

I3. Temsirolimus in the treatment of advanced renal cell carcinoma: drug use review

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Background

Temsirolimus is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC) who have at least three of six prognostic risk factors (less than one year from time of initial renal cell carcinoma diagnosis, Karnofsky performance status of 60 or 70, haemoglobin less than the lower limit of normal, corrected calcium of greater than 10 mg/dl, lactate dehydrogenase >1.5 times the upper limit of normal, more than one metastatic organ site).
The objective was to overview the effectiveness and safety of temsirolimus in the treatment of adult patients with active RCC.

Methods

Medical record review and retrospective analysis (from October 2008 to September 2009) of prescriptions recorded in the outpatient pharmacy department (ATHOS-APD drug prescription database) in a general teaching hospital. Clinical condition, previous drug use, side effects and tolerance were analysed.

Results

A total of 7 patients with metastatic disease were prescribed temsirolimus (3 male (42.86%), 4 female (57.14%), mean age = 54.29 years).
Four patients (57.14%) received temsirolimus as first-line treatment, whereas two patients (28.57%) were given it as second line after sunitinib (discontinued because of toxicity) and one patient (14.29%) as a third line of treatment, after having had sunitinib and sorafenib, because of disease progression with these drugs.
No one presented significant side effects.
The mean time on treatment was 10.14 weeks.
Four patients (57.14%) were continuing treatment at the end of the period of study while three (42.86%) didn't continue, 1 patient (14.29%) due to disease progression; 2 patients (28.57%) had died.

Conclusions

Data from more patients and longer-term studies are required before it can be concluded that temsirolimus shows an acceptable safety and efficacy profile for the treatment of RCC.

Conflict of Interest

No conflict of interest

I4. Cancer patient care

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Background

The large number of treatment protocols and the extensive supportive therapy associated with each cancer makes oncology a challenge to the clinical pharmacist. The narrow window between toxic and therapeutic effect and regimen complexity increase the risk of drug-related problems (DRPs).

Oncology DRPs have far more serious consequences than DRPs from any other therapeutic area. They require greater responsibility and a more specialised knowledge by the pharmacist.

Method

Between April and August 2009 a team of oncology pharmacists analysed all drug prescriptions for antineoplastic and supportive therapy, for necessity, safety, efficacy and adjustment to the National Comprehensive Cancer Network guidelines (NCCN), suggesting changes when applicable.

Results

Over the five-month period of the study a total of 36 pharmaceutical interventions were made in 35 patients. Average patient age was 65 years (minimum age: 30 years, maximum: 86 years). The most common cancer locations were colorectal and breast. Of all interventions performed, 21 were about dosage alteration related to efficacy, 6 about dosage alteration due to toxicity, 2 were in prescriptions without drug dosage, 1 was related to the prescription of a non guideline-recommended protocol and in the remaining 6, the addition of supportive therapy was suggested. All interventions were discussed with the physician, accepted and the prescription changed.

Conclusions

Despite the brevity of the study, the results show that cancer patients are one of the groups most at risk of DRPs, requiring continuous and systematic pharmacotherapeutic monitoring. The analysis, characterisation and quantification of pharmaceutical interventions performed in the oncology unit are an important step to documenting the activities of the hospital pharmacist in this area. It also allows greater integration of the hospital pharmacist into the multidisciplinary team, who contact cancer patients daily.

Conflict of Interest

No conflict of interest

I5. Assessment of clinically important drug-drug interactions for 63 drugs used on a pediatric oncology department

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Background

As shown in a 2007 study (JNCI;99:592) about one quarter of cancer patients are at risk of a potential drug-drug interaction. Therefore, knowledge of the risk of potential interactions of drug combinations as well as the appropriate management is crucial to ensure patient safety. Data from the literature, except for a few databases and textbooks, mainly provide a confusing mass of unevaluated drug-drug interactions, of which only a limited number is important in clinical practice. The goal of this survey is to evaluate the relevant interactions of drugs used frequently in the paediatric oncology department of our hospital.

Method

Interaction data (effects, mechanism, management, references, summary, onset, documentation) and grading of the clinical relevance (severity and/or significance) were searched and compared within 5 databases or textbooks providing both (Drugdex, Stockley's Drug Interactions, David S Tatro: Drug Interaction Facts, ABDA Datenbank, Schmoll: Kompendium Internistische Onkologie). References were added by an additional search in PubMed.

Results

The assessment of drug-drug interactions for 63 selected drugs revealed many differences in the grading of the clinical significance of individual interactions by the different databases. Taking all data together, a final grading of significance from 1 to 5 of all drug-drug interactions was undertaken for each drug and presented in table format. These tables, as well as the data concerning clinically important drug-drug interactions with significance 1 or 2, their effects, mechanism, references and suggestions for the management of the interaction concerned will be summarised in a booklet.

Conclusion

The resulting compendium of clinically relevant drug-drug interactions is a valuable tool to improve patient safety by avoiding drug interactions in daily practice.

Conflict of Interest

No conflict of interest

I6. Monoclonal antibodies assigned to ATC Code L01XC: Assessment with regard to occupational safety

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Background

Today the health and safety risk with handling most anticancer drugs is well recognized and as a result of regulatory requirements safety measures have been established. At the moment little is known about the occupational risk caused by monoclonal antibodies (MAbs) approved for anticancer therapy. Therefore a German working party with members of the national occupational safety and health organisation 'Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege' (BGW) and the German Society of Hospital Pharmacists (ADKA e.V.) evaluated the hazard risk of monoclonal antibodies assigned to ATC Code L01XC.

Methods

A systematic literature review was performed, European public assessment reports and other official documents were checked and expert opinions were obtained with regard to the carcinogenicity, mutagenicity, reproductive toxicity and sensitising properties of MAbs. The MAb active substances were categorized following the classification and labelling regulations of the European Commission for dangerous substances, published in Annex VI of Directive 67/548/EEC. The results were agreed in a joint committee, including representatives from pharmaceutical companies, pharmacists and experts for occupational safety.

Results

All monoclonal antibodies examined were assessed as substances with developmental toxicity. In addition the gemtuzumab ozogamicin conjugate was categorised as mutagenic. Because of the high molecular weights and the proteinogenic nature of monoclonal antibodies the route of exposure is limited to inhalation for healthcare workers, except in the case of an accident.

Conclusions

Employers should implement necessary administrative and engineering controls, e.g. for pregnant workers, and employees should follow the standards in order to avoid occupational exposure. The assessments of the occupational risks of MAbs will be incorporated in the German Technical Rules for Hazardous Substances.

Conflict of Interest

No conflict of interest

I7. Use of intralesional vinblastine in Kaposi's sarcoma

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Background
Kaposi's sarcoma is a cancer characterized by numerous bluish-red nodules on the skin, usually on the lower extremities. Vinblastine is a vinca alkaloid and a chemical analogue of vincristine. It binds tubulin, inhibiting the assembly of microtubules.

Objective
To determine the effectiveness and safety of using vinblastine therapy intralesionally into individual Kaposi's sarcoma (KS) lesions.

Method
Retrospective study of two patients diagnosed with KS treated with intralesional vinblastine.

Results
Patient 1: A 60-year-old man was diagnosed with classic KS by Dermatology in 2003 (HIV negative). Surgical excision of the skin lesion (1.2 x 1 cm) the same year.
January, 2006: New red - purplish lesion 2 cm in diameter.
Follow-up until August by Oncology.
August, 2006: Treatment started with intralesional vinblastine 0.2 mg/mL by Dermatology .
November, 2006: Reduction of the area of Kaposi lesions after three cycles.
A reduction in the number and size of the lesions was observed after 18 cycles. The patient did not experience any adverse reactions.
Patient 2: A 77-year-old man diagnosed in May 2005 by Dermatology with classic multifocal indolent KS (lesions on the feet, penis and scrotum), HIV negative. Penis and scrotum resection with reconstruction the same year.
August, 2005: Dermatology began treatment with vinblastine (0.2 mg/mL) every three months.
February, 2006: Vinblastine infiltration in the back of the left foot.
April, 2006: Some lesions disappeared.
His disease has followed an indolent course. After 11 cycles, vinblastine treatment has resulted in a reduction in the number and size of the lesions. The patient did not experience any adverse reactions.

Conclusions
Intralesional vinblastine was effective in reducing the size and induration of localised KS lesions in both patients.
The treatment with intralesional vinblastine was well tolerated for localised control of KS lesions.

Conflict of Interest
No conflict of interest

I8. Study of the use of pemetrexed in routine clinical practice

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Background
To evaluate the use and effectiveness of pemetrexed in patients with pleural mesothelioma and non-small cell lung cancer.

Method
Retrospective observational study of patients treated with pemetrexed between January 2007 and June 2008 in our health area.
Data was recorded from the pharmacology department's own selection software and the clinical histories of the patients were reviewed, selecting the age, sex, smoking habits, diagnosis, treatment regime and efficiency measured in terms of general survival.

Results
During the study period, 22 patients were treated with pemetrexed (18 male and 4 female), with a mean age of 56.66 years old. At the time of diagnosis 11 were active smokers and 11 ex-smokers. Of the patients studied, 2(9.09%) were diagnosed with stage IV pleural mesothelioma, and the remaining 20 with non-small cell lung cancer: 2(9.09%) with stage IV squamous cell carcinoma (pemetrexed was provided on compassionate grounds), 3(13.63%) with stage III adenocarcinoma, 10(45.45%) with stage IV adenocarcinoma and 5(22.73%) with stage IV large-cell carcinoma. The patients suffering from mesothelioma were prescribed 500 mg/m2 pemetrexed for 21 days as a first treatment option, one as a monotherapy and the other associated with 75 mg/m2 cisplatin. The patients with non-small cell lung cancer were prescribed 500 mg/m2 pemetrexed combined with 75 mg/m2 cisplatin as the first treatment in two patients (10%), and 50 mg/m2 pemetrexed as a monotherapy in 18 patients (90%), after failure of other treatment regimes. Each patient was given a mean of 3.68 cycles (range1-8) and the average cost per cycle was 2,400 €. Nine months after ending the study 5 patients were still alive (22.72%), and the mean survival time of the deceased patients was 3.29 months (range 2-11 months).

Conclusions
The use of pemetrexed treatment matched that described by the clinical practice guidelines; in two patients compassionate use was allowed.
Notable differences were observed regarding overall survival between patients, therefore, it is important to optimise patient selection to get a favourable cost-effectiveness relationship.

Conflict of Interest
No conflict of interest

I9. Lenalidomide, causes of dose modifications

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Background
Lenalidomide (LEN) is an immunomodulating agent authorised by the EMEA since June 2007 in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy. Dose modifications are not rare and cause many clinical and financial worries. We evaluate the characteristics of dose modifications in our hospital.

Method
Retrospective review from 1/06/2007 to 1/10/2009 of the pharmacy department internal records, electronic medical files (clinic) and Haematology department internal records.

Results
55 patients were treated with LEN for a variety of diseases: 44 (80%) multiple myeloma, 8(15%) MDS (myelodysplastic syndromes), 6 (11%) various diseases.
LEN dose modifications were required for 19 (35%) patients. The causes were: impaired renal function 5 patients (26%), infections 5 (26%), disease progression 4 (21%), neurotoxicity 2 (11%) and other causes for 3 patients (16%).
Of the 19 patients who required dose modification, 8 had to stop treatment due mostly to disease progression (4), severely impaired renal function (2) and infections (2).

Conclusions
Dose modifications in patients treated with LEN are quite common during the treatment. The main causes of modifications were renal impairment, infections and progression of the disease. These patients need careful monitoring during their treatment in order to be given the appropriate dosage as soon as renal impairment is detected and /or to stop the treatment if needed.

Conflict of Interest
No conflict of interest

I10. Trabectedin in soft tissue sarcoma : clinical experience in a French university hospital

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Background

Soft tissue sarcoma (STS) is a rare and histologically diverse group of illnesses. Once the tumour has progressed beyond possible surgery, chemotherapy remains the treatment of choice. The European Medicines Agency approved trabectedin on September 2007 for the treatment of patients with advanced STS, after failure of adriamycin and ifosfamide therapies. We relate our clinical experience of this new alkylating drug in our institution.

Method

A retrospective study of all patients treated with trabectedin on the oncology ward was performed from September 2007 to October 2009. Tumour assessment, ECOG Performance Status, haematological and liver parameters, blood chemistry were recorded: adverse events (AEs) were assessed at each visit. Trabectedin at 1.5 mg/m², 24-h IV infusion was administered once every three weeks. Premedication (Setron-corticoid) was administered 30 minutes prior to infusion. Three trabectedin regimens were planned initially.

Results

Three female patients (62-78 years old, 1.8 m² body surface area, performance status PS = 1) with unresectable/metastatic leiomyosarcoma after failure of standard therapy were given trabectedin as third line therapy.

Two patients received only one regimen, and one received it twice: all the patients experienced early disease progression associated with a deeply altered general condition. The treatment was changed to palliative care. During the infusion the drug was well tolerated: nausea and vomiting were common but not severe (grade1-2). The delayed tolerance was worse with altered general condition (PS=3) and sepsis. For one patient, grade 4 pancytopenia with sepsis, grade 4 liver toxicity, rhabdomyolysis and heart failure occurred one week after the first infusion.

Discussion

Trabectedin is considered an important new option to control advanced STS. Nevertheless, our experience shows no benefit for these 3 patients. They could not receive the entire regimen: trabectedin was interrupted because of disease progression and severe AEs. All these AEs had already been described in the literature except cardiotoxicity. The use of trabectedin should be examined in terms of benefit/risk profile and cost.

Conflict of Interest

No conflict of interest

I11. prediction of adverse effects based on cluster analysis by demography and clinical factor in the outpatients treated with cancer chemotherapy

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Objective

The incidence of adverse effects in drug treatment is an important factor affecting the patient's QOL. Particularly in anticancer chemotherapy, which has a high frequency of adverse effects, a patient's understanding of the risk of adverse effects affects tolerance of, and compliance with, the treatment. In addition, outpatients are often poorly managed by medical care takers, and require information about adverse effects in order to deal with them by themselves at home. We attempted to correlate early laboratory results with later adverse effects in outpatients under anticancer chemotherapy. We used cluster analysis to try and identify associations of adverse effects.

Method

Fourteen adverse effects including bone marrow suppression, nausea, vomiting and anorexia and 20 laboratory parameters including WBC, RBC, and platelet count were analysed retrospectively in 70 breast cancer outpatients who were treated with chemotherapy including docetaxel hydrate from April 2007 to March 2008. Information about the adverse effects was collected for cluster analysis from the assessment sheet linked to the electronic medical records. Use of the information about adverse effects and laboratory reports of patients was previously approved by our institutional ethics committee.

Results

The 70 patients were classified into 5 clusters based on the data obtained from their assessment sheets. The results of cross analysis of these 5 clusters and adverse effects demonstrated different trends regarding the incidence of the adverse effects nausea, anorexia, malaise, constipation and diarrhoea among these clusters. Based on these results, laboratory results were compared with each cluster. The results suggested that some laboratory results (WBC, BUN, total protein, and heart rate) were correlated with adverse effects.

Conclusion

Adverse effect monitoring based on the assessment sheet linked to electronic medical records made possible efficient and exact analysis of adverse effects. In addition, the results of cluster analysis suggest that adverse effects can be predicted from the laboratory results at an early stage of the treatment. In particular the white blood cell count seems to correlate strongly with the incidence of adverse effects. In the future, if adverse effects can be predicted from our results, it will greatly contribute to their early prevention or treatment in the individual patient.

Conflict of Interest

No conflict of interest

I12. Effectiveness and safety of 5-azacitidine in the treatment of patients with myelodysplastic syndromes

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Background

5-azacytidine (azacitidine)is an hypomethylating agent indicated for the treatment of myelodysplastic syndromes (MDS) in adult patients who are not eligible for haematopoietic stem cell transplantation.

The aim of this study is to evaluate the effectiveness and safety of this treatment.

Method

Descriptive and retrospective study of patents with MDS treated with 5-azacytidine in our hospital. Demographics and clinical parameters were collected from the clinical history.

Effectiveness was evaluated by the reduction of cytopenias and changes in the bone marrow (BM) of the patients (measured by flow cytometry and FISH).

Safety was evaluated by the appearance of adverse reactions (ARs).

Results

7 patients (4 men, 3 women) with a mean age of 61 years (42-71) received treatment with 5-azacytidine, mean dose of 471 mg (300-700) monthly per cycle, in our hospital. All were patients with MDS: 3 intermediate-1, 3 intermediate-2, 1 high-risk MDS according to the International Prognostic Scoring System.

5 patients responded in one of the haematological parameters (neutrophils increased in 3 patients after 3, 1 and 3 cycles (mean: 2.3) of treatment; platelets in 3 patients after 2, 1 and 2 cycles (mean: 1.6) of treatment; and haemoglobin in 4 patients after 1, 1, 2 and 3 cycles (mean: 1.7) of treatment. 4 patients are still continuing with the treatment. Length of response: median not reached. In the 5th patient treatment was suspended by progression to LMA after 8 cycles of treatment. In 2 patients there was no response.

In BM of 3 patients there was maturation of the initial blasts The only ARs were: thrombocytopenia in 4 patients, hyperglycaemia in 1 patient.

Conclusions
5-azacytidine has shown effectiveness in 5 of our 7 patients with reduction of cytopenias and maturation of blasts in BM.
It is necessary to keep a strict check of the ARs, although none of our patients had to discontinue treatment.

Conflict of Interest
No conflict of interest

I13. Temsirolimus: Evaluation of drug use in a general hospital
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Background
The aim of this study is to evaluate the safety and efficacy of temsirolimus in patients with metastatic renal cell carcinoma (mRCC).

Method
Observational retrospective study of patients treated with temsirolimus in mRCC in our hospital. Information was collected from patients' clinical histories and the Farmatools programme. The information collected was: age, sex, previous surgery and treatment, number of cycles and adverse effects. Response was evaluated according to RECIST criteria (CR: complete response, PR: partial response, SD: stable disease, PD: progressive disease).

Results
4 patients were treated with temsirolimus during the period studied (3 male and 1 female). Median age was 66 years (range 43-75). All of them had previous nephrectomy and treatment with tyrosine kinase inhibitors. Median dose received was 8 (range 5-34). None of the temsirolimus doses had to be reduced because of adverse effects. Response evaluation after 2 months of treatment was: CR 0 patients, PR 0 patients, SD 2 patients and PD 2 patients. Currently 2 patients are continuing the treatment, one of them with 9 months of progression-free survival. The main adverse effects were: fatigue and raised liver enzymes, 75% of patients; hypercholesterolaemia, hypertriglyceridaemia and anorexia, 50% of patients; raised creatinine level, oedema, diarrhoea, vomiting and hyperglycaemia, 25% of patients.

Conclusions
Adverse events identified in our series of patients are consistent with those described in the literature. Most adverse reactions associated with temsirolimus can be managed medically or addressed by supportive measures. Temsirolimus appears to be efficacious in patients with mRCC.

Conflict of Interest
No conflict of interest

I14. Lenalidomide for multiple myeloma: results of 10 months of monitoring in Palermo
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Background
Lenalidomide is a new, orally active immunomodulatory drug, validated for the treatment of relapsing and/or refractory multiple myeloma (MM). The Italian Medicines Agency regulated its supply as follows (HOsp2 pharmaceutical product): prescription by an hospital specialist, distribution by hospital pharmacies, domiciliary use. All prescriptions of lenalidomide must be recorded on a national website intended for intensive monitoring of antineoplastic agents. The drug is given orally at 25 mg daily from 1 to 21 (28-day therapeutic cycle). The treatment schedule foresees association with dexamethasone 40 mg/day. The Pharmacy Department of Palermo Provincial Health Unit provides the drug and, for continuity of care after hospital discharge, supplies patients through its 14 branch pharmacies.

Method
Patients followed up between December 2008 (since the introduction of lenalidomide to the hospital formulary) and September 2009 were reviewed via the website database.

Results
The total series comprised 29 patients, 16 treated for relapsing and 13 for refractory MM (failure of at least one prior treatment cycle). Male/female ratio was 16/13; median age 68 years (range 40–85). 17 patients (58.6%) were still in treatment with stable disease in September 2009. In this group the median number of therapeutic cycles was 4.3 (range 2-10). The incidence of adverse reactions was 23.5% (4 patients), in these patients dose reduction (25 mg to 15 mg) was necessary due to haematological adverse effect (3 cases) or fatigue (1 patient). 7 patients (24.1%) interrupted treatment due to progression of the MM; in this group the median number of cycles was 4.7 (range 1-9). Finally, 5 patients (17.2%) with refractory MM died after a median of 3.4 cycles (range 1-6).

Conclusion
Lenalidomide was useful in more than 50% of patients suffering from relapsing and/or refractory MM. Associated with dexamethasone, it was well tolerated in the majority of patients; only 4 patients presented adverse drug reactions. Our experience demonstrated that a dedicated website platform enables the Hospital Pharmacy Unit to monitor lenalidomide use in clinical practice in a complete and timely manner.

Conflict of Interest
Noconflict of interest

GROUP J: PHARMACOKINETICS

J1. Optimization of posaconazol plasmatic levels: A case report

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Background
Posaconazole is a new oral antifungal. In vitro data encouragingly demonstrate the opposite activity to other azole antifungal agents, to which fungi are resistant. The usual dosage is 400 mg twice daily by the oral route. Its bioavailability is very variable, increasing with food intake. Its mechanism of absorption is saturable. Steady state is reached after 7-10 days of treatment.

Method
A 53-year-old patient, with a renal transplant, came to accident and emergency complaining of backache. Osseous lesions in the spine and hip, aortic penetrating sore and mycotic cutaneous abscesses were detected. Screening for circulating *Aspergillus* galactomannan (GM) antigen was positive (Index: 5.1). Treatment was started with voriconazole until the microorganism (*Neosartorya pseudofischeri,* the anamorphic form of *Aspergillus thermomutatus*) was identified as resistant. Then it was replaced by caspofungin + amphotericin B. Due to lack of response, we decided to change to oral posaconazole. Because it is known to be erratically absorbed, plasma levels (PL) were monitored - therapeutic range: 0.5-1.5 µg/mL - by high-pressure liquid chromatography (HPLC) in order to check the dosage.

Results
The PL obtained with the initial dose of posaconazole 400 mg twice daily was 0.4µg/mL. A change in the method of administration was recommended, adding an acidic, high fat meal at each administration and as well as dividing the total daily dose (800 mg) into 200 mg four times daily. After these changes, the PL obtained was 1.20 µg/mL. Galactomannan antigen testing continued positive (Index: 3.38-4.43).

Conclusion
Our experience demonstrates the great effect of suitable concomitant food intake (acidic, high-fat food), as well as the change in the interval between doses, smaller doses taken more often. This corroborates the information on the saturable mechanism of absorption of posaconazole.

Conflict of Interest
No conflict of interest

J2. Phenytoin monitoring in hypoalbuminemic patients. Which patients would benefit from free fraction determination?

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Background
Phenytoin, an anticonvulsant with a narrow therapeutic range, has a high plasma protein binding (PPB) that is mainly modified by hypoalbuminaemia and renal impairment. The free fraction is responsible for pharmacologic and toxic effects. However, only the total phenytoin concentration (t-PC) is generally measured in clinical practice. The Sheiner-Tozer equation (STE) is intended to correct t-PC in hypoalbuminaemia and haemodialysis, but it is highly variable. Determination of free phenytoin concentration (f-PC) may be necessary in certain patients.

Objective
To evaluate the consistency of t-PC corrected by STE (c-PC) compared to f-PC in hypoalbuminaemia.
To establish which patients could benefit from f-PC determination.

Method
Retrospective observational study performed in a 450-bed university hospital including all hypoalbuminaemic patients (albumin <3.8 g/dL) with determinations of t-PC and f-PC from 12/2008 to 08/2009. Samples were measured by fluorescence polarisation immunoassay (TDx). Samples for f-PC determination were filtered through Centrifree filters. Therapeutic range: t-PC: 10-20 mcg/mL; f-PC: 1-2 mcg/mL. f-PC >15% of t-PC was considered a risk factor for toxicity. Statistical analysis was performed with SPSS (ver. 13.0).
Data: demographics, daily dose (DD), t-PC, c-PC, f-PC, % f-PC, albumin, haemodialysis.

Results
Patients: 18, age: 57.4 years (CI95%: 46.6-68.3), men: 9 (50%), DD: 399.2 mg (CI95%: 345.3-453.1), determinations: 30 (range:1-5 determinations/patient), t-PC: 11.3 mcg/mL (CI95%: 9.4-13.2), c-PC: 18.5 mg/dL (CI95%: 15.9-21.2), f-PC: 1.78 mcg/mL (CI95%: 1.49-2.06), % f-PC: 17.3%, albumin: 2.6g/dL(CI95%: 2.4-2.9), patients on haemodialysis: 2 (11%).

Comparison of therapeutic status:

	Below therapeutic level	Therapeutic level	Above therapeutic level	p	Kappa
f-PC	4	13	13	-	-
t-PC	11	19	0	<0.001	-
c-PC	4	11	15	<0.001	0.67

The c-PC and f-PC therapeutic status distribution had a tendency to differ in haemodialysed patients (p=0.169).
Albumin was lower in patients with % f-PC >15% (2.4 g/dL, CI95%: 2.1-2.6) vs. those with % f-PC <15%(3.2 g/dL, CI95%: 2.9-3.6) (p<0.001)
No other factors were statistically significant.

Conclusions
The f-PC-based therapeutic status categorisation did not agree with the t-PC or c-PC-based categorisation.
Patients in haemodialysis or with lower albumin could benefit from f-PC determination.

Conflict of Interest
No conflict of interest

J3. Alteration of intravenous tramadol pharmacokinetic parameters in post urological surgery population

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Background
Pain is a significant cause of morbidity and unwanted physiological changes in patients after all types of surgery especially in major operations. Surgical morbidity associated with poor postoperative pain control is increasingly became a matter of concern. Numerous studies have described the unacceptability of poorly-controlled postoperative pain. Around the clock (ATC) analgesia protocols are designed based on healthy population pharmacokinetic data. As patient pain management following urological surgery was not acceptable in many cases using ATC, this study was designed to compare the data obtained from post-urological surgery patients with standard data and to finf the mean serum concentration of analgesic when patients request repeating the administration of the drug.

Method
We enrolled 28 ASA (American Society of Anaesthesiologists) I or II patients in this study following urological surgery. Pain intensity was assessed by a visual analogue scale through a 4-step scaling. Serum samples were obtained and tramadol concentrations were analysed by a valid High Performance Liquid Chromatography (HPLC) method.

Results
Although no significant correlation was detected between tramadol serum concentration and pain intensity this study showed that the serum concentration of tramadol at the time of request for analgesia was undetectable in 65% of patients (below 10 ng/ml). In the other 35%, mean serum concentration was 42.94±33.29 ng/ml. Mean half life in this population was calculated about 1.75±0.96 hours. Also no significant correlation between age and volume of distribution or half life of tramadol could be detected in this population.

Conclusions
It was shown that some clinically important differences may exist between pharmacokinetic parameters in the literature and in post-operative populations. It seems that extrapolating from healthy population pharmacokinetic parameters to post-surgery populations is not always a functional and reliable way of managing pain in these patients.

Conflict of Interest
No conflict of interest

J4. Immunosuppressant level monitoring in composite tissue allograft transplantation

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Objective
The aim of this study was to evaluate immunosuppressant levels in recipients of composite tissue allografts.

Method
Three patients underwent bilateral upper limb transplantation at our institution in the 2006-2009 period. The medical records were reviewed and the daily dose (DD), levels of immunosuppressants and frequency of therapeutic drug monitoring (TDM) were recorded.

Results
After alemtuzumab induction therapy, tacrolimus and mycophenolate mofetil with or without prednisone were given to maintain immunosuppression. All recipients were switched to sirolimus due to side effects from tacrolimus, namely hypertension and increasing creatinine. The first patient's mean tacrolimus level was 13.1±3.8 ng/mL [8.1 ng/mL (4 mg DD) - 19.6 ng/mL (6 mg DD)] and mean sirolimus level was 12.4±3.8 ng/mL [4.5 ng/mL (3 mg DD) - 19.3 ng/mL (4 mg DD)]. The number of days of TDM was 8.0 (tacrolimus) and 20.9 (sirolimus). Mean levels of tacrolimus for the second patient were 10.1±4.2 ng/mL [2.3 ng/mL (6 mg DD) – 18.2 ng/mL (36 mg DD)] the TDM lasted 15.7 days. The third patient's mean tacrolimus level was 10.8±3.2 ng/mL [5.5 ng/mL (20mg DD) - 17.6 ng/mL (16 mg DD)]. The TDM lasted 7.2 days. Three episodes of rejection, visible as maculopapular lesions, were observed in two patients, and one episode of acute rejection in the third patient. Rejection episodes were successfully treated with a 3-day course of corticosteroid and adjustment of the triple immunosuppressant regimen.

Conclusion
Data suggest that Therapeutic Drug Monitoring should be done frequently. If the patient has a blood level under the target, a dose adjustment and a new check 7 days after the first one may be helpful to avoid possible rejection. From our experience, we may set the target immunosuppressant level in composite tissue allograft transplantation tightly at around 10 ng/mL, as in induction of solid organ transplantation. However, with such a small sample no definitive conclusions could be drawn and suitably designed studies must be undertaken.
Conflict of Interest
No conflict of interest

J5. What is the right TDM level for critically ill patients recieving valproic acid?

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Background
Monitoring valproic acid (VPA) concentrations is challenging due to its variable pharmacokinetics. As VPA is 90-95% bound to serum albumin, hypoalbuminaemia affects free VPA (FVPA).
The aim of this study was to establish the effect of total VPA (TVPA), normalised TVPA (NTVPA) and FVPA serum levels on therapeutic drug monitoring (TDM) in critical patients.

Method
Retrospective observational study in critical patients treated with VPA included in a TDM program with TVPA and FVPA concentrations. Parameters recorded: sex, age, albumin level, TVPA and FVPA. TVPA was normalised according to the serum albumin (Hermida et al, 2005).
NTVPA, TVPA and FVPA values were classified as at subtherapeutic, supratherapeutic and therapeutic levels. Therapeutic concentrations of TVPA and NTVPA were established as 50-150mg/L and FVPA as 5-20mg/L. Discrepancies between those groups were analysed comparing TVPA/NTVPA with FVPA.

Results
25 patients were included (18 men). Mean age was 52 years [19-84].
Valproic acid concentrations were measured in 40 cases (1.6 analyses/patient [1-8]). Mean TVPA, NTVPA and FVPA (mg/L): 44.9, 133.5 and 18.6 respectively. Mean unbound fraction: 35.5% [8.4-68.2%]. Mean albumin level: 27.3 g/L. Patients received a mean VPA dose of 2 g/day.
In 16 cases TVPA was subtherapeutic, while concentrations were in the therapeutic range when NTVPA was calculated and FVPA was determined.
In 8 (20%) cases, clinical decisions using TVPA were the same as those made with FVPA. In 31 (77.5%) cases, NTVPA led us to the same clinical decisions as we made using FVPA.

No of determinations	Subtherapeutic concentrations	Therapeutic concentrations	Supratherapeutic concentrations
TVPA	23 (57.5%)	17 (42.5%)	0 (0%)
NVPA	3 (7.5%)	23 (57.5%)	14 (35%)
FVPA	3 (7.5%)	24 (60%)	13 (32.5%)

Conclusions
Free valproic acid (FVPA) is the best TDM parameter for critically ill patients receiving valproic acid. In the absence of FVPA levels, the valproic acid level normalised according to the serum albumin level (NTVPA) is the right alternative. However, other factors that can modify FVPA levels such as concomitant treatments should be considered. TVPA is not useful for TDM.

Conflict of Interest
No conflict of interest

J6. Valproic acid-meropenem interaction: a case report

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Background
Antiepileptic and anti-infective drugs are usually used together in clinical practice. Reductions in valproate serum level (VSL) due to co-administration of carbapenem have been reported. In our hospital, we have reported a clinical case which probably presented this interaction.

Method
Medical records and Pharmacokinetic Unit database review.

Results
A female patient, 16 months old weighing 10 kg, suffering from Down's and West's syndromes, was being treated with vigabatrin (625mg/12h) and valproic acid (400-450mg). Because of probable drug-induced thrombocytopenia, the valproate dose was reduced to 300mg/12h. After achieving a steady state, VSL was 107mcg/ml (therapeutic serum levels 50-125mcg/ml). The patient was transferred to paediatric intensive care unit because of a complicated upper respiratory infection. Meropenem IV (500mg/8h) and vancomycin continuous IV infusions were started due to a nosocomial sepsis caused by *Enterobacter cloacae*. Three and six days later, VSL was determined and 12.6mcg/ml and 0.5mcg/ml respectively were recorded, and the patient had seizures which were controlled with midazolam. Meropenem and vancomycin were continued for eight days, and seven days after the last dose of antibiotics the patient had a new seizure which disappeared spontaneously. No more VSL determinations were requested and there were no more episodes of seizure.

Discussion
Themechanism by which valproic acid and carbapenem antibiotics interact is not well known yet. Carbapenem antibiotics seem to reduce the intestinal absorption of valproic acid. They also seem to activate UGT1A6, the enzyme that conjugates valproic acid with glucuronic acid. They also reduce valproic glucuronide hydrolysis. Moreover, they increase liver levels of glucuronic acid and intraerythrocytic concentrations of valproic acid.

Conclusions
Carbapenem antibiotics may dramatically reduce VSLs complicating anticonvulsant therapy and causing unexpected seizures.
New prospective studies are needed to evaluate this interaction, clarifying its mechanism.

Conflict of Interest
No conflict of interest

J7. Monitoring of vancomycin use: a 5-year experience in Home Care

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Background
The growing practice of home use of antimicrobial drugs led to this retrospective study that evaluated parenteral vancomycin use in patients receiving it through a home care service (HCS). Trough serum vancomycin levels are the most accurate and practical method of monitoring the effectiveness of vancomycin, and should be maintained at more than 10 mg/L to avoid resistance developing.

Method
Retrospective study of all patients discharged from Garcia de Orta Hospital to complete a course of intravenous vancomycin via HCS, from January 2004 to December 2008. All data were collected as part of routine patient care in the pharmacy database: demographic information, level of serum creatinine (SCr) on the day of discharge, reasons for vancomycin use, initial dose, length of home treatment, trough serum concentrations and pharmacist interventions resulting in dose change.

Results
During the study period, the HCS received 33 patient referrals for continuation of parenteral vancomycin therapy after hospitalisation (accounting for 18% of the total number of patients with home IV therapy). The mean age was 58 years, 54.5% were male and the mean SCr on discharge was 0.77 mg/dL. More than 90% of the patients had MRSA infections (sepsis, osteomyelitis and diabetic foot) and in 76% of cases the initial dose was 1g every 12h. The mean of length of home treatment was 29 days and the average mean of trough serum concentrations was 11.1 mg/L (based in a weekly evaluation of SCr and trough serum concentrations).
All pharmacist interventions led to changing the dose of the intravenous vancomycin.

	2004	2005	2006	2007	2008
Vancomycin patients	2	10	4	11	6
Pharmacist interventions	5	5	3	18	8

Conclusions
Vancomycin can be safely administered in the home setting when it is being properly monitored by the pharmacist and clinician. Trough level monitoring is preferred to optimise treatment outcomes and to monitor nephrotoxicity. The trend toward increasingly severe illnesses and shorter hospital stays will undoubtedly increase this practice.

Conflict of Interest
No conflict of interest

GROUP K: CASE REPORTS

K1. Pharmacotherapeutic approach in Pompe's disease

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Background
Pompe's disease is a rare autosomal recessive muscular wasting disease, with an incidence of 1/60,000 Caucasian adults.

Objective
The aim of this study is to describe the use of alglucosidase alpha in a case of Pompe's disease in our centre.

Method
We undertook a retrospective analysis of a patient with Pompe's disease, including the clinical and pharmacotherapeutic history. The alglucosidase alpha product information was reviewed.

Results
A woman, whose onset of disease was probably in 2000 (45 years old), developed difficulty walking, tendency to lordosis and hyperlipidemia. In 2008, the patient showed a waddling gait, muscle weakness, difficulty in accomplishing everyday activities and exhaustion at the end of the day.
An increase in creatine kinase (782IU/L) and severe respiratory insufficiency with marked decrease in Forced Vital Capacity in the supine (29%) and sitting (27%) position were observed in the analytical results. A deletion of exon 18 and a mutation IVS1-13T>G were detected in the molecular study of the GAA gene on chromosome 17q that encodes the lysosomal enzyme acid alpha-(1-4)-glucosidase. The enzymatic study revealed decreased activity of this enzyme. Pompe's disease was diagnosed.
Replacement therapy was initiated with recombinant human alpha alglucosidase 20 mg/Kg every 15 days by intravenous infusion. After two months of treatment, the creatine kinase value had decreased to 482 IU/L and an improvement in motor function and respiratory were observed. After 15 months, the treatment is well tolerated and no adverse effects have been detected.

Conclusions
In our patient, after initiation of therapy and during the time period involved, the progression of the disease appeared controlled based on analytical results as well as motor and respiratory function. Early diagnosis is essential for patients diagnosed with Pompe's disease to avoid irreversible damage developing.

Conflict of Interest
No conflict of interest

K2. Increase in the infusion time of cetuximab: one case report

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Background
Handling and rechallenge with cetuximab after a grade 2 infusion reaction suffered at the first cycle of palliative chemotherapy (CHT).
Cetuximab is a chimeric monoclonal IgG1 antibody produced in a mammalian cell line by r-DNA technology indicated for the treatment of patients with epidermal growth factor receptor– expressing, KRAS wild-type metastatic colorectal cancer. Mild or moderate adverse events have very frequently been described associated with cetuximab infusion. Thus, the administration of an antihistamine and/or a corticosteroid is recommended prior to all the infusions and close monitoring is required during the infusion and at least one hour after it is finished. According to the manufacturer, if the patient presents a mild or moderate infusion reaction, the speed of the infusion can be reduced and it should remain lower in all the subsequent infusions. If a serious infusion reaction occurs, the treatment should be stopped immediately and permanently.

Method
A 57-year-old woman was diagnosed in exploratory laparoscopy in October 2008 with inoperable recurrence of rectal adenocarcinoma. Owing to prior unacceptable toxicity to 5-fluorouracil, cetuximab 500 mg/m2 + irinotecan 180 mg/m2 day 1, every 15 days was proposed. The patient received routine premedication consisting, in our centre, of dexchlorpheniramine 5 mg intravenously (IV). 60 minutes after starting the cetuximab infusion the patient complained of breathlessness, facial sweating, shivering and nausea. The infusion was suspended. Methylprednisolone, dexchlorpheniramine, metoclopramide and paracetamol were promptly administered IV, to treat the clinical condition described. After being observed for one hour, she went on to be given irinotecan, ending the CHT session without incident.

Results
After extensive explanations of the potential risks and benefits of continuing treatment with cetuximab the patient agreed. More robust premedication was prescribed, dexchlorpheniramine 10 mg and methylprednisolone 60 mg IV, and the infusion time was increased to 180 minutes. She tolerated this dose and the following doses without symptoms.

Conclusions
Increasing the infusion time of cetuximab as well as reinforcing the premedication can be effective and safe measures in the re-treatment of cetuximab after a grade 1-2 reaction related to the infusion.

Acknowledgement
To N. Perez Hoyos.

Conflict of Interest
No conflict of interest

K3. Therapy with romiplostim in chronic refractory idiopathic thrombocytopenic purpura : a case report

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Background
Idiopathic thrombocytopenic purpura (ITP) is an acquired disorder in which isolated thrombocytopenia is present. Relapse is frequent in adults, following initial treatment with glucocorticoids, requiring additional treatment. It is usually considered refractory ITP if:

- ITP persists for >3 months
- Failure to respond to splenectomy
- Platelet count <50,000/mcL

The aim of this case report is to describe the use and effectiveness of romiplostim, a new thrombopoietin receptor agonist.

Method
The subject of this study was an splenectomised 84-year-old man diagnosed 3 years ago with ITP who had an insufficient response to corticosteroids, immunoglobulins and eltrombopag. Romiplostim was used at an initial dose of 2 mcg/kg once weekly as a subcutaneous injection. The dose was adjusted weekly by increments of 1 mcg/kg until the platelet count reached ≥ 50,000/mcL.
The efficacy endpoints were:

- Overall platelet response, defined as achieving durable (weekly platelet count ≥ 50,000/mcL 6 or more times for weeks 18-25 in the absence of rescue therapy any time during the treatment period) or transient platelet response (weekly platelet count ≥ 50,000/mcL 4 or more times during weeks 2-25 but without durable platelet response);
- Number of weeks with platelet response, defined as number of weeks with platelet counts ≥ 50,000/mcL during weeks 2-25.

Results
The patient received 14 administrations in 17 weeks (3 weeks without administration because platelet counts were > 400,000/mcL).The median average weekly dose was 6 mg/kg. Overall platelet response was achieved. Platelet count was > 50,000/mcL in 8 of the 17 weeks of treatment.

Conclusions
In this patient romiplostim was an effective treatment in the short term, but results beyond week 17 remain uncertain. Median average weekly dose was higher (6 mcg/ml) than reported in other studies for splenectomised patients (3 mcg/ml).

Conflict of Interest
No conflict of interest

K4. Ribavirin aerosol in respiratory syncytial virus pneumonia treatment in an immunocompromised patient
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Background
Respiratory Syncytial Virus (RSV) is responsible for respiratory infections. In adults, the risk of RSV infection is higher in the elderly, patients with cardiopulmonary dysfunction and immunocompromised patients, including solid transplant recipients. Ribavirin aerosol (RA) may be used to treat RSV infection in patients with a high risk of complications/severe illness. However, it is only approved in paediatric patients. In adults and children, RA has level of recommendation class IIb and level of evidence category C.

Objective
To report a case study of the use of RA in the treatment of RSV pneumonia in an immunocompromised ICU hospital patient.

Method
Bibliographical research on the use of ribavirin aerosol in immunocompromised patients. Clinical process analysis of an ICU patient treated with RA: clinical history, drugs, evolution of symptoms, laboratory and other tests, in the period between diagnosis of RSV pneumonia and suspension of RA.

Results
One study reported that 5/7 solid transplant recipients infected with RSV were treated with RA:1 died and 3/5 improved after 7 days' treatment. Both untreated patients survived. In another study, 3/6 bone marrow transplant patients treated with RA required assisted ventilation and died. In another study, 5/11 immunocompromised patients were treated with RA. Of these, 3 patients improved, although 1 died shortly after discharge.
The ICU patient, male, 59 years old, recipient of a kidney transplant on immunosuppressant therapy, who required assisted ventilation, presented pneumonia with acute respiratory distress syndrome. Although undergoing antibiotic treatment, the patient presented fever with slow improvement of clinical and laboratory infection parameters. Bronchoalveolar lavage was positive for RSV. RA was prescribed at a dose of 6g/300 ml (20 mg/ml) as the initial solution in the reservoir of SPAG-2 (Small Particle Aerosol Generator Model-2), connected to the ventilator circuit, in continuous nebulisation for 14 hours a day. RA was suspended after 2 days due to intense bronchospasm and respiratory distress. The patient recovered and was discharged a month later.

Conclusions
Studies of RA use in adults are limited and inconclusive due to the small number of patients. The efficacy RA is still unknown. It is necessary to evaluate the requirements for use and safety of this drug in immunocompromised patients.

Conflict of Interest
No conflict of interest

K5. Evaluation of compliance for patients treated with oncologic drugs under AIFA monitoring
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Background
The lack of compliance is an important problem in clinical practice. Causes are various and derive from patients and therapy. As far as the oncology drugs are concerned, correct use and the continuity of treatment is fundamental. The purpose of this paper was to identify whether a cohort of patients maintained long-term therapy or not and, if not, for how many days it was paused.

Method
We assessed 15 patients who were taking medicines containing erlotinib, fulvestrant, nilotinib, sorafenib and sunitinib for at least 2 cycles. The choice was set out for patients taking these drugs to have an AIFA monitoring form, where date of drug prescription, delivery, and administration were printed.
For each patient we recorded the gender, age, drug name, distance from the hospital and the compliance, calculated as the sum of the amount supplied daily obtained over a series of intervals between prescriptions, divided by the total number of days from the beginning to the end of the observation period for the entire regimen.
Multiple variable analysis was used to estimate the statistical relationship between patient compliance and the other variables.

Results
The study population ranged in age from 36 to 87-year-old patients, mainly females. The mean therapy period was 126 days and the mean period for which therapy was not taken was 5 days.
Approximately 69% of patients complied with at least 95% of their doses of medicine. By using multiple variable analysis, compliance was shown to be related to gender, age and number of retire.

Conclusions
In our study several factors related to cancer treatment compliance were identified. These can be used to target patients who may have a higher tendency to be non-compliant with their medication. Moreover the use of the multiple variable analysis approach provides an important framework that might contribute to the recovery of non-compliant people.

Conflict of Interest
No conflict of interest

K6. Papaverine use in massive ischaemia. A case report
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Background
Papaverine is a phosphodiesterase inhibitor used as a vasodilator and antispasmodic. The aim of this work is to describe the use of intra-arterial papaverine (IAP) in a patient with massive ischaemia.

Methods
Medical record review and bibliography research of papaverine HCl.

Result
Male, 68 years old with a history of COPD, cardiomyopathy with biventricular failure, chronic atrial fibrillation, non-smoker, ex-drinker, diabetes mellitus, obesity, bladder cancer. Treatment: aspirin, oral anticoagulant. Came to the Emergency Department presenting diffuse abdominal pain with sudden onset. The patient was admitted to Observation and his condition worsened, presenting hypotension with anuria refractory to treatment, leukocytosis, renal insufficiency. Physical exploration: abdomen slightly distended with signs of depressible peritonitis. CT scan of the abdomen without contrast: abundant intra-abdominal fluid. Unable to rule out ischemia. Intervention. Findings: micronodular cirrhosis, ascites of 3 litres. Intestinal ischemia affecting 90% of the small intestine and right colon with signs of hypoperfusion, also in the proximal jejunum. The surgeon needed vials of papaverine. The pharmacist told him that Sulmetin Papaverine intravenous had been withdrawn from the market by the Spanish Medicines Agency as it did not meet pH specifications and the only way to purchase this product was to buy papaverine hydrochloride 2% for pharmaceutical compounding. The pharmacist found the solution and the requested

medicine was dispensed. Embolism was suspected in the mesenteric loop. A level dissection was performed following the same injection and 40 mg IAP. Pulse was checked and a new injection of 20 mg of IAP made to prevent vasospasm after impact. Obvious improvement was observed in the proximal jejunum, terminal ileum and right colon. Resection performed for ischemic bowel. The patient was moved to the Intensive Care Unit, improving renal failure and moved the third day to a hospital ward. Good clinical and blood test evolution.

Conclusions
Although the employment of IAP is a technique no longer used in general surgery, the case showed excellent results. The pharmacist has an important role in drug information and to provide drugs that the patient needs.

Conflict of Interest
No conflict of interest

K7. Severe acute intermittent porphyria: a case history

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Background
Severe acute intermittent porphyria (AIP) is a hereditary disease related to porphobilinogen (PBG) deaminase deficiency. PBG is an enzyme involved in biosynthesis of the haem group. AIP is the most common of three types of acute porphyria. The prevalence is 1-2/100,000 population. The disease frequently occurs in young women. The main clinical presentation is an attack of intense abdominal pain usually associated with low back pain, vomiting and constipation. Many drugs (barbiturates and some analgesics) are contraindicated because they can exacerbate an attack.

Method
We report the case of a 39-year-old male with AIP who arrived at Emergency with abdominal pain which he had had for 5 days. He was admitted to the intensive care unit.

Results
The patient had severe hyponatremia (113 mEq/L), and 145 micrograms/L of porphyrins in the urine (normal value <30). A mutation was found in the R116W gene which encodes PBG deaminase.
Supportive measures adopted were mechanical ventilation, fluid therapy including a high dose dextrose infusion (375 grams / day), analgesics and antibiotics.
The combination of hyponatremia and an intensely painful attack can point to porphyria. A high dextrose infusion allows patients to be fed (AIP usually causes vomiting and makes it impossible to eat) and may normalise excretion of porphyrins and precursors.
Because of an inadequate response, a dose of 200 mg of human haemin per day was administered for four days (3 mg/kg/day). Human haemin succeeded in restoring normal haemoprotein and respiratory pigment levels.
The patient achieved normal laboratory values and the clinical response due to human haemin was good. No severe adverse reactions were detected.

Conclusion
A sufficient and early administration of haemin is important to control symptoms of the disease.
It is important to know which drugs can potentially trigger acute attacks and evaluate the benefits and risks of their use.

Conflict of Interest: No conflict of interest

K8. Use of eculizumab in paroxysmal nocturnal hemoglobinuria: A case report

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Background
Eculizumab is a humanised monoclonal antibody used for treating paroxysmal nocturnal haemoglobinuria (PNH) .
We describe a case and analyse its cost effectiveness.

Method
A descriptive study, checking the information from medical reports and the pharmacy database
Our 22-year-old patient was diagnosed with PNH in 2001. She was included in an eculizumab clinical study from June 2005 to March 2008. During this period, she did not suffer any thrombotic events or adverse effects, although blood transfusions and steroid treatment were needed to control her anaemia. In May 2008 she was diagnosed with severe medullary aplasia because of the transfusions. This was treated with methylprednisolone, ciclosporin and thymoglobulin. Finally, eculizumab was started again on 1 December 2008 and stopped 17 April 2009.
During this time haemoglobin (Hb), LDH levels, and number of transfusions were checked as well as her quality of life.

Results
The patient was treated with eculizumab at the usual dosage schedule: an initial dose of 600 mg/week for 4 weeks and then 900 mg /2 weeks.

Evolution of LDH and Hb was as follows:

Week	LDH (IU/L)	Hb (g/dl)
1	2944	9.1
2	532	9.1
4	421	8.8
6	455	9.4
8	319	9.3
10	505	8.5
12	412	8.7
14	456	8.7
16	384	8.7
18	417	7.8
20	447	8.3
22	417	8.5

She had no transfusions or side effects due to eculizumab, but her quality of life did not improve.
The treatment cost 6942 €/week or 356,000 €/annum (only direct costs included).

Conclusion
Although eculizumab has been demonstrated to improve the quality of life and to decrease morbidity in patients with PNH, our patient only got normal values in LDH levels. Her haemoglobin levels remained low and her quality of life did not improve significantly. All of this, added to its high cost, did not justify keeping the patient on the agent.

Conflict of Interest
No conflict of interest

K9. use of bendamustine in patients with refractory or relapsed chronic lymphocytic leukemia: 8 cases reports in Amiens University Hospital

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Objective
To evaluate the efficacy and safety of bendamustine, a unique cytotoxic agent that combines alkylating and antimetabolite effects, in patients with refractory or relapsed chronic lymphocytic leukaemia (CLL).

Method
We analysed the first 8 patients (sex ratio 1.7) in advanced stage CLL, at Amiens university hospital (France), enrolled in the French compassionate use scheme. They received 64 to 120 mg/m²of bendamustine, on 2 days, every 3-4 weeks, for a maximum of 6 cycles. The median age was 70 years (range, 66 to 74 years) and the median number of prior regimens was 3 (range, 2 to 4 regimens). Bendamustine was use as a single agent (3/8) or associated with rituximab (5/8) at the dose of 375mg/m².

Results
In the 31 cycles of bendamustine used, the median dose was 88 mg/m² with a 4-week mean duration of cycle. 6/8 patients (75%) responded to treatment, three with the bendamustine/rituximab combination. One patient achieved complete remission and three patients had a partial response. Two patients achieved disease stability but stopped their treatment because of severe toxicity after 3 and 4 cycles of bendamustine respectively. Disease progression occurred for one patient after 3 cycles. One patient is undergoing his second cycle. The most frequent adverse events were haematological, including thrombocytopenia (25%), anaemia (25%) and neutropenia (12.5%). Non-haematological side effects were fatigue (25%) and CMV infection (12.5%) in 3 patients.

Conclusion
Bendamustine is effective as a single agent or in combination with rituximab and provides a treatment option for patients with refractory or relapsed CLL. Analyses of the first patients who benefited from bendamustine, at the hospital of Amiens, suggested ways of improving bendamustine treatment (dose modification for toxicity, combination with rituximab, management of toxicities).

Conflict of Interest
No conflict of interest

K10. Treatment of intradermal perianal carcinoma associated with human papilloma cirrus infection subtype 16

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Background
To evaluate the treatment available for a patient with intradermal perianal carcinoma associated with human papillomavirus infection subtype 16 (HPV 16). Currently podophyllin solution, cryotherapy with liquid nitrogen, laser therapy and trichloroacetic acid are often used as first line treatment, while 5-fluorouracil, interferons, electrosurgery and excision are used as second line. In this study we describe the efficacy of imiquimod, intralesional interferon alpha 2b, 5-fluorouracil and cidofovir in a recurrent lesion of VPH 16.

Method
A 48-year-old woman diagnosed with intradermal perianal carcinoma associated with papillomavirus subtype 16 is reported. The clinical history was reviewed, a Papanicolaou test and retroscope biopsy confirmed the diagnosis.

Results
After unsuccessful treatment with 2 series of photodynamic therapy and topical imiquimod 5%, the patient was treated with intralesional interferon alpha 2b (2 cycles of 3x106 IU) three times a week for three weeks. Adverse events such as fever and malaise were treated with paracetamol. A second recurrence was treated with 5-fluorouracil 5% and topical cidofovir for 2 months, but the lesion persisted. Finally surgery was undertaken. Despite good postoperative recovery, the patient showed pathological evidence of recurrent lesions at the one year follow up.

Conclusion
The evaluation of treatments for Condyloma acuminata is imprecise because it is not possible to distinguish between relapse and reinfection. A further complication is that current treatments aim to clear visible lesions, which is not a proof of cure as human papillomavirus may persist in a latent state. In this case all available treatments proved unsatisfactory. More studies are necessary to corroborate these data.
Conflict of Interest
No conflict of interest

K11. Spontaneous subdural haematoma following antiaggregant and anticoagulant therapy: case report

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Background
Spontaneous (non-traumatic) subdural haematoma (SSH) is rare and can cause serious neurological symptoms. The possible causes of SSH are many, and triggering by drugs, such as anticoagulants, has been described in a few cases. We report a case of SSH in a patient treated with antiaggregant therapy.

Method
A 74-year-old man, with a history of dyslipidaemia and ischemic cardiopathy, underwent surgery for a descendent aortic thoracic aneurysm with insertion of an endoprosthesis. His treatment to discharge was: acetyl salicylic acid 100 mg/ day, clopidogrel 75 mg/day and Bemiparin 2500 IU/ day. Six days later, he turned up at a clinic complaining of severe headache, nausea, vomiting and left paresis without traumatism. His laboratory values on admission were: PT = 90%, PTT = 31 and platelet count = 129000/mm3. Cranial computed tomography (TC) showed acute subdural haematoma in the right fronto-temporo-parietal region. Due to this serious situation, the patient was operated on urgently. The surgical procedure was craniotomy and evacuation of the haematoma to prevent or minimise permanent neurological damage. He was admitted to the Intensive Care Unit (ICU) for postoperative monitoring.

Results
Postoperative recovery was uneventful and he was discharged home six days after admission. This time, his treatment with antiaggregant and anticoagulant drugs was stopped because of the adverse reaction. After checking the bibliography and the medical report, we found the association between SSH and antiaggregant /anticoagulant therapy. We used Naranjo´s algorithm and discovered a probable relation.

Conclusions
SSH is an adverse reaction with a very low incidence, but a high mortality. So, we should focus on improving medication safety.
Pharmaceutical monitoring of patients treated with risky long-term medication, e.g. antiaggregant and anticoagulant treatments, will help to prevent adverse reactions and hospital admissions.

Conflict of Interest
No conflict of interest

K12. Treatment of severe valproic acid poisoning

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Background
Valproic acid is an antiepileptic drug that is used for a variety of neurological and psychiatric indications. It is now a common agent to be taken in overdose.

Objectives
To describe a case of severe valproic acid poisoning and perform a

systematic literature search for specific treatment.

Case report
A 22-year-old woman was admitted to the intensive unit care after divalproex sodium delayed release tablets (Depakote) self poisoning (1000 mg/kg). She quickly became comatose and developed hypotension, lactic acidosis and hyperammonaemia as the valproic acid blood level increased to over 1400mg/L. Eight hours after admission haemofiltration was performed for 27 hours. The half life was 9.5h during the procedure compared with half life before (31.6h) and after (37.7h), suggesting that haemofiltration effectively eliminates valproic acid. So the serum valproic concentration decreased to 165 mg/L during extracorporeal elimination. L-carnitine treatment (100 mg/kg per day for 2 days and 50 mg/kg per day for 6 days) was also started. Progressive haemodynamic improvement and neurological recovery led to extubation at 10 days and the patient made a full recovery.

Discussion
There are few official recommendations about the treatment for severe valproic acid poisoning. However some treatments are widely described in the literature. Several studies or isolated clinical observations have suggested the potential value of oral L-carnitine but suggested administration and dosage vary. In published papers all extracorporeal elimination techniques (haemodialysis, haemoperfusion, continuous renal replacement techniques, association) appear to be effective in assisting the elimination of valproic acid. But the advantages and disadvantages of all these techniques must be considered before treatment.

Conclusion
Based on our experience in this patient and a review of the literature, extracorporeal elimination and L-carnitine should be considered in the treatment of valproic acid overdose. However more experience is required to better characterise the effect of extracorporeal treatment and L-carnitine on clinical outcome.

Conflict of Interest
No conflict of interest

K13. infra-red thermography, predictive method for the evolution of orthopaedic surgery: A case study

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Introduction
The early diagnosis of an infection allows treatment to be initiated early and more successfully. Infra-red thermography allows the emission of radiation from the surface of an object to be measured in the infra-red range of the electromagnetic spectrum.

Objective
To evaluate the use of infra-red thermography as a predictive method for the evolution of orthopaedic prosthetic surgery.

Method
An 80-year-old patient who, after undergoing surgery to replace the right knee, suffered an infection in the joint and had to have it replaced a second time. During post-op follow-up the thermal evolution of the operated knee was monitored using thermographic imaging, which recorded the temperature of the operated knee and of a healthy control. An infra-red thermographic camera was used with a resolution of 640x480 pixels and a sensitivity of <0.055K(Kelvin), obtaining a total of 8 thermal images which were processed using ThermaCAM software. An area was selected from each photograph, and the points measured were reproduced on a graph of temperature (ºC) against the percentage of points (%). Three straight lines were drawn on each image which went through points on both knees and which allowed us to see the temperature differences between symmetrical points.

Results
Comparing the evolution of the graphs, we observed that the temperature of the selected points reduced as the days passed.
The lines that crossed points on both knees allowed us to observe how the temperatures equalised during the post-operative period, so, in the image obtained 5 days after surgery, a temperature difference between the two knees of 6ºC was observed. This temperature progressively decreased in the following images to reach less than 2ºC 12 days later.

Conclusions
The evolution of thermographic images reflects the clinical progress of the patient, whose post-operative evolution was favourable, who did not show signs of active infection and whose intra-operative cultures were negative.
It is necessary to widen the study to determine the sensitivity of infra-red thermography in the early diagnosis of infections in orthopaedic prostheses. This diagnosis will allow antibiotic treatment to be initiated early, with a greater likelihood of success.

Conflict of Interest
No conflict of interest

K14. Use of anakinra in the treatment of refractory juvenile idiopathic arthritis: a case report

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Background
Anakinra is considered a third-line alternative treatment in rheumatoid arthritis and its use is not recommended in children and adolescents under 18 years of age. No paediatric presentation is available. The aim of this study is to evaluate the effectiveness and safety of anakinra in a paediatric patient with Juvenile Idiopathic Arthritis (JIA) refractory to other treatments.

Method
Retrospective review from medical report and pharmacy database from January 2009 to October 2009. A patient 1 year and 10 months of age was diagnosed with systemic-onset JIA when he was 1 year old. He had previously been treated without success with corticosteroids, methotrexate and non-steroidal anti-inflammatory drugs. Biological treatment with etanercept was started in April 2009, but suspended three months later because of lack of efficacy. The Spanish Medicines Regulatory Agency authorised the treatment with anakinra on compassionate grounds in July 2009. The current treatment is methotrexate 7.5 mg every week and anakinra 30 mg/24h.

Result
Under aseptic conditions the pharmacy department repackaged the marketed presentation to adjust it to a suitable paediatric dosage. The patient's response was quick in clinical and haematological terms. After 12 weeks of treatment, the main values of non-specific inflammatory markers had decreased remarkably: reactive protein C: 37.56 ± 24.12 to 1.35 ± 1.04 mg/l, erythrocyte sedimentation rate: 51.60 ± 22.97 to 4.55 ± 3.08 mm. Furthermore, platelets returned to normal levels: 747.50 ± 123.75 to 445.00 ± 107.80 $x10^3$ /µl, and the haemoglobin level increaed from 10.72 ± 1.38 to 11.43 ± 0.67 g/dl. The patient reported a mild injection site reaction.

Conclusion
Anakinra was safe and effective. There have been significant improvements in the patient's blood and clinical parameters, though he will need to be followed up to evaluate long-term outcomes and adverse reactions.

Conflict of Interest
No conflict of interest

K15. Use of pegvisomant for treatment of acromegaly: description of a case

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Background
Acromegaly is an uncommon disease that results from persistent hypersecretion of growth hormone (GH). Diagnosis must be confirmed by measurement of IGF-1(³ 420 ng/mL) and GH levels (³ 1 ng/mL).
Somatostatin analogues (SA), dopamine agonists (DA) and GH receptor antagonists (GHRA) are used when surgery is not effective. Radiotherapy may be useful when disease is not controlled by surgery or drugs.
Pegvisomant is a GHRA used for acromegaly that has not responded to other treatments.
We describe the efficacy of treatment used in a patient with acromegaly.

Methods
Review of clinical history and several databases. Variables: serum GH and IGF-1 concentrations and clinical symptoms.

Results
41-year-old man with acromegaly caused by a somatotrophic adenoma of the pituitary. Since 1999 he has had headaches and arthralgia without visual defects.

DATE	TREATMENT	POSOLOGY	GH (ng/mL)	IGF-1 (ng/mL)
Before treatment	-	-	51.6-68.1	1059
March-June 2005	transsphenoidal surgery	-	9.17-9.85	746
June-December 2005	lanreotide	90 mg monthly	8.59-9.81	676
December 2005-November 2006	lanreotide	120 mg monthly	10.7-11.9	615
November 2006-June 2007	pegvisomant	10 mg daily	18.4-18.9	521
	cabergoline	0.5 mg weekly		
June-September 2007	pegvisomant	20 mg daily	19-19.3	508
	cabergoline	0.5 mg weekly		
September 2007-May 2008	pegvisomant	25 mg daily	10.1-10.3	372
	cabergoline	0.5 mg twice a week		
March-May 2008	radiotherapy	51.52 Gy		
May 2008-At present	pegvisomant	25 mg daily	13-13.6[a]	1181[a]
	cabergoline	1 mg twice a week	6.03	217
			4.31-4.6	250

a: The patient was 2 weeks without treatment

Conclusions
The goals of treatment are to lower IGF-1 and GH to the reference range. An important reduction in serum IGF-1 concentrations was achieved without worsening of clinical symptoms.
Management of acromegaly was adjusted as described in literature.
Pegvisomant was more effective in this patient than other alternatives.
Increasing pegvisomant to 30 mg daily and adding SA would improve results.

Conflict of Interest
No conflict of interest

K16. Two cases of irinotecan-induced dysarthria

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Background
Irinotecan (IRI) is a topoisomerase I inhibitor with anti-tumour activity in solid neoplasia. Its main adverse side effects, such as cholinergic syndrome, diarrhoea and bone marrow suppression, are common and well understood. Much more unusual is the occurrence of dysarthria. Dysarthria is difficulty in articulating words, caused by impairment of the muscles used in speech. Two cases were reported the same month in our teaching hospital. Given its rarity and threatening appearance, we tried to find a guideline and a potential mechanism. To do this the literature and the pharmacovigilance were reviewed.

Results
The patients were 49 and 56 years old. They were being treated for pancreatic and gastric adenocarcinoma with IRI 180 mg/m2 in combination with 5-fluorouracil and folinic acid (FOLFIRI). Both developed a heavy tongue and dysarthria 20 minutes after starting their first IRI infusion. The treatment was immediately stopped, and dysarthria resolved within 2 hours without the use of any medicines.
Neurological evaluation did not reveal any abnormalities. Other medicines were cleared of involvement, in particular metoclopramide, known for inducing extra-pyramidal syndrome.
It was decided to re-initiate the IRI infusions at reduced dose and rate. Dysarthria always reappeared, so irinotecan was definitively withdrawn. Fortunately resolution was always complete, without after effects.
Five cases with this toxicity have been described in the literature so far. Patients were 38 to 64 years old, treated with IRI for a colorectal tumour. In all cases toxicity occurred during the first administration, within one hour, with stammering or aphasia always being reversible. IRI infusions were never interrupted, and no other disorders were found upon neurological examination.

Conclusion
Irinotecan-induced dysarthria is rarely described but is spontaneously reversible after stopping the infusion. Currently, its exact pathogenesis is unclear, but pharmacokinetic variability should be studied further. UGT1A glucuronyl transferase, an enzyme active in IRI metabolism, can be genotyped before the first IRI infusion: this polymorphism can also alter systemic clearance of IRI.

Conflict of Interest
No conflict of interest

K17. Assessment of cytochromes P450 1A2 and 3A4/5 activity in a woman with high clozapine plasma concentrations - are phenotyming and genotyping?

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Background
Clozapine, an atypical antipsychotic, is mainly prescribed in the treatment of resistant schizophrenia. Clozapine is eliminated by demethylation and N-oxidation in the liver, predominantly by cytochrome P4501A2 (CYP1A2) with additional contributions by other CYP isoforms, particularly CYP2C19, and CYP3A4 at high concentrations. There is a great inter-individual variability in clozapine plasma concentrations for the same dose, due to the effect of inhibitors, inducers and genetic factors on CYP1A2 activity. Dose-related clozapine adverse effects are sedation, seizure and myoclonus.

Methods
Finding high clozapine plasma concentrations in one patient, we first screened all potential drug interactions on CYP450 with our patient's treatment: amiodarone + flecainide + acenocoumarol (abnormal variability of INR observed) + fenofibrate. Then we decided to explore the patient's phenotype and genotype.

Results

1. Plasma concentrations of clozapine and norclozapine		
Daily dose of clozapine	clozapine ng/ml (target 50 to 700ng/ml)	norclozapine ng/ml (demethylation product)
200mg bd	**3 130**	**1 100**
100mg bd	**1 075**	**452**
150mg (50mg + 100mg)	**578**	**193**

2. Analysis of drug interactions						
clozapine metabolised by	**CYP1A2***	CYP2C9	CYP2C19	CYP2D6		CYP3A 4/5
inhibitors	*none*	*amiodarone*	*none*	*amiodarone and flecainide*		*amiodarone*
Acenocoumarol metabolized by	CYP1A2	**CYP2C9***	CYP2C19			
**** major metabolic pathway***						

3. Phenotype status		
	CYP1A2 - oral caffeine test metabolic ratio (plasma) paraxanthine / caffeine	CYP3A4/5 - oral midazolam test metabolic ratio (plasma) 1'OH-midazolam / midazolam
patient	**0.24**	**2.01**
healthy population	0.72 ± 0.43 (mean±SD)	6.23 ± 2.61 (mean±SD)

4 CYP1A2 Genotype status
No known-polymorphism usually related to an abnormal activity of the CYP450 1A2 was identified.

Conclusions
Phenotyping CYP1A2 and 3A4/5 confirmed the hypothesis of low activity of these enzymes, leading to the high clozapine plasma rate detected. The lack of CYP1A2 and 3A4/5 inhibitors in the treatment plus the medical history of our patient strongly suggested she was a poor metaboliser. But genotyping failed to find any mutation associated with CYP1A2 underactivity. Clozapine is the key treatment for refractory schizophrenia. So, preventing dose-related adverse effects could be of great routine importance. Phenotyping seems to be the optimal method but is difficult to use in clinical practice. More genetic mutations associated with enzyme polymorphisms need to be identified before genotyping can be of real interest in daily practice.

Conflict of Interest
No conflict of interest

K18. Eculizumab: efficient for all Paroxysmal Nocturnal Hemoglobinuria patients?
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Background.
Paroxysmal Nocturnal Hemoglobinuria (PNH) is a rare clonal blood disorder characterised by non-specific complement-mediated intravascular haemolysis with resulting anaemia, haemoglobinuria and venous thromboses. Eculizumab is a monoclonal antibody that inhibits terminal complement activation by blocking complement factor C5. Recently some studies have suggested another potential mechanism to explain residual haemolysis in some patients despite eculizumab treatment: complement factor C3-mediated extravascular haemolysis. We assessed the response to eculizumab in a PNH patient, as well as its safety.

Method
A 75 year-old woman was diagnosed with PNH about 15 years ago, requiring periodic blood transfusions and treatment with intravenous immunoglobulins, zoledronic acid and occasionally with oral corticosteroids. We reviewed the clinical history from March 2007 to September 2009. The patient had been treated with eculizumab for a total of 16 months between January 2008 and May 2009, when it was definitively discontinued. At present, she is being treated with intravenous immunoglobulins, oral corticosteroids and vincristine, showing a good response. To evaluate the efficacy of eculizumab we compared transfusion requirements (TR), levels of lactate dehydrogenase (LDH) - a biomarker for intravascular haemolysis, haemoglobin levels and the results of Coombs' test (to prove possible drug-induced immune haemolytic anaemia), without and during eculizumab treatment. Safety was evaluated according to adverse events.

Results

Median values	Without eculizumab	During eculizumab treatment	Mann-Whitney
TR per month	2 units	1.75 units	p = 0.242
Hb levels	8.72 g/dL	8.93	p = 0.067
LDH levels	1481 U/L	383 U/L	p < 0.001
Direct anti-C3 Coombs' test	Negative	Positive	

Adverse events: pneumonia and decline in renal function.

Conclusion
1. In this patient, eculizumab reduced intravascular haemolysis parameters (LDH) but neither haemoglobin levels nor transfusion requirements changed significantly.
2. The positive direct anti-C3 Coombs' test indicated that immune extravascular haemolysis was occurring, which was counteracting the reduction in intravascular haemolysis.
3. Taking into account these efficacy results, the important side effects of eculizumab and its high price, we must select patients who could profit from this therapy, and look out for immune extravascular haemolysis.

Conflict of Interest
No conflict of interest

K19. Changes in a patient´s bone marrow with Acute Myeloid Leukaemia after treatment with the hypomethylating agent 5-azacitidin: a case report
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Background
One of the mechanisms of carcinogenesis is the aberrant epigenetics phenomena that contribute to the oncogenes overexpression. One of them is DNA methylation, concretely of repressors genes. This methylation would leave out of control the oncogenes responsible for the growth of tumour. The use of hypomethylating agents theoretically restore normal function to genes that are critical for differentiation and proliferation.
The aim of this study is to evaluate the effectiveness of the treatment with an hypomethylating agent, 5-azacitidine, in a patient with Acute Myeloid Leukaemia (LMA).

Methods
Effectiveness was evaluated by the changes in the patient´s bone marrow (BM) by means of flow cytometry before and after four months treatment.
Case: 67 years-old male patient diagnosed of LMA M-2 with 20% of myeloid blast in BM with the following phenotype: CD13, CD33, DR, CD117, CD34 and cytoplasmic myeloperoxidase: positive. Moreover, CD11b, CD14, CD15 and CD16: negative.

Results
After seven months of treatment, our patient, hematologycally only had thrombocytopenia. In BM, after four months of treatment, blast number persists, but with characteristics different in phenotype: two populations CD33 appears, with gain in intensity of one of them and positivisation of CD11b, CD15 (before negative) and great increment in the myeloperoxidase expression.

Conclusions
Appearance of a new population very intense CD33, as well as that of CD11b, CD15 and gain in mieloperoxidasa intensity make us think about an evolution toward more mature cells and a progressive lost of leukemic phenotipe. This fact is corroborated from clinical and analytical point of view by the patient's stability that, without treatment, it should have worsened notably.
The hypomethylating agent 5-azacitidine has shown analytical and clinical effectiveness in this patient with LMA inducing maturation of the initial blasts.

Conflict of Interest
No conflict of interest

K20. Use of romiplostim in chronic idiopathic thrombocytopenic purpura: three case reports
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Background
Idiopathic thrombocytopenic purpura (ITP) is a bleeding disorder in which the immune system produces antibodies against platelets. These patients have a high risk of haemorrhage. Romiplostim is a fusion protein analogue of endogenous thrombopoietin, a hormone that regulates platelet production.

Methods
We report the cases of three patients with ITP who were refractory to treatment with corticosteroids and immunoglobulins. Splenectomy was not performed because surgery was contraindicated. The aim of romiplostim treatment was to achieve a platelet count between 50 – 200 x 10^9/L. The drug is administered weekly as a subcutaneous injection. Patients received an initial dose of 1 µg/kg bodyweight. This dose was increased by increments of 1 µg/kg until the patient achieved and maintained a platelet count superior to 50 x 10^9/L.

Results
Two patients responded well to the treatment. Patient 1 needed to increase the dose successively; he received 5 doses of 250 µg, 6 of 500 µg and 9 of 750 µg. Patient 2 did not respond after four doses so romiplostim was suspended. Patients 1 and 3 are continuing treatment. In all cases, romiplostim was well tolerated.

	Sex	Age	Previous treatment	Splenectomy	Number of doses	Last dose	Response (platelets>50x10^9/l)
Patient 1	Male	60	Corticosteroids, immunoglobulins, rituximab	Contra-indicated	23	750 µg	Yes
Patient 2	Male	91	Corticosteroids, immunoglobulins, rituximab, danazol	Contra-indicated	4	400 µg	No
Patient 3	Female	76	Corticosteroids, immunoglobulins	No date	4	250 µg	Yes

Conclusions
Romiplostim could be an effective and safe treatment for ITP but long-term studies are necessary to evaluate adverse reactions and confirm that platelet counts remain stable when it is discontinued.

Conflict of Interest
No conflict of interest

K21. Etanercept therapy in graft against host disease
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Background
Graft versus host disease (GVHD) is the leading cause of death following bone marrow transplantation. Due to the rise in the number of transplants performed, the incidence of GVHD has increased in recent years. For this reason, new protocols are being developed for prevention and treatment.

Method
The evolution of GVHD was monitored in 2 patients undergoing autologous bone marrow transplantation who were treated with etanercept, an anti-TNFα agent. Patient 1 (26 years old) was diagnosed with acute myeloid leukaemia in 2008; Patient 2 (66 years old) was diagnosed with B-cell chronic lymphocytic leukaemia in 2004. Both of them received prophylactic treatment against GVHD with methotrexate at 10 mg/m2. Yet both developed acute GVHD; patient 1 at 30 days post-transplant, and patient 2 at 30 and 100 days post-transplant.

Results
Both patients were initially treated with ciclosporin and corticoids, but did not respond. In patient 1, GVHD progressed with intestinal and hepatic involvement, while in patient 2, the skin and digestive tract were affected. Treatment of patient 1 was changed to tacrolimus, budesonide and etanercept 0.4 mg/kg (to maximum 25 mg) s.c. twice per week; and patient 2 was treated with etanercept in addition to ciclosporin and corticoids. In both patients the initial GVHD was successfully resolved, but later (100 days post-transplant) patient 2 suffered severe GVHD which was treated with corticoids, octreotide, tacrolimus and basiliximab. On this occasion the patient died of GVHD.

Conclusions
Previous studies of steroid-refractory GVHD have shown that anti-TNFα agents have significant efficacy, but most patients still die from GVHD or its complications. The mechanism of action of etanercept, different from other drugs used in GVHD treatment, combined with its relatively easy administration by subcutaneous injection and generally minor side effects, make etanercept attractive as first-line treatment of GVHD.

Conflict of Interest
No conflict of interest

K22. Effectiveness and safety of epoetin beta in a pregnant woman with anaemia and metrorrhagia: a case report
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Background
The use of synthetic erythropoietins in patients for whom transfusion of blood products is not allowed due to religious beliefs is sometimes necessary to treat resistant anaemia and other haematological illnesses. The objective was to study the efficacy and safety of epoetin beta and intravenous iron therapy in one anaemic pregnant Jehovah's witness.

Method
The clinical history of an anaemic pregnant woman with metrorrhagia was reviewed. A bibliographic review and multidisciplinary study of the clinical and pharmacotherapeutic treatment were conducted: a programmed Caesarean and haematology preparation were required to avoid complications. We had to ask for the approval from our health authorities to use epoetin beta in this patient. To measure efficacy we reviewed changes in laboratory parameters: red blood cell count, haemoglobin and haematocrit.

Results
A 32-year-old patient, 31 weeks pregnant, who had been anaemic for seven weeks. Red blood cell count, haemoglobin and haematocrit before haematology preparation were: 2.96 x10^6/µL (normal 3.8-6 x10^6/µL), 9.2 g/dL (normal 12-16 g/dL) and 29.5% (normal 38.5-48.5%) respectively. After an intravenous iron therapy 100 mg twice a week (five doses) and epoetin beta 150 IU/Kg (10,000 IU three times a week, nine doses) the laboratory parameters improved: red blood cell count, haemoglobin and haematocrit were 3.58 x10^6/µL, 11.4 g/dL and 35.7%

respectively. These values never attained normal levels, however as the patient's overall health improved it allowed the Caesarean to be performed without complications. During these three weeks of treatment the patient did not suffer adverse effects.

Conclusion

The use of epoetin beta and iron intravenous therapy in patients who are not allowed transfusion of blood products, in this case an anaemic pregnant Jehovah's witness, seems to be effective and safe.

Conflict of Interest

No conflict of interest

GROUP L: HOSPITAL PHARMACY PRACTICE

1. A pharmacist as part of the clinical team prepared a local guide for postoperative pain in the critical care unit

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Background
Postoperative pain is experienced in a majority of patients after surgical interventions. A need was felt to make a local guide for the treatment of postoperative pain in the critical care unit; to decide which medicines should be used and be available in the hospital pharmacy. When the local guide was made, hospital pharmacists were included as a part of a clinical team. They contributed information about the procurement of medicines, as well as their expertise in rational pharmacotherapy.

Method
A multidisciplinary group was involved in making this guide, which included anesthesiologists, surgeons and pharmacists of our hospital. Evidence-based recommendations and guides to pain treatment for different surgical interventions and clinical situations contributed to making our local guide. Priority in the selection of medicines was given to medicines registered in the Republic of Serbia that had been approved by the national health policy.

Results
An easy-to-use guide was designed that offered a choice of appropriate medicines based on the type of surgical intervention and dosage regiments. A tabular format shows indications, contradictions, side effects and interactions.

Conclusion
With the participation of a hospital pharmacist in the clinical team, a guide was produced that provides all relevant information to clinical doctors related to medicines that are used in the management of post-operative pain.

Conflict of Interest
No conflict of interest

L2. aluminium levels in parenteral nutrition - time to change to plastic ampoules of Calcium Gluconate?

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Background
Very high levels of aluminium (5000 microg/L, 5ppm) have been reported (Frey and Mayer 2000) in some solutions used to prepare parenteral nutrition. Frey and Mayer suggested this was likely to be due to calcium gluconate forming complexes with the aluminium present in the glass used to manufacture the ampoules in which they are supplied. Much lower levels of aluminium are reputedly present in plastic ampoules. Adverse effects of even low levels of aluminium for neonates include impairs neurological development and causes bone mineralisation problems. Calcium gluconate 10% injection is now available in the UK in plastic ampoules. The aim of this research was to investigate Frey and Mayer's observations.

Methods
The aluminium levels in calcium gluconate 10% injection in both plastic and glass ampoules were analysed in duplicate by inductively-coupled plasma mass spectrometry for both recent batches and batches approaching their expiry.

Results

Batch no.	Expiry	Ampoule	'Age'	Aluminium (mcg/L)	Aluminium (mcg/L)
7154C12	03.2010	Plastic	Old	31	33
8214C13	04.2011	Plastic	Recent	27	30
639003	09.2009	Glass	Old	6135	6160
830017	07.2011	Glass	Recent	4890	4925

Conclusions
Levels of aluminium are significantly higher in calcium gluconate injection packed in glass rather than plastic. Calcium gluconate injection used in the preparation of parenteral nutrition should be packed in plastic ampoules. Injections packed in glass ampoules should not be used, particularly for neonatal patients.

Conflict of Interest
No conflict of interest

L3. Evaluation of the use of omalizumab after its inclusion in a university hospital formulary

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Background
Omalizumab is a recombinant humanised anti-IgE antibody used to improve the control of severe persistent asthma that is caused by an allergy. It was listed in the hospital formulary in October 2008. The aim was to evaluate the use, efficacy and safety of omalizumab in our hospital.

Method
Observational, retrospective study from March to September 2009. Patients treated with omalizumab were located through the dispensing record and data were obtained from clinical histories. Use was considered correct if the pharmacy committee protocol was followed: non-smoking patients with severe persistent allergic asthma who had a positive skin test, had FEV1 <80% (Forced expiratory volume in one second) and had asthma exacerbations despite high dose of inhaled corticosteroids plus inhaled beta2-agonist. They had to be patients with baseline IgE between 75-700IU/ml and weight ≤150 kg. Safety was assessed by recording any allergic reactions after the first dose. Effectiveness was measured by the number of hospital readmissions and the increase in FEV1.

Results
Seven patients were included, 5 women and 2 men (median age: 32 years). Three patients had baseline IgE >700 UI/ml. There was a case of cold-induced asthma (negative skin test) that was considered an off-label use. In the course of 3 months, two patients needed to increase the dose from 150 to 375 mg. Treatment was discontinued in two patients, one for inefficacy and one because of pregnancy. Two patients had an anaphylactic reaction after the first administration of 300 mg of omalizumab so the following dose was divided into 5 doses. The FEV1 improved in five patients. No patients were admitted to hospital.

Conclusions
Omalizumab has been prescribed without taking into account the upper limit of IgE described in the protocol. It was effective in all patients who continued treatment. When anaphylactic reactions occurred, fractionating the next dose delivered a safe alternative.

Conflict of Interest
No conflict of interest

L4. Antiretroviral dispensing: the experience in a French hospital

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Background
In France, specific HIV care centres known as CISIHs (Centres d'Information et de Soins de l'Immunodéficience Humaine) have been created to ensure the best possible patient follow-up with a multidisciplinary staff. Pharmacists are included to dispense antiretroviral drugs and give advice about treatment. However, patients can get their treatment in any pharmacy either in hospital or in town. In this study, we present the activity of our pharmacy implanted in the medical care unit for this task and the profile of patients who come there to get their treatment.

Method
Antiretroviral prescriptions dispensed over the 3 last years were examined and 132 patients agreed to fill in a questionnaire. We evaluated the patient profile and quantified antiretroviral drugs and protocols dispensed per month and per medical prescription.

Results
About 352 patients were followed every month from September 2006 to September 2009 and no significant variation appeared during the 3 years. They comprised 35% of those monitored by CISIH doctors. The patient population was composed of 65% male and 35% female with a median age of 48 years. 49% of patients had been monitored for more than 10 years and 42% had travelled more than 10 km to get their treatment. The main reasons why they chose the CISIH pharmacy was discretion (56%) and availability of medical consultation on the same day (55%). Pharmacist advice was also a reason for 17%. About 802 antiretroviral drug prescriptions were dispensed per month. It represented a mean of 2.3 antiretroviral drug per patient without significant change during the 3 years. A majority of patients were treated with 2 nucleoside reverse-transcriptase inhibitors and 1 protease inhibitor but the proportion decreased between 2006 and 2009, from 65 to 53%. By contrast, the proportion of patients treated by more than 3 antiretroviral drugs with or without new antiretroviral family drugs (fusion, CCR-5 and integrase inhibitors) increased from 4 to 20%.

Conclusion
CISIH's pharmacy of the Sainte-Marguerite hospital followed a limited but regular patient population, most of whom had been treated for a long time. A majority of these patients got the antiretroviral treatment there because discretion was guaranteed. Protease inhibitor triple therapy was the basic approach but new drugs recently approved have been able to treat multiresistant HIV patients. The therapeutic advice given by the pharmacist forms part of patient education for compliance. Further work is planned to establish the effect of this activity on reducing therapeutic failure.

Conflict of Interest
No conflict of interest

L5. Risk model for the exposure to toxic substances during the preparation of medicines
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Background
Exposure to toxic substances causes a health risk. The risk of handling cytostatics is considered so high that the utmost is done to reduce exposure to negligible levels. But how should less toxic substances be handled, especially when they are in their unprocessed form during preparation of medicines? To answer this question, one has to:
- classify substances by their toxicity
- measure personnel exposure during preparation
- put both factors in a risk model
- decide what health risk is acceptable

Methods
The literature and the procedures for determining limits were studied to classify the substances. Personnel exposure at various preparation steps in different models was measured by filtration techniques, commonly used in occupational health studies. A risk model had to be developed from the definition of risk (= level of toxicity X exposure) and using models for toxicity classification and exposure. Levels of risk accepted by 'society' were used to gauge an acceptable risk level.

Results
5 categories of toxic substances were distinguished. A procedure was established whereby every substance can be categorised by the pharmacist. This procedure explicitly included human toxicological data. From the exposure measured during small scale preparation (up to 100 grams of substance), it appeared reasonable to distinguish 4 levels of exposure, each corresponding to the dry or liquid state of the substance and to the type of air ventilation and filtration.
The resulting risk model shows how risks can be minimised, and - after including the level of social acceptance - shows the necessary measures for the acceptably safe preparation of medicines.
This 3-step model was then coupled to a batch preparation records model to decide protective measures before the start of preparation.

Conclusions
The health risks from almost every type of small scale preparation of medicines can be estimated and reduced to a socially acceptable level by the 3-step model that has been developed.

Conflict of Interest
No conflict of interest

L6. Effect of perfusion rates on parenteral nutrition support
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Background
Nutrition support by the parenteral route (PN) should be administered when enteral nutrition is not feasible and should be initiated after 7 days without any nutrition support. When goal feeding is achieved too soon it can lead to a complex disorder called refeeding syndrome. In this, patients can develop fluid-balance abnormalities, electrolyte disorders (hypophosphataemia, hypokalemia, hypomagnesaemia and hypocalcaemia) among other metabolic problems. It was our purpose to study the effect of a PN protocol change on serum electrolyte levels. The target for achieving goal calories was changed from within 24 hours (Group 1) to a 72-hour target, in which a perfusion rate corresponding to 50% of the feeding goal is achieved on day 1, 75% on day 2 and 100% on day 3 (Group 2).

Method
A retrospective chart review was conducted between January 2006 and August 2009. Patients who had been placed on hospital-wide parenteral feeding and electrolyte replacement protocols were assessed and we examined whether there were any positive clinical consequences to introducing food slowly. All patients receiving parenteral nutritional support for a period of not less than 5 days with no previous electrolyte imbalances were included. Serum levels of phosphorous, magnesium, potassium and calcium were compared before and after nutritional support in the two groups.

Results
Both groups were homogenous in gender, age, body mass index. Group 1 (n= 45) and Group 2 (n=58) developed depletion of phosphate, magnesium, potassium or calcium after initiation of parenteral feeding in 24.4% and 15.5% respectively, compatible with refeeding syndrome. The changes were: hypophosphataemia (82% vs. 67%), hypomagnesaemia (62% vs. 56%), hypokalemia (58% vs. 56%) and hypocalcaemia (58% vs. 57%). Hospital length of stay was similar in both groups (40 vs. 42 days).

Conclusions
The improvements achieved in changing the protocol led to fewer refeeding syndrome events. The greatest improvement related to hypophosphataemia, where depletions over 0.16 mmol/L and/or phosphate levels below 0.65 mmol/L were reduced. This study showed that a minor change in nutrition protocol affected patient serum levels significantly, particularly in those at risk of refeeding syndrome. An electrolyte replacement protocol is an effective way of minimizing the electrolyte imbalances and should be further improved regardless of its frequency. It seems that applying similar protocols to patients requiring enteral support will lead to significant results as well.

Conflict of Interest
No conflict of interest

L7. Safety assessment of pharmaceutical distribution in a hospital environment

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Background
The Institute of Medicine in the United States (*To Err is Human: Building a Safer Health System, IOM report September 1999)* concluded that the US health care system is not as safe as it should be. Adverse events appear to be responsible for 44,000 to 98,000 accidental deaths each year. This means there is one death in every 343 to 764 admissions. In comparison, aviation averages one death for every 8 million flights. These shocking numbers are an indication that health care should be considered a high-risk industry.
Many catastrophic errors are related to process inadequacies rather than incompetence of health workers. Clearly, robust preventative action is required to minimise the risks inherent in the prescribing, dispensing and administration of medicines. Redesign of process subsystems is a step towards improving overall hospital safety.

Method
Many organisations in US and Europe are beginning to apply traditional aerospace engineering methodologies to the study of patient safety concerns. While these approaches have produced some notable successes, in general, far too often error and adverse event reports are simply accumulated but the data are not effectively used. Failure mode and effects analysis (FMEA) was recommended by the US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (*Standard LD 5.2 , 2001*) and by the Italian Healthcare Minister (*DM 5 March 2003*) as an efficient too with which to conduct a proactive risk assessment.

Results
A FMEA analysis was performed on the pharmaceutical distribution in SG Battista Hospital in Turin (Italy), from receiving goods to delivery to wards.
From risk matrices and risk priority number (RPN) analysis two main high risk activities were identified. The first one was in the picking and packing phase and the second one due to low efficiency of pharmacist random checks. The analysis also pointed out some medium-risk activities associated with the department's refill requests, monitoring of storage temperatures and consignment to the delivery service.

Conclusions
The FMEA tool gives an opportunity to quantify safety within a specific hospital environment and to identify feasible corrective actions. The introduction of a barcode system could potentially reduce the RPN rating of high risk activities by about 75% and for the medium risk activities the most effective improvement should be the introduction of temperature monitoring devices that would potentially reduce the RPN by about 50%. The effectiveness of the proposed actions would then need to be verified by further monitoring.

Conflict of Interest
No conflict of interest

L8. Prospective evaluation and follow up of patients with enteral nutrition

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Background
The pharmacy department is mainly responsible for preparing parenteral nutrition and selecting the enteral diets that will be used in our hospital. ASPEN, the American Society for Parenteral and Enteral Nutrition, supports pharmacists in their work as specialist nutrition support professionals in providing and managing enteral and parenteral nutrition. Pharmacists may work either independently or as part of a nutrition support team. The aim of our study was to evaluate if enteral nutrition and medicines were being administered correctly.

Method
The study was carried out from June to August 2009 and we evaluated all patients who were being fed enterally, excluding ICU patients, and analysed the type of enteral nutrition, total calorie intake per day, technique of administration and medicines administered via enteral feeding tube, suggesting alternatives for drugs that could not be crushed.

Results
A population of 67 patients with enteral nutrition was enrolled in this study.
The errors detected were:
1. Inadequate type of enteral nutrition: 3 patients (5%) with uncontrolled hyperglycaemia who should have received a diabetes-specific formula.
2. Insufficient calorie intake per day: 2 patients (3%).
3. Incorrect administration technique: 9 patients (13%): use of polyethylene tube feeding (not recommended), insufficient flushing of feeding tubes, etc.
4. Inadequate administration of medicines through nasogastric tube/ percutaneous endoscopic gastrostomy. 15 administration errors were detected in 10 patients (15%): crushing modified-release dosage forms (11), not administering separately from enteral nutrition when it was necessary (3) and therapeutic duplicity (1).

Conclusions
The most common error detected was the inappropriate administration of medicines through nasogastric tube/PEG followed by incorrect technique of administration. It is very important to include a pharmacist as part of the nutrition support team to provide information to medical and nursing staff on rules for administration and storage of diets and to screen these patients' medicines and improve the quality of oral drug administration in patients with enteral feeding tubes.

Conflict of Interest
No conflict of interest

L9. Description of emergency kit for metabolic disorders in a tertiary hospital

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Introduction:
Congenital metabolic disorders (CMD) are genetically disorders based on an alteration of a protein by an enzyme which blocks a metabolic process.

They are inherited diseases, the majority of which are autosomal recessive, with various clinical pictures and mainly hepatic, neurological and muscular symptoms. Although their individual incidences are low, the ever growing description of new diseases (more than 700 at present), makes these disorders, when grouped together, more frequent: 1 out of every 800 live newborns (NB) is born with a CMD and approximately 50% of them develop the disorder during the neonatal period.

Objective:
To establish a minimum first aid kit of medicines and compounded medications, accepted by the paediatric service; and the description of how to acquisition the medicines involved.

Methods:
The pharmaceutical service, in collaboration with the paediatric service, defined a selection of drugs and compounded formulae, necessary to attend emergencies due to CMD, based on previously attended metabolopathies and through a bibliographic review.

Results:
From all the pharmacotherapeutic arsenal available for the treatment of these disorders the following have been agreed upon: vitamins (thiamine, pyridoxine, cianocobalamine, biotine, folic acid), L-carnitine, arginine aspartate, nitisinone, sodium phenylacetate/sodium benzoate, carbaglumic acid, betaine anhydrous, which may be acquired via the usual laboratory suppliers and riboflavin, oral sodium benzoate solution, and intravenous arginine chlorohydrate, made as compounded formulae by the pharmaceutical service

Conclusions:
The seriousness of these disorders justifies the immediate availability of a minimum first aid kit of these medicines; since this supposes that a patient, generally a newborn, can have their life saved and with the absence of or minimum neurological sequelae.
Due to the fact that the selection of medicines has been based on previous metabolopathies attended in our hospital, it is necessary to review the first aid kit before the appearance of new pathologies.

Conflict of Interest
No conflict of interest

L10. Abatacept: a new modulator for rheumatoid arthritis. Drug use and safety evaluation.

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Background
Abatacept is a new immune modulator, approved in combination with methotrexate to treat adults suffering from moderate to severe active rheumatoid arthritis (RA) that has not responded to previous drug treatment, including at least one tumour necrosis factor (TNF) blocker. The aim of this study was to evaluate the use and safety of abatacept in our hospital.

Method
Retrospective observational study in patients treated with abatacept from November 2008 to September 2009. Data were recorded from the medical report and pharmacy database: age, sex, diagnosis and previous drug treatment. Abatacept was given as an intravenous infusion every two weeks in the first month (3 doses), then every 4 weeks. The dose was adjusted to the patient's weight following the summary of product characteristics. The use of abatacept was evaluated considering the authorised recommendations and the safety was evaluated considering adverse reactions.

Results
Five patients were identified (3 women and 2 men), median of age 46 years (41-68). The diagnosis was of moderate to severe active RA. All the patients had failed the first line therapy with anti-inflammatory drugs and disease-modifying anti-rheumatic drugs. TNF blockers were used as a second-line treatment, including adalimumab (5 patients), etanercept (2) and infliximab (1). In three patients, after second-line failure, other biological treatments were needed: rituximab (2 patients) and anakinra (1). Abatacept was used as a rescue treatment in these five patients. No adverse reactions were reported, but there was one case of mild hypotension.

Conclusions
Abatacept was used according to the authorised indications. The safety profile was acceptable. However, additional studies, including more patients, are necessary to evaluate its long-term safety and the place of the agent in treatment.

Conflict of Interest
No conflict of interest

L11. Analysis of pharmacotherapeutical recommendations on medical prescriptions in different clinical units

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Background
Several studies have demonstrated the positive effect of pharmacist-validated prescriptions. We examined the relevance of pharmacotherapeutic recommendations (PhRs) made in different clinical units to solving treatment-related problems.

Method
Retrospective, descriptive study (January-December 2008) in a 400-bed hospital (46% of beds had a Unit-Dose Drug Dispensing System (UDDS) and a manual prescription system). Pharmacists made PhRs on forms designed for this purpose and sent them to a prescriber who could optionally agree or not with the suggestion. The PhRs were made in order to improve drug treatment during the medical order validation in clinical units with UDDS. They were recorded in a database (Excel). Data collected: clinical unit, drug classes involved (ATC classification), type of PhR, degree of acceptance.

Results
This study collected 892 PhRs of which 667 could be included (the others were non-evaluable (transferral, treatment withdrawn etc.)). The degree of acceptance of the PhR by prescribing doctor averaged 52% with the highest in 65% Urology / Neurology. The most important drug classes involved were antibiotics and anti-inflammatory agents.

Distribution of PhRs and number accepted according to the different clinical units:

Unit	Number of PhRs	Accepted	Rejected	Non-evaluable
Surgery	386	164	127	105
Orthopaedic surgery	327	105	145	77
Gynaecology	47	18	18	11
Urology / Neurology.	132	60	30	42

Classification of type of PhR and drug classes involved

Type of pharmaceutical interventions	Number of PhRs	ATC group
Duplication of pharmacologically similar drugs	42	J-Anti-infectious for systemic use (26%)
Incorrect dose or incorrect frequency of administration	223	A-Digestive tract and metabolism (39%)
Pharmacological interactions	6	J-Antinfectious for systemic use (67%)
Risk of drug toxicity with anti-inflammatory treatment	128	M-System skeletal muscle (82%)
Optimisation of drug therapy	14	G-Urinogenital therapy (57%)
Inappropriate route of administration	188	N-Nervous System (40%)
Contraindicated drug, probability of adverse effects	66	A-Digestive tract and metabolism (92%)

Conclusions
More than fifty percent of the PhRs were accepted and the drug therapy was optimised. Based on this result we decided to design a protocol of sequential pharmacotherapeutic and other agents to prevent drug toxicity with anti-inflammatory treatment.
This study underlines the benefits of clinical units where pharmacists validate medical prescriptions, because the integration of the pharmacists into the supporting team contributes to maximising the results of pharmacotherapy and improves patient safety.

Conflict of Interest
No conflict of interest

L12. Pharmaceutical care in narcoleptic patients with cataplexy taking sodium oxybate

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Objective
Due to lack of pharmaceutical care in these patients, the aim was to implement a pharmaceutical care programme for patients diagnosed with narcolepsy associated with cataplexy and treated with sodium oxybate (Xyrem). Preliminary assessment of the efficacy and safety.

Methods
A personal interview is held with the patient, both at the start of sodium oxybate treatment and at dose changes. In the interview, we review the indication, dosage, adherence, management and safety. An information leaflet has been written with instructions for preparation, delivery, schedule, a diagram indicating the volume per shot, precautions and other recommendations. To assess the efficacy and safety, the medical histories of patients who started treatment from June 2007 to the present were reviewed in April 2009.

Results
From June 2007 to April 2009 10 patients were interviewed under the pharmaceutical care plan which resulted in an adequate understanding of treatment and drug management.
Population data: 70% male, 30% women, 14 to 62 years with a body mass index above normal.
9 of the 10 patients had already been treated with stimulants (66.67% methylphenidate and 33.33% modafinil), 44.44% took them in combination with venlafaxine and 22.22% with fluoxetine. No data for one patient. All of them continued their previous treatment after starting with sodium oxybate. 100% had cataplexy and excessive daytime sleepiness, 40% and 60% hallucinations, sleep paralysis. They scored an average of 20 to 24 points on the Epworth scale (daytime sleepiness) (normal <10) and 31 / 40 on the Ullanlinna narcolepsy scale (normal <14). Patients reported a decrease in daytime sleepiness and a reduction in the number of episodes of cataplexy. The Epworth and Ullanlinna questionnaires are being administered again to verify the improvement in the condition of patients. Adverse effects reported by patients were enuresis (20%) and dizziness (10%), which disappeared after dose adjustment of sodium oxybate, both described in the summary of product characteristics.

Conclusions
The pharmaceutical intervention led to a proper understanding and use of treatment. Training is fundamental to preparing the medicine. According to clinical trials, sodium oxybate appears to reduce cataplexy and daytime sleepiness in this patient group.

Conflict of Interest
No conflict of interest

L14. Development of ready-to-use cefuroxime syringes for use in ophtalmology

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Background
Cefuroxime is administered as intravitreous injections for the prophylaxis of postoperative endophthalmitis after cataract surgery. Given the low stability of cefuroxime in aqueous solution, ophthalmic preparations are usually reconstituted in the operating theatre just before use. To improve safety while making the medicine more available, we decided to develop ready-to-use syringes. For that purpose, a method was developed to perform stability tests and routine analyses of this new formulation.

Method
A capillary electrophoresis method with UV detection was selected due to the low cost of capillaries, the reduction in solvent consumption and the fast step development compared to liquid chromatography. An aqueous buffer, consisting of 20 mM Tris-phosphate at pH 7.2 was used as background electrolyte. The applied voltage was 30 kV, the sample injection performed in the hydrodynamic mode and the detection was set at 200 nm. All analyses were carried out in a fused silica capillary with an internal diameter of 50 µm and a total length of 64.5 cm. A cefuroxime solution (10 mg.mL-1) was filled under aseptic conditions into 0.5 mL syringes. Stability tests were performed on syringes stored at -18°C for 4 months and, after defrosting, at 4°C for 1 month. During this period, syringes were analysed each week.

Results
A complete separation of cefuroxime and its main degradation products was achieved in less than 6 min. The CE-UV method was validated and successfully applied for the stability test and routine analyses of ready-to-use cefuroxime syringes. A maximum period of 4 months at -18°C was defined to store syringes of cefuroxime without significant loss in potency. After defrosting, two degradation products progressively appeared. As these derivatives can represent up to 10% degradation of cefuroxime in terms of peak area after 1 month, use of the syringes within one hour of thawing was recommended.

Conclusions
The availability of ready-to-use cefuroxime syringes for use in ophthalmology is improved, as they can be stocked in the ward freezer and can be administered immediately after defrosting.
Conflict of Interest
No conflict of interest

L13. Quality control of parenteral nutritions: analysis of inorganic ions by capillary electrophoresis

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Background
Parenteral nutrition (PN) is the practice of feeding a person intravenously, with nutritional formulas containing essential nutrients such as glucose, amino acids, electrolytes and vitamins. In our hospital, individualised solutions are prepared daily and standardised formulations are also regularly produced, using a MM12 MicroMacroR compounder. An error in the concentration of the electrolytes increases the risk to the patient, especially in neonates. The objective of this study was to develop a quality control method to check the main electrolytes in TPN before administration to the patient.

Method
A simple method based on capillary electrophoresis with a capacitively coupled contactless conductivity detector (CE-C4D) was developed for the determination of potassium, sodium, calcium and magnesium in PN. A hydro-organic mixture, consisting of 100 mM Tris-acetate buffer at pH 4.5 and acetonitrile (80:20, v/v), was selected as the background electrolyte. The applied voltage was 30 kV, and sample injection was performed in hydrodynamic mode. All analyses were carried out in a fused silica capillary with an internal diameter of 50 µm and a total length of 64.5 cm.

Results
The CE-C4D method was validated. Trueness values between 98.6% and 101.8% were obtained for the four cations with repeatability and intermediate precision values of 0.4-1.3% and 0.8-1.8%, respectively. No interference due to amino acids, vitamins or another compounds usually present in PN was observed. Moreover, with a run time of 4 minutes, analysis of PN can be performed in the pharmacy before delivery to the ward for administration to the patient.

Conclusions
The method developed was found appropriate for checking potassium, sodium, calcium and magnesium in PN formulations and it has been successfully introduced into our daily quality control.

Conflict of Interest
No conflict of interest

L15. Analysis of drug interactions in discharge prescriptions in an Italian hospital

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Background
Medication-related patient safety is an essential aspect of healthcare quality. Drug interactions occur often and reduce the quality of health care.
There is a little information and awareness among physicians about potential drug interactions; furthermore, patients can be discharged on polymedication and the risk of potential drug interactions is very high.

Method
A retrospective study was performed on the discharge prescriptions from 3 hospital wards (Internal Medicine ward I, Internal Medicine ward II and Nephrology) from March to June 2009. Data were collected from computerised medical records in an Excel database.
Prescriptions containing 4 or more drugs were analysed for potential drug interactions: the Thomson MICROMEDEX Healthcare Series System was used.

Results
Out of the total cohort of prescriptions (135), only those containing ≥ 4 drugs were selected for the analysis; in this cohort (34 prescriptions), the average number of drugs prescribed per person was 4.97.
In 30 prescriptions (96.3%) patients were exposed to at least one potential drug interaction and in 6 cases (17.66%) there were two potential interactions.
Overall 111 potential drug interactions of any severity were identified including 11 major interactions.
Among these, the most frequent consisted of the combination of a potassium-sparing diuretic (amiloride, spironolactone) with either an angiotensin converting enzyme (ACE) inhibitor or a potassium supplement.
In two cases there was a potential interaction between spironolactone and digoxin, which may result in increased digoxin plasma levels and ultimately digoxin toxicity (nausea, vomiting, cardiac arrhythmias).

Conclusions
According to the data obtained, there is a risk of drug interactions in discharge prescriptions. Hospital pharmacists have a central role in detecting them: monitoring of discharge prescriptions and an information programme is ongoing, in order to provide and improve safety for patients discharged from our hospital.

Conflict of Interest
No conflict of interest

L16. Drug retention by inline filter

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Background
0.2 µm membranes are used as in-line filters in order to minimise the particle and microbiological burden on patients. In preterm intensive care units drugs have to be administered via infusion or injection because gastro-intestinal immaturity leads to the poor bioavailability of orally administered drugs. The amounts of drug s given, the overall available volume and the flow rate are extremely small. In this study two different filter membranes were investigated with regard to their potential to interact with drugs. In order to study the effect of different ions, water for injection and an aqueous solution of NaCl, $NaNO_3$ and CH_3COONa in different concentrations were used as solvents.

Methods
Each drug was filtered at a flow rate appropriate to the filter volume. The quantitative examination was done with a UV-Vis spectrometer equipped with a flow-through cell.

Results
Furosemide sodium:
As the ion concentration in all three solutions declined, the retention time increased when passing through a positively charged membrane. A relationship between retention time and hydrodynamic volume of the anion could be seen. When passing through an uncharged filter, no correlation between the retention time, the ion concentration or the hydrodynamic volume could be observed.
Digitoxin: The retention time was longer when passing through a positively charged membrane than for the uncharged membrane. The time period needed to pass both filters was constant in all solutions.
Adenosine:
The time period needed to pass through both filters was equal and constant in all solutions.

Conclusions
When administering drugs via IV in a premature infant, attention must be paid to possible interactions between all compounds of the solution and the materials used for administration. When using a charged filter, one has to bear in mind the risk of total drug retention, therefore of total therapy failure. In general, different drugs should not be mixed in an infusion.

Conflict of Interest
No conflict of interest

L17. Assessment of a newly referenced fibrin sealant in a surgical ward of the Nancy teaching hospital: a survey of 75 patients

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Background
Efficient control of blood loss is a major concern during surgical procedures. Today many haemostasis techniques are available (clamping, suturing, cauterising, tissue glue (such as fibrin sealant, etc)), and surgeons can choose among them according to their preferences as there are no established standards. Fibrin sealants, also known as “fibrin glue” or “fibrin tissue adhesive” are biological haemostatic agents obtained from plasma, which can be used as a complementary haemostasis method if necessary (French marketing label).

Quixil, also known as Crosseal in US, is a fibrin sealant referenced at the teaching hospital of Nancy, France, since April 2008. It has exclusively been used by the ward for “emergency, general and thoracic surgery”. After one year’s experience of use, we aimed to assess this “new” fibrin sealant especially when it has shown valuable haemostatic properties in orthopaedic and liver surgery (Martinowitz & al., 1997, Tanaka S & al., 2002).

Methods
Our inquiry concerned a period of one year (April 2008 to March 2009). First, we reviewed patients’ medical records to collect medical data (type of surgery, haemorrhagic risk factors, post surgery complications etc.); two main criteria were used to evaluate the benefit of Quixil use: the need for a blood transfusion or drain. We also conducted a survey (2 questionnaires: surgeons and nurses) in order to assess the medical staff’s opinion of the new fibrin sealant.

Results
Quixil was used in 75 patients. More than 90% of procedures were thyroid removal. No side effects were found with Quixil. The blood transfusion rate was 4% (3 patients) and drains were applied to 11 patients (14.6%). These numbers are insignificant compared with the total. The medical staff appreciated the biological glue is for its ease of use and harmlessness. The obligation of traceability, due to its status of derived plasma product, is the main negative side of Quixil. Our results, particularly the staff opinion, obviously remain subjective, belonging to the medical staff of only the "emergency, general and thoracic" surgical ward of the teaching hospital of Nancy.

Conclusion
Quixil seems to be harmless; it is appreciated for being simple to use. Our inquiry has made a preliminary appraisal of Quixil use. Only randomised clinical trials can demonstrate the real benefit of the use of Quixil.

Conflict of Interest
Conflict of interest

L19. Multidisciplinary collaboration between hospital and university departments in stability assessment of drugs in intravenous solutions

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Background
Injectable preparations other than parenteral nutrition admixtures and injectable cytotoxic drugs could be prepared by a Centralised IntraVenous Admixture Service (CIVAS) if the long-term stability of the drugs is known. However, this information is not always available. Thirteen years ago, a programme of chemical drug stability analysis was started in collaboration between a Hospital Pharmacy, Medical Laboratory and Biostatistics Centre to determine the long-term stability of commonly-used injectable anti-infectious and non anti-infectious drugs.

Method
After establishing a High Performance Liquid Chromatography (HPLC) method, 20 drugs (8 antibiotics, 3 anaesthetics, 2 propulsives, 2 detoxifying agents for antineoplastic treatment and 5 with other properties) were reconstituted under a laminar air flow hood. 18 of them were stored directly at 5 ± 3°C and 14 were stored in the freezer at –20°C, thawed by microwave following a standardised procedure and stored at 5 ± 3°C before use. Stability of the active ingredients was evaluated by regression analysis.

Results
The long-term stability of the drugs varied from 11 days to 70 days. The freeze-thaw treatment by microwave may increase stability (from 30 to 120 days) and allow batch-scale production of intravenous drugs, less expensive in term of manpower and sterile devices than drug reconstitution on the ward.

Conclusions
Our findings are contributing to extending the range of drugs that may be taken on by a CIVAS. This collaboration has led to the foundation of a drug stability research group in the new Louvain Drug Research Institute at the Université Catholique de Louvain in Brussels.

Conflict of Interest
No conflict of interest

L18. Effects of freezing and microwave thawing on the stability an ondansetron / dexamethasone mixture stored in dextrose 5% polyolefin bags.

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Background
Ondansetron is a well-known serotonin type 3-receptor antagonist effective in reducing nausea and vomiting associated with antineoplastic treatment, which is sometimes given with dexamethasone to improve effectiveness. This combination is mostly given intravenously diluted in dextrose injectable solution. Advance preparation of these intravenous solutions could be useful to improve quality assurance, time management and cost savings of drug delivery. The purpose of this study was to investigate how freezing, long-term storage and microwave thawing can affect the stability of this mixture in polyolefin bags.

Methods
The stability of five polyolefin bags of solution containing 8 mg ondansetron and 10 mg dexamethasone sodium phosphate per 100 ml of dextrose 5% prepared under aseptic conditions and stored at 5 ± 3°C was studied over 16 days. Concentrations were measured by high-performance liquid chromatography using a reversed phase C18 column, a mobile phase composed of 35% acetonitrile and 65% 0.05M CH3CNH4, buffered to pH 5.0 and a diode array detector at 241 nm. Solutions were also inspected visually and the pH measured.

Results
Neither colour change nor precipitation was observed.
Based on a shelf life of 90% residual potency, the ondansetron/dexamethasone mixture was stable for at least 16 days at 5 ± 3°C after freezing and thawing. In this period the 95% lower confidence limit of the concentration-time profile remained above 90% of the initial concentration. During this stable period, the pH values decreased slightly without affecting chromatographic parameters.

Conclusion
Within these limits, advance preparation of batches ondansetron/ dexamethasone mixture may be considered and added to the range of drugs reconstituted by a Centralised Intravenous Additive Service (CIVAS). The preparation of IV anti-emetic treatments by a CIVAS contributes to the global management of cancer treatment, by providing physico-chemical and bacteriological quality-guaranteed and ready-to-use drugs.

Conflict of Interest
No conflict of interest

L20. Quality control in the dispensation process of ward medicine kits replacements

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Background
The quality of the process of replenishing medicines kits on hospital wards was checked by quantifying the errors committed, to identify deficiencies and establish the necessary measures to resolve them.

Method
A four-month prospective study (April-July 2009).
One consumption agreement (CA) and one internal order (IO) were checked every day. Both were randomly selected from the electronic request programme.

- Consumption agreement: an agreed list of medicines for the weekly replenishment of the ward medicines kit.
- Internal order: additional medicines order depending on specific

needs.
- Protocol for the detection of errors:
- Agreement between the medicines requested and prepared was reviewed.
- The transcription of dispensed medicines into the management programme was verified.

Error classification:
Regarding the supply**:**
- Wrong medicine: different from the prescribed one
- Omitted medicine: prescribed but not dispensed
- Erroneous amount: different number of units
- Wrong pharmaceutical form: different pharmaceutical form
- Wrong dose: change in dosage
- Damaged medicine: misidentified or expired.

2.Regarding the transcription:
- Quantitative error: A failure regarding the amount.
- Qualitative error: The medicine was arbitrarily added to, or withdrawn from, the stock.

Results:
136 orders were reviewed: 49 CAs and 87 IOs, with a total of 2,297 medicine lines.
130 errors were detected, with an average of 1± 2.49 errors per order:

Errors in the preparation (80%)	Wrong medicine	2.88
	Omission	17.31
	Wrong amount	69.23
	Wrong pharmaceutical preparation	0.96
	Wrong dose	7.69
	Damaged medicine	1.92
Errors in management registration (20%)	Qualitative	15.38
	Quantitative	84.62

Conclusions:
- The stage generating the greatest number of errors was the order placement.
- Most errors in both processes were quantitative, resulting in changes in the internal stock and making system management difficult .
- Training, ongoing monitoring and modification of standard operating protocols were needed in order to minimise errors.

Conflict of Interest
No conflict of interest

L21. Prescription of octrotide in paediatric patients with congenital hypersulinism: the pharmacists intervention
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Introduction
The Health Office Inspectorate of Sicily has provided for the distribution of drugs and food products for patients with rare metabolic disease by means of a special decree. At AUSL6 in Palermo and the surrounding area the direct distribution of these drugs has been centralised in the Operative Territorial Unit (UO) of the Pharmaceutical Department. Congenital hyperinsulinism is classified as a rare metabolic disease. It involves severe hypoglycaemic crises beginning from the first days of life with characteristic symptoms such as mournful crying, cold sweats, tremors and convulsions. If that crisis are not promptly and correctly treated they can cause cardiac arrhythmias, syncope and convulsions up till coma and death.

Method
PTOR (Regional Therapeutic Manual) – PTN (National Therapeutic Manual). The treatment with octreotide of three paediatric patients with congenital hyperinsulinism was evaluated from a single prescriber in the same clinic. The appropriateness of prescriptions was evaluated and the content of the product information was examined.

Results
The daily therapeutic strategy used for congenital hyperinsulinism involved the use of 210-220 mcg/day in four fractional administrations for a total of number of 120 0.1 mg/ml phials of octreotide for month.
If this dose had been prescribed in single dose phials, more that 50% of the drug would have been wasted for every single administration. The hospital pharmacists oriented prescriptions towards the use of multi-dose phials of 1mg/5ml.

Conclusion
The careful evaluation of the prescriptions by the pharmacist allowed prior agreement with clinic prescriber and the re-evaluation of the previous therapeutic plans. The prescriber was advised to use a multidose phial, which allowed the prescribed dose to be administered in half the volume of solution, making the injection process less painful for the little patients. The pharmacist's intervention resulted in both an appropriate use of drug, safe administration in a rare paediatric pathology and a relevant saving

Conflict of Interest
No conflict of interest

L22. Off label use of octreotide in lar formulation
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Introduction
In Italy, a national law called 648/96 provides for certain drugs to be made available free of charge for some off label indications for patients without other alternative treatment. In the list of drugs made available, according to the provisions of law no. 648/96, octreotide was employed from 2000 for the following therapeutic indications:
- Refractory secretory diarrhoea due to short intestine
- Severe orthostatic hypotension.
- Pancreatic fistula
- Angiomatosis not susceptible to other pharmacologic treatment in slow release formulation.
- Non-syndromic neuroendocrine tumours .

The objective of this study was to monitor octreotide so that all the therapeutic indications provided for by law 648/96 were obeyed.

Method
648/96 law – evaluation of therapeutic plans - evaluation of drugs' summaries of product characteristics– PTOR (Regional Therapeutic Manual) – PTN (National Therapeutic Manual).

Results
In the first semester of 2009 42 therapeutic plans were examined and as a result 30 male patients and 12 female patients were found to be taking octreotide. Moreover we found that:
- 16 patients used octreotide for refractory secretory diarrhoea due to short intestine.
- 20 patients for neuroendocrine tumours without syndromic symptoms.
- 6 patients for angiomatosis not susceptible to other pharmacologic treatments.

For this last indication 4 inappropriate prescriptions were noted because for this pathology the drug octreotide was not prescribed in slow release formulation, as is provided by the 648/96 law.

Conclusion
From the processing data the off-label prescription of octreotide emerged for "Angiomatosis not susceptible to other pharmacologic treatments"; the clinic prescribers were informed with a formal letter and

invited to re-evaluate the prescriptions regarding the use of LAR formulation respecting the provisions of law 648/96.

Conflict of Interest
No conflict of interest

L23. Leakage of plasticizers to ready-to-use analgesic mixtures
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Background
Danish hospital pharmacies produce a large variety of ready-to-use analgesic infusions, which are contained in various medical devices. The infusions are used for postoperative pain relief and palliative care, and they are administered by the use of different pumps.
The aim of this study was to register the analgesics in use, their shelf life and leakages from the container. The first part of this study being the study of leakages is reported in this abstract.

Method
The most common medical devices and solutions were identified by a questionnaire send to all hospital pharmacies in Denmark
The 4 most frequent solutions and 3 most commonly used containers were identified for further analysis.
Migration of di(2-ethylhexyl)phthalate (DEHP) from the 3 containers was measured by gas chromatography after storage of bupivacain in the containers for 3 days at 25oC.

Results
Morphine, sufentanil and bupivacain, and mixtures of these, were the most frequently used substances in the analgesic infusion products.
The CADD® Medication Cassette (Smith Medical), Drug Bags for APII pumps (Baxter) and the Intracon® container (Promens) were identified as the most commonly used containers. Chemical analysis of the CADD Cassette showed PVC plasticized with approximately 25% DEHP. Baxter informed that their bag was made of PVC and the Intracon container is known to be made of polypropylene without plasticizers. No leakage of DEHP to the aqueous solution of bupivacain was detected at a level of detection of 2,6 microgram/100 ml. No difference in relation to migration from the plastic containers was identified, and the level of DEHP in the water solution did not exceed the level of the outside environment.

Conclusions
The 4 most commonly used mixtures and the 3 most commonly used containers for storage of ready-to-use analgesic infusions were identified. The containers did not release DEHP into the aqueous phase of the bupivacain solution within 3 days.

Conflict of Interest
No conflict of interest

L24. compounding service and pharmaceutical care to paediatric outpatients
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Background
Numerous medicines are not in an appropriate pharmaceutical form or dosage for paediatric patients. It is necessary to prepare suitable extemporaneous formulations (EF) and give appropriate information and pharmaceutical care to ensure they are used correctly.
The aim was to describe and set up a Pharmaceutical Care Programme (PCP) for paediatric patients receiving EF.

Method
Observational study in a tertiary hospital from September 2008 to September 2009. To establish the PCP, including compounding procedures and patient information leaflets, the product information, the Spanish National Formulary, the Paediatric Dosage Handbook and other compounding resources were used. A PubMed/Medline search was conducted, using the search terms extemporaneous, drug formulations, pharmaceutical care, compounding service, paediatric.
Data collected: number of paediatric patients on treatment with EF, number of EF prepared, drug ATC codes, pharmaceutical forms and starting material used.

Results
A total of 375 EF were prepared, for 33 outpatients. 90.13% were liquid oral preparations and 9.87% were capsules. They were compounded by crushing tablets (32.00%), from raw materials (56.54%) or licensed injections (11.46%).

Extemporaneous formulations	Drug ATC code	Prescriptions (%)	Extemporaneous formulations	Drug ATC code	Prescriptions (%)
Ranitidine	A02BA	25.33	Ursodiol [1]	A05AA	2.67
Furosemide	C03CA	11.47	Amlodipine	C08CA	2.13
Atenolol	C07AB	8.53	Sulfasalazine	A07EC	1.07
Captopril	C09AA	8.26	Folinic acid	B03BB	1.07
Propranolol	C07AA	7.73	Flecainide	C01BC	1.06
Phenobarbital	N03AA	7.73	Pyrimethamine	P01BD	0.27
Levothyroxine	H03AA	7.73	Indomethacin	C01EB	0.27
Hydrochlorothiazide	C03AA	5.33	Spironolactone	C03DA	0.27
Isoniazid	J04AC	4.80	Caffeine citrate	N06BC	0.27
Diazoxide	V03AH	4.00			

1. also known as ursodeoxycholic acid

A leaflet was written for each EF including indications, how to administer, interactions with food or medicines and side effects. At the first appointment or when treatment changed, patients were given both written and verbal information by the compounding pharmacist to explain the effective and safe use of the EF. Patients were given an appointment according to EF expiry date.

Conclusions
Monitoring the programme for one year showed that a need continues for EF of brand and generic drugs for paediatric patients, due to the lack of commercially available products. However, it is difficult to obtain raw materials for all EF. In Spain, the need to use commercially available medicines is a controversial issue.
A regular interview with the pharmacist ensured that patients/caregivers knew about their medicines and how to use them safely.

Conflict of Interest
No conflict of interest

L25. Assessment of the adherence to a protocol of the use of erythropoiesis-stimulating agents in oncohaematology
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Background
Erythropoiesis stimulating agents (ESA) have shown effectiveness in the correction of anaemia in oncohaematology. Recently several safety alerts related to their use have been published. In consequence, a multidisciplinary team formed by the Oncology, Haematology and Pharmacy Departments has devised a protocol based on the most important practice guidelines. The objective was to assess the adherence to this protocol and examine the real cost involved in use and compare it with the calculated cost if the guidelines had been adhered to.

Methods
Prospective observational study in a third-level hospital (March-September 2009). All oncohaematological patients who started treatment with ESA in a pharmaceutical outpatient care unit and agreed to participate were included. The degree of adherence to the indication criteria was assessed: anaemia related to chemotherapy or myelodysplastic syndrome (MDS), baseline haemoglobin (<10g/dL), iron use if ferritin <100ng/dL and/or transferrin saturation index (TSI) <20%, dosage (if weight <78Kg: 30000IU epoetin/week or 150mcg darbepoetin/week; ≥78Kg: 40000IU epoetin/week or 300mcg darbepoetin/week; MDS 60,000-80,000IU epoetin/week or 300mcg darbepoetin/week). Any non-compliance with the protocol required a pharmaceutical intervention as is established in protocol.

Results
Forty-nine patients (61.2% male) were included.

Indication criteria	*Degree of adherence: N (%)*
Anaemia related to chemotherapy or MDS	42 (85.7%)
Baseline haemoglobin	41 (83.7%)
Iron use	3 (6.1%)
Dosage	14 (28.6%)

Ferritin and/or TSI were determined in only nine patients; of those, three fulfilled the protocol. 59.2% of patients were overdosed and 12.2% under-dosed according to the protocol. Regarding the expense, the total cost for four weeks of treatment was 48490.7€, while if the protocol had been followed the cost would had been 40638.9€. This indicated an extra expenditure of 7851.9€ in only four weeks.

Conclusions
Adherence to the protocol has been high in relation to diagnosis and baseline haemoglobin. Nevertheless, as regards iron use and dosage the adherence must be improved to assure the effectiveness, safety and cost containment of the treatment.

Conflict of Interest
This study was sponsored by Roche Farma, SA

L26. Assessment of a validated screening tool to identify potentially inappropriate prescriptions in elderly patients
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Background
Elderly patients often suffer multiple co-morbidities and are prescribed multiple medicines thereby increasing the risk of adverse drug events. The most frequently cited criteria by which to identify potentially inappropriate prescriptions (PIPs) in older people are Beers' criteria. The aim of our study was to identify PIPs in elderly inpatients at discharge from a second-level hospital.
Method
Descriptive, retrospective study over 6 months (March-August 2009) in an internal medicine short-stay ward performed during the trial of a pharmaceutical care programme called "Inf@rma". A pharmacist reconciled medicines at any transition point in care and informed the patient personally of the medicines at discharge.
- Patients included: ≥ 65 years.
- Data were collected from discharge reports:
- Demographics: sex, age.
- Ward: diagnosis, length of stay.
- Pharmacotherapeutics: Number, name and therapeutic group according to ATC classification of the drugs prescribed.

Results
We studied 129 patients (73 females), median age: 81± 8 years, average length of stay: 4±3 days. The most common clinical diagnoses at discharge were: infections and respiratory failure (20), congestive/ decompensated heart failure (16) and asthma/ COPD (9). A total of 908 medicines were prescribed (median: 7±3 drugs/patient) which largely belonged to the cardiovascular group (28.3%, n=257), digestive apparatus and metabolism (19.8%, n=180) and nervous system (14.1%, n=128). Beers' criteria identified 12 potentially inappropriate prescriptions (1.32%) in 10 patients: 9 of them resulting in high severity and 3, low severity risks. The drugs involved were amitriptyline, butyl-scopolamine (2), hydroxyzine, doxazosin (3), naproxen, dexchlorpheniramine (2), diazepam and clorazepate.

Conclusions
Beers' criteria are a validated screening tool for systematically identifying inappropriate medicines in clinical practice and increasing the quality of prescribing, improving safety for elderly patients.
A supporting pharmacist on a ward can detect drug-related problems and can ensure the safe use of medicines.

Conflict of Interest
No conflict of interest

L27. Prospective randomized study of reconciliation of treatment in surgical patients
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Objective
To estimate the reduction in medication errors in hospitalised surgical patients after the introduction of a reconciliation system.

Method
Prospective, randomised study (6 months). Inclusion criteria: age ≥ 60 years, polypharmacy (≥ 4 chronic medicines), reliable chronic treatment (report of the Emergency Department, clinical interview with the patient and/or companion and primary care treatment record). Regular medicines were recorded on a sheet designed a priori and validated by the prescribing physicians for medicines reconciliation. Discrepancies were classified as follows: justified discrepancy and discrepancy that requires clarification. The severity of the errors was graded according to the National Coordinating Council for Medication Error Reporting and Prevention classification.

Results
140 errors were detected in 53 patients (2.64 discrepancies per patient). Chronic treatment of these patients amounted to a total of 225 medicines and there were discrepancies in 52.88% of them. 49.28% of discrepancies were justified and 50.72% required clarification. Of these, 42.14% were missing medicines, in 6.42% the medicines had been changed without clinical justification, 1.43% because the medicine was not available in the hospital and in 0.71% of cases, changes in dose, route of administration or frequency of a drug were not explained by the clinical situation. The pharmaceutical recommendation was to continue in 64% of cases, suspend the new drug in 29.8% of cases or in 6.2% change the drug. There was no potential harm in 71.82% of the discrepancies, 27.14% reached the patient and would need monitoring to prevent harm and in 1.40% the error would have caused harm over time, had the pharmacist not intervened. Acceptance of pharmaceutical recommendations was 89.28%.

Conclusions
Errors in the drug history at the time of admission are common and potentially significant. A checking system that involves pharmacists can help reduce their frequency.

Conflict of Interest
No conflict of interest

L28. Pharmaceutical intervention program to avoid clopidogrel and proton pump inhibitors interaction

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Background
To evaluate the result of introducing a pharmaceutical intervention programme to check the suitability of the indications, contraindications and dosage authorised when clopidogrel and proton pump inhibitors are prescribed concomitantly.

Method
Implantation of a pharmaceutical intervention (PI) programme aimed at optimising the joint use of clopidogrel and proton pump inhibitors. The programme was carried out from 1 June 2009 after the EMEA publication of possible interactions between clopidogrel and proton pump inhibitors. All the PIs were analysed until September 15 determining: the degree of acceptance, the type of intervention, the result of the intervention and the services involved.

Results
During the study phase 224 patients in total was treated initially by the combination of clopidogrel + proton pump inhibitors. Every patient was individually evaluated: in 58.9% of the interventions the treatment was changed to ranitidine, in 15% of the cases the proton pump inhibitor was suspended, and in the remaining 25.9% the concomitant treatment was approved. 95% of the PIs were accepted. The services involved in the programme were the following: vascular surgery 24% of the patients, 20% cardiology, 17% neurology and in 39% other services.
We also analysed 54 patients, where the pharmacological interaction could not be avoided during the hospital review: in 70% of the cases the joint treatment was chronic; during the review it was not modified but possible substitution was recommended in 30% in the report at discharge. In 12% of the cases the joint treatment began in the hospital as treatment of heart attack and it was stopped upon discharge. In 18% of patients, clopidogrel was used as chronic treatment for the prevention of ischaemic strokes or acute coronary syndrome. In 30% of patients it was decided to use omeprazole for a history of stomach ulcer.

Conclusions
The pharmaceutical intervention allowed us to optimise the treatment with these drugs where a significant interaction had been described. The system of direct notification has proved to be highly effective.

Conflict of Interest
No conflict of interest

L29. Working group on extemporaneous orphan drugs and preparations for Rare Diseases: organisation and management of an Inter-regional Network

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Background
In Italy, a national network for the prevention and treatment of rare disease was created in 2001 in accordance with decree D.M. 279/2001. Piedmont and Aosta Valley adopted this legislation and created an Inter-regional Network for the prevention, surveillance, diagnosis and treatment of rare diseases. The coordinating centre is located at the S. Giovanni Bosco Hospital in the Multidisciplinary Immunopathological Research and Documentation Department (CMID). Hospital pharmacists in these regions are working to create an Inter-regional Network to manage the extemporaneous compounding of preparations, to ensure best practice in treating patients suffering from rare diseases.

Method
Activities of the Hospital Pharmacies Network include:
- Profiling the extemporaneous compounding of preparations prepared by Piedmont and Aosta Valley hospital pharmacies to treat rare diseases.
- Creating an appropriate data form for each preparation that includes the ingredients, preparation procedures, appearance and stability of the preparation, warnings, therapeutic use, expiry date, label, quality controls, literature references
- Writing up a list of instructions for each preparation to make it easier for the patients to use the medicine.
- Creating follow-up forms for new or dangerous preparations, to improve the pharmaco-surveillance system, to confirm efficacy and quality data, to acquire data for epidemiological and pharmaco-economic analysis.

Results
Both a registry and a network of extemporaneous compounding preparations have been created.
The registry is available on the website: www.malattierarepiemonte.it.
Follow-up data allow to us monitor the efficacy and safety of the preparations. Another aim is to create a registry of orphan drug extemporaneously compounded preparations to standardise preparation methods among pharmacists with regard to quality, efficacy and safety.

Conclusions
The registry and the network are useful, currently available tools that can be used to spread and share data about extemporaneous compounding of preparations for rare diseases, to standardise preparation methods, dispensing and monitoring, thus improving the quality of patient care.

Conflict of Interest
No conflict of interest

L30. Self-evaluation of the compounding activity: improvement of the quality system of a French hospital pharmacy department

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Background:
As part of the "V. 2010" certification of French hospitals, one of the criteria is related to the quality and safety processes of the patient treatments and within that, an item concerns the evaluation of the compounding activity. In this context, we conducted a self-evaluation in the pharmacy department Saint Eloi. Our objective was to determine whether the compounding activities are covered by quality assurance, and whether to make improvements.

Method
The Public Health Code states that the compounding of medicines in hospitals must be conducted in accordance with best practices: Good Hospital Pharmacy Practice and Good Preparation Practice (GPP). Residents drew up an evaluation with a system of closed questions regarding key criteria for achieving best practice: management of the organisation and quality in general, personnel, premises and equipment, raw materials, the compounding process, any abnormal events.

Results
A total of 118 points was evaluated including 5 without results because they were not applicable to compounding activity. 32% of the assessed criteria did not comply with GPP. The lack of compliance observed was mainly related to the criterion "management of abnormalities" (36% compliance). For the criteria organisation and quality management, personnel, premises and equipment, raw materials and compounding process, results of non-conformities were respectively 30, 29, 25, 18 and 12%.

Conclusions
In order to improve the safety of medicines supplied, it seems important to improve the quality of our compounding processes. This self assessment targeted improvements we should make to meet GPP standards. The most critical points have led to corrective measures being taken, including management of abnormal events with the setting up of a register of non-compliance and a detailed procedure for the

destruction of faulty batches. Regarding the criterion "Organisation and Quality Management", a major revision of the documentation system is in progress with revised procedures for compounding activities and instructions to facilitate adherence to them. In addition, training will be improved with a periodic evaluation of technicians.

Conflict of Interest
No conflict of interest

L31. Implementation of clinical protocol for the rational use of Omalizumab

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Objective
To analyse the use of omalizumab after the implementation of a clinical protocol.

Method
To ensure the rational use of omalizumab, a protocol for its use was developed jointly by the pharmacy service and the Allergology and Respiratory Medicine services as the condition for its inclusion in the hospital formulary (January 2007).The protocol combines two phase. The first presents a dose diagram which relates baseline IgE with the patient's weight, as well as recommendations for the first and subsequent doses to be prescribed; the second describes the preparation of omalizumab and its adverse reactions. The use of omalizumab is also included in an annex which contains the patient's weight, diagnosis, baseline IgE concentration, dose, frequency and long table of the different possible doses. To optimise the contents of the vial, patients whose dose was not an exact multiple of 150 mg received alternating doses. In a prospective study, data were collected from January 2007 to September 2009.

Results
14 patients (50% men/women) were included. 92.9% of the diagnoses were included in the protocol and 7.1% were for off-label indications. Only 78.6% of the doses were according to our diagram and the drug was discontinued in 4 patients for adverse reactions such as frequent headache.

Conclusions
The implementation of a multidisciplinary protocol for use of omalizumab improves the process of prescription, preparation and dispensing. In addition, the protocol supports the value of the hospital pharmacist in selecting the correct dose and avoiding errors.
Conflict of Interest
No conflict of interest

L32. Study into the use of intravenous infusion iron sucrose in hospitalized patients

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Objective
To compare the use of iron (III) hydroxide sucrose complex (Venofer 100 mg) by different clinical services.

Method
A retrospective study of hospitalised patients treated with intravenous iron with a lower baseline haemoglobin level than 13.5 g/dL (me) and 12 g/dL (women), from the internal medicine (MIN), digestive (MDI), general surgery (CIR) and vascular surgery (CVA) services. Variables studied were age, gender, type of anaemia, iron posology, total dose of iron administered, previous haemoglobin levels and other blood parameters.
Results
Fifty patients with an average age of 64 were given Venofer (25 men and 25 women) distributed as follows: MIN 32%, MDI 26%, CIR 11% and CVA 20%.The type of anaemia by mean corpuscular volume values was 64% normocytic anaemia, 32% microcytic anaemia and 4% macrocytic anaemia. According to the observed serum iron concentration 60% was iron deficiency anaemia. The average dose of Venofer per patient varied with the ward: 550 mg on MIN, 320 mg on MDI, 790 mg on CIR and 420 mg on CVA. The weekly maximum dose (6 ampoules) recommended by the product information was exceeded in 14% of the total patients. In only 24% of cases was the anaemia investigated prior to a prescription being written. In 68% of cases, an initial average haemoglobin value of 8.62 g/dL reached 10.09 g/dL at the end of treatment, i.e. a significant increase of 1.48 g/dL

Conclusion
The use of intravenous infusions of iron sucrose differs depending the medical service. At time of the prescription, a prior study of the anaemia had not been made for most patients and a standard dose for intravenous iron has not been established at our hospital. It would be advisable to standardise the use of Venofer.

Conflict of Interest
No conflict of interest

L33. Pharmaceutical care for patients with antithrombotic pharmacotherapy in a Brazilian teaching hospital

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Background
Patient education increases compliance and reduces toxicity or lack of effect during antithrombotic treatment.

Method
Study 1 was prospective, randomised, between August 2000 and March 2002 in the University Hospital of the University of São Paulo, Brazil and divided into two groups, one of which received pharmaceutical care and another that did not, in an ambulatory care setting. Patients were eligible for this study if they were prescribed antithrombotic therapy at discharge and provided consent. Study 2 was conducted retrospectively from 2005 to 2008, with patients with similar characteristics to those of Study 1, whose medical records were examined.

Results
Of the 56 patients in Study 1 who consented and enrolled in the groups, 31 patients were followed by a pharmacist (Group P) who counselled them about pharmacotherapy, the appropriate way of wearing compression socks, and diet. The control group included 25 patients seen only by a doctor for individual anticoagulation appointments. 77.4% of International Normalised Ratio (INR) values for patients from Group P were within the desired INR range compared with 22.6% of those in the control group. In addition, 24 pharmaceutical interventions were made in group P. In Study 2, 122 medical records were analysed from 122 patients who were prescribed warfarin at discharge. The main indications for the use of warfarin were: atrial fibrillation (50.8%), deep vein thrombosis (35.6%) followed by cardiac insufficiency (10.8%). It was found that 79.5% were concomitantly taking medicines that could potentially interact with warfarin. As the result of these two studies our institution is setting up a multidisciplinary call centre for these patients.

Conclusions
By working collaboratively with patients and other health care providers, pharmacists who have the necessary knowledge, skills and resources are able to provide an advanced level of care that results in successful management of antithrombotic pharmacotherapy, improving the patients' INR values.

Conflict of Interest
No conflict of interest

L34. Exploring pharmacists' perceptions of the feasibility and value of pharmacist prescribing in secondary care in Scotland

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Background
There are two models of non-medical prescribing (NMP) in the Supplementary prescribing (SP) describes an arrangement where a doctor diagnoses and a supplementary prescriber then manages the patient within the framework of an individual clinical management plan (CMP). More recently, independent prescribing (IP) has been introduced, allowing the non-medical prescribers to manage patients with diagnosed or undiagnosed conditions and prescribe licensed medicines within their competence. Pharmacists have been practising SP since 2004 (1) and IP since 2007 (2).
In secondary care, pharmacist prescribing has been described as "a natural extension" to the ward-based pharmacist's role (3). The aim of this research was to explore pharmacists' perceptions of the feasibility and value of pharmacist prescribing in secondary care in Scotland.

Method
Focus group discussions were conducted in five Scottish regions. Senior ward-based pharmacists were invited to participate. Discussions were audio recorded and transcribed. The 'framework' approach to data analysis was used (4).

Results
Six focus groups met and recurring themes are presented. Pharmacists felt more comfortable prescribing according to defined guidelines and for diagnosed conditions; they did not feel they had sufficient skills to assess and diagnose a patient.
Pharmacists believed that IP or SP was the more feasible depending on the patient's condition. IP for a diagnosed condition was deemed more suited to managing inpatients where the patient's condition will change rapidly and a CMP will be too restrictive; SP may be more suited in managing outpatients where the condition is more stable. However, most pharmacists thought that overall, IP was the more suitable option in secondary care.

Conclusion
Pharmacists perceive that it is more feasible to adopt a "hybrid" approach to prescribing in secondary care where they IP but mainly for a diagnosed condition. This would ensure both safe prescribing and allow the patient rapid access to their medicines without the restrictions of the CMP if SP.

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Conflict of Interest
No conflict of interest

L35. Prescription monitoring by pharmacists: use of nimesulide in Italy before and after EMEA alert.

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Background
In Italy nimesulide was one of the most widely used drugs as demonstrated by data from the Italian Medicines Agency (AIFA). Although it has a lower incidence of adverse GI reactions in comparison with other NSAIDs, its recent use has frequently been associated with adverse hepatic events. When the Irish Medicines Board announced suspension of marketing and sale of oral nimesulide due to six reports of liver failure in May 2007, AIFA decided that nimesulide could only be bought on the prescription of a physician, which had to be kept as a receipt at the community pharmacy, allowing strong control over selling.

Method
Hospital pharmacists of the Italian Local Health Units (LHUs) monitor all the prescriptions of the community pharmacies. In this study, we collected nimesulide prescriptions in order to check and observe the period before and after the sales limitation introduced by AIFA.

Results
Two LHUs in central (Piacenza) and southern Italy (Palermo), population 1,600,000 total inhabitants, observed nimesulide sales in the period 2006-2008. They checked private purchases and prescriptions issued within the health service for the indications osteoporosis, gout, neoplastic pain and arthropathy.
2006: 438,518 prescribed units of oral nimesulide (217,635 branded; 220,883 generic).
2007: 344,197 units (169,785 branded; 174,412 generic).
2008: 279.374 units (137.505 branded; 141.869 generic).
In 2008, one year after the AIFA limitation, the units of nimesulide decreased substantially (36.3%). As shown, branded nimesulide has the same percentage of use as generic formulations.

Conclusions
Our data demonstrates that the EMEA alert and AIFA limitation on prescription had a significant effect on the use of nimesulide compared with its past use.No rationale exists for selecting nimesulide as the first drug for fever or pain. LHU hospital pharmacists have to discourage its use when the risk-benefits profile is uncertain and overall have to promote the spontaneous reporting of adverse effects.

Acknowledgement to Silvia Vecchio,Pavia

Conflict of Interest:
No conflict of interest

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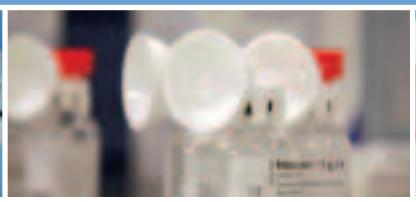

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