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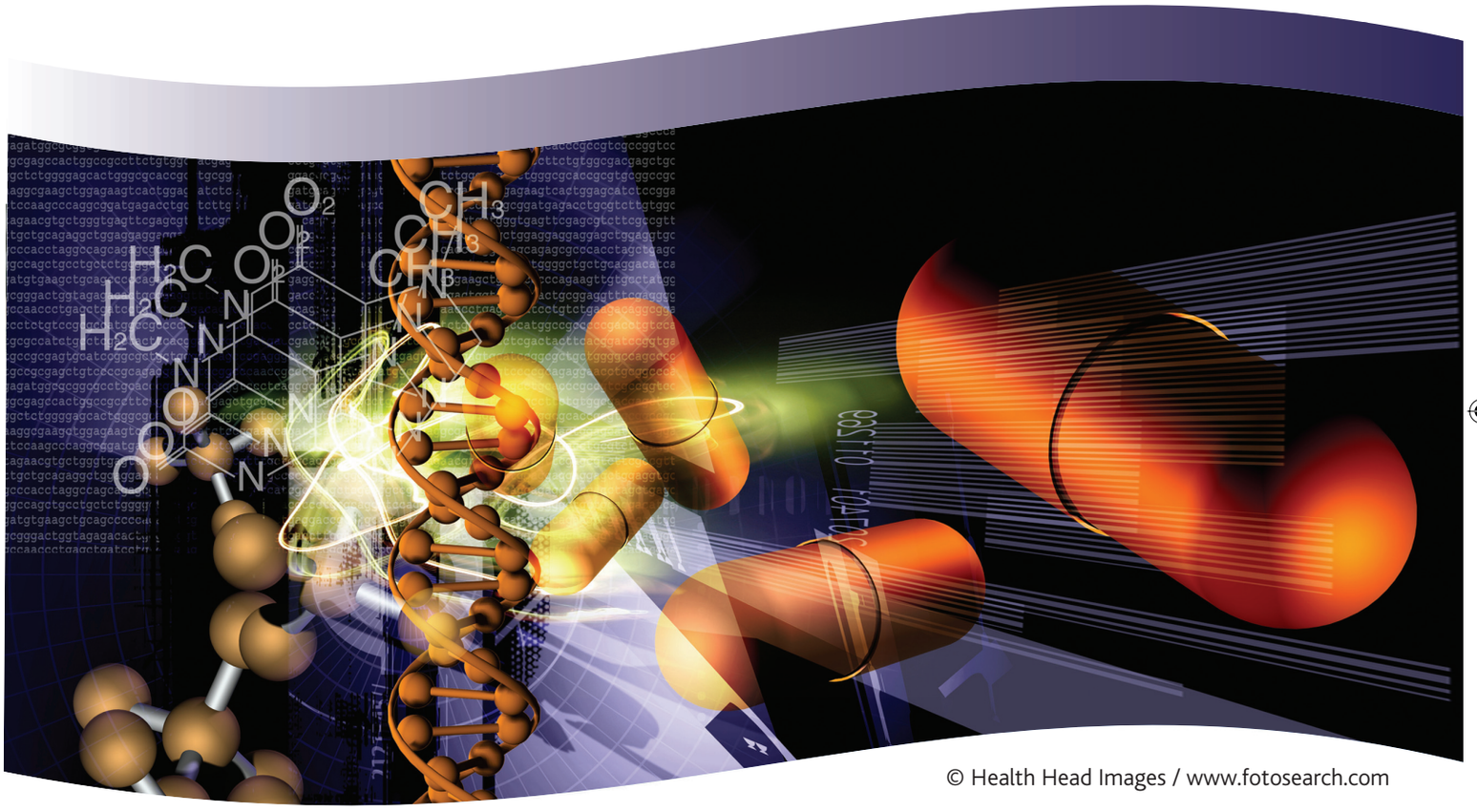

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Special patients, specialised care

Arnold G Vulto

In most European countries, pharmacy students spend some time in hospital pharmacies to learn more about the different forms of practice they can choose once qualified as a pharmacist. Also, in our pharmacy, we welcome several students each year for an 8–10 week internship. Over the years we have developed an intense programme to show these students how the theory of their studies is applied in the practice of hospital pharmacy. At the end of the internship we ask them to write a brief essay, answering four questions:

- Describe the concepts behind the management of our hospital pharmacy
- How can you justify the employment of 30 pharmacists (which to Dutch standards is quite high for a 1200 bed university hospital)?
- Please provide some recommendations on how we can do a better job
- Can you describe some essential differences between community pharmacy and hospital pharmacy?

What surprises us almost every time is how little sixth year pharmacy students – even after 8 weeks of internship – have thought about some of the principles of hospital pharmacy. We all know that the organisational concepts behind a hospital pharmacy are quite different from a community pharmacy. The difference in scale, I think, is rather irrelevant. We have large community pharmacies and small hospital pharmacies, so there is overlap. Most community pharmacies are very much prescription driven, in contrast with most hospital pharmacies. Our 'clients' are predominantly nurses, doctors and medical departments, although the focus of our care is the patient. Hospital pharmacists play a more dominant role in determining the assortment of drugs we have, for example, via a drug formulary committee. What most students have perceived are differences in complexity of patients and drug treatment.

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An important feature of hospital pharmacy is the specialised pharmaceutical care we offer to sometimes very special patients that may not be found in standard textbooks.

It is therefore very timely that the European Association of Hospital Pharmacists (EAHP) has chosen 'Special Patient Groups – hospital pharmacists creating standards of care' as a theme for the 2012 annual congress. The congress programme highlights traditional special groups, such as children and geriatric patients but newer concepts will also be discussed. To mention just a few: care after transplantation, the limits of treatment, compassionate drug use, the difficulties in assessing the real value of new treatments and the potential of genetic screening of patients. Although we expect well above 2000 hospital pharmacists to participate in the conference, the majority of EAHP members will be dependent on the journal to savour some of the highlights of the congress. In this issue, we begin with a few previews of the programme, and in the next issue we will report further on the congress. Most presenters have agreed to write for the journal, and most seminars will be made available online for perusal after the congress.

An important group of 'special patients' are the elderly. They are usually more sensitive to drug effects, regularly use several drugs (five or more) at the same time and the older they get, the more organ functions, such as the kidneys, become compromised. As a result, the majority of patients admitted to hospital for drug side effects via the emergency department are aged over 65 years. An illustrative study from Ireland that was published last year in the *Archives of Internal Medicine*[1] showed how a new STOPP algorithm (Screening Tool of Older Persons' potentially inappropriate prescriptions) can predict (and therefore also avoid) such disasters. This excellent study offers the possibility for (hospital) pharmacists to take better control over inappropriate medicine use by elderly patients.

A specific problem with special patient groups is that often no medicines have been licensed for such a particular group. Although we usually know how to choose and prescribe drugs and the doses needed, based on our collaborative experience and possibly also published studies, the situation is not ideal. The reason is wider than just lack of knowledge. The current situation around clinical trials approval and drug legislation is counterproductive to getting drugs researched and licensed for small populations. Drug licensing is in the hands of a license holder, almost exclusively the pharmaceutical industry. Drug research and licensing is very costly, and companies will look at cost effectiveness before embarking on a clinical study and applying for a license extension to smaller patient groups. I am curious what kind of solutions the speakers of the seminar (Compassionate use and off-label medicines) will present for this dilemma.

An important new feature in our journal is that all abstracts for poster and oral presentations that have been accepted by the congress Scientific Committee will be published in *EJHP*. Hence these abstracts will be easily accessible for all members, and not just those attending the congress.

If you have the privilege of attending the 2012 EAHP congress you will be able to savour the beauty of Milan as a city and also replenish your hospital pharmacy knowledge. I am proud that we as a journal can also serve the less fortunate who have to stay home. Someone has to look after our patients when the others are away! It is my sincere conviction that all EAHP members should benefit from all of the educational activities that EAHP is offering, and our journal plays a pivotal role in that process.

In this way, we can offer you the kind of continuous education that is required to make sure you offer your patients the best specialised pharmaceutical care, based on the latest insights developed by our profession.

Competing interests None.

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1. **Hamilton H**, Gallagher P, Ryan C, *et al.* Potentially inappropriate medications defined by STOPP criteria and the risk of adverse drug events in older hospitalized patients. *Arch Intern Med* 2011;**171**:1013–19.

EAHP Statement on Hospital Pharmacy specialisation

Hospital Pharmacists are key stakeholders in medication management in hospitals. This is a role which encompasses the entire way in which medicines are selected, supplied, quality assured, prescribed, and administered with the overall aim being to improve the safety and quality of all medicine related processes affecting patients.

To achieve this, a hospital pharmacist must be able to operate in a complex hospital setting and work collaboratively within multi-disciplinary healthcare teams in order to provide the best treatment for patients in acute situations or receiving care in specialised ambulatories.

The basic education of 5 years for pharmacists as required by the European Directive on Mutual Recognition of Professional Qualifications 2005/36/EC does not provide sufficient competencies to work independently in the hospital environment. Additional competencies are necessary to fully understand the processes in hospitals and to manage the specific requirements of certain patient groups (i.e. paediatrics, oncology, intensive care, rare diseases.) A comprehensive list of the competencies necessary to improve hospital pharmacy outcomes has been produced by EAHP with the support of the EU funded Pharmine project (http://www.eahp.eu/Advocacy/Hospital-pharmacy-specialisation).

EAHP believes that post graduate education in the hospital setting of at least 3, preferably 4 years with a final assessment of individual competency is essential to ensure that where pharmacists are providing front office hospital pharmacy services, patients benefit from the highest levels of expertise.

Many EU Member States have already formally recognised the need for specialisation in hospital pharmacy and the way in which this improves patient care. However, a lack of EU level mutual recognition of Hospital Pharmacy as structured specialisation creates substantial differences in the qualifications of pharmacists working in hospitals across Europe. It also undermines the efforts of certain European countries to advance the level of pharmaceutical care in the hospital setting and creates inequalities in patient access to the best possible care.

The review of the EU Directive on Mutual Recognition of Professional Qualifications provides an opportunity to address these issues. As an advocate of patient safety and in particular the safe and effective management of medication in hospitals, EAHP firmly asks that the European rules on professional mobility be updated to introduce Hospital Pharmacy as a mutually recognised speciality. This should be done in a way which is comparable to what has already been implemented for physicians under similar conditions. We believe that this is an essential step forward to ensure that all patients in acute situations benefit from pharmaceutical care that is underpinned by the highest levels of knowledge, skills, and experience.

European Study for Neonatal Excipient Exposure (ESNEE)

Mark A Turner[1], Thomas Storme[2]

Excipients are frequently used to facilitate the manufacture and storage of medicines. Pharmacological effects and adverse events can be attributed to excipients. Examples in adults include effects of excipients on taxane pharmacology. There is significant overlap between medicinal excipients and food additives. Safety assessments of excipients and food substances draw on laboratory science, toxicology and assessment of the clinical consequences of exposure. The application of these methods allows a reasonable assessment of excipient and food additive safety in adults.

Children are different from adults, and neonates are different from children. Neonates (babies born prematurely or within 28 days of term birth) are particularly vulnerable to medicines and excipients because of organ immaturity. While the principles of excipient safety can be applied to children and neonates, the findings of clinical assessments may not be directly applicable—that is, excipients that appear to be safe in adults are not necessarily safe in neonates. Examples of this are the consequences of administering sodium benzoate or benzoic acid to preterm neonates or high doses of polysorbate. Excipient exposure appears to be common in neonates, and studies of estimated exposure suggest that neonates are likely to be exposed to systemic concentrations of excipients that would not be tolerated in older age groups. The tools used to systematically evaluate excipients and food additives in older age groups have not yet been deployed to safeguard neonates.

We have been funded to conduct the European Study for Neonatal Excipient Exposure (ESNEE). This study will develop a platform for the systematic assessment of excipients in neonates. The aims of this seminar are to give the Association an update on the assessment of excipient safety in neonates.

The first step of our programme is to establish which excipients are in use and how much of each excipient is included in medicines given to neonates. A pan-European survey is underway. Preliminary results will be presented with key difficulties. The major challenge has been accessing data about excipients in existing medicines.

The second step of our programme is to determine what is known about the effects of excipients in neonates and juvenile animals. We are developing a series of systematic reviews about excipient toxicity. Preliminary results will be presented together with important issues in the design and analysis of a systematic review of this nature.

The third step of our programme is to measure systemic concentrations of key excipients in neonates using dry blood spots and plasma samples. A clinical study is in progress. We will outline the study, including the process of prioritisation of excipients

The final step of our programme is to integrate the work from the other steps into a systematic assessment of safety for each excipient. We will outline a generic framework for the assessment of excipient safety in neonates and illustrate how this can be applied by prescribers, pharmacists, manufacturers and regulators. Propylene glycol will serve as a case study with reference to other excipients.

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Clinical challenges on how to optimise the use of drugs beyond the label

Birte van Elk, Sandra Kruger-Peters, Aimad Torqui, Hubertus Leufkens, Yechiel Hekster

It is well recognised that medicinal products are often used beyond the approved labelling and patient groups for which the drug has been licensed. This is referred to as off-label use of drugs. Off-label use most often concerns the drug's indication and dosing, which occurs in various patient groups, such as children. It is a major concern that about 70% of the medicines used in the care of children are not studied, and are applied off-label in one or more of their age groups. Off-label prescribing takes place in daily clinical practice. In some cases, off-label prescribing occurs more frequently than in-label, both for new drugs and for much older drugs.

Currently there is focused media attention on this issue and many articles have discussed this topic. Moreover, off-label promotion seems common practice worldwide. Healthcare providers do often not understand the legal consequences, and are not always aware of the problems involved. Off-label use of drugs should have a higher priority for health authorities, considering the impact on patient care and the promotion of safe and appropriate use of drugs.

Health authorities determine the benefit/risk ratio during the assessment of a medicinal product, aiming to establish the appropriate indication and dosing within a particular population based on the submitted clinical data. If deemed necessary, the sought indication and/or population is subject to adjustments based on the benefit/risk ratio. However, it should be stated that in practice, not all indications are applied for by the pharmaceutical industry. The health authorities are only able to assess what is submitted for approval, which subsequently can lead to an approved, adjusted or updated labelling (SmPC, patient information leaflet).

There are several reasons for off-label use in clinical practice. The drug licensing process is long and costly, with randomised clinical trials required for all indications. The initial application focuses mainly on obtaining a license for the primary indication, with limited attention to specific patient groups, such as children, the elderly and patients with poor organ functions. The requirements for planning studies in children based on the paediatric regulation is an important step forward, but data become available most often years after introduction.

In addition, there is a lack of financial incentives for drugs already on the market, with no protection (off-patent drugs), while reimbursement for off-label indications is occurring. Off-label prescribing is also common due to factors such as lack of marketability and size of the population with a (medical) need. Licensing a new indication for an already existing drug is an expensive and lengthy, sometimes unprofitable, process and to date, licensing is only possible for a pharmaceutical industry.

Also, medical practice is a continuing fast process where individualisation is required for particular patient characteristics—for example, in cancer treatment. Medical specialists rely on indications described in (inter)national protocols and treatment guidelines based on the medical literature. These indications are either still being assessed or have never been submitted to health authorities. Thus no formal risk/benefit balance has been made.

Off-label use of drugs is a dilemma for health authority regulators. When they are (for) positive, it could lead to an indication that is accepted and a license is given for an indication that is not fully supported by clinical data. It is clear that it is unlikely that these data become available. This means uncertainty about efficacy and safety data in the population. However, when health authorities ask for additional data for safety reasons, there is no incentive for industry to register a new indication and thus off-label use remains current practice. In this situation it is unlikely that these data become available, which will also lead to uncertainty.

Such a situation has the following consequences: research data are not made available by industry; no specific research data are assessed by authorities with the consequent lack of a balanced opinion about the benefit–risk for this indication; and trial and error dosing in clinical practice, with unclear therapeutic responses, unknown adverse reactions, delay in information supply and legal issues related to the prescribing physician, patient and parent (in the paediatric population).

Currently, initiatives from health authorities with the new pharmacovigilance legislation are underway with the goal of monitoring off-label use for example. This will provide more possibilities for postmarketing surveillance, data collection and also for conditional approval under strict conditions.

Prioritising off-label monitoring should focus on drugs for indications with a potentially negative benefit–risk balance. This can be caused by the drug, the patient at risk or the environment. Key aspects for the drug include new potent drugs, interaction potentials and limited experience. For the patient at risk, comorbidity with polypharmacy, extremes of age (children, the elderly), organ function impairment and pregnancy/lactation need to be taken into account. With regards to the environment, aspects such as easy access, many prescribers and difficult to follow-up play major roles.

In the presentation, these aspects are discussed in more detail, reasons for off-label use are presented and views are developed on how to optimise the use of drugs beyond the label with the goal of striving for license through regulatory processes.

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Better medicines for children

Anthony Nunn

Children have been described as 'therapeutic orphans', indicating a lack of authorised, age appropriate formulations of medicines to treat a variety of illnesses. Access to appropriate medicines can be particularly problematic in resource poor countries. There is some evidence that adverse drug reactions are more likely when using unlicensed or 'off label' medicines for children. Adherence and medication error may also be issues. In the UK, a national formulary for children was developed by paediatricians and paediatric pharmacists through the 'Medicines for children' project, and the British National Formulary for Children is now distributed to provide evaluated information to all doctors and pharmacists in the UK. This is complemented by a series of leaflets about unlicensed and off label medicines aimed at carers and is freely available on the internet.

Several initiatives are in place to improve the 'orphan' situation, with the USA starting the process with legislation designed to increase our knowledge of paediatric medicines and to improve the availability of those suitably authorised. This has had little effect outside the USA. EU legislation came into force in 2007 and offers both 'carrot and stick' to encourage and require pharmaceutical manufacturers to study and authorise medicines for children at similar times to those for adults if there is the prospect of benefit to children. Although more than 1000 paediatric investigation plans have been submitted to the European Medicines Agency, there is a considerable lag before significant improvement occurs because many paediatric clinical trials have been deferred for several years until safety and efficacy has been established for adults. The Paediatric Use Marketing Authorisation part of the regulation has disappointed, with only one authorisation being granted to date for buccal midazolam in status epilepticus. However, the prospect of increased numbers of paediatric studies has stimulated the formation of clinical trials networks in several European countries. The UK government funded Medicines for Children Research Network has been particularly successful, adopting more than 160 industry sponsored studies since its creation in 2006. One effect of the new legislation is that more medicines are being considered for use in neonates and infants. This has exposed a lack of knowledge of the kinetics and dynamics of excipients such as propylene glycol, ethanol, polysorbates and parabens, and the influence of developing physiology in their handling.

Access to paediatric medicines remains a problem in developing countries, yet some of the clinical studies for authorisation of new paediatric medicines in Europe and the USA are undertaken with children in developing countries with little prospect of the medicines being affordable in those countries. The WHO has produced an essential medicines list for children, a priority list, model paediatric formulary and specific initiatives around HIV, tuberculosis and the development of paediatric medicines. There has been a demonstrable increase in the uptake of antiretroviral medicines for children with HIV but little evidence of change for many other diseases. Several fixed dose combinations with unified dosing instructions have become available for paediatric HIV but producing a suitable solid, oral, fixed dose combination for the three or four drugs used in the treatment of tuberculosis remains a pharmaceutical challenge. Funding for global initiatives has largely been philanthropic in origin and there are concerns that a systematic approach to increasing access is lacking.

The European Paediatric Formulations Initiative has brought together formulation scientists from the industry, academia and hospitals to jointly address the challenges of producing age appropriate medicines for children. There are work streams on taste masking and testing, age appropriate formulations, excipients, administration devices and compounded medicines.

The 'GRIP' (Global Research in Paediatrics) project funded by the EU focuses on increasing capacity to undertake studies on paediatric medicines by improving teaching and training in paediatric clinical pharmacology. Clinical pharmacists will be eligible for such training and are fully involved in its development, as well as leading a work package on paediatric formulation designed to establish a network of experts and increase access to appropriate formulations, including use of innovative technologies. GRIP will work with organisations such as the WHO, the Commonwealth Pharmacists Association and pharmacists in resource poor countries to improve access to children's medicines and, in particular, to work on improving the quality and safety of extemporaneous compounding.

In contrast with general paediatric medicines, intravenous nutrition for babies and children has seen significant development and improvement in resource rich countries since its implementation as a treatment modality in the 1960s. Pharmacists should be proud of their integral role in the success of this treatment which has improved survival rates for many paediatric conditions and has been essential to the survival of babies born preterm.

The gap between the availability of authorised medicines for children and for adults is beginning to reduce in Europe and the USA. We should all be concerned that the 'better medicines for children' initiatives will 'run out of steam', especially if there is a global economic downturn.

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Changes in development and evaluation of new cancer drugs: what is needed to guide practice?

Wolf-Dieter Ludwig

Cancer remains an important public health problem in Europe. Due to an ageing population, the total number of new cases of cancer in Europe will continue to increase even if age-specific rates remain constant. There has been a reduction in cancer mortality during the past two decades that could be explained mainly by behavioural changes and screening procedures. At the same time, given a gradual shift from cytotoxic drugs to more or less selective, high-cost targeted therapeutic agents, the price spiral of cancer drugs that frequently achieve only marginal benefits is under increasing scrutiny. Moreover, important questions have been raised about allocation decisions and value issues in the reimbursement of cancer drugs by insurance companies.

Recent advances in cancer research have elucidated many cellular and molecular mechanisms of tumour development, growth and metastasis. This has led to the identification of new more or less cancer-specific molecular targets and helped to create new options for the diagnosis, prognostic stratification and treatment of malignant disorders. Based on research into the biology of human tumours, we now understand that cancers are very heterogeneous in terms of morphology, histology and clinical outcome, and also at the molecular level. For a given type of cancer there is extensive genetic variation with a variety of high-frequency and low-frequency mutations, including mutations that are responsible for driving the initiation, progression or maintenance of the tumour. This makes treatment suboptimal when the 'one-size-fits-all' approach is applied or a single drug regimen is used for patients with the same tumour type or histology. Additionally, numerous bottlenecks along the path of converting a genome discovery into a tangible clinical endpoint have been identified. Therefore, the need to 'personalise' or to 'stratify' cancer therapy has been recognised. By focusing on recently approved targeted therapeutics in cancer, methodological and practical challenges for stratified cancer therapies are presented. Furthermore, crucial steps in the implementation of 'personalised medicine' in oncology are discussed (eg, comprehensive assessment of the biological characteristics of tumours from each patient, validation of biomarkers and mechanisms to identify subgroups of patients who are most likely to benefit from a specific therapy, establishment of multidisciplinary translational and research teams). Better evidence of efficacy and effectiveness is urgently needed to guide rational and cost-efficient use of new drugs in oncology (ie, delivery of the right drug to the right patient at the right time). This requires appropriate patient selection, novel clinical trial designs and biomarker-driven trials.

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Focus on genetic screening by hospital pharmacists

Mary W Roederer

Personalised medicine, tailored therapy or individualised therapy are all terms used to describe providing the best drug at the best dose to the right patient and include using pharmacogenomics, or the study of genetic related differences in an individual's drug response. There are several excellent examples of the clinical application of pharmacogenomics and the use of pharmacogenomics information in drug prescribing information approved by the European Medicines Agency (EMEA) or the United States Food and Drug Administration (FDA). For example, both the EMEA[1] and the FDA[2] include HLA-B*5701 genotype in the prescribing information to prevent abacavir hypersensitivity drug reaction based on information from large clinical trials.[3,4]

If the genetic test results are available (pre-emptive testing), then the pharmacist can consider the potential drug–gene interactions. If the test result is not available, a pharmacist considers the relevant pharmacogenomic test that may advise drug response. It is essential for any clinician to consider the type of test and to verify the availability of the test to the hospital. Many pharmacists may believe that the challenges to evaluating the data and the test and obtaining the test results is insurmountable; reassuringly, at least one institution has implemented a clinical pharmacogenomics service.[5] With the new science integrated into practice at one hospital, pharmacists should be encouraged to find ways to make it work at their institution.

With pharmacogenomics as a new tool, why are pharmacists poised to be the champion? What is the role of the pharmacist in pharmacogenomics? The pharmacist is the clinician familiar with individualising drug doses based on patient specific factors, such as renal function, age or weight.[6] The pharmacist is the educator, teaching pharmacy learners and teaching physician colleagues about the relevance of pharmacogenomics to drug disposition.

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And, most importantly, pharmacists are in an excellent position to influence the research agenda. Hospital pharmacists can use ADR data to identify problem drugs for the hospital or health system and work with researchers to investigate potential genetic associations. Overall, the pharmacist is the drug expert with the most in depth knowledge of metabolic pathways and drug targets and the practitioner most appropriate to assess the need for pharmacogenomics to influence drug selection.

Most pharmacists, busy with patient care, are assuring drug appropriateness and drug safety and wonder how relevant is pharmacogenomics and is it necessary to incorporate it into medication therapy management? In one study, Grice *et al* found that more than one in four patients in primary care take a drug where pharmacogenomics is relevant.[7] In general, pharmacists interested in incorporating pharmacogenomics information should approach the new information much like any new data or service and ask a series of questions to identify best practice.

The most important question a pharmacist must ask is how does one prepare for pharmacogenomics to hit your pharmacy? The key factors are identifying a mechanism to learn the basic and more advanced pharmacogenomic concepts and to establish a systematic way to evaluate the evidence to find areas of application appropriate for their institution. These factors will influence and provide the necessary information to evaluate the need for specific services.

Shockingly, very little literature exists to describe the education, knowledge and interest in obtaining continuing education for pharmacists who have completed their training. In one recent study, pharmacists proved to be good at assessing their own knowledge and most scored between 40% and 70% on the knowledge questions. Not surprisingly pharmacists with fewer years of experience scored higher on the knowledge assessment questions related to both genetics and pharmacogenomics. Most pharmacist respondents (77–93%) want to obtain education related to pharmacogenomics as a continuing education course, and especially as a web based continuing education course.[8]

Where do pharmacists get the information needed to allow for clinical application of pharmacogenomics after the basic continuing education courses? There are three key groups that are providing crucial and clinically relevant evaluations of drug–gene relationships or pharmacogenomic tests. The groups are the Evaluation of Genomic Applications in Practice and Prevention working group,[9] the Clinical Pharmacogenetics Implementation Consortium[10] and the Dutch Pharmacogenetics Working Group.[11] Considering the amassing data and the potential for widespread application, how do pharmacists integrate the new data to make an individualised drug therapy plan? The precise place to integrate pharmacogenomics remains undetermined. There are many potential entry points: the prescribing level, the dispensing level, the patient level and the formulary level. Interesting areas for integration of the information are pre-emptive testing and using the information to inform formulary decisions.[12–15] Both scenarios require understanding on how to create a plan that uses all the standard information and adds pharmacogenomics data to make the decisions better.

Realistically, there are important barriers to patient and pharmacist acceptance of new therapies and new tests. For pharmacists, the barriers that stand out are the lack of robust information on clinical application, additional time to complete any new tasks and the practicality of using pharmacogenomics information at the point of patient care despite insufficient health information technology. Two important publications from the American Society of Health-System Pharmacists and Dr. Vulto of the European Association of Hospital Pharmacists identified several barriers to pharmacist clinical use of pharmacogenomics; but both pieces highlighted the enormous opportunity for pharmacists to include pharmacogenomics in routine care.[16,17] Ultimately, pharmacists are the drug experts. Pharmacists constantly synthesise patient specific data to optimise pharmacotherapy. Pharmacogenomics is just one more piece of information

to perfect drug selection, dosing and monitoring. Pharmacists are the best medical professional to balance the addition of new pharmacotherapy information and make pharmacogenomics clinically useful.

Competing interests None.

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The young pharmacists (SIFO)

Silvia Adami,[1] Laura Fabrizio[2]

SIFO is a cultural and pharmaceutical association of hospital pharmacists and community pharmacy services for local health centres. SIFO includes nearly all public pharmacists employed within the National Health Service and employees of private hospitals.

SIFO has 2776 members, 686 of which are under the age of 35 and work as hospital pharmacists or in community pharmacy services for local health centres (figure 1). The regions with the most members are Campania (15%), Emilia Romagna (10%) and Sicilia (10%) (figure 2).

Most members are employees in a hospital or territorial pharmacy, only 15% indefinitely (figure 3). A total of 31% of young members are postgraduate residents and other members are grant holders (13%) or self-employed (6%). Only a small proportion of members (6%) are community pharmacists.

The Young Pharmacists Group was established in 2008 to delineate a specific role for young pharmacists within the scientific association and to meet the educational and research needs of all young members.[1] The lack of a permanent job at the end of studies and difficulties during training in hospital pharmacy are important issues for the Young Pharmacists Group.[2]

In Italy, the school of specialisation in hospital pharmacy (SSFO) has undergone extensive changes. It now offers more extensive training—that is, more lessons and longer internships—so that postgraduate residents are unable to work during training. This reform has been well accepted by SSFOs and by postgraduate residents; however, it raises important questions about the underlying problem, namely the lack of grants for postgraduate residents.

Another feature of the new SSFOs is that postgraduate residents learn all aspects of hospital and territorial pharmacy. This has not been undervalued because during their internship, postgraduate residents should learn as much as they can and should not be 'used' to do unskilled tasks, which unfortunately can happen.

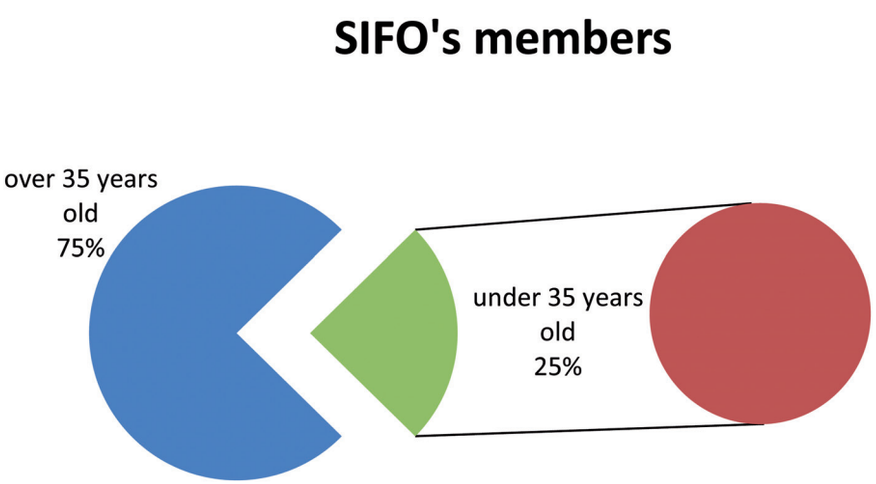

Figure 1 SIFO's members under 35 years old (from SIFO's database, November 2011).

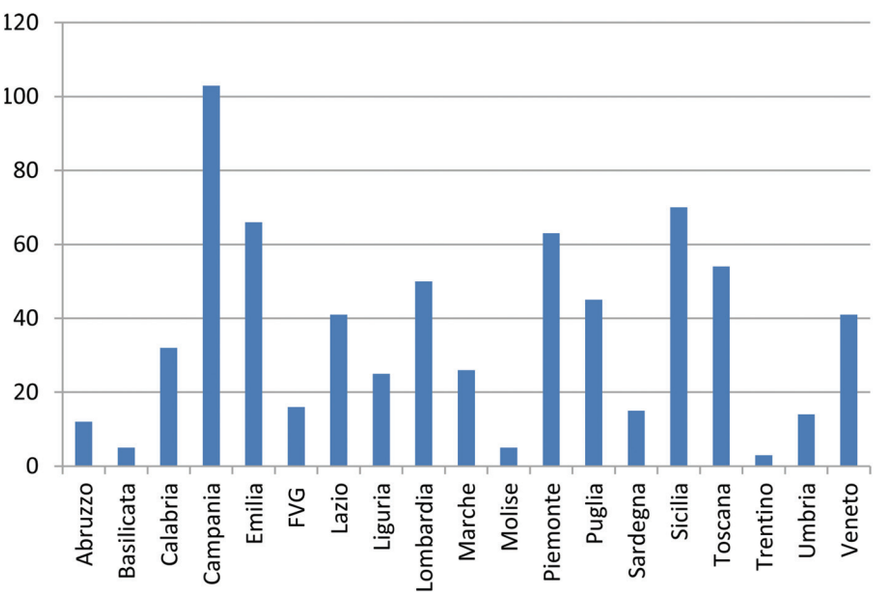

Figure 2 SIFO's members under 35 years old: regional distribution (from SIFO's database, November 2011).

Considering the importance of these issues, the Young Pharmacists Group has organised meetings with representatives from universities to find solutions. One innovative proposal by SIFO emphasises that training should be assessed on the basis of the hours carried out and the 'production' of different activities, moving towards more analytical internship documentation based mainly on quantitative data (eg, days worked in various sectors, number of health technology assessment reports produced). An online register would be created to record all documents produced and projects completed during the internship.

Another critical issue for young pharmacists is the need for continuing education. In the past, postgraduate residents

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EDITOR'S CHOICE

were thought to be ready to work at the end of training. Today, this is no longer the case because it has become clear that without continuous updates, pharmacists can lose competence even if they are already working. Therefore, the Young Pharmacists Group has organised training courses that are fundamental for all pharmacists, such as the use of biomedical databases and pharmacovigilance, scientific information and statistical models in clinical trials.[3–5] Unfortunately, during traditional training activities participants mainly take a listening role, which tends not to change professional practice, whereas initiatives that actively involve participants and provide practical tools do make a difference. Therefore, the Young Pharmacists Group has aimed to involve colleagues in research projects in which all pharmacists can contribute to training in specific research areas.[6–11] The most important project is about formularies ('IPER-PTO Project'), which is proving valuable for local and national health.[6–8]

In Italy, the Therapeutic Hospital Formulary was most prominent during the 1980s and 1990s, when pharmacological treatments supported by sufficient efficacy data were separated from those without supporting data. Currently the scenario has radically changed, mainly due to the greater efficiency of regulatory agencies (eg, European Medicines Agency (EMA), Italian Drug Agency (AIFA)), which has prevented market access to therapies without so-called evidence. Therefore, the Therapeutic Hospital Formulary is nowadays likely to be considered as simply a positive list, integrated by short 'notes' at best.

The IPER-PTO Project aims to realise a model formulary with a structure that is directly integrated with the concept of guidelines. This project aims to make a hypertext formulary (IPER-PTO) based on guidelines that is a tool of clinical governance and is available online. Therefore, it will only be possible to add active agents to the Iper-PTO if they are accompanied by a guideline indicating their 'place in therapy'. Currently the database contains about 400 active agents and 236 guidelines.

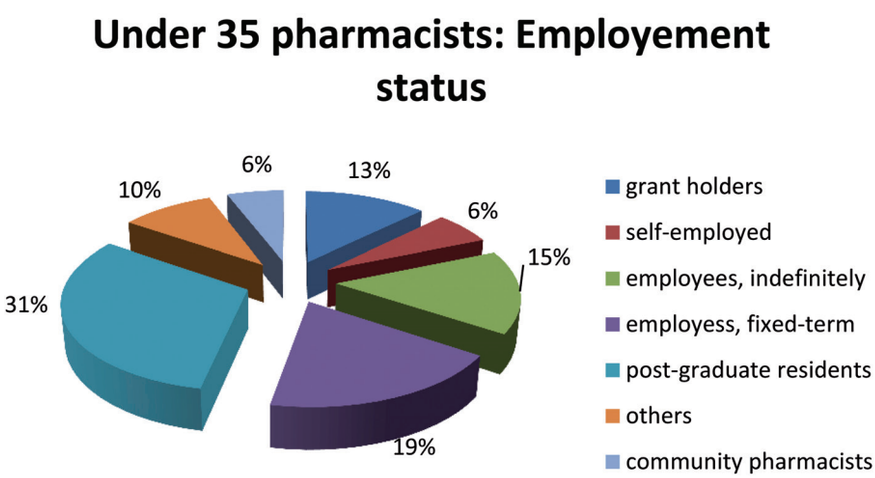

Figure 3 SIFO's members under 35 years old: employment status (from SIFO's database, November 2011).

Continuing education is an important component of SIFO's activities and is widely agreed to be an objective that ranks as high as research. So, as well as planning research, the association will be seeking to develop new professional patterns.

Competing interests None.

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The role of the hospital pharmacist in chemical and biological risk management: disinfectants as an example

Roberto Lombardi,[1] Maria Grazia Cattaneo,[2] Laura Fabrizio[3]

Due to their role, it is mandatory that hospital pharmacists are involved in chemical and biological risk management of hospital processes and they increasingly have to consider the health and safety regulations. In Italy, reference must be made to the 'Testo Unico sulla Sicurezza', D.Lgs 81/2008 (Art. 15, 1(c)), and updates, with particular reference to 'Titolo IX, Sostanze Pericolose' (EU directives 98/24 and 90/394), 'Protezione da agenti chimici, Protezione da Agenti Cancerogeni e Mutageni' and Title X (EU directive 54/2000 and updates).

The knowledge of hospital pharmacists should be used to develop a quality management system aiming at risk prevention, and the protection and safety of the working environment through drafting documents and protocols, training, monitoring, auditing and research activities. Typical processes include management of drugs and medical devices, preparation of chemotherapy and antiviral drugs, selection of disinfectants, and making decisions about general protection and self-protection devices such as hoods, gloves, protective clothing and masks, for their own use and to protect other healthcare professionals and patients during clinical procedures. For example, when choosing instruments, devices and surface disinfectants, pharmacists must consider the activity, contact time, substrates and interferences. In addition, they should evaluate the potential exposure of operators and patients to chemicals and the toxicity of the concentrations used (eg, formaldehyde, gliossale, gluteraldehyde, etc). Hospital pharmacists should adopt a multidisciplinary approach and make these decisions in consultation with doctors and safety managers.

It is important that hospital pharmacists consider the technical and scientific documentation and specific standards published by public independent administration organisations (table 1).

Table 1 European standards to test and use disinfectants, as applied in our hospital

EN 1040:2006	Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics.
EN 13727:2004	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area.
EN 14561:2006	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements.
EN 14476:2007	Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements.
EN 13624:2004	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity in the medical area. Test methods and requirements.
EN 14562:2006	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area. Test methods and requirements.
EN 14347:2005	Chemical disinfectants and antiseptics. Basic sporicidal activity. Test methods and requirements.
EN 14348:2005	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements.
EN 14563:2009	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area. Test methods and requirements.
EN 14563:2008	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area. Test methods and requirements.

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Competing interests None.

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GENERAL INFORMATION

- The poster judging will take place on Thursday, 22 March 2012.
- Poster presenters must check in with the hostesses in the poster area (Level 0 of the congress centre) on Wednesday, 21st March, and they will be assisted with information on where to hang the posters.
- The poster prize winners must be present at the closing ceremony on Friday, 23rd March in order to win.
- An online poster walk will be available on the EAHP website (www.eahp.eu) as of 15th April 2012.

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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.

CALL FOR ABSTRACTS – 2013 PARIS

18th Congress of the EAHP, 13-15 March 2013, Paris, France

Original contributions from all fields of hospital pharmacy are encouraged and welcomed for poster presentation.

Deadline for submission: 15 October 2012

During the review process, the award nominees will be selected and the presenting author of the nominated abstracts will be invited to give an oral presentation after which the final judging will take place.

Please be sure to provide an email address which will not be blocked by spam servers so that we may notify you for modifications and nominations.
(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.

The format and guidelines for the online abstract submissions will be changed. Please visit the EAHP web site at http://www.eahp.eu/Congresses/Abstract-information to view the new guidelines and to submit abstracts for the Paris congress 2013.

The abstracts are to be entered into the system by section according to the guidelines. These 5 sections will be as shown below. Abstracts will not be accepted unless they meet the guidelines which will be posted during the summer of 2012.

- Background
- Purpose
- Material and methods
- Results
- Conclusion

We look forward to receiving your abstracts for Paris!

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40th 1972-2012 EAHP ANNIVERSARY

Since its beginning, the European Association of Hospital Pharmacists (EAHP) has been growing and evolving through time, and is now proud celebrate its 40th anniversary!

Many challenges have been encountered since its creation, and we are happy to say we have successfully faced them, with a main goal of helping hospital pharmacists improve their professional knowledge and level of expertise, resulting in better care for patients.

Important Milestones in EAHP's History

1972
Foundation of EAHP
First president: Marcel Lebas
Members: Belgium, Denmark, France, Germany, Italy, The Netherlands and United Kingdom

1984
The first EAHP journal, "European Journal of Hospital Pharmacy", is published

1993
English becomes the working language of EAHP

1995
First EAHP Survey (comparing data from 18 countries)

1996
First EAHP Congress is held in Amsterdam
(around 750 participate, but only 250 were expected)

2002
The first female president, Jacqueline Surugue, is elected

2006
First Foundation Seminar is held in Budapest
EAHP establishes its own bureau in Brussels

2011
The EAHP officially became an International Not-for-Profit Organization

2012
The EJHP is published by the British Medical Journal Group

POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, March 21st , 14:00 - 15:30, Amber 1 & Thursday, March 22nd, 8:30 - 10:00, Amber 1

Presentations on Wednesday, March 21st , 14:00 - 15:30, Amber 1

TCH015 TCH015 EFFECT OF BAR-CODE TECHNOLOGY ON THE SAFETY OF CYTOSTAIC DRUGS ADMINISTRATION

M.C. Serrano Vicente, M.C. Viñuales Armengol, M.P. Amador Rodríguez, A. Martínez Crespo, L. Ortas Buil [1]*Hospital San Jorge, Pharmacy, Huesca, Spain*

Background Serious medication errors are common in hospitals and often occur during order transcription or administration of medication. To prevent such errors, technology has been developed to verify medications by incorporating bar-code verification technology within an electronic medication-administration system (bar-code eMAR)

Purpose Incorporate an electronic system of validation and control of cytostatic drug administration using bar codes and an electronic medication-administration system (eMAR).

Materials and Methods Bar-codes wristbands have been used to identify patients and we acquired PDAs as eMAR, which were connected to e-prescribing program by the hospital WIFI. After having received the medication sent from Pharmacy Department the cytostatic drugs administration circuit in day hospital consists of: the nurse scan the bar codes printed on patient's wristband, automatically drug information about medicines to be administered appears on the screen of the PDA (patient data, route, speed and time of administration, sequence order, components, and number of administrations). After scanning the bar code on the patient's wristband the nurse scan the bar code on the medication's labels of cytostatic drugs. Validated variables by the scan are: patient, drug administration sequence, start and end times. If the dose being scanned corresponds to a pharmacist-approved medication order and the patient is due for this dose, administration is automatically documented. However, if the dose does not correspond to a valid order, the application issues a warning.

Results During the first month and a half since its introduction, this system has been used in 202 oncology-hematological patients (24.3% hematology, 75.7% oncology patients), 486 medication orders scanned (28.8% hematology and 71.2% oncology) and 1522 doses identified (14.2% hematology and 85.8% oncology).

Because the eMAR imports medication orders electronically from either the physician's order entry or the pharmacy system, its implementation may reduce transcription errors.

Possible detected errors: incorrect order of administration, already administered drug and selected drug that does not belong to scanned patient. During study period we detected: 4 cases of incorrect administration order, 2 cases of already administered drug and 9 cases of selected drug that does not belongs to scanned patient.

Conclusions The implementation of bar-code medication-verification technology embedded in an eMAR in an onco-hematological day hospital act as an additional safety net in medication administration and in patient safety. This system also improves treatment efficiency and achieve a greater inte-disciplinary collaboration.

No conflict of interest

PHC006 PHC006 BEHIND CYP450 INTERACTION TABLES Ñ THE EFFECT OF GENDER AND AGE ON PHARMACOKINETICS

H. Jenzer, L. Sadeghi, C. Krause, F. Pfister, P. Stute, Z. Stanga [1]*Bern University of Applied Sciences - health division, aR&D Nutrition and Dietetics, Bern, Switzerland;* [2]*Bern University Women's Hospital, Department of Gynecologic Endocrinology and Reproductive Medicine, Bern, Switzerland;* [3]*Bern University Hospital, division of Endocrinology Diabetes and Clinical Nutrition and Department of Internal Medicine, Bern, Switzerland*

Background Interaction tables are restricted to unspecified isoenzymes of the families CYP1, CYP2, and CYP3. Data on gender impact has been required by the FDA only after 1993.

Purpose The aim is to assess the effect of gender and age on pharmacokinetics and to explain inconsistent data reported so far.

Materials and Methods A systematic online literature research was performed on the usual platforms. 168 references could be evaluated.

Results Ontogeny, peri- and postnatal phase

- CYP450 inducibility begins in the earliest embryonic stage and reaches high rates before birth. Drugs are not distributed freely to all parts of the body in newborns.
- Childhood
- Preadolescent fasting boys absorb 35.2%, girls 45% of an oral iron loading dose. This explains the higher prevalence of iron anaemia in boys aged 11-15 (12.1%) compared to equally aged girls (6.1%).
- Adulthood
- Mean gastric fasting pH is 2.15 for men and 2.8 for women corresponding to a 5-fold H^+ activity in men. Women secrete gastrin and bicarbonate at the moment of substrate afflux, men more steadily. Gastric emptying, small intestine motility and colon transit times are downregulated by oestrogen and progesterone.
- In men, isoenzymes CYP1A2, CYP2C9, CYP2E1 are more active (CYP1A2 up to 40-fold), in women CYP3A4,5,7, CYP2A6, CYP2B6, and CYP2D6 (CYP2D6 only in the fertile phase). CYP3A4,5,7 activity depends on the menstrual cycle and peaks before ovulation and in pregnancy.
- Hepatic and intestinal P-gp (permeability glycoprotein) is expressed more in men than in women. Confused reports arise if the authors do not account for any mutually opposed effects of P-gp and CYP3A4,5,7.
- Pharmacokinetics change markedly in pregnancy due to slow motility, haemodynamics, cardiac output, etc. Incomplete protein digestion due to PPI treatment in pregnancy is a documented risk factor for predisposition to immune responses and asthma of the child (5.6% versus 3.7% in the untreated population).
- Copper absorption is higher in women aged 20-59 (71%) than in men of the same age (64%). This difference between the genders does not exist in the 60-83 age range.

Conclusions Inconsistent data arise from crossed effects of co-localised P-gp and CYP3A4,5,7. Thus, only studies involving drugs that are not transported by P-gp are appropriate in CYP3A4,5,7 studies and vice versa. Interaction tables are limited tools. They do not distinguish between special patient groups or age ranges and thus need improvement.

No conflict of interest

PHC007

PHC007 GENETIC RISK FACTORS FOR TYPE 2 DIABETES MELLITUS AND RESPONSE TO SULFONYLUREA TREATMENT

J.J. Swen, J.A.M. Wessels, W.J.J. Assendelft, H.J. Guchelaar

Background Following the identification of alleles that increase the risk of type 2 diabetes mellitus (T2DM), models have been developed to identify high-risk subjects. We hypothesise that these risk alleles affect the treatment response to oral antidiabetic drugs.
Purpose To investigate whether genetic risk factors for T2DM are associated with response to sulfonylurea (SU) treatment.
Materials and Methods Patients starting treatment with SUs (tolbutamide, glibenclamide, glimepiride, gliclazide) with T2DM were recruited from 4 primary care centres. Data were retrieved from the electronic patient records. Primary endpoint was achieving stable SU dose defined as the 1st period of ≥270 consecutive days without dose adjustment, initiation of other SU, insulin or metformin. Secondary endpoints were stable dose of prescribed SU, and time to stable SU dose. 20 SNPs [Single nucleotide polymorphs]consistently associated with T2DM in 19 genes were selected: TCF7L2, KCNJ11, HHEX/IDE, SLC30A8, CDKAL1, CDKN2A/CDKN2B, IGF2BP2, KCNQ1, PPARG, FTO, NOTCH2, WFS1, JAZF1, THADA, CDC123/CAMK1D, TSPAN8/LGR5, ADAMTS9, HNF-1β, MTNR1B. A genetic risk score per patient was calculated based on the number of risk alleles. The χ^2-test was used to compare the primary endpoint between groups scoring differently for genetic risk.
Results The mean genetic risk score was 19.0 (95% CI 18.7-19.4) in our T2DM population (n=207). The genetic risk score was negatively associated with achievement of stable SU dose: 84.7% of the patients in the low risk group (n=59) achieved a stable dose vs. 74.1% and 62.3% of the patients in the intermediate risk (n=81) and high risk group (n=62; p=0.004). No significant effect of the genetic risk score on the stable SU dose achieved during this study was found. Carriers of more than 17 T2DM risk alleles showed a marginally significant increased time to stable dose (hazard ratio: 0.81; 95% confidence interval, 0.75-1.01, P=0.058).
Conclusion Patients with an increased genetic risk of T2DM are less responsive to SUs.

No conflict of interest

PHC010

PHC010 CHANGE IN RESPONSE TO CLOPIDOGREL AFTER SWITCHING FROM OMEPRAZOLE TO PANTOPRAZOLE

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Background Clopidogrel is an approved antiplatelet agent used in the treatment of atherothrombotic disease. Proton pump inhibitors (PPIs) are often prescribed in combination with clopidogrel. The use of omeprazole is associated with decreased antiplatelet activity and adverse clinical outcomes of clopidogrel because of cytochrome P450 (CYP) 2C19 interaction.
Purpose We investigated the effect of switching from omeprazole to pantoprazole on the clopidogrel response expressed as the platelet reactivity index (PRI) measured by vasodilator-stimulated phosphoprotein phosphorylation.
Materials and Methods Clopidogrel users (N = 25) switched from omeprazole to pantoprazole and were given pantoprazole 40 mg daily for this prospective, pre-post cohort study. Data collected were age, clopidogrel indication, PRI results, comorbidities, comedication and CYP2C19 genotype (*2, *3 mutations). Primary endpoint was PRI of clopidogrel which was measured on the day before switching and after at least three weeks of pantoprazole use.
Results Clopidogrel users taking pantoprazole had a significantly lower mean PRI than during the omeprazole period (difference PRI 4.6%; 95% confidence interval (CI95) 1.0-8.2%; P = 0.015; figure 1). The mean PRI was also significantly higher in CYP2C19*2 allele carriers compared to the wildtype CYP2C19 group during omeprazole (difference PRI 16.7%; CI95 3.7-29.7%; P = 0.014) and pantoprazole use (difference PRI 17.4%; CI95 2.4-32.5%; P = 0.025).
Conclusions In this study switching from omeprazole to pantoprazole resulted in better clopidogrel response. Patients with variant CYP2C19 alleles had a significantly higher clopidogrel PRI when using omeprazole or pantoprazole compared to wildtype patients. If a PPI is indicated, clopidogrel users should use pantoprazole instead of omeprazole.

No conflict of interest

CPC012

CPC012 DEVELOPMENT AND EVALUATION OF A WARD-BASED CLINICAL PHARMACY SERVICE ON A NEONATAL INTENSIVE CARE UNIT (NICU)

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Background Several international documents highlight the benefits of ward-based clinical pharmacy services. The 2007 NPSA document "Safety in doses – Medication incidents in the NHS" indicates that serious medication errors may be three times more common amongst children than in adults. Therefore a clinical pharmacy service was piloted on the 16-bedded NICU.
Purpose To evaluate the clinical significance of interventions made by a pharmacist on "medicines management" and assess the perceptions of healthcare professionals.
Objectives:
1. Literature review
2. Develop a clinical pharmacy Standard Operating Procedure for NICU.
3. Implement a clinical pharmacy service; evaluate clinical significance and level of risk of interventions.
4. Evaluate the perceptions of healthcare professionals on NICU to new service.
5. Recommend on future clinical pharmacy requirements in NICU.
Materials and Methods The pharmacist attended the NICU to review prescriptions in accordance with a pre-defined SOP over a three month period. Activities were categorised into interventions* and other activities. All interventions were assessed by a clinical pharmacist for both clinical significance and level of risk. A random sample of these interventions was also assessed by a NICU/PICU pharmacist and a consultant neonatologist for validation. An anonymous questionnaire was circulated to healthcare professionals in the NICU to assess their perception of the new service.

* An intervention was defined as any recommendation made by a pharmacist with the intent to change treatment or monitoring.
Results 110 patients were reviewed and 73 interventions made; the incidence rate for interventions was 5.4/100 patient care days and 9.1/100 reviewed prescriptions. Dosing errors accounted for 47.9% of all interventions. Over 69% of the interventions were considered significant and 11.1% very significant. The clinicians' acceptance rate of the interventions was 91.8%. The majority of responders to the questionnaire agreed that the presence of the ward pharmacist improved medication safety and the quality of care.
Conclusions The clinical significance of the interventions made demonstrates the requirement for a permanent specialist clinical pharmacist in the NICU.

No conflict of interest

CPC057 CPC057 SELF-ADMINISTERED HOME PARENTERAL ANTIBIOTIC TREATMENT USING ELASTOMERIC INFUSION PUMPS IN ORTHOPAEDIC PATIENTS

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Background Aarhus Hospital Pharmacy offers portable elastomeric infusion pumps containing dicloxacillin and piperacillin/tazobactam to selected patients. During 2009, we documented stability data for both antibiotics in elastomeric infusions pumps. The expiry date for dicloxacillin 10 mg/ml in normal saline (NS) is 4 days at 2-8 °C, and 7 days at 2-8°C followed by 1 day below 32°C for piperacillin/tazobactam 12 g and 16 g in 270 ml NS.
Purpose Infections in bone and joints are treated with intravenous antibiotics for weeks and they need hospitalisation. In order to maintain the patients' physical and social skills and to minimise the need for hospitalisation, a number of selected orthopaedic patients were offered self administration of their parenteral antibiotics at home.
Materials and Methods All patients were fitted with a central venous catheter (CVC) and the patient or parent was trained to administer intravenous antibiotics during the period of waiting for the organism identification report. The patients were discharged with all equipment needed and written instructions. Due to the expiry date of the antibiotics, the patients returned to the hospital for new pumps.
Results From August 2009 to April 2011 twelve patients with median age of 37 (1-59) years self-administered their intravenous antibiotics, required due to osteomyelitis (n=10) and septic arthritis (n=3). Two patients received piperacillin/tazobactam and the rest dicloxacillin. Totally intravenous antibiotics were administered for 193 days. The period of self-administration was 133 days, thus decreasing hospital stay by 69 %. One patient developed allergic erythema due to dicloxacillin and was hospitalised and received cefuroxime. All other patients fulfilled their treatment without complications. The patients/parents felt secure and were satisfied with the treatment and preferred the treatment offered over hospitalisation.
Conclusions Self-administration of parenteral antibiotics at home for selected patients can reduce hospital stays significantly. The patients/parents preferred the treatment offered to hospitalisation.

No conflict of interest

Presentations on Thursday, March 22nd, 8:30 - 10:00, Amber 1

GRP094 GRP094 PREVENTION OF MEDICATION ERRORS: AN OBSERVATIONAL STUDY

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Background Medication errors represent an important problem of patient safety and have consequences on healthcare services. We used an observational national multicentre study to monitor the medicines use process in wards as a tool to control and to prevent these incidents.
Purpose To improve the medicines use process in our tertiary hospital.
Materials and Methods We first conducted a pre-study to estimate the rate of medication errors in our hospital. In the light of this rate we calculated the number of observations required to obtain a representative sample of the population studied. At the same time, we checked the prescription validation process in the pharmacy as well as the initial process for prescribing medicines.
Then during the months of April- September 2011, we performed a prospective, observational, not-disguised study using the modified Barker-McConnell method. We observed nurses from when they were preparing patient medicines until administration in the patient's room to detect opportunities for error. The study included all the wards open during this period. Each drug administered to a patient was reported as an observation.
Thus, we evaluated the complete medicines use process.
Results We performed 1167 observations in 297 patients (52.2 % were women). The mean age was 72.1 (SD 15.4) (ranges 17-98). 34.1% of patients were over the age of 80. The error rate was 14.8% (173 errors/1167 observations). The distribution of 173 medication errors detected was as follows: 45.1% omission, 19.6% time error, 8.6% wrong method or administration rate, 6.4% drug not prescribed, 5.7% incorrect dosage (less), 5.2% no nurse checking, 2.3% prescription error and 7.1% others. The most frequently omitted group of drugs was analgesics.
Conclusions The observational method used to monitor drug administration by nurses revealed itself as a good system to study the present state of the medicines use process in the hospital. It helped to identify weak points in the process which should be modified and establish strategies for preventing medication errors and improving patient safety.
No conflict of interest

GRP104 GRP104 CLOSING THE GAP Ñ IMPROVING PATIENT SAFETY WITH BETTER DRUG INFORMATION

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Background The problem of poor information transfer exists at the interface between clinical and ambulatory treatment. Patients are not sufficiently informed about their current and future drug treatment.

Purpose To compare knowledge of medicines to be managed at discharge with or without the involvement of a clinical pharmacist.
Materials and Methods The amount and depth of information given to the patients about drug treatment started during hospital with and without the intervention of clinical pharmacists were investigated consecutively in a controlled, comparative study at 5 different hospitals (11 wards).
The satisfaction of patients and their general practitioners (GP) with the different style of discharge management was investigated by means of questionnaires.
Results In phase 1 (no involvement of a clinical pharmacist, 847 patients) approximately 50% of patients were prescribed new drugs which were recommended to be continued after discharge. 12% of these patients were not instructed in hospital or in outpatient settings about their newly-prescribed medicines. Even if they were informed about their medicines, 22% of patients were not, or only partially, satisfied.
In phase 2 (617 patients), all patients were trained in using their newly-prescribed medicines, so the information ratio rose to 100%. Patient satisfaction regarding the quality of education increased to 89%. Each patient got an illustrated patient-specific medicines plan, which was reported to be helpful by more than 80% of patients. GPs confirmed that their patients were better informed (36% improvement) thus reducing their effort (22% less GP effort required).
Conclusions By involving clinical pharmacists, the gap in patients` knowledge about their medicines was reduced. GPs found their patients better informed and appreciated the reduced time and effort.

No conflict of interest

TCH023

TCH023 EVALUATION OF SURFACE CONTAMINATION WITH EIGHT ANTINEOPLASTIC DRUGS IN PREPARATION AND ADMINISTRATION AREAS IN POLISH HOSPITALS

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Background There is a lack of awareness of contamination levels on surfaces in Polish hospitals and pharmacies where antineoplastic drugs are handled. No studies so far have evaluated the surface contamination with these hazardous pharmaceuticals in Poland.
Purpose To evaluate the surface contamination with 8 antineoplastic drugs in 4 Polish hospitals in the pharmacy (pharmaceutical preparation) and on the ward (use).
Materials and Methods Wipe samples were taken from 5 comparable surfaces in the pharmacy (workbench inside biological safety cabinet (BSC), floor in front of BSC, checking counter inside and outside the preparation room, refrigerator door) and 5 similar surfaces on the ward (checking counter at nurses' station, lid of cytotoxic waste container, top of patient armchair, floor under the drip infusion stand, phone). The samples were analysed using LC-MS/MS for surface contamination with cyclophosphamide, docetaxel, etoposide, 5-fluorouracil, gemcitabine, ifosfamide, methotrexate, paclitaxel.
Results 37 of the 40 surfaces sampled were contaminated with at least one substance (92%).The most contaminated surfaces in preparation areas were: workbenches in BSC (total: 8.21 ng/cm^2), floors (5.43 ng/cm^2), checking counters (3.63 ng/cm^2). The administration areas with the highest total contamination were: floors (145 ng/cm^2), top of patient armchairs (10.76 ng/cm^2) and phones (3.71 ng/cm^2). Two pharmacies with the highest number of drug preparations had significantly less cytotoxic drug contamination than the other pharmacies. The most common surface contaminant in all pharmacies was identified as gemcitabine (on 80% surfaces) but the highest concentration was found of ifosfamide. 26 surfaces (17 in 4 wards; 9 in 2 pharmacies) were contaminated with drugs that were not used on the day of sampling. This old contamination shows that the cleaning procedures must be improved as well as the preparation procedures.
Conclusions Measurable amounts of at least one agent were detected on almost all of the sampled surfaces in the preparation and administration areas in all hospitals investigated. The level of surface contamination was significantly higher in wards than in pharmacies.

No conflict of interest

TCH034

TCH034 PROTEOMIC APPROACH TO INVESTIGATING THE MOLECULAR INTEGRITY OF INFLIXIMAB AFTER RECONSTITUTION AND DILUTION IN TYPICAL HOSPITAL CONDITIONS

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Background The active substance of Remicade is infliximab. It is a chimeric human-murine monoclonal antibody directed against tumour necrosis factor alpha (TNF-α), manufactured from a recombinant cell line. Remicade is presented as powder for concentrate for solution for infusion (100 mg/vial), to be reconstituted with water for injections, diluted with saline and thereafter administered via intravenous infusion.
Purpose The purpose of this study was to investigate the suitability of a proteomic approach using MALDI-TOF mass spectrometry to test the molecular integrity of infliximab when reconstituted and diluted in the usual hospital conditions.
Materials and Methods Infliximab was reconstituted in water for injection (10.0 mg/ml) and diluted with NaCl 0.9 % solution (2.0 mg/ml and 0.5 mg/ml). 10 µL of the samples containing the antibody were reduced with DTT and alkylated by iodoacetamide in darkness for 30 minutes and they were digested by trypsin at pH 8.5 for 4 h at 37°C. The digest was loaded onto the MALDI target plate using 5 mg/ml alpha-cyano-4-hydroxycinnamic acid in 0.1% trifluoroacetic acid, 50% acetonitrile as the matrix. Each digest was analysed five times by MALDI-TOF mass spectrometry using a Voyager DE-PRO (Applied Biosystems) in positive reflector mode.
Results The peptide fingerprint map (PFM) of the infliximab was obtained for the reconstituted sample and for the diluted samples right after their preparation. In this way, the molecular integrity of infliximab can be described and characterised.
Conclusions This proteomic approach for the analysis of infliximab is suitable to be used in a long stability study of the antibody reconstituted, diluted and stored refrigerated (4°C) and frozen (-20 °C) since possible changes in the antibody structure could be detected by changes in the corresponding PFM. This study stability is currently being performed by our research group.
No conflict of interest

PHC023 PHC023 ARE THE OFFICIAL RECOMMENDATIONS FOR AMIKACINE SERUM LEVELS SUITABLE FOR ELDERLY PATIENTS?

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Background The aminoglycosides represent the mainstay in the treatment of serious Gram-negative infections. Their use is difficult in elderly patients because of high potential toxicity and the large observed inter-individual variability. In recent years, higher peak serum concentrations have been suggested in official recommendations for amikacin treatment (peak level: 60 to 80 µg/ml, trough level: < 2.5 µg/ml). The applicability of these target concentrations is questionable in geriatric patients.

Purpose Our objective was to check the applicability of those target levels in elderly patients.

Materials and Methods A retrospective study was undertaken with the medical files of all patients who were treated with amikacin during the last 3 years. Anthropometric data (age, weight, creatininemia) and history of amikacin administrations and serum levels were used to estimate individual pharmacokinetic parameters with a Bayesian software program (USC*Pack). The dosage regimen needed to reach a peak level of 60 µg/ml and a trough of 2.5 µg/ml was calculated. When a dose interval of more than 48 h was needed, a complementary calculation was done to estimate trough concentration after a week of treatment with infusions every two days.

Results Twenty-eight patients were considered, with a male/female ratio of 13/15, age 83±8 years, weight 64.2±3.7 kg and estimated creatinine clearance 55±21 ml/min. Mean estimated pharmacokinetic parameters were respectively: volume of distribution of 0.31±0.11 L/kg and amikacin clearance of 45.2±36.1 ml/min. Ideal dose interval was above 48 hours for 12 patients (43%) with a mean dose interval of 62.5 hours. For these patients, trough serum concentration level after a week of treatment, with infusions every two days, was 7.72±5.88 µg/ml.

Conclusions This study shows that for more than 40% of elderly patients, the target peak cannot be reached without potentially toxic trough levels even after 48 h, or without expanding the dose interval above. Such a wide dose interval can risk inefficacy for serious infections.

For a large number of elderly patients, actual amikacin target serum concentrations should be used with caution to avoid potential toxicity.

No conflict of interest

OHP031 OHP031 DESIGNING AND IMPLEMENTING A STANDARD NUTRITIONAL STARTER SOLUTION FOR PRETERM INFANTS

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Background Administering parenteral nutrition to preterm infants in their first hours of life improves their survival. As it is not always possible for the pharmacy department to compound individual parenteral nutrition solutions, preparing a standard starter solution for preterm children to be administered within the first 24 hours after birth was arranged with the Neonatology Department.

Purpose To design and implement a standard starter solution of suitable composition and stability for preterm infants, as a means of meeting their nutritional requirements during their first hours of life.

Materials and Methods We performed a literature search to determine the nutritional requirements for neonates. In order to ensure a positive nitrogen balance and to avoid protein catabolism, adequate inputs of amino acids and glucose should be administered within the first hours of life in order to provide at least 4 g/kg/day of glucose and 1 g/kg/day of amino acids.

Results A standard nutritional starter solution was prepared in syringes. Each syringe contained 52.5 ml of solution (+3.5 ml of purge) comprising 1.5 g of amino acids (15 ml Primene 10%) and 3.75 g of glucose (37.5 ml of 10% glucose), with an osmolarity of 629 mOsm/l (allowing either peripheral or central IV administration) and a total calorie input of 21 kcal per syringe (15 kcal were non-protein). The stability of the solution was 7 days at 2-8°C, as recommended in the literature. From February 2010 (implementation) until August 2011, 840 starting syringes were prepared in the pharmacy department.

Conclusions This formulation makes it possible to meet the glucose and amino acid requirements for preterm neonates within their first 24 hours of life, thus preventing excessive protein loss. Its long-term stability makes it possible to store it in the Neonatology Department, thus guaranteeing its availability at times when it is not possible to prepare a parenteral solution in the pharmacy department.

No conflict of interest

General and Risk Management, Patient Safety (including: medication errors, quality control)

GRP001 SEVEN-YEAR EXPERIENCE USING AUTOMATED CABINETS WITHIN AN ONCO-HAEMATOLOGY DEPARTMENT

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Background Managing of hospital supplies, within a complex trust such as ASL Salerno 1, requires an enormous expenditure of human and economic resources. The absence of a computerised system for checking and managing the logistic flows may generate waste and increase the risk of items obsolescence.

Purpose To use the latest logistic management technologies for the rationalisation of costs through logistic processes optimisation.

Materials and method In 2004, 27 automated cabinets were installed within the wards and operating rooms of five hospitals. The onco-haematology ward was the reference department due to the high volumes of high cost drugs. To evaluate the economical and organisational benefits achieved after 7 years of use, the authors used reports from a central server placed in the hospital pharmacy and connected to the automated cabinets.

Results Economical reports have outlined a reduction of 30–40% of economic stock value for a sample group of drugs, steadily used within the onco-haematology department. Management reports allowed a reduction of stock within the ward, through the evaluation of items turnover rates and the consequent redefinition of the minimum stock value.

Conclusions The implementation of new technologies allows the real optimisation of resources through a punctual check of main hospital logistic activities. The cooperation of health personnel facilitates the achievement of excellent results. In 2001 the onco-haematology ward required the installation of another automated cabinet to extend the benefits so far achieved to medical device management.

GRP002 MEDICATION ERRORS ASSOCIATED WITH RECONCILIATION IN A HOSPITAL WITH COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEM WITH ACCESS TO PRIMARY CARE TREATMENT

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10.1136/ejhpharm-2012-000074.2

Background A recently introduced computerised physician order entry system (CPOES) in hospital and a primary care electronic record system help prescribing and provide information about patients' medicines. These tools should improve the reconciliation process and diminish potential errors associated with chronic medication.

Purpose The aim of this study is to describe and analyse the discrepancies between chronic medication recorded on the electronic health record system and the prescription of this medication upon admission to hospital.

Materials and methods From March through May 2011, information was collected about patients admitted older than 60 years with chronically-prescribed medication and an updated preadmission treatment file. The pharmacist compared the computerised prescriptions with the current chronic medication listed by the prescription program (e-Osabide). Chronic medication data were verified with the patient primary care electronic record system (GlobalClinic). If discrepancies were found the admission reports were checked to decide if they were justified. Unjustified discrepancies were reported and classified as reconciliation errors.

Results Chronic treatment of 88 patients was analysed (average age: 73.3 years. 48 women, 40 men). 33 patients were admitted as emergencies (E), 26 to surgical wards (S) and 29 to medical wards (NS). The average number of chronically-prescribed medicines per patient prescribed at admission were 7.3 and 5.4, respectively. 32 unjustified discrepancies were found (26.1% of patients, 0.36 per patient). Classified by route of admission: E, 24.2% of patients (0.42/patient); S, 30.8% (0.38); NS, 24.1% (0.28). By reconciliation errors: dose/frequency incorrect (21), omission (6), added medicine (5). The acceptance of interventions made was 56.3% (18/32).

Conclusions The integration of CPOES and the electronic healthcare record system makes the reconciliation process easier and reduces prescription errors. With recently introduced CPOES incomplete prescriptions are no longer a problem. However, preventable prescription errors associated with reconciliation occur due to not using the tools now available.

Competing interests None.

GRP003 SHOULD PERISTOMAL INFECTION AFTER PERCUTANEOUS ENDOSCOPIC GASTROSTOMY BE CONSIDERED A HEALTHCARE-ASSOCIATED INFECTION? ROLE OF ANTIBIOTIC PROPHYLAXIS

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10.1136/ejhpharm-2012-000074.3

Background Percutaneous endoscopic gastrostomy is a widely used method for inserting a gastrostomy tube in patients who are unable to eat but have a normally functioning gut. Peristomal wound infection is the most common complication. Risk factors for local infection are largely unknown. Evidence suggests that antibiotic prophylaxis and preventive strategies related to infection control may reduce infection rates.

Purpose To evaluate the incidence of peristomal infection and to discover the potential patient risk factors following PEG tube placement.

Materials and methods An observational analytic prospective study was carried out at Garcia de Orta hospital between October 2010 and May 2011 and 31 patients were included. A minor adaptation of the Centres for Disease Control (CDC) definitions for superficial surgical site infection was used to detect PEG site infections. Medical records were reviewed for demographic data, use of prophylactic antibiotics, complications and comorbid conditions. Statistical analysis SPSS 17.

Results Peristomal infections were identified in 15/31 (48.38%). A global incidence rate (30 days) of 16.12 per 1000 days and an incidence density of 9.44 were found. Wound isolates included *Pseudomonas aeruginosa* (39.1%) and *Staphylococcus aureus* (61%) of which 50% were methicillin-resistant (MRSA). Of the patients who had received antibiotic prophylaxis (51.8%), 55.5% developed PEG-site infections. Diabetes mellitus and obesity were significantly associated with peristomal infections ($p<0.05$).

Conclusions Patients with diabetes mellitus and a BMI>30 kg/m^2 had a higher risk of peristomal wound infections after percutaneous endoscopic gastrostomy. High incidence of MRSA (30.4%) illustrates the need to review the antibiotic prophylaxis protocol but the efforts to reduce MRSA occurrence with infection control measures and an epidemiological surveillance program should remain a priority.

Competing interests None.

GRP004 IMPACT OF A PROGRAM TO PROMOTE SEQUENTIAL THERAPY WITH PARACETAMOL AND OMEPRAZOLE

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Background Oral route is safer and less costly than intravenous route; however, sometimes intravenous therapy is used longer than necessary. Paracetamol and omeprazole are two widely used drugs in hospitalised patients whose oral presentation have a biodisponibility similar to intravenous presentation; therefore, both are good options for sequential therapy.
Purpose To implement and to analyse a program to promote sequential therapy with paracetamol and omeprazole in a general public hospital with 120 beds.
Materials and methods Prospective study in hospitalised patients for 2 months (July–August 2011). The program consisted on a daily checking of intravenous paracetamol and intravenous omeprazole prescriptions by a pharmacist. If the patient could tolerate oral diet, a proposal to change to oral presentation was made. The recommendation is transmitted to prescribers by the electronic prescription program. Interventions were registered in a database and classified as accepted: change to oral presentation and rejected: no change after 5 days. Demographic characteristics were collected. Economic impact was assessed, analysing costs reduction with regard to cost drugs.
Results 76 interventions were recorded (86.8% paracetamol, 13.2% omeprazole). 73 patients (53.9% men) were included; mean age 77.5 years. Mainly, patients were admitted to internal medicine (67.1%). 39.5% (paracetamol: 30.3%, omeprazole: 50.0%) of recommendations were accepted; 15.8% (paracetamol: 15.2%, omeprazole: 20.0%) of patients were discharged or medication was removed the same day; 44.7% (paracetamol: 45.5%, omeprazole: 30%) of recommendations were rejected due to patients' oral tolerability worsened. Mean response time was 0.9 days. Cost savings were 342 (paracetamol: 327, omeprazole: 15) euros.
Conclusions 39.5% of recommendations resulted in change in patients' pharmacotherapy. Pharmaceutical validation improves efficiency of pharmacotherapy. Cost savings is not very high since the cost of these drugs is low. Similar programs could be implemented in some antibiotics to achieve greater savings.

Competing interests None.

GRP005 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS CARRIED OUT VIA ELECTRONIC PRESCRIPTIONS†

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Background Hospital pharmacists play an important role in pharmacotherapy. Pharmaceutical care contributes to securing efficacy and safety in the use of medicines. Validation of the prescriptions allows pharmacists to detect, prevent and solve medicines-related problems.
Purpose To collect and assess the clinical interventions made by a pharmacist in a general public hospital with 120 beds.
Materials and methods Prospective, observational study of hospitalised patients for 2 months. Every day (from July to August 2011) a pharmacist checked the prescriptions electronically. Prescribers were informed of drug-related problems by the electronic prescribing program. Variables collected were: prescriptions written, reason for intervention, the drug involved, acceptance of the intervention by the physicians and response time.
Results 140 interventions were recorded. Patients were mainly admitted to internal medicine (57.9%). Common reasons for interventions were: sequential therapy (55.7%), dose adjustment for renal failure (27.9%), inappropriate dosage (5.0%), missing information or clarification (5.0%), drug duplication (2.1%), excessively long treatment (2.1%) and inappropriate route of administration (2.1%). 38.6% of interventions resulted in a change to patients' pharmacotherapy. Mean response time was 1.1 (SD: 0.9) days. In the majority of non-accepted interventions, the patient's oral tolerability worsened or his/her renal function improved, so no change was required. Drugs most involved were paracetamol: 47.1% (especially in 'sequential therapy') and antibiotics: 15.0% (especially in 'dose adjustment for renal failure'). Potential toxicity was avoided by reducing doses of drugs in 17 patients.
Conclusions The most common intervention was to promote the oral route. This route is safer and less costly than the intravenous route. Patients with renal failure deserved special attention in pharmaceutical validation to avoid toxicity, as the doses of several drugs needed to be adjusted, especially when an antibiotic was prescribed. The drug charts review identified real and potential medication errors.

Competing interests None.

GRP006 ANALYSIS OF AWARENESS ON ADVERSE EVENT REPORTING AMONG PHYSICIANS AND NURSES AND CONTRIBUTION OF PHARMACOVIGILANCE TRAINING

A. Ozyildirim

10.1136/ejhpharm-2012-000074.6

Background Pharmacovigilance, derived from the Greek word; 'pharmakon', a drug or medicine, and from the Latin 'vigilans' watchful or careful, is defined as 'all methods of assessment and prevention of adverse drug reactions' (Mann and Andrews, 2002). WHO defines it as the science and activities relating to the detection, evaluation, understanding and prevention of adverse drug reactions or any other drug-related problems.
Purpose The aims of this research are to assess the awareness of Turkish physicians and nurses of pharmacovigilance and to study the impact of a seminar on their perception and attitude towards pharmacovigilance and adverse drug reactions reporting.
Materials and methods The study was conducted in the Vehbi Koç Foundation American Hospital. The participants (15 physicians and 15 nurses) were asked to answer two questionnaires before and after they attended an educational seminar, which aimed to provide the participants with the theoretical aspects and necessary knowledge about pharmacovigilance. The responses of the participants were subjected to frequency analysis, and the existence of any difference between groups of participants based on profession and age, was investigated using non-parametric tests.
Results Only 53.3% of the physicians and 60% of the nurses knew the correct definition of adverse drug reaction. All of the physicians and 60% of the nurses claimed that they had

experienced an adverse drug reaction in their patients. 46.6% of the physicians and 40% of the nurses stated that they had never reported an adverse drug reaction. All in all, only 36.3% of the respondents knew the correct definition of the adverse drug reactions, had experienced an adverse drug reactions and cared to report to a correct authority. Non-parametric tests demonstrate that the nurses and physicians differ significantly in their responses when they were asked whether they had experienced an adverse drug reactions in their patients.

Conclusions The results show that the practitioners are not aware of the importance of pharmacovigilance and do not know the correct definition of adverse drug reaction. The results of the second questionnaire demonstrate that an educational seminar would be very helpful to improve awareness and to increase adverse drug reactions reporting. Nevertheless, elimination of ignorance on pharmacovigilance would not be sufficient if the attitude problem towards pharmacovigilance remains unsolved.

Competing interests None.

GRP007 THE EFFECT ON OUTPATIENT PRESCRIPTIONS OF RIVAROXABAN AFTER ITS INCLUSION IN OUR HOSPITAL FORMULARY

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Background Adding new drugs to the hospital formulary affects outpatient prescribing greatly in secondary care. Ambulatory rivaroxaban was included in the hospital formulary in November 2010 for approved indications only.

Purpose To assess the effect on the prescription of ambulatory rivaroxaban for restricted use for approved indications: prevention of venous thromboembolism in patients adults undergoing elective hip or knee replacement.

Materials and methods Analysis of prescription data by prescription, supplied by the Pharmaceutical Inspection of the Health Management Area, during the 5 months prior to the inclusion of the drug in the formulary (June to October 2010) and the subsequent 5 months (November 2010 to March 2011). The following data were collected: number of patients treated with rivaroxaban, number of prescriptions dispensed per patient, number of defined daily doses (DDD) per patient, duration of treatment and prescribing physician's specialty.

Results During the 5 months prior to the inclusion of the drug in the formulary, five patients received a total of eight prescriptions for rivaroxaban in pharmacies, whereas after 5 months, 32 patients collected the prescribed drug a total of 48 times. The authors note that both the number of prescriptions and patients increased by 600% after the inclusion of rivaroxaban in the formulary. The prescribing physician was a specialist in traumatology in 31 of the 37 cases (84%). The remaining six (16%) were prescribed by a specialist in urology; with these patients the drug could have been used in conditions other than those approved. It was further found that seven patients (19%) were dispensed a total number of DDD that exceeded the time required for the recommended treatment by clinical indications.

Conclusions Inclusion of rivaroxaban in the formulary had a clear impact on outpatient prescription in our health area, with specialist drugs significantly affecting prescriptions in secondary care. It is important to assess the fundamental impact that might result from prescriptions for it, before including a new drug in the formulary. Once included, extra monitoring is important to minimise discrepancies between the approved indication and the way the drug is prescribed.

Competing interests None.

GRP008 A STUDY OF THE IATROGENIC EFFECTS OF DRUGS ON OLDER PEOPLE

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10.1136/ejhpharm-2012-000074.8

Background Adverse effects caused by pharmacotherapy are a problem that particularly affects the older.

Purpose To help prevent iatrogenic problems, the authors wanted to measure and describe them in a particularly vulnerable population, recently hospitalised patients aged over 70.

Materials and methods A retrospective analysis was performed of 100 new patients aged 70 and older, hospitalised in internal medicine between 1 April 2011 and 30 June 2011. Only side effects commented upon in the patient record that justified stopping or changing the dose of the drug were selected.

Results Of the 100 patients, there were 70 women and 30 men. The average age was 85 years. 30 patients (30%) experienced an adverse effect. These were 25 women and 5 men, average age 83.5. Of these 30 patients, 25 patients (83%) required the drug involved before admission while for 11 patients (37%) the reason for hospitalisation was related to the iatrogenic effect. For five patients (17%) the drug was prescribed during hospitalisation. When the iatrogenic problem was related to the reason for hospitalisation, drugs involved were psychotropic drugs, diuretics, antihypertensives and antiplatelet agents, anticoagulants, NSAIDs and oral hypoglycaemic agents. When the iatrogenic problem was related to a drug prescribed during hospitalisation, drugs involved were neuroleptics, cortisone and diuretics.

Conclusions The adverse effects of drugs in the older are an important factor of morbidity and often underestimated. 11% of hospitalisations are related to iatrogenic effects. Efforts to prevent iatrogenic problems should reflect the risk/benefit ratio. The introduction of drugs known to cause problems requires close monitoring; adverse effects require early and rapid reporting and more frequent dialogue between hospital doctors and other health professionals prior to the discharge of the patient. The pharmacist's role in the validation of requirements remains central.

Competing interests None.

GRP009 COMPARISON OF THE PHARMACY WORKLOAD MORNING AND AFTERNOON

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10.1136/ejhpharm-2012-000074.9

Background Most of the pharmacist's work is performed in the morning shift, but little is known about the volume and nature of the work done during the afternoon shift.

Purpose The aim is to quantify, analyse and compare the pharmacist's work pattern during the afternoon shift with that of the morning shift.

Materials and methods Retrospective study at a tertiary university hospital from January 2010 to March 2011. During the morning, 10 pharmacists and six residents review and approve

medical orders (MOs) of inpatient treatments. In the afternoon this activity is undertaken by one pharmacist and one resident. A search for starts and changes on drug treatments (SAC) (electronic prescribing and transcription of MOs), approved MOs (AMOs), pharmacist's interventions (PIs) and medication errors (MEs) was performed electronically. Then, results recorded between 8:00 a.m and 2:59 p.m were compared with those between 3:00 p.m and 8:59 p.m using descriptive statistics.

Results Total SACs: 822 440 (29.5% in the afternoon) and total AMOs: 551 011 (26.3% in the afternoon), with a mean of 2.4 (SD 0.15) more SACs and a mean of 2.8 (SD 0.22) more MOs approved per month during the morning.

Conclusions During the period studied, nearly one third of the total work done was during the afternoon shift, while the staff was reduced to approximately 10%. Notification of MEs accounted for nearly half of the total. Type of PIs and MEs were similar between the two shifts.

Competing interests None.

GRP009 Table 1 Distribution of PIs and MEs. A median of 2.4 (range 1.4 to 8.3) more PIs and a median of 1.4 (range 0.5 to 2.6) more MEs per month were recorded during the morning shift

Number and types of pharmacist interventions and medication errors

	Morning	Afternoon
Pharmacist interventions (n;%)	5018 (69)	2303 (31)
Inadequate software use	925 (18.4)	695 (30.2)
Scheduled time change	766 (15.3)	326 (14 2)
Dosage form change	603 (12)	286 (12.4)
Stop treatment	568 (11.3)	259 (11.2)
Dose change	554 (11)	323 (14)
Start treatment	412 (8.2)	116 (5)
Route change	330 (6.6)	56 (2.4)
Medication change	327 (6.5)	86 (3.7)
Frequency change	231 (4.6)	81 (3.5)
Others	302 (6)	75 (3.3)
Medication errors (n;%)	640 (56)	493 (44)
Wrong dose	166 (25.9)	139 (28.2)
Wrong/contraindicated/not indicated drug	89 (13.9)	75 (15.2)
Wrong frequency	72 (11.3)	42 (8.5)
Dose or drug omission	65 (10.2)	29 (5.9)
Duplication of treatment	62 (9.7)	56 (11.4)
Administration error (speed, route, time/day)	29 (4.5)	42 (8.5)
Preparation, handling or packaging	27 (4.2)	19 (3.9)
Inadequate dosage form	22 (3.4)	30 (6.1)
Wrong patient	20 (3.1)	19 (3.9)
Others	88 (13.8)	41 (8.4)

GRP010 MANAGEMENT OF CLINICAL TRIALS BY THE HOSPITAL PHARMACY DEPARTMENT

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Background The management of errors by the hospital pharmacy department is a critical aspect for the conduct of clinical trials (CT).

Purpose To evaluate early identification and resolution of CT problems in order to improve our working procedures within a quality system.

Materials and methods Data about the identification and resolution of CT errors detected were recorded using the following items: date, person reporting, identification of the CT, department conducting the CT, process (protocol, reception, storage, prescription, validation, preparation, dispensing, administration, return, record keeping), professional involved, description of the problem and corrective measures. The findings recorded during 2009–2010 were reviewed.

Results 123 events were recorded in a total of 174 CTs conducted. The most frequent events were mainly related to the prescribing (50%), dispensing (19%), and reception (7%) phases. 1.8% of the prescriptions presented some finding (72/3928). The most common causes were: no specification that the patient was included in a CT (54%), incomplete prescription (22%) and non-adherence to the study protocol (21%). In these cases there was an immediate intervention with a communication to the investigator. In relation to dispensing the most frequent mistakes were the number of units dispensed (30%) and the omission of information to patients (26%). Other mistakes included dispensing commercial medicines instead of research samples (13%) and non-compliance with administrative requirements (13%). When receiving CT materials, discrepancies between the delivery note and the goods really delivered (33%) and delivery problems (33%), were the most common errors.

Conclusions The opportunities for improvement identified were to expand electronic prescribing, to implement and uphold standard operating procedures (SOPs) for conducting the CTs and to report all discrepancies noted to the staff involved (monitor, sponsor, carrier). The purpose of a process for identifying corrective and preventive actions is to ensure that discrepancies and non-compliance are visible and the causes are determined and resolved, improving the efficiency of the process.

Competing interests None.

GRP011 CRITERIA FOR HIGH-PERFORMANCE MEDICINES' MANAGEMENT IN HOSPITALS†

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10.1136/ejhpharm-2012-000074.11

Background Chronic kidney disease (CKD) is currently an important complication of HIV infection once HAART treatment has been introduced.

Purpose The aim of this study was to investigate the prevalence of CKD and patient characteristics in HIV-infected patients.

Materials and methods This was a retrospective cross-sectional study. In May 2011, using a cross-sectional method, the authors selected all HIV patients receiving antiretroviral treatment at a tertiary university hospital in Spain. The medical charts were reviewed from the moment the HAART treatment was started. Exclusion criteria included those who did not follow the treatment throughout the study period and those who were on treatment less than 6 months. The following demographic, clinical and laboratory parameters were abstracted from the clinical database: age, nadir CD4 T cell count, viral load, estimated glomerular filtration rates (GFR), hepatitis B and C co-infection, medicines, hypertension, diabetes mellitus and other co-morbidities. GFR was ascertained according to the Modification of Diet in Renal Disease (MDRD-4) criteria. CKD was defined as GFR <60 ml/min for at least 3 months.

Results During the study period 149 patients needed antiretroviral treatment at the HIV consulting service. CKD prevalence

was 7.38% (11 patients). The patients' characteristics were: CKD (n=11) No CKD (n=133) p-value age (mean (SD)) 45 (9.1) 44.9(8.0) 0.92 male gender (n(%)) 8 (72.7) 99 (74.4) 0.81 homosexual 1 (9) 33 (24.8) IDU 8 (72.7) 58 (43.6) 0.06 heterosexual 2 (18.2) 43 (32.3) HCV infection (n(%)) 8 (72.7) 51 (38.3) 0.04 HCV-HBV co-infection (n(%)) 1 (9) 3 (2.2) Nadir CD T cells (median) 358.70 355.25 undetectable viral load (n(%)) 11(100) 118 (88.7) 0.35 tenofovir (TFV) exposure 6 (54.5) 83 (63.4) 0.78 lamivudine exposure 5 (45.4) 15 (11.2) <0.005 Hypertension 3 (27.3) 15 (11.3) 0.31 diabetes 1 (9) 3 (2.2).

Conclusions The prevalence of CKD among HIV-infected patients was higher than expected and reported by other authors. The only factors analysed that appeared to affect the presence of CKD were co-infection with HCV and exposure to lamivudine. Consequently, patients in treatment with lamivudine must be monitored and dose adjustments made. In our study, the exposure to TFV seems not to affect the prevalence. In spite of that it should be used cautiously because of its known nephrotoxicity.

Competing interests None.

GRP012 INTRODUCING COLOUR CODES TO DRUG LABELLING TO INCREASE PATIENT SAFETY

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10.1136/ejhpharm-2012-000074.12

Background Administering the wrong drugs is one of the most common medication errors in Denmark. A system for reporting adverse events has revealed that use of unsuitable or differing drug labels leads to medication errors in Anaesthetics and ICU wards at the Danish North Region Hospital.

Purpose To develop a colour-coded drug labelling system to improve patient safety in Anaesthetic and ICU wards at the Danish North Region Hospital.

Materials and methods A literature study was conducted to identify recommendations regarding colours and designs of drug labels. The search terms drug labelling, user-applied drug labels and syringe labelling were used. Legal requirements and international standards for user-applied anaesthetics labels were ascertained. Qualitative input from clinicians was collected from the anaesthetic and ICU wards by e-mail.

Results New standardised drug labels complying with national legal requirements were designed.

The labelling design addresses a number of elements contributing to medication errors:

- Trade name and strength have a prominent placement and are emphasised in bold.
- Drugs with similar names are differentiated using 'tall man letters' for example epinephrine and norepinephrine.
- Size of drug label is adjusted to different sizes of syringes.
- Colour code reflects the effect of the drug for example blue signal opioids while yellow indicate induction agents.

Further procedures have been established for assessing compatibility in practice, and for updating the labels as trade names change due to adjustments in drug supply.

Conclusions The labels were successfully designed and brought into use. Whether the patient safety has actually improved will be evaluated by assessing the number of reports of adverse events involving drug labelling.

Competing interests None.

GRP013 INVESTIGATION INTO RAPID (ALTERNATIVE) MICROBIAL DETECTION METHODS TO IMPROVE THE QUALITY ASSURANCE OF NHS MANUFACTURED ASEPTIC PRODUCTS

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10.1136/ejhpharm-2012-000074.13

Background Real-time QA is a challenge for short-expiry, high-risk aseptic products and is often retrospective. There are documented examples of quality failure with aseptic manufacture. Rapid microbiological methods (RMMs) have been used in the pharmaceutical and food industry for many years and early pilot work from our group with aseptic national health service (NHS) products has been encouraging.

Purpose To evaluate three commercial RMM technologies for their ability to improve the traditional QA processes associated with NHS aseptic manufactured products.

Materials and methods The three commercial RMM systems evaluated were BacT/ALERT (bioMerieux), AkuScreen (Celsis) and BactiFlow ALS (AES Chemunex). A deliberate contamination study was carried out in which 50 µl of four microbes was inoculated into four aseptic products (heparin 100 u/ml; parenteral nutrition (PN) 7.5%; vancomycin inj. 10 mg/2 ml and methotrexate inj. 15 mg/0.6 ml) and left for 10 min (final concentration 10–100 CFU/ml). Total aerobic microbial counts (TAMC) were compared with RMM results. All work was carried out in a Grade A environment.

Results The recovery rates are presented below as percentage concordance together with time to detection.

All three RMM systems were able to provide 100% concordance when used to detect contamination in PN and heparin within their recommended time frames. All rapid methods had problems recovering Gram +ve organisms from vancomycin and methotrexate, although recovery of other organisms from these products was equivalent. The BacT/ALERT system was technically the easiest to use and had the highest concordance when results were read after 3 days.

Conclusions The authors believe this data describes a true reflection of the alternative rapid detection methods and demonstrates that RMM can improve QA of selected NHS manufactured aseptic products.

Competing interests None.

GRP013 Table 1

	Traditional	BactiFlow ALS	AKu Screen	BacT/ ALERT
Time to detection	7–14 Days	24 h	18 h	3 Days
Concordance: TAMC versus RMM	100%	78%	79%	88%

GRP014 INVESTIGATION INTO THE USE OF RAPID (ALTERNATIVE) MICROBIAL DETECTION METHODS TO DETERMINE BIOBURDEN OF NHS PHARMACY-MANUFACTURED NON-STERILE MEDICINES†

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Background Rapid microbiological methods (RMMs) have been shown to improve aseptic NHS QA activities. This study

GRP014 Table 1 Equivalence evaluation data for RMM and TAMC

Dilution	% Positive		% Difference	95% CI
	Alt. method (RMM)	Ref. method (TAMC)		
1 in 50	90	82.5		
1 in 100	70	45	25	10.9 to 39.9
1 in 1000	12.5	2.5		

investigates the potential to use these new rapid qualitative technologies for quantitative bioburden testing. The principle of dilution to extinction, extrapolation and an inference on original sample bioburden will be investigated. Non-sterile medicines manufactured within NHS pharmacy are required to meet regulatory standards for microbial bioburden of ≤100 cfu/ml, currently measured by reference microbial methods (eg, total aerobic microbial counts (TAMC) after 5 days incubation at 30°C). RMM can give results within 24 h. Initial studies will be required to determine equivalence or non-inferiority between the reference and alternative methods.

Purpose To investigate the potential to use RMM (BacT/ALERT (bioMerieux)) to determine the bioburden of non-sterile products.

Materials and methods A non-sterile oral product, tranexamic acid 5% w/v mouthwash, was inoculated to 100 cfu/ml with *Staphylococcus aureus* (n=8). Serial dilutions of 1 in 10 to 1 in 1000 were then prepared (n=10) and split sampling methods used to test TAMC and RMM simultaneously. Equivalence of the alternative method was initially assessed using EN ISO 16140:2003 and subsequently with non-inferiority statistics.

Results Equivalence evaluation data for RMM and TAMC is presented below.

Data analysed using ISO 16140 indicates that the 1 in 100 dilution is used for analysis and then concludes that the two methods are not equivalent. However further analysis with non-inferiority statistics and investigation of 95% CI demonstrates that BacT/ALERT is superior to TAMC (p=0.003, McNemar test).

Conclusions The authors propose that BacT/ALERT can be used as a presence/absence test to determine the dilution to extinction point of a contaminant and thus infer an original sample bioburden.

Competing interests None.

GRP015 TO INVESTIGATE HOW DISRUPTIVE INTERRUPTIONS ARE ON PAEDIATRIC DISPENSARY ACCURACY CHECKERS

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10.1136/ejhpharm-2012-000074.15

Background It is well documented that interruptions adversely affect task performance. What is less well known is the impact of interruptions in the context of the paediatric dispensary accuracy checking process.

Purpose To measure the effect that interruptions have on dispensary accuracy checkers.

Materials and methods The study instrument was non-participant, direct observation of a discrete, clearly identifiable step within the dispensing process (the accuracy-checking phase of the dispensing process). A prescription requiring two bottles of medicines to be dispensed was created. The medicines were labelled and placed in a tray together with the required paperwork, additional spoons or oral syringes and a dispensing bag. The operatives, both pharmacists and pharmacy technicians, volunteered to participate and were told that they would be timed accuracy checking a prescription and that the object of the observations was to measure the effect of the environment on their work only and that they themselves were not being assessed. They were also advised that the prescriptions were non-complex, had been clinically screened, and did not contain any errors by design. Each observation (n=34) consisted of two arms as determined by a Latin square. The observations were undertaken in the dispensary and in an office; the latter ensured a quiet environment. In addition a designed interruption was introduced into some of the variants.

Results A statistical analysis of variables was carried out using Minitab. A calculation of least squared means for time showed that individuals were 28.41% less efficient when interrupted in the dispensary. The mean time taken to accuracy check the standard prescription increased from 121.20 s to 155.63.

Conclusions It was found that interruptions adversely affected dispensary accuracy checkers who were checking a standardised prescription of two items in the dispensary at BCH. Dispensary design should support the reduction of interruptions in critical areas.

Competing interests None.

GRP016 PHARMACOVIGILANCE IN A PUBLIC TERTIARY HOSPITAL IN BRAZIL

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10.1136/ejhpharm-2012-000074.16

Background Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Purpose The aim of this study is quantify and assess the suspected adverse drug reactions (ADRs) that occurred and related technical defects (TDs) with four types of drugs available in Brazil.

Materials and methods This descriptive, prospective and exploratory study was conducted January to December 2010 in a Public Tertiary Hospital (359 beds). Data involving adverse drug reactions and technical defects were collected in the Pharmacovigilance section of the hospital (ADR and TD notification form, internationally known as the 'yellow card'). The information was acquired through multidisciplinary spontaneous (voluntary) reporting. The reactions were classified according to the mechanism of action, severity and causality (using the Naranjo algorithm). The drugs were classified according to their therapeutic class and the symptoms according to the organ involved. The technical defects were classified according to the type of quality deviation and the type of medicines available in the Brazilian market (branded, generic, 'similar' (Brazilian Class Drugs) and compounded drugs).

Results A total of 70 forms were examined. Adverse drug reactions accounted for 38.6% of yellow card reports, technical defects for 58.6% and two reports contained both (2.8%). The skin was the organ most affected (28.0%) and the therapeutic

class mostly associated with ADRs was general anti-infectives for systemic use (40.7%). The largest category of patients to suffer from ADRs were the over 60s (29.7%), there was no important difference between the sexes (51.5% male). The most common adverse reactions were type B (74.0%), moderates (37.0%) and probables (55.6%). Generic drugs showed more technical defects (36.4%) the more common of which were breaks/cracks/leaks (20.9%) and lack of product inside drug packaging/ volume less than that reported in the label (20.9%).
Conclusions Every drug has a risk and besides detecting adverse events, it is essential to prevent them, mainly through monitoring by clinical/hospital pharmacists, and also for the drug control authority to ensure the quality.

Competing interests None.

GRP017 IMPACT OF A MULTIDISCIPLINARY INTERVENTION PROGRAM ON QUALITY AND SAFETY OF PARENTERAL NUTRITION

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10.1136/ejhpharm-2012-000074.17

Background Parenteral nutrition is a live-saving therapy but it is associated with complications.
Purpose Describe the results of a monitoring and intervention program (MIP) in patients with total parenteral nutrition (TPN).
Materials and methods Patients with TPN were selected between May and June, the year before and after MIP implementation. MIP was carried out by a nutritionist, a pharmacist and a hospital pharmacy resident. MIP involved the patient nutritional evaluation (nutritional history, anthropometry and biochemical markers), daily monitoring of vital signs and glycaemia, complete analytical control (weekly, at the beginning and at the end of TPN; including GOT-GPT, GGT, alkaline phosphatase, triglyceride, albumin, prealbumin and electrolytes), management of TPN complications and elaboration of a nutritional report in the patient clinical history.
Results The authors obtained patients before MIP (group 1, n=24) and after MIP (group 2, n=38). Thanks to MIP, quality of TPN was notably increased (table 1). Group 2 had a more appropriate monitoring (analytical control, nutritional evaluation, vital signs monitoring, reports in clinical history), individualised calculation of requirements and less TPN<7 days compared to group 1. After MIP, albumin and prealbumin increased in 66% and 88% of patients, respectively. No patient reached triglyceride >400 mg/dl. 34% of patients showed glycaemia >140 mg/dl (100% were solved adding insulin to TPN). 26% of patients showed hepatic dysfunction due to TPN (50% were solved using cyclic TPN and taurine). Thiamine was added in patients at risk of refeeding syndrome (34%). No refeeding syndrome was reported. None of these results could be calculated in group 1, as this group did not have any kind of monitoring.
Conclusions The implementation of MIP improves the quality, safety and efficacy of TPN. The use of appropriate indicators has led to quantify the benefit provided by MIP. This study shows the importance of multidisciplinary nutritional teams work and the role of the pharmacist in them.

GRP017 Table 1

	Group 1 (n=24)	Group 2 (n=38)	p
Patients with TPN<7 days	67%	22%	0.001
Patients with complete analytical control	4%	79%	0.001
Patients with nutritional evaluation	0%	100%	0.000
Patients with nutritional report in the clinical history	0%	100%	0.000
Patients with daily monitoring of vital signs	0%	100%	0.000
Patients with individualised calculation of requirements in TPN	0%	100%	0.000

Competing interests None.

GRP018 ADJUSTMENT OF IMIPENEM THERAPY TO RENAL FUNCTION

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10.1136/ejhpharm-2012-000074.18

Background Postoperative infections are very common complications. Considering patient's renal function is important when prescribing antibiotics, but this is not a usual practice.
Purpose To evaluate the use of Imipenem in hospitalised patients in the Vascular Surgery Unit of the General Hospital.
Materials and Methods A retrospective observational study of 3 months duration was undertaken (June–August 2011) in 51 beds of Vascular Surgery with Unit Dose Distribution System. All patients treated with Imipenem are included and patients with creatinine clearance (CrCl) lower than 60 ml/min are evaluated. Age, genre, CrCl, estimated by the Cockcroft–Gault method, empirical treatment or not and drug related problem (DRP) were registered. The authors took as standard weight 70 kg in men and 60 kg in women. Dose and posology are adjusted to CrCl according to two sources of information. Patients are classified according to the K/DOQI guidelines criteria: stage 1 and 2 CrCl≥60 ml/min, stage 3 CrCl 30–59 ml/min and stage 4 and 5 CrCl<30 ml/min).
Results The authors evaluated 30/61 patients (21 men, 9 women), average age of 75 years old (51–92). 51 DRP were identified in 30 patients. It would be necessary to decrease the dose in 4/30 patients; to increase the therapeutic interval in 3/30 and to apply both measures in 22/30 patients. 8/30 patients have confirmed infection and in 22/30 patients Imipenem is prescribed empirically. Classification of patients according to K/DOQI guidelines: 34 patient's stage 1 and 2; 21 patient's stage 3; 6 patients stage 4 and 5.
Conclusions Imipenem does not adjust to renal function in 50% of the patients.

- Imipenem is used empirically in Vascular Surgery Unit due to medical and surgical complexity of the patients
- An improvement multidisciplinary program for the quality of antibiotic pharmacotherapy in patients with renal disease must be implemented.

Competing interests None.

GRP019 APPROPRIATENESS OF ENOXAPARIN PRESCRIBING IN PATIENTS WITH REDUCED RENAL FUNCTION

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10.1136/ejhpharm-2012-000074.19

Background Enoxaparin is a safe drug but could cause adverse effects if it accumulates.
Purpose To assess the renal function in patients requiring enoxaparin admitted to several wards in our hospital.

Materials and methods The authors conducted a prospective observational study for a month (March 2010) which involved the review of prescriptions for enoxaparin on the traumatology, internal medicine and geriatrics wards. The authors recorded the dose of enoxaparin, other drugs prescribed, age and serum creatinine (Cr). The authors calculated the creatinine clearance (CrCl) with abbreviated MDRD in patients with Cr values over 1.1 mg/dl. According to the product information for Clexane, the dose should be adjusted in patients with CrCl≤30 ml/min and clinical monitoring is recommended with CrCl=30–50 ml/min. The standard treatment for deep vein thrombosis is 1 mg/kg/24 h and for thromboembolic disease prophylaxis it is 20 mg/24 h. The authors advised prescribing physicians of potentially risky patterns in writing through the prescription process. The authors drew their attention to patients with CrCl<30 ml/min and patients aged over 75 prescribed excessive doses of enoxaparin.
Results Enoxaparin was prescribed to 256 patients, 85 in traumatology, 130 in internal medicine and 41 in geriatrics. The authors detected 141 potential risk patterns: 81 in internal medicine, 37 in traumatology and 23 in geriatrics. Among these 141, 120 were due to high doses of enoxaparin in patients aged over 75 and the remaining 21 were patients with CrCl<30 ml/min. The distribution pattern of the risk was: 36 in traumatology because of age and none for CrCl, 65 in internal medicine due to age and 16 due to CrCl, and 19 in geriatrics due to age and 5 due to CrCl. After alerting the doctors, five treatment regimens were changed.
Conclusions More than half (55%) of the prescriptions analysed were potentially dangerous considering the renal function, and in most cases no change was made after the Pharmacy department drew attention to the risk. Enoxaparin is a safe drug but more attention should be paid to the kidney function of treated patients.

Competing interests None.

GRP020 TROUBLESHOOTING ADMINISTRATION FROM UNIT DOSE DISPENSATION AREA

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10.1136/ejhpharm-2012-000074.20

Background Patient's proper dose is essential for an adequate treatment.
Purpose Checking the proper administration of prescribed treatments in a General Hospital.
Materials and methods The authors conducted a cross-sectional study about the detection of treatment administration errors, by means of two indicators: the treatment order signing before administration (preadministration signing) and the administration of a different pattern from the prescribed one by nursery (wrong pattern). Original treatment orders were reviewed in the unit dose dispensation area, and errors were reported in writing to the different services. Also, a data collecting sheet was designed, including medical service name, number of treatment orders, number of treatment lines and types of error.
Results 168 treatment orders were checked (1085 treatment lines) corresponding to nine hospital floors (traumatology, urology, two surgery services, two internal medicine services, haematology/ophthalmology/oncology, geriatrics/neurology and gynaecology) 48 management errors were detected, 86.33% of them caused by preadministration signing and 16.7% by wrong pattern. Attending to a classification of all these data, six errors (20 treatment orders) were detected in Traumatology, 83.3% of them by wrong pattern and 16.6% by preadministration signing; 1 wrong pattern out of 7 treatment orders in urology; 8 errors (27 orders) in right surgery and 11 errors (18 orders) in left surgery, all due to preadministration signing; 3 errors (27 orders) were detected by preadministration signing in right internal medicine; 11 errors (29 orders) in left internal medicine, 90.9% of them caused by preadministration signing and 9.1% by wrong pattern; in haematology/ophthalmology/oncology services, no administration errors were detected after checking 9 treatment orders; 4 errors (19 orders) were detected by preadministration signing in geriatrics/neurology; and 4 errors (12 orders) in gynaecology, 75% of them by preadministration signing and 25% by wrong pattern.
Conclusions Preadministration signing was the most common error, particularly within the surgery service. Apart from that, notifying the administration errors by the pharmacist helps to detect them on time so that they do not continue during hospitalisation.

Competing interests None.

GRP021 THE INTRODUCTION OF SAFE PRACTICES FOR THE ADMINISTRATION OF POTASSIUM CHLORIDE IN HOSPITALISED PATIENTS

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10.1136/ejhpharm-2012-000074.21

Background Incorrect intravenous administration of concentrated potassium chloride (KCl) solutions is potentially lethal. The Quality Agency for the Spanish National Health System has recommended safe practices to reduce this risk.
Purpose To describe the implementation of standardised labelling of KCl solutions by nursing staff and evaluate adherence.
Materials and methods In May, 2011 the hospital group for the safe use of medication identified KCl as a hazardous drug. It decided to introduce labelling of diluted KCl solutions by the nursing personnel responsible for preparing and administering them in cardiology, cardiac surgery, emergency observation, coronary care, postoperative care, postcardiac care and intensive care. Information on the label should include patient identification, prescribed KCl dose, volume and solution type. A month-long (22 August–26 September 2011) prospective observational study with 10 cross-sectional time points was conducted. Two independent observers evaluated adherence to the safe practice. The percentage adherence (%) was calculated by dividing the number of patients with labelled KCl solution by the total number of patients prescribed KCl.
Results Of the total 898 patients hospitalised in these wards during the study, those prescribed KCl included 14 in cardiology, 18 in cardiac surgery, 34 in coronary care, 14 in emergency observation, 8 in postoperative care, 32 in postcardiac and 78 in intensive care. The percentage adherence for labelling of KCl solutions by nursing staff was 100% in all units except cardiac surgery (88.8%) and intensive care (97.4%).
Conclusions Adherence to the labelling initiative of the group for the safe use of medication was very high, almost 100%. Safe practices that reduce patient risk increase the quality of health systems and the level of satisfaction among healthcare professionals.

Competing interests None.

GRP022 PHARMACIST EDUCATIONAL INTERVENTIONS PROGRAM FOR OUTPATIENTS WITH CHRONIC HEART FAILURE

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10.1136/ejhpharm-2012-000074.22

Background Patients with chronic heart failure (CHF) take several medicines and frequently manage their medicines inappropriately. In our hospital, a postdischarge pharmacist educational interventions program (PEIP) has been introduced as a part of a multidisciplinary CHF disease management program.

Purpose To describe CHF patient profiles, adherence, treatment knowledge and detection of drug-related problems (DRP) through the PEIP. To analyse the relation between DRPs detected and CHF patient characteristics.

Materials and methods Prospective observational study including all CHF patients attending the PEIP from May 2010 to August 2011. Data: demographics; New York Heart Association (NYHA) class; mean ejection fraction (EF); cardiovascular risk factors (CRF); self-administration of medicine (SA); self-reported adherence to diet (AD) and medicine (AM) and motivation (M) (Modified Morisky Scale); knowledge of CHF medicines: %dose (D), frequency (F) and indication (I); contraindicated drugs (CID) and DRP (DRP1: did not use a needed medicine; DRP2: used a medicine not needed; DRP3: ineffective treatment; DRP4: infradose; DRP5: overdose; DRP6: adverse reaction) and cases of acute decompensation. Statistical test: χ^2 and Fischer exact test for dichotomous variables and t-test for continuous variables.

Results Patients: 75. Patient profile: 54 (72%) male; age: 71.8±1.3; patients/NYHA class: I: 2 (2.7%); II: 58 (77.3%); III: 14 (18.7%); IV: 1 (1.3%), EF< 45%: 42(56%); smokers: 20(26.7%); alcohol consumption: 17(22.7%). Adherence and knowledge: SA: 41(54.7%); AD: 56(74.7%); AM: 75(100%); M: 61(81.3%); Mean knowledge of CHF medicine: DFI: 29.7%± 32.0; DF: 47.8%± 41.5; patients who were aware of CID: 12(16%). DRP: 17 patients (22.7%); DRP1: 9 (12%); DRP2: 2(2.7%); DRP3: 6 (8%); DRP4: 3 (4%); DRP5: 2 (2.7%); DRP6: 4(5.3%). Patients with decompensation: 11(14.7%). Comparison between patients with and without DRP: decompensated: 5/17(29.4%) versus 6/58(10.3%)(p=0.05); SA: 12/17(70.6%) versus 29/58(50%) (p=0.134). No other significant differences were observed between the two groups.

Conclusions The PEIP evaluated the adherence and knowledge of the treatment in CHF patients and allowed us to detect DRPs in about 23% of the patients. The presence of any DRP was only correlated with acute decompensation and self-administration of drugs, suggesting the importance of an appropriate CHF treatment self-management.

Competing interests None.

GRP023 EXPERIENCES WITH MEDICATION RECONCILIATION IN A DANISH HOSPITAL

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10.1136/ejhpharm-2012-000074.23

Background Hillerød Hospital is a mid size teaching hospital in the capitol region of Denmark with 49.105 discharges in 2010. The hospital has one emergency room/admission unit and has 19 wards where medication reconciliation (MR) is performed. Before this effort, MR was not routinely performed, putting patients at risk of receiving wrong or inadequately dosed medications during admissions and after discharges.

Purpose The purpose of the task is to improve medication reconciliation (MR) at admission and discharge.

Materials and methods

- A pharmacist together with a physician or nurse audited 10 files monthly for up to 10 clinical units. Variables (yes/no) were:
- MR at admission
- List of medications in admission note
- All medications registered in the electronic medication system
- MR at discharge
- MR in discharge summary
- Identical list in electronic medication system and discharge summary
- Data were registered in a spreadsheets
- The authors calculated the percentage of patients with MR at admission and discharge for each unit. Results were aggregated for the whole the hospital. All data were plotted as run charts for MR at admission and at discharge for each variable.

Results MR at admission increased from 60% to up to 90%, on some wards to 100% during 2008–11. MR at discharge increased from 20% to 80%. The authors find large variations by ward of MR at discharge (5 to 100%).

Conclusions It is possible to implement medication reconciliation at admission and discharge because of the positive forces for change in our organisation. Most important is a committed change agent (Nina Grüner), interdisciplinary teamwork and the availability of high quality data and support from leaders in the later phase of the project. Well even higher reliability of medication reconciliation requires deeper integration of process routines in the clinical units through small scale testing.

Competing interests None.

GRP024 CLINICAL USE OF DRUGS MONITORING VIA LABORATORY TESTS: PILOT STUDY IN A GENERAL HOSPITAL

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10.1136/ejhpharm-2012-000074.24

Background The interest of monitoring patients treated with several medicines using blood tests has been demonstrated in many publications. However, most citations refer to the outpatient setting. A consensus about 'drug-laboratory test' pairs that should be prioritised for follow-up which has been published recently.

Purpose To evaluate the prevalence of prescription drugs that should be monitored by lab tests and how often these test values change, with the aim of establishing the clinical relevance of alerts on 'drug-laboratory test' pairs in our hospital.

Materials and methods The authors screened for the blood levels of particular drugs based on a review carried out by earlier researchers (poster presented at 16th Congress EAHP), and the consensus recently published in the American Journal of Health-System Pharmacy. The authors selected 22 'drug-laboratory test' pairs. The authors reviewed the pharmacological treatment of all patients admitted to internal medicine and psychiatry for a month. These wards were chosen by the greater likelihood of finding treatments with the selected drugs. The authors assessed the prevalence of prescriptions for the selected drugs, and also looked for laboratory test values

that were likely to be altered as the result of taking these medicines.

Results The authors checked 122 patients treated with some of the selected drugs, of whom 109 were in internal medicine and 13 in psychiatry. 50% of the patients were women. The average age was 72±17.5 years, and the average stay of 7.2±4.9 days. Patients taking some of the selected drugs corresponded to 64.6% of patients admitted during the study period. 351 drugs were selected, with an average of 2.9 drugs per patient. The overall incidence of patients with some drug associated with abnormal laboratory tests was 60 cases per 100 patients. Numbers of patients found with 'drug-abnormal analysis' pairs are shown in the following table:

GRP024 Table 1

Laboratory test	Drugs	Patients
POTASSIUM	>5.5 meq/l	
ACEI/ARA		2
Creatinine	>1.4 mg/dl	
High-efficiency diuretics		2
Potassium supplement		1
ACEI/ARA		
Potassium-sparing diuretic + potassium supplement		1
Lithium		
ARA + Potassium		1
Aminoglycosides		
Platelets	<140000/mm^3	
LMWH		12
Vancomycin		
Sodium	<135 mmol/l	
Oxcarbamazepine		1
Allopurinol		
Altered thyroid hormones		
Lithium		1
LMWH		3
Amiodarone		1
Metformin		
Potassium	< 3.6 meq/l	
High efficiency diuretics		13
*Combination of two of these drugs		14
Diuretics high efficiency + digoxin		1
*Combination of three of these drugs		10
ALT/AST	>31/32 U/l	
Oxcarbamazepine		1
*Combination of four of these drugs		4

Conclusions The high prevalence in our hospital of patients with prescribed medicines included in the selected alerts and the high incidence of lab test abnormalities associated with their prescription drugs highlights the importance of performing this type of monitoring from the pharmacy department, since it may affect the patient's clinical situation. The drug-abnormalities analytical pairs most often found have been creatinine increase- nephrotoxic drugs, diuretics high efficiency-hypokalaemia, thrombocytopenia-LMWH, and hyperkalaemia-drugs that increase serum potassium, suggesting the appropriateness of prioritising these alerts in the monitoring pharmacotherapy.

Competing interests None.

GRP025 PRESCRIBING ERRORS DETECTED AFTER AN ELECTRONIC PRESCRIBING SYSTEM IMPLEMENTATION

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Background Assisted electronic prescribing system (EPS) is a tool with enormous potential for improving the safety of hospitalised patients. But it can also lead to medication errors (ME).

Purpose To assess the ME generated by an EPS during the medical prescription process.

Materials and methods Prospective study of two clinical inpatient units (internal medicine and haematology) in a general hospital, 4 months after an EPS was implemented (May and July 2010).

ME detected during pharmacist validation:

- Omission of allergies.
- Medication related errors (MRE): A) inadequate medication, B) inadequate pharmaceutical form (IPF), C) inadequate selection of medication (ISM) (drug not included in hospital formulary, when a formulary alternative existed), D) contraindicated drug (interaction), E) therapeutic duplication, F) omitted medication, G) not clear medication (NCM).
- Wrong dose.
- Wrong frequency of administration.
- Wrong way or route of administration (WRA).
- Wrong length of treatment.

Analysis of results: Excel database.

Results Average number of admitted patients was 25 patients/day (20–29). 177 ME were detected in 111 different patients, which mean an average of 4.4 errors/day and 1.5 errors/patient. Most of ME were due to discrepancies found between the prescription and observations stated by the doctor.

Conclusions Increasing medication safety and improving efficiency using EPS needs a culture change through a complex process, which involves physicians, pharmacists and nurses working as a team, as well as proper training of the EPS users of the EPS.

Competing interests None.

GRP025 Table 1

ME detected	ME distribution	Number
Omitted allergies		2
MRE	Inadequate medication	1
	IPF	35
	ISM	7
	Interaction	2
	Duplication	4
	Omitted medication	11
	NCM	12
Dose		27
Frequency		36
Time		11
WRA		14
Length treatment		15

GRP026 ANTIBIOTICS SURVEILLANCE: A SURVEY ON THE SUSCEPTIBILITY OF MICROORGANISMS TO ANTIBIOTICS IN RESPIRATORY TRACT INFECTIONS

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10.1136/ejhpharm-2012-000074.26

Background Susceptibility of microorganisms to antibiotics is clearly decreasing in many Asian countries and is of particular concern in *Streptococcus pneumoniae*. The genetic relationship between penicillin-resistant *S pneumoniae* strains from across Asia suggests that resistant clones have spread within and between countries.
Purpose The study was designed to determine the susceptibility of respiratory microorganisms to antibiotics by using antibiogram reports.
Materials and methods The bacterial strains were isolated from patients suffering from respiratory tract infections (sputum, bronchial wash and throat swab, pleural fluids). Patients with respiratory tract infections having antibiogram were collected retrospectively and prospectively from the patient records and microbiology laboratory respectively. 147 subjects whose antibiogram reports available were included in the study.
Results The duration of stay in hospital varied among the population. In the retrospective study most of the patients (37.27%) were admitted for 6–10 days while 25.45% stayed for 1–5 days. In prospective study, most of the patients (37.83%) had a hospital stay of 6–10 days while 27.02% were admitted for 1–5 days. Due to increased resistance shown by previously susceptible organisms patients were at a risk of longer hospital stays. In retrospective phase, most of the patients received more than one antibiotic as part of the treatment. 34.54% patients were on two antibiotics while 25.45% were on three antibiotics. In the prospective study, the number of patients receiving only one antibiotic was high (43.24%), while 32.43% were on three antibiotics. The susceptibility of microorganisms was more evident in hospitals where the antibiotic usage is maximum. Hence pathogenic microorganisms can now defy antibiotics to which they were previously susceptible.
Conclusions The study emphasises that, antibiotic susceptibility testing should be carried out for all the patients who is in need of antibiotic therapy. Because of the immediate unavailability of antibiogram report it is better to obtain gram stain report before starting empirical therapy. Thereby it helps in choosing appropriate antibiotics having a narrow spectrum of activity. After obtaining the antibiogram report the sensitivity of the empirically started antibiotic should be checked against the same. Moreover the patient should be cautioned to follow the correct therapeutic regimen even after getting discharged from the hospital.

Competing interests None.

GRP027 IDENTIFICATION AND PREVENTION OF DELETERIOUS EFFECTS OF SUPPLEMENTARY HEALTH PRODUCTS ON MEDICAL THERAPY Ñ A CHALLENGE FOR CLINICAL PHARMACISTS

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Background In the last decade it has become a challenging problem for the pharmaceutical profession that alongside their prescribed drug treatment patients take supplementary products (OTC, herbal remedies, food supplements, 'panacea' etc.) without consulting their physician or pharmacist. The authors propose clinical pharmacists gather detailed information about drugs, additional remedies and their procurement sources, as interactions with medicines may harm health, decrease efficacy of the medical treatment and reduce patient compliance.
Purpose Our study aims at exploring and analysing interactions between drugs and additional remedies among inpatients and outpatients at departments of internal medicine. This is a pilot study to confirm the practical applicability of our interaction monitoring system, which the authors plan to introduce at the clinic.
Materials and methods A database has been developed by our department in collaboration with HC Pointer Ltd., which contains all the authorised or notified paramedicines and food supplements having a noteworthy market in Hungary. Screening is based on the evaluation of 155 components with potential for interactions, the synonyms of which give us a total of 3184 entries to be searched. Patient interviews and review of the medical records were performed by clinical pharmacists. The authors have gained information regarding current medication and additional remedies, past medical history, immunisation status and known allergies with the aid of a medication history worksheet.
Results The authors have surveyed 98 patients so far, 58 of them (59,2%) have reported use of supplementary products (OTC, vitamins, herbal products, homeopathic remedies) along with their prescribed medicines. Potential interactions have been identified in seven cases (7,1%). Antithrombotic and antidiabetic agents were most commonly involved in interactions.
Conclusions Gathering detailed information about the use of supplementary products should be included in medical histories in clinical pharmaceutical practice. Documentation and evaluation of interactions between herbal products and prescribed drugs can prevent adverse reactions and introduce higher standards for patient care. Special software and databases are indispensable due to the complexity of possible interactions.

Competing interests None.

GRP028 TO REVIEW THE ADEQUACY OF INR MONITORING WITH AN ANTICOAGULATION DOSAGE-CONTROL PROGRAMME

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10.1136/ejhpharm-2012-000074.28

Background Vitamin K antagonists (VKAs) warfarin and acenocoumarol are considered by the Institute for Safe Medication Practices (ISMP) high-risk medicines when used incorrectly. For that reason pharmacists follow a strict anticoagulation control procedure implemented at our hospital that consists of entering in full the haematologist's dosage recommendations to the inpatient's computerised treatment to inform nursing staff of the exact daily dosage through the management sheet. No VKAs are dispensed from the pharmacy in the INR monitoring day until new haematology recommendations are made.
Purpose Our aim was to review the adequacy of INR monitoring in these inpatients.
Materials and methods The inpatient use of VKAs, except in the intensive care unit, was reviewed for one month. Only inpatients on VKA without concomitant low molecular weight heparin treatment were selected. INR data were extracted from the laboratory computer program (Omega) and VKA use data were obtained from the Unit Dose computer program (Dominion).

Results In 1 month 88 inpatients (4.6%) were treated with VKAs: 81 with acenocoumarol (92%) and 7 with warfarin (8%). 194 INR determinations were performed in 78 patients (2.5 measurements/patient) which means that 11.4% of them were not monitored. VKAs were used without concomitant enoxaparin in 40% of patients. The mean INR of these patients was 2.17 (95% CI) (1.61 to 2.74). Considering that the aim of treatment, according to international guidelines for vascular risk, is an INR of 2–3 (2.5–3.5 for phospholipid syndrome and mitral mechanical prosthesis) the authors found that only 23% of patients were always within range, 63% were underdosed and 13% overdosed.
Conclusions Although monitoring is intense and a dosage-control pharmacy program exists, most inpatients were outside the recommended INR range, underdosing being the most common problem. Based on these results, the authors think that closer follow-up is needed, checking drug interactions, dietary habits or altered physiological states. In this setting, pharmacists could play an important role.

Competing interests None.

GRP029 THE EFFECTIVENESS OF ANGIOTENSIN RECEPTOR BLOCKER THERAPEUTIC INTERCHANGE IN HOSPITALISED PATIENTS

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10.1136/ejhpharm-2012-000074.29

Background The role of therapeutic interchange (TI) has increased substantially in recent years as a result of the rapid expansion in the number of drugs within similar therapeutic classes.
Purpose To evaluate the effectiveness of the angiotensin receptor blockers (ARB-II) TI protocol used in our hospital.
Materials and methods A retrospective cross-sectional study which included hypertensive patients who were switched to losartan between January and May 2011. Primary response variable: proportion of patients maintaining blood pressure values (BP) within the established therapeutic target for prevention of cardiovascular events (130/80 in patients with diabetes mellitus (DM) or chronic renal failure (CRF) and 140/90 in the rest of the patients). Other variables: difference between BP values the month prior to admission (BP1) and after 8 days of the TI (BP2). The analysis was performed using STATGRAPHICS PLUS 5.1 program. A total of 104 patients were analysed, with a mean age of 75.5 years (range 39–96). There was also a subanalysis of patients with associated risk factors (CRF and/or DM).
Results The analysis of the total population, the BP1 (DBP±SD/SBP±SD) average was 74.6±10.8/138.6±16.9 mm Hg and the BP2 69.9±10.7/131.6±20.5 mm Hg. The proportion of patients who maintained BP values within the established therapeutic goal at home was 39%. After the TI, this proportion increased to 64%. In the subgroup of patients with associated risk factors, the BP-1 was 74.9±11.1/139.0±16.8 mm Hg and the BP-2 67.8±10.9/131.2±22.9 mm Hg. The proportion of patients controlled at home was 21% and 53% after the TI.
Conclusions The effectiveness of TI of ARBs in hypertensive patients studied, including patients with associated risk factors, was high, allowing the BP control not only to be maintained but even improved. The decrease in blood pressure found in our study should be studied further in order to evaluate the effect of better treatment adherence in the hospital compared to home.

Competing interests None.

GRP030 CAUSES AND FACTORS ASSOCIATED WITH INAPPROPRIATE PRESCRIBING IN OLDER PATIENTS IDENTIFIED AT HOSPITAL ADMISSION: APPLICATION OF THE CRITERIA STOP-START

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10.1136/ejhpharm-2012-000074.30

Background Inappropriate medication use is a major patient safety concern, especially for the older population
Purpose To analyse the causes of potentially inappropriate prescribing (IP) in patients over 64 admitted to the hospital and to determine factors associated with their presence in the treatment.
Materials and methods Observational study was conducted in a referral area hospital. The authors included all patients over 64 admitted to the hospital in the last quarter of 2009, and selected a representative sample randomised and prospectively. Inappropriate prescription (IP) was considered according to STOP-START criteria[1] as well as the low therapeutic value (LTV) prescriptions. Prevalence and causes of IP and the factors associated were determined. All tests were performed using SPSS version15.0.
Results In the study were included 382 patients with a mean age of 77,7 years. 58,1% of patients had at least one IP. After applying the STOP-START criteria, IP were detected in 45,8% of patients and in and in 23,8% LTV prescriptions. Common IP categories were long-term use of potent opioids for treatment of mild to moderate pain (18.8% of patients), prescribing omission of metformin in patients with type 2 diabetes mellitus (17, 1% of patients) and prescribing omission of fibre supplements in chronic symptomatic diverticulosis and constipation (16.6% of patients). These three cases comprised 35.3% of the IP and affected 52.6% of patients. Factors associated with a higher prevalence of inappropriate prescriptions by STOPP criteria were musculoskeletal diseases, autoimmune or CKD and polypharmacy. According to START criteria the factors associated were chronic heart disease, and symptomatic peripheral arterial disease or diabetes with visceral injury.
Conclusions There is a high prevalence of IP for older patients. Should be systematised the detection of this kind of prescriptions giving preference to the polypharmacy and with certain types of comorbidity.

Competing interests None.

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GRP031 PREVALENCE AND SPECTRUM OF CHRONIC KIDNEY DISEASE IN HIV-POSITIVE PATIENTS

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10.1136/ejhpharm-2012-000074.31

Background Chronic kidney disease (CKD) is currently an important complication of HIV infection once HAART treatment has been introduced.

Purpose The aim of this study was to investigate the prevalence of CKD and patient characteristics in HIV-infected patients.
Materials and methods This was a retrospective cross-sectional study. In May 2011, using a cross-sectional method, the authors selected all HIV patients receiving antiretroviral treatment at a tertiary university hospital in Spain. The medical charts were reviewed from the moment the HAART treatment was started. Exclusion criteria included those who did not follow the treatment throughout the study period and those who were on treatment less than 6 months. The following demographic, clinical and laboratory parameters were abstracted from the clinical database: age, nadir CD4 T cell count, viral load, estimated glomerular filtration rates (GFR), hepatitis B and C co-infection, medicines, hypertension, diabetes mellitus and other co-morbidities. GFR was ascertained according to the Modification of Diet in Renal Disease (MDRD-4) criteria. CKD was defined as GFR<60 ml/min for at least 3 months.
Results During the study period 149 patients needed antiretroviral treatment at the HIV consulting service. CKD prevalence was 7.38% (11 patients). The patients' characteristics were:
Conclusions The prevalence of CKD among HIV-infected patients was higher than expected and reported by other authors. The only factors analysed that appeared to affect the presence of CKD were co-infection with HCV and exposure to lamivudine. Consequently, patients in treatment with lamivudine must be monitored and dose adjustments made. In our study, the exposure to TFV seems not to affect the prevalence. In spite of that it should be used cautiously because of its known nephrotoxicity.

Competing interests None.

GRP031 Table 1 Patients' characteristics

	CKD (n=11)	No CKD (n=133)	p Value
Age (mean (SD))	45 (9.1)	44.9(8.0)	0.92
Male gender (n(%))	8 (72.7)	99 (74.4)	0.81
Homosexual	1 (9)	33 (24.8)	
IDU	8 (72.7)	58 (43.6)	0.06
Heterosexual	2 (18.2)	43 (32.3)	
HCV infection (n(%))	8 (72.7)	51 (38.3)	0.04
HCV-HBV co-infection (n(%))	1 (9)	3 (2.2)	
Nadir CD T cells (median)	358.70	355.25	
Undetectable viral load (n(%))	11(100)	118 (88.7)	0.35
Tenofovir (TFV) exposure	6 (54.5)	83 (63.4)	0.78
Lamivudine exposure	5 (45.4)	15 (11.2)	<0.005
Hypertension	3 (27.3)	15 (11.3)	0.31
Diabetes	1 (9)	3 (2.2)	

GRP032 DRUG-RELATED PROBLEMS CAUSE MANY ADMISSIONS TO A BRAZILIAN HOSPITAL PAEDIATRIC EMERGENCY UNIT: A PROSPECTIVE AND OBSERVATIONAL STUDY

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Background Paediatric patients are one of the most vulnerable patient populations. There are many unlicensed medicines and the so-called 'off-label' uses for which they are prescribed may increase the risk of drug-related problems (DRPs) such as lack of efficacy and adverse drug reactions (ADRs).
Purpose The objective of this study is determine the incidence of DRPs for patients admitted to the hospital's paediatric emergency unit, and provide information about drug use, with the intention of improving the rational use of medicines.
Materials and methods A prospective observational study took place in July to September 2011. Pharmacists interviewed the people who were responsible for children up to 15 years old, without race restrictions, from both sexes, to obtain information about medicines the children had been taking. The results were evaluated and the DRPs were related to the admission to the hospital emergency paediatric unit of the State University Hospital of Campinas (UNICAMP). The DRPs obtained were classified as ineffective treatment, ADRs, inappropriate use, compliance, poisoning, drug interactions and technical defects.
Results The authors interviewed 348 patients or those responsible for them and the proportion of hospital admissions due to DRPs was 14.7% (51 patients). Among the DRPs identified, 23 (45.1%) were due to ineffective treatment, 11 (21.6%) due to ADRs, 9 (17.6%) to inappropriate use, 4 (7.8%) to non-compliance, 2 (3.9%) to intoxication, 1 (2%) to a technical defect and 1 (2%) to a drug interaction. The respiratory and gastrointestinal systems were the most commonly affected organs, and antipyretics/analgesics were the drugs most commonly associated with ADRs.
Conclusions This data may be used to construct the epidemiology profile of paediatric patients, showing that there is a high incidence of DRPs that cause hospitalisation. More study is necessary in both pharmacoepidemiology and pharmacovigilance in the paediatrics area to understand the DRPs involved and improve the use medicines in children.

Competing interests None.

GRP033 INCIDENCE AND NATURE OF ADVERSE DRUG EVENTS IN SURGICAL PATIENTS

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Background Medication is one of the major causes of adverse events in hospitalised patients.[1] Of these so-called adverse drug events (ADEs), 15–60% is preventable.[2] Surgical patients may be especially at risk for ADEs due to many inhospital transfers with medication related handovers. However, detailed information on the nature of surgical ADEs is lacking.
Purpose The aim of this study was to determine the incidence and nature of ADEs in surgical patients in order to evaluate the effect of future clinical pharmacy interventions on surgical ADEs.
Materials and methods This observational cohort study was conducted in eight surgical units of three Dutch hospitals. Elective surgical patients hospitalised for more than 48 h were included. A trigger tool tailored for the surgical population was developed to preselect medical records for potential ADEs. Causality, severity and preventability of ADEs were assessed by an independent expert panel of surgeons and clinical pharmacologists.

Results Medical records of 567 included patients (March–June 2009) were screened for triggers. Records (n=340) with one or more triggers were evaluated by the expert panel. They found 28 ADEs per 100 admissions of which a major part (75%) was classified as mild. Almost half of the ADEs was related to gastro-intestinal harm such as nausea. Particularly opioids (52%) were responsible for ADEs. Over 15% of the ADEs was judged preventable, of which 25% was classified as severe or life-threatening. Harm caused by anticoagulants accounted for 21% of the preventable ADEs.
Conclusions Surgical patients are indeed at risk for mainly mild ADEs. A quarter of the preventable ADEs is classified as severe or life-threatening. Major problems concern the use of opioids and anticoagulants. The results of this study provide enough evidence that the pharmaceutical care in surgical patients can be improved. The effect of clinical pharmacy interventions on surgical ADEs is now being evaluated.[3]

Competing interests None.

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GRP034 THE EFFECT OF PHARMACEUTICAL INTERVENTIONS ON PARENTERAL NUTRITION IN A NEONATAL INTENSIVE CARE UNIT 5 YEARS AFTER THE INTRODUCTION OF ELECTRONIC PRESCRIBING

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10.1136/ejhpharm-2012-000074.34

Background Parenteral nutrition (PN) prescriptions are not error-free regarding calculations. The errors are more important the more premature the patient. Electronic prescribing aims to automate the process and therefore reduce errors, helping the pharmacist to validate the prescriptions.
Purpose To assess the impact of electronic prescribing (for PN) in the neonatal intensive care unit, comparing the year prior to computerisation to the fifth year after, in order to improve the prescription tool.
Materials and methods All PN prescriptions in the year before computerisation (2347) and the fifth year after (2155), were reviewed and the following parameters compared concerning prescribing errors: calcium/phosphorus relation (Ca/P relation), final volume (when the final volume is smaller than the sum of all components), osmolarity, phosphorous prescription (source: sodium glycerophosphate) when sodium is not wanted in the parenteral nutrition solution (phosphorous without sodium) and omission of nutrients.
Results There was a decrease in prescribing error in three parameters: Ca/P relation (–10.0%), osmolarity (–97.2%) and final volume (–66.7%). However there was an increased error in the PN prescription of phosphorous introducing unwanted sodium (236.4%) and omission of nutrients (35.3%).
Conclusions The use of electronic prescribing for PN has contributed to error reduction and simplified the process. Moreover it was possible to evaluate the prescription tool parameters that need to be improved (phosphorous prescription).

Competing interests None.

GRP035 A PROCESS-ORIENTED APPROACH TO MEDICATION RECONCILIATION AT ADMISSION IN A SURGERY DEPARTMENT

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Background The 2007 WHO guidelines underscore the importance of using medicines reconciliation (MR) in hospitals in order to assure the correct medicines at transitions in care.
Purpose To develop a process-oriented approach in order to implement a MR process in an abdominal surgery ward.
Materials and methods This study was divided into three parts of 1 month each. First, The authors compared the medicines history (MH) taken by the pharmacist with the physician's computerised prescription at admission. Unintended medication errors (UMD) were identified with the physician in order to obtain the mean number of UMD per patient. In the second study, the MH taken by the pharmacist was copied onto an MH form (MHF) that was used by the practitioner to help prescribe treatment at admission. Before beginning the third part, the MR process workflow was optimised by a multi-disciplinary working team. In the second and third part the average days to complete MHF and the mean number of UMD per patient were measured in order to assess the efficiency of our MR process.
Results 44 (average age 53, 3.4 treatments/patient), 50 (average age 50.5, 2.9 treatments/patient) and 55 (average age 48.3, 2.3 treatments/patient) patients were included in parts 1, 2 and 3 respectively. UMDs per patient decreased from 0.41 in part 1 to 0.24 in part 2 and 0.25 in part 3. Workflow optimisation before the third part led to the pharmacist performing MHF for scheduled patients before their admission. Average days to complete the MHF decreased from 1.1 to 0.82 between parts 2 and 3.
Conclusions Our approach, which was to introduce small improvements, communicate actively with the clinical unit and improve the workflow enabled us to successfully introduce MR into the abdominal surgery unit. The MR process now relies on a structured organisation and no longer on individuals.

Competing interests None.

GRP036 THE EFFECT OF DRUGS USED CONCOMITANTLY WITH ANTIPLATELET TREATMENT

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Background Antiplatelet therapy is a cornerstone for prevention and treatment of cardiovascular atherothrombotic diseases. Low-dose aspirin is usually the first choice antiplatelet drug. Furthermore, aspirin combined with clopidogrel has become the gold standard for patients receiving coronary stent or suffering from acute coronary syndrome. In cases when antiplatelet therapy fails, potential interactions with other concomitant drugs should be considered.
Purpose was to identify possible aspirin and clopidogrel interactions with co-administrated drugs and to work out a recommendation for optimisation of pharmacotherapy.
Materials and methods In this study 70 patients were included from practices of family doctors in Riga who used

antiplatelet drugs concomitant with other drugs at the time from July 2010, to January 2011. In the questionnaire such facts from the outpatient cards as sex, age, clinical diagnosis, duration of antiplatelet drug use, dosage and other drugs used were collected. In collaboration with family doctors the information about drug using-habits was summarised.
Results 53% of patients were taking dual antiplatelet therapy (ie, aspirin and clopidogrel combination). The daily dose of clopidogrel was 75 mg. The daily dose of aspirin used frequently was 100 mg (69%). From information collected about concomitant drugs that possibly interact with aspirin prescription, non-steroidal anti-inflammatory drugs (27%) with diclofenac should be noticed as most common (74%) and non-prescription non-steroidal anti-inflammatory drug ibuprofen (25%). Among patients who received dual antiplatelet therapy 59% also used proton pump inhibitors with omeprazole as mostly used (55%) and 38% – statins with atorvastatin as most common (57%). These drugs are stated to have a potential interaction with clopidogrel.
Conclusions Clinicians should probably judge patients taking such combination therapies as aspirin with diclofenac as at high risk of bleeding; also those taking combinations of aspirin and ibuprofen, clopidogrel and omeprazole and/or atorvastatin as a reduced efficacy of antiplatelet therapy.

Competing interests None.

GRP037 INCIDENT AND MALFUNCTIONS COMPENDIUM AT THE PHARMACY: REVIEW AND ANALYSIS AFTER 1 YEAR OF STATEMENTS RECORD

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Background The establishment of a recording and incidents processing system to the medication circuit is an important element in the risk management associated with drug therapy.
Purpose The aim is to identify adverse events, analyse the causes and consider corrective actions to reduce or delete dangerous situations.
Materials and methods A card for reporting adverse events and a registration database was established. This card can be filled by any staff of the pharmacy for incidents that had a proven or potential impact on the patient management or service organisation.
Results After 1 year, 255 statements were recorded. 87% of events have been reported by a pharmacist and 13% by a dispenser. 33% of the events involve a prescription problem (contraindications, wrong dosage…). 24% of incidents are related during dispensing (wrong product, wrong pharmaceutical form...). 18% of collected incidents indicate a malfunction in the pharmacy (stock error, storage error...). 4% of events are due to an organisational problem in the care services that have an impact on the pharmacy. 8% of declarations are due to a computer problem, 7% to a lack of communication between care services and pharmacy, 5% to a problem in the delivery to care services, and 1% to a security problem. On 255 statements, 33% are considered by declarants as having a potential impact on patient management.
Conclusions Immediate corrective actions are taken for serious incidents; the longer-term interventions were implemented to recurring malfunctions. However, no action is planned about incidents not directly related to the pharmacy. This approach is included in a global quality approach and improves the pharmacy operational system and thus, the patient management. Since the introduction of these cards, a staff awareness of the most frequent incidents is carried out. The authors have now to assess these actions impacts on dangerous situations.

Competing interests None.

GRP038 MEDICATION RECONCILIATION AT HOSPITAL ADMISSION IN INTERNAL MEDICINE SERVICE. A NECESSITY?

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10.1136/ejhpharm-2012-000074.38

Background The medication reconciliation (MR) is a key point to increase patient safety that allows to detect medication errors, called discrepancies. MR at hospital admission consists in comparing the patient's usual treatment with intrahospital prescription.
Purpose To measure the incidence of medical error in the admission process in our hospital in internal medicine service (third level hospital). Solve possible unintended discrepancies to assess the need to implement a MR process into the clinical practice.
Materials and methods Observational and interventional pilot study in September 2011. The pharmacological history was obtained from patient history completed with an interview, and then compared to the prescription of the hospital within 24 h of admission. Discrepancies were recorded and classified as justified or not justified, and these were reported to the prescriber by written notice and then classified as intentional or non-intentional (medication error, ME).
Results 71 patients from 126 admitted in the service were included. The mean age of the patients was 79.6 years old, 53.7% were women. The authors reconciled 616 drugs, with an average of 8.68 drugs/patient (SD 3.75) at admission. Pharmacist detected 112 discrepancies not justified which 43 was ME in 26 patients (omission, discrepancies on dosage or frequency, extra medicine 'unnecessary', different drug). That represents a rate of 36.6% patients with ME and the 6.9% of drugs reconciliated. The pharmaceutical interventions in reconciliation were accepted by physicians in 23 cases (53.5%). The average of drugs in patients with ME were 9.9 and in those without 8 ($p<0.038$).
Conclusions An important number of patients have a ME, particularly those with a higher number of drugs. Despite half pharmaceutical interventions were accepted, the authors must design a MR record file to make the intervention easier and improve patient safety at admission. To develop the MR in the patient with more incidence of ME in all the services, we will need a full-time pharmacist.

Competing interests None.

GRP039 DRUGS ADMINISTRATION IN PATIENTS WHO RECEIVE ENTERAL NUTRITION: ANALYSIS OF PHARMACEUTICAL INTERVENTIONS

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10.1136/ejhpharm-2012-000074.39

Background The concomitant use of enteral nutrition (EN) and medicines through enteral feeding tube (EFT) can cause drug administration errors and adverse drugs events.
Purpose The aim of this study is to describe pharmaceutical interventions (PI) performed in patients who receive EN to prevent and solve drug-related problems.

Materials and methods One month prospective study, conducted in patients admitted to clinical wards with single-dose distribution system, who started receiving EN. The authors daily reviewed all prescription orders and recorded prescribing service, access device (checked in patient medical record), time of treatment with EN, and prescribed drugs. PIs were classified into drug-EN incompatibilities and proper drug administration through EFT. PIs were notified in writing to physicians and nursing staff. The authors noted if PIs were accepted by the prescribers.

Results 30 patients were included. EN was administered through nasogastric tube to 12 patients and through gastrostomy to one patient. Average EN treatment length was 6 days and average concomitant medication was 10. The authors carried out 81 PIs and 61 of them (75%) were conducted in patients who had an EFT. These PIs involved 80% of patients.

The authors accomplished:

- 32 PIs (39,5%) to correct the EN route of administration and medication, because it was unmentioned or incorrect on prescription order.
- 11 PIs (13,6%) to avoid incompatible drugs with administration through EFT.
- 38 PIs (46,9%) conducted to avoid EN-drug incompatibilities.

The authors observed that clinicians accepted 74 PIs (91, 3%).

Conclusions Drug-related problems can be identified in a high percentage of patients receiving EN. The development of a pharmaceutical care plan can solve these problems and optimises quality of patient care. Most of PIs were conducted in patients who had an EFT. Drawing up a drug administration guideline and indepth healthcare team education are needed. Real and potential administration errors of medication through EFT can be identified and reduced by means of pharmacist's review of medication charts.

Competing interests None.

GRP040 QUALITY IN PHARMACEUTICAL COMPOUNDING FOR PAEDIATRIC PATIENTS

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10.1136/ejhpharm-2012-000074.40

Background Licensed medicines for children are rare. Pharmacy preparation plays a crucial role in this vulnerable patient group but its quality must be assessed carefully. Our hospital pharmacy prepares various capsules for children by crushing and diluting licensed products. For the requested low concentrations, high and sometimes serial dilutions are necessary. The authors follow good pharmacy practice and use uniformity of mass as our routine quality control.

Purpose This study was conducted to assess the quality of our children's capsules and therefore contribute to patient safety. Specifically, the authors investigated the feasibility and quality of our dilutions and to see if conformity of mass was sufficient as a single routine quality check.

Materials and methods Simulating standard concentrations, procedures and quantities, sample NaCl capsules were produced by each member of the production team.

The capsules were analysed for uniformity of mass and content according to PH.EUR.6.

Means, minimum and maximum values (in % of the labelled concentration) were identified.

Results 22 samples, each containing 50 capsules of either 0.1 mg or 1 mg were produced. All samples met the PH. EUR. requirements for uniformity of mass. As for content: of the 0.1 mg group (n=11), 2 (18%) met PH. EUR. criteria, 2 (18%) required further analysis and 7 (64%) failed. The average content was 83.5% (53.1%-105.5%) of the labelled concentration. In the 1 mg group (N=11), 3 (27%) conformed to the PH. EUR. criteria, 3 (27%) were eligible for further analysis and 5 (46%) did not meet the criteria. The average content was 86.1% (78.1%–95.3%) of the labelled concentration.

Conclusions Our study indicates that a routine check of conformity of mass is not sufficient for quality assurance of our preparations. It also showed that the dilutions do not seem to result in acceptable concentration ranges in the capsules. A re-evaluation of the products and our production methods is planned.

Competing interests None.

GRP041 ANALYSIS OF INFECTIONS ASSOCIATED WITH CENTRAL VASCULAR CATHETERS USED FOR PARENTERAL NUTRITION ADMINISTRATION

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10.1136/ejhpharm-2012-000074.41

Background Catheter-related infections(CRI) are highly prevalent and often associated with fatal complications. One year ago, intensive care unit (ICU) of our Hospital implemented a 'Zero Bacteremia Project.'

Purpose To determine the rate of CRI in hospitalised patients receiving parenteral nutrition (PN) and to determinate whether there is any relationship with the route of administration and place of insertion (hospital ward or operating room).

Materials and methods Prospective study conducted in a General Hospital during 13 months. All patients who received PN by central line were included, and The authors registered the Medical Department, insertion date, localisation (peripherally inserted central line, subclavian, jugular, femoral or implanted ports), the place of insertion and, in case of infection, the date and the causal agent.

Results 177 central vascular catheters (CVC) were registered in 159 patients, of whom 62% were inserted by the surgery department, 20% by ICU, 12% by internal medicine and 6% by other ones. 71% of the CVC were inserted in the operating room. Subclavian route was mainly used in surgery and digestive departments (62% and 67% respectively), while in internal medicine and ICU there were more jugular vein insertions (76% and 63%). A total of 42 CVC were removed for suspected infection (24%), with positive cultures in 22 of them (12% of total). There were no case of infection in ICU patients, while digestive department had the highest rate (37%) followed by surgery (12%) and internal medicine (11%), probably because CVC were inserted in patients that had been hospitalised longer. Mean time between catheter insertion and infection was 11 days. The genus found in 73% of the cases was Staphylococcus and the most frequent species were *Staphylococcus epidermidis* (38%) and *Staphylococcus hominis* (19%). In three cases, polymicrobial infection was found.

Conclusions There is no uniformity among departments in using jugular or subclavian route. It was necessary to remove a high percentage of CVC on suspicion of infection, but only half of them had positive cultures. Based on these results, the Hospital Infections Committee has agreed to extend the 'Zero Bacteremia Project' to other inpatient Units.

Competing interests None.

GRP042 RISK MANAGEMENT FOR BIOLOGICAL AGENTS I IN RHEUMATOID ARTHRITIS

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10.1136/ejhpharm-2012-000074.42

Background TNF antagonists have been successfully used for the treatment of rheumatoid arthritis (RA). However, data from clinical trials and databases have shown that patients treated with these biological agents have an increased risk of reactivation of latent tuberculosis (TB), hepatitis B virus (HBV) or hepatitis C virus (HCV) infections. The Spanish Society of Rheumatology (SSR) has made some recommendations. According to these guidelines it is mandatory to exclude tuberculosis infection with an evidence level (EL) 2b, Grade of evidence (GR) B. Serology for HBV (EL4, GRC) and HCV (EL4, GRC) are recommended as complementary tests.
Purpose To establish the percentage of patients who underwent the recommended tests prior to treatment in a tertiary hospital. Latent infections are ruled out by a tuberculin test and chest x-rays (tuberculosis), HBV markers and HCV antibodies.
Materials and methods Retrospective observational study of patients with RA who started treatment with biological agents between January 2010 and August 2011. Data were extracted from Farmatools and Sinapsis care databases. The variables collected were: age, sex, biological agent, BCG skin tests, chest x-rays, anti HCV antibodies and HBV markers.
Results A total of 36 patients (78% female, 22% male), started a biological treatment for RA. The average age was 55 years. The drugs used were: etanercept 28%, adalimumab 69% and certolizumab 3%. Tuberculosis was evaluated in all patients, HCV in 58% and HBV in 56%. HCV and HBV tests were positive in 3% and 11% of the patients respectively.
Conclusions Screening for tuberculosis infections is a common practice in this hospital. Serology for HCV and HBV were tested in a noteworthy percentage of patients although these complementary tests had recently been recommended by SSR. The pharmacy department may improve this goal by making a double check before the first dose is dispensed.

Competing interests None.

GRP043 PRESCRIPTION OF PROPHYLACTIC PROTON PUMP INHIBITORS AT HOSPITAL DISCHARGE

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10.1136/ejhpharm-2012-000074.43

Background Proton pump inhibitors (PPIs) are used in the treatment of conditions such as dyspepsia, gastro-oesophageal reflux disease and Zollinger-Ellison syndrome. They are also used in the prevention of peptic ulcer disease (stomach ulcers) or haemorrhage induced by non-steroidal anti-inflammatory drugs or antiplatelet agents, in patients with additional criteria. The literature refers to an overuse of PPI in patients who do not match these indications.
Purpose To evaluate PPI prescriptions at discharge from our hospital (a tertiary hospital).
Materials and methods The authors carried out a cross-sectional observational study in a tertiary care hospital located in Barcelona. The study included patients older than 18 years discharged during the months of July and August 2011. The authors excluded patients whose PPI treatment was justified. The authors included patients with preventive prescriptions for PPIs, patients without any PPI prescription at discharge and patients with another antacid at discharge. The authors calculated the percentage of patients who met the criteria for preventive PPI prescription but for whom it was not prescribed at discharge, and likewise the percentage of patients with an appropriate preventive prescription of PPI at discharge.
Results The authors included 96 patients, seven were excluded because the PPI prescription fitted the indication for PPI treatment. The 89 patients included had a mean age of 77.48 years (SD 13.57). 59.6% of these had a PPI prescribed at discharge (average age of 79.92 years (SD 11.45) and 50.9% were women). 37.1% of patients did not have a PPI prescription at discharge and 3.4% were prescribed other antacids. These two groups made a total of 36 patients, five of whom met criteria for PPI preventive prescription (13.9%). Of the patients who were prescribed a PPI at discharge, only 17 (32.1%) met criteria for preventive PPI prescription.
Conclusions The prescription of PPI at discharge for patients who do not meet the criteria for prevention of stomach disorders is a noticeable problem in our hospital.

Competing interests None.

GRP044 QUALITY MANAGEMENT OF ANTIMICROBIAL PROPHYLAXIS FOR SURGERY

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10.1136/ejhpharm-2012-000074.44

Background The surgical site infection (SSI) is one of the most important issues affecting the safety of the surgical patient. Surgical antimicrobial prophylaxis (SAP) is a protective factor for SSI. Proper application of SAP is a surgical units quality indicator.
Purpose To describe the process of implementing a quality management system (QMS) in the implementation of SAP in a tertiary general hospital.
Materials and methods SAP was based on kit of prophylaxis (KP), which is prepared in the pharmacy and contains the antibiotic dosages required for each SAP. There are four different KP available to cover all surgical procedures. The KP contains cefazolin, vancomycin or amoxicillin -clavulanate. The phial containing the antimicrobial is connected to a saline solution that allows the reconstitution and dilution without needles. The KP incorporates a form that provides administration information. Fill in the form is used to justify the administration of the drug.
Results QMS consists of the implementation of a strategy to measure and improve the SAP. QMS was implanted in a progressive way in the hospital. It was based on the following sequential steps: 1) development of SAP protocols based on KP. Protocols were consensus among the surgical unit and the pharmacy department and validated by pharmacy and infectious committees. 2) Circuit implementation of a prescription-dispensing-administration of KP. The KP are prepared at pharmacy department when requested and sent to the surgical units so that each dose is administered in the appropriate time and place. 3) Conducting the assessment of quality standards of SAP through an annual audit. Audit results are sent to the

hospital's medical management and each surgical unit and it is usefully as a measure of evaluation of objectives and to take action for improvement.
Conclusions The implementation of a QMS based on KP promotes proper application of SAP.

Competing interests None.

GRP045 ADVERSE DRUG REACTIONS CASE REPORTS: A SYSTEMATIC LITERATURE SURVEY

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10.1136/ejhpharm-2012-000074.45

Background Case reports of suspected adverse drug reactions (ADRs) are common in the medical literature, but there is a high variation in their characteristics, quality and relevance.
Purpose The aim of the study is characterise the publications of adverse drug reactions (ADRs) published as letters to the editor (LE) in four Spanish medical journals.
Materials and methods Systematic literature survey was realised. The authors evaluated all case reports of adverse drug reactions published as LE during 2 years (since April 2006 to March 2008) in four Spanish medical journals (Medicina Clínica, Revista Clínica Española, Atención Primaria and Anales de Medicina Interna). Reports were excluded if the event was due to medicinal plants or drug abuse, or if the publication was a cases serie. The evaluation of the cases selected for the study was realised by a group of experts made up of three physicians, a pharmacologist and a pharmacist. Main outcome measures are number of suspected adverse reactions and the following characteristics: therapeutic group of the implied drug, seriousness of the reaction, notification to the pharmacovigilance system, year of commercialisation, and previous knowledge of the reaction.
Results A total of 771 LE were reviewed and 93 corresponded to suspected ADRs, 20 cases were excluded and finally The authors evaluated 73 publications corresponding to 79 patients and 97 active principles. About active principles implied:39, 2% were nervous system drugs; 22, 8 were antineoplastic and immunomodulating drugs (18, 6%); and 11, 4% were alimentary tract and metabolism drugs. About the seriousness of the ADRs: 44% were serious; 37% were moderate; 16% were mild; and only two cases (3%) were mortal reactions. Nine LE had been notified to the Spanish pharmacovigilance system, and nine active principles corresponded to a drug of recent commercialisation (less than 5 years from its approval). These new active principles were: telithromycin, erlotinib, ezetimibe (two cases), dutasteride, pioglitazone, tenofovir, inhaled iloprost and pregabalin. Analysing previous knowledge of the reaction: 54, 4% were well-known reactions, 31, 6% were anecdotal events, and 13, 9% were unknown reactions.
Conclusions The drugs which are used for treat nervous system pathologies and antineoplastic and immunomodulating drugs are highly associated with ADRs. However it does not represent the real percentage of adverse effects of these groups as the main percentage remains underreported. It is necessary more information about new drugs, and a better collaboration between health professionals and the Spanish pharmacovigilance system.

Competing interests None.

GRP046 TERATOGENICITY PHARMACOTHERAPEUTIC REPORT AS A NEW STANDARD OF CARE FOR PREGNANT WOMEN

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Background Pregnant women are usually excluded from clinical drug trials. However, many women take medicines while they are fertile. Because of this, the pharmacy department agreed with the Department of Obstetrics and Gynaecology (DOG) to write drug teratogenicity reports (TDR) for pregnant women (or women who desired a child).
Purpose To evaluate drug teratogenicity and write reports as requested by the DOG. Furthermore, to assess the suitability of prescriptions in the light of recommendations drawn up by the clinical pharmacist.
Materials and methods Drug teratogenicity was reviewed from September 2009 to October 2011. Drugs were classified according to drug class and the FDA teratogenicity category (A, B, C, D, X). Category recommendations were as follow: categories A and B: continue treatment; Category C: consider the risk-benefit balance; Categories D and X: stop treatment. The suitability of prescriptions in the light of TDR recommendations was assessed by reviewing the electronic medical records and the electronic ambulatory prescription records.
Results 32 TDRs were written, with 59 drugs reviewed. The FDA classification categories were: A (n=2), B (n=6), C (n=31), D (n=18), X (n=2). 49% of drugs taken belonged to the classes antidepressant, benzodiazepines or antiepileptics. During the study period seven of the 32 women were lost to follow-up. In three cases, pregnancy was legally interrupted, and the last 22 women were monitored to the end. Of all the drugs of each of the 22 women monitored, 21 drugs were discontinued (B=1; C=10; D=10; X=1), 12 drugs were continued (A=2; B=1; C=6; D=3) and it was not possible to figure it out in two drugs (B=1; C=1). The prescriptions were appropriate in the light of the TDR recommendations in 88% of the cases.
Conclusions The contribution of clinical pharmacists to the multidisciplinary team is increasingly valuable. The TDR and the subsequent monitoring of these special patients improved the knowledge of drugs during pregnancy.

Competing interests None.

GRP047 ANALYSIS OF MEDICATION ERRORS IN A PRIVATE HOSPITAL: PHARMACIST INTERVENTIONS

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Background The medication errors (ME) represent the largest single cause of errors in the hospital setting, and some of them result in serious patient morbidity/mortality. A knowledge of ME in every hospital would lead to improve pharmacotherapy process and patient safety.
Purpose To describe and analyse ME reported in our hospital and quantified pharmacist interventions.
Materials and methods The site of the study was a 300-bed private hospital, accredited by the Joint Commission of International. The report of ME detected in inpatients was extracted as Excel files from January to September 2011 and included: drug involved, description of the event, cause of error,

patient consequences and health professional who reported the ME. The pharmacists report ME and make interventions reviewing all the prescriptions in a Computerised Physician Order Entry.

Results During the study period 213 ME were reported (0, 78 ME/day–0.044% of total prescriptions). The main class of drug involved in ME were anti-infective agents (108; 50, 7%). The most frequent types of ME were: 69 (32, 4%) overdosage (30 in renal impairment), 41 (19, 2%) underdosage, 23 (10, 8%) inadequate schedule, 21 (9, 9%) wrong drug and 16 (7, 5%) drug omission. The wrong prescription was the main cause of ME (165; 77, 5%). The pharmacists were the health professionals who reported most of the ME (167; 78, 4%), with 140 interventions carried out (83, 8% of total ME reported by the pharmacists). The 75, 7% of interventions were accepted. Classification by the reporters were: 134 (62, 9%) reached the patient and did not cause harm, 69 (32, 4%) did not reach the patient, 8 (3, 8%) required health monitoring and 2 (0, 9%) resulted in temporary harm (one required medical treatment and the other required prolonged hospitalisation).

Conclusions Real and potential ME in inpatients can be identified mainly reviewing drug prescriptions by the pharmacists. The most of interventions are focused in wrong anti-infective dosages. Prevention strategies for ME deriving from analyses of the reports are contributing directly to patient safety.

Competing interests None.

GRP048 OFF-LABEL ORAL TRANSMUCOSAL FENTANYL CITRATE ANALGESIA FOR BONE FRACTURE ALIGNMENT IN CHILDREN

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Background Oral transmucosal fentanyl citrate is indicated for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.

Purpose To evaluate off-label transmucosal fentanyl citrate use for bone fracture alignment in children.

Materials and methods In December of 2010 the Pharmacy and Therapeutics Committee approved a protocol for off-label transmucosal fentanyl citrate use for bone fracture alignment in children older than 3 years old. A retrospective, observational study was carried out December 2010 through October 2011. Inclusion criteria were an ASA (American Society of Anaesthesiologists) physical status 1 or 2 and a body ≥12 kg. Dose to be administered depends on the patient's weight:

- Between 12 and 22 kg: 200 mcg
- For patients >23 kg: 400 mcg.

Dose can be repeated if it is not effective. The sedoanalgesia is evaluated by Wong-Baker faces pain rating scale and numeric pain rating scale before and after the process. Vital signs like glasgow, hart rate, respiratory drive and oxygen saturation are evaluated during the process. Children's parents must be informed and provide informed consent

Results 15 childrens were treated with transmucosal fentanyl during a fracture alignment, 11 boys and 4 girls, the average age of those patients were 8, 26 years old (3–13). Before the process 10/15 patients had between 6 and 10 points in numeric pain rating scale, the rest of them had four or less points. The average pain reduction were 5, 1 points (0–8) – this date were not evaluated in four patients. There was no significant changes in any patient vital signs during and after medication. Only 1/15 patient presented an adverse reaction, with vomiting 60 min after transmucosal fentanyl administration.

Conclusions

- Transmucosal fentanyl analgesia for bone fracture alignment in children could be used as an alternative to other pain medications.
- It is necessary a larger study to establish an effective dose and to observe its safety use.

Competing interests None.

GRP049 HOW OBSERVATIONS ON WARDS LED TO A CHANGE IN THE DANISH NATIONAL GUIDELINE

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Background Patients poisoned with paracetamol are treated with the antidote N-acetylcysteine (NAC). According to the previous Danish national guidance the first infusion with NAC has to be mixed in 300 ml 5% glucose (or isotonic NaCl). In Denmark 300 ml solutions are only supplied in glass bottles. These are not designed to be used with IV poles. As an alternative 500 ml solution are supplied in infusion bags designed to be used with IV poles. This requires the nurse to withdraws 200 ml of the solution. Pharmacy staff from the Capital Region had been asking the Medicines Information Centre (MIC) whether it was possible to use 250 ml of glucose solution instead of 300 ml.

Purpose The task was to investigate the possibility of changing practice when preparing NAC infusions, in order to secure easier, faster and more rational treatment of patients poisoned with paracetamol.

Materials and methods Pharmacy staff visiting hospital wards daily had independently been observing the inappropriate and time-consuming preparation of NAC infusions. The MIC was asked to provide a more manageable handling routine in the hospital.

The MIC task involved:

- Reviewing the antidote/emergency management guidelines
- Reviewing the relevant literature regarding treatment with NAC
- Discussing the case with the clinical pharmacologist connected to the national Danish Poison Control Hotline.

Results The conclusion finally resulted in a change in the national guideline for the treatment of paracetamol poisoning.

This change of volume for preparation of NAC infusions further provided additional benefits:

- faster initiation of treatment
- improved patient safety due to simpler handling
- price reduction of approximately 10€ per treatment

Conclusions The MIC concluded that 250 ml solution can be used equivalent to 300 ml.

Competing interests None.

GRP050 EVALUATION OF THE EFFICACY AND SAFETY OF ROMIPLOSTIM IN IDIOPATHIC THROMBOCYTOPENIC PURPURA: A CASE REPORT

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Background Romiplostim is a new second-generation thrombopoietic agent that stimulates thrombopoietin receptors and platelet production.
Purpose To evaluate the efficacy and safety of romiplostim in a splenectomised man with idiopathic thrombocytopenic purpura (ITP) who had not responded to other treatments.
Materials and methods Follow-up over 2 years of treatment with romiplostim in a 64-year-old patient diagnosed with ITP in 2005. Previously high doses of steroids and non-specific intravenous immunoglobulins (IVIG) had been tried with a bad response; the patient was splenectomised in 2007. In spite of treatment with IVIG 2 g/kg and rituximab 375 mg/m^2/week the platelet count did not rise. In September 2009 he started romiplostim 1 mcg/kg/week (dose=75 mcg), increasing gradually as indicated in the SPC. The authors evaluated the efficacy through the platelet count (noted in the clinical history), aim: 50–200 10^9/litre without bleeds. The adverse effects evaluated the safety.
Results Splenectomy, treatment with IVIG and rituximab increased the platelet count in a short time to over 50×10^9/litre; but this count reduced drastically. After the first dose of romiplostim the platelet count rose from 12 to 99×10^9/litre. The right platelet count was achieved with a dose of 3 mcg/kg (225 mcg) reduced to 150 mcg when the count was over 200×10^9/litre. During this period the dose was: 19 weeks of 225 mcg, 30 weeks of 150 mcg and 4 weeks of 75 mcg, aligned with the blood test results. During the 2-year follow-up the average platelet count has been 147×10^9/litre (between 30 and 323×10^9/litre). There were no episodes of bleeding (hematomas or epistaxis). The only adverse effect has been colds when the dose was administered.
Conclusions Romiplostim has proved as an effective option for maintaining the platelet count in this splenectomised patient with ITP who was resistant to other treatments. Romiplostim is well tolerated with no need to reduce the dose because of adverse effects. Although this drug does not cure the disease it improves the quality of life of the patients without causing bleeds.

Competing interests None.

GRP051 NURSES PERCEIVED PROBLEMS WITH 'HIGH-ALERT DRUGS': RESULTS FROM THE EUROPEAN INSTITUTE OF ONCOLOGY†

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Background Patients' growing interest in maintaining their own health and quality of life can certainly be linked to a significant increase in their knowledge of their rights. The Italian Ministry has published a series of documents that makes recommendations to support the management of drug treatment to reduce the risk of accidental exchange of one drug with another.
Purpose At the European Institute of Oncology it has been decided to participate fully in the appreciation of the processes of prescribing, preparing and administering high-alert drugs, starting with an assessment regarded as central: the perception of the operator, which is at the forefront of having to deal with the drug in his/her department, with the aim of better understanding the day-to-day problems with which he/she has to cope.
Materials and methods A questionnaire was written within an audit, which was designed to investigate nurses' knowledge of high-alert drugs and their training in handling. The questions sent to nurses evaluated what nurses considered high-risk medicines, investigated the sites where the drugs were reconstituted, and asked for suggestions for practical and hypothetical solutions to the definition of a common management procedure.
Results 216 questionnaires were sent to nurses of all hospital units (medical oncology, intensive care, surgery, etc.). The survey concluded that the main issues to which attention should be paid were: proper storage in separate places (12%), drugs should be easily recognisable with the help of alert signals (15%), care should be taken with the procurement of materials that were LASA (look-alike/sound-alike) high-alert drugs so that packaging was not similar whichever pharmaceutical companies were involved (11%), physician prescriptions should be clear and readable and always active and specialties, dedicated sites should be created for the preparation of treatments (14%) without distractions/discomfort (6%), shift work and workload patterns should be reviewed (26%) in order to introduce double checks in the preparation and administration of drugs.
Conclusions In the light of these opinions a procedure was defined that governs the management of EIO high alert drugs in order to reduce the occurrence of medication errors, improve the quality of service provided and patient quality of life.

Competing interests None.

GRP052 MEDICATION RECONCILIATION DURING ASSISTENCIAL TRANSITIONS IN INSTITUTIONALISED OLDER PATIENTS

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Background Older patients in nursing homes often have comorbidities that might derive in medical consultations and hospital admissions with changes in their treatment.
Purpose To describe a program of medication reconciliation during assistencial transitions, between specialised and primary care, in a nursing home.
Materials and methods Prospective study of new admissions and assistencial transitions in a geriatric residence of 172 patients between April 2010 and April 2011, by means of the review of the pharmacotherapeutic profile of the nursing home patients'. Data collected: demographics, diagnoses, treatments and analytical data. Data extraction: electronic clinical history of specialised and primary care (IANUS, SIFAR), program of dispensation to inpatients and outpatients (SINFHOS, DIPEX), reports of discharges and consultations of private health centres and reports of the emergency department.
Results 204 patients were included. Pharmacotherapeutic profile was performed and/or updated after each assistential transition (32 admissions in residence, 50 discharges, 63 consultations in specialised care and 7 in emergency department). 79% of these originated discrepancies. In 83 patients (41%) at least one discrepancy was detected. Median age and sex of patients with discrepancies: 81, 5±9,3 years, 53 women. The number of discrepancies detected was 170: 62 in the residence's admission from primary care, 54 after discharges, 50 after consultation in specialised care and 4 were generated

from emergency department. 100% of discrepancies were corrected after pharmacist's intervention. Distribution of discrepancies was as follow: 38 therapeutic alternative for adaptation to the pharmacotherapeutic guide, 29 forgotten drugs, 25 deletion of drug from therapy, 20 adjust/change of treatment, 11 end of treatment to the discharge, 8 therapeutic drug monitoring, 9 duration of treatment, 5 duplicated drugs, 3 frequency adjustment, 3 stream lining of antibiotics, 1 wrong drug and 18 other discrepancies.

Conclusions Our program of reconciliation shows that a high percentage of the discrepancies concern to the efficacy and the safety of the patient.

Competing interests None.

GRP053 OPTIMISATION OF AVAILABLE RESOURCES IN THE IMPLEMENTATION OF A NUTRITIONAL SCREENING METHOD

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Background The prevalence of hospital malnutrition ranges between 30 and 55%. As malnutrition increases with hospital stay duration, consequences are both clinical and economic, resulting in increased morbidity and mortality.

Purpose To analyse if the current resources allow us to implement a nutritional screening system NRS-2002 (Nutritional Risk Screening-2002) or the authors should adapt this method to our centre.

Materials and methods Study carried out in a 300-bed hospital. The authors included all patients>18 years and with expected stay>1 day. The authors calculated the time spent in each interview, how many patients may require nutritional assessment and whether it would be possible to perform screening of all income. Finally, The authors evaluated how to implement the NRS-2002 to detect the maximum number of patients at risk of malnutrition.

Results During the study period 505 patients were admitted in our hospital, 45% were excluded (stay≤1 day). Of the 277 included, 20% did not know or could not answer to the nutritional survey (NK/NA). The average age of the NK/NA group was higher than the rest: 84.3 (SD11.4) versus 71.5 (SD15.6) years (F=8.8 p<0.003). The average time spent doing the interview was 10.8 (SD3.3) min. The average hospitalisation stay was 7.5 (SD6.6) days with significant differences (F=7.2 p=0.008) by services: medical (MS) 8.7(SD7.1) and surgical (SS) 6.1 (SD 5.5). 57.9% of patients of MS had nutritional risk compared to 37.3% of patients of SS (χ^2=9.4 p=0.002). 92.5% of the patients needed the 'final-test'; wherein>50% required nutritional assessment. Admissions average by day in our hospital is 38 patients. According to the results of this study, screening should be performed in 17 patients, and eight may require nutritional assessment.

Conclusions The authors can not implement this screening method for all admitted patients using the available resources. In order to optimise resources and to detect a largest number of nutritional risk patients, The authors decide to perform the NRS-2002 at 5th day of stay. For those patients that can not answer the NRS-2002, the authors decide to implement the short MNA-2009 (Mini Nutritional Assessment-2009).

Competing interests None.

GRP054 ANTIRETROVIRAL THERAPY IMPACT ON CARDIOVASCULAR RISK AND LIPID PROFILE HIV-INFECTED PATIENTS

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Background Antiretroviral therapy (ART), especially the ones based on boosted protease inhibitors (PI/r) may induce dyslipidaemia and therefore increase cardiovascular risk (CVR) on HIV-infected patients. Some studies suggest that Tenofovir (TDF) could be a protective factor.

Purpose To describe the CVR score in HIV-infected patients and identify which kind of ART (PI/r or TDF) is more convenient for lipid profile (LP).

Materials and methods Descriptive cross-sectional study on HIV-patients in a 300 bed hospital during July 2011. Overall 10-years probability for cardiovascular events was evaluated by the Framingham risk score. The authors analysed CVR and LP according to gender, body mass index (BMI), ART-naives and ATR based on PI/r or TDF. Patients were classified as having low, moderate, or high CVR (<10%, 10%–20% and <20%, respectively). Statistical analysis was performed with SPSS.

Results The authors enrolled 47 HIV-infected patients. Values were: median age 48.3±9.8 years, 70.2% male, 30.4% current smokers, mean BMI 23.6±3.3 kg/m^2, 23.4% ART-naives, 29.8% on PI/r and 61.7% on TDF. The mean 10-years probability for cardiovascular events was 7.1±6.9%. Patient's prevalence with low, moderate and high CVR was 82.2%, 11.1% and 6.7% respectively. CVR was 8.1% in males compared to 4.7% in women. 4.7% in ART-naïve patients compared to 7.8% in ART-treated patients. 5.6% in BMI<25 kg/m^2 patients compared to 10.8% in BMI>25 kg/m^2 patients. ART based on TDF had lower CVR than the based on PI/r (5.9% vs 7.8%). ART based on TDF presented lower total cholesterol values than patients treated without TDF (183.4 mg/dl vs 203.2 mg/dl). The opposite was observed with PI/r (196.6 mg/dl vs 188.6 mg/dl). HDL was higher in TDF-ART patients (0.53 mg/dl vs 0.48 mg/dl) and lower in IP/r-ART patients (0.44 mg/dl vs 0.54 mg/dl).

Conclusions The results show that our HIV-patients have better CVR compared to the studies reported in the literature. An ART regime change in patients with bad LP should be considered.

Competing interests None.

GRP055 ZOLEDRONIC DOSE ADJUSTMENT IN CANCER PATIENTS

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Background Zoledronic acid (ZA) is used in the prevention of skeletal related events in patients with advanced malignancies involving bone as well as in the treatment of tumour-induced hypercalcaemia. Due to its renal uptake and elimination, ZA can cause nephrotoxicity, especially when given in high doses or over short infusion times, meaning a significant potential limiting factor to its use. When initiating treatment with ZA, serum creatinine and creatinine clearance (CLcr) should be determined, and if necessary, make a dose adjustment, but regrettably this is not such a common practice.

GRP055 Table 1 Patients' classification in the different CLcr levels and its corresponding ZA dose adjustment. Prescriber doctors accepted 100% of dose adjustments.

Baseline creatinine clearance (ml/min)	ZA recommended dose	Number of patients
>60	4.0 mg	94
50–60	3.5 mg	14
40–49	3.3 mg	4
30–39	3.0 mg	1

Purpose The authors aimed to implement and develop a working method that allows detecting patients undergoing treatment with ZA that show CLcr<60 ml/min. For those patients with CLcr< 60 ml/min, a dose adjustment will be suggested and released to the doctor in order to assess the dose reduction.
Materials and methods It was an observational, three-months prospective research in a general hospital with 630 beds. All ZA prescriptions achieved in the hospital between April and June, 2011 were looked through: 125 prescriptions corresponding to 113 patients (61 women and 52 men). For each patient, serum creatinine was measured and CLcr was determined by means of MDRD-4 formula. If need be, a dose adjustment was suggested following the technical data sheet instructions.
Results Average age of patients: 63 years; Average CLcr value: 75.3±4.8 ml/min.; 19 (16.8%) of the 113 patients required a ZA dose adjustment.
Conclusions ZA dosage should be considered only after evaluating the patients' CLcr. The authors recognise the need of determining this parameter as part of routine work in the oncological pharmacy unit. An important percentage of patients treated with ZA show low baseline CLcr values, threatening even more their renal function when using this medicine.
Moreover, the dose adjustment suggestions are properly considered by oncologists.

Competing interests None.

GRP056 PRESCRIPTION SCREENING TO PROMOTE SAFE TREATMENT: DRUG-DRUG INTERACTIONS IN THE OLDER

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Background Nowadays polytherapy is widely used in older patients affected by comorbidity but it implies changing kinetics and dynamics which can increase the probability of negative drug interactions resulting in therapeutic failure and/or adverse drug reactions.
Purpose The aim of this study was to retrospectively assess the prescriptions of discharged patients to assess potential drug interactions in terms of frequency and characteristics.
Materials and methods The retrospective study was carried out considering the data within the period from 1 January to 31 March 2011. The study examined prescriptions with at least two drugs for patients older than 65 who were discharged from the General Medicine Unit of Azienda Ospedaliero Universitaria S. Maria della Misericordia in Udine. Drug interactions were identified and assessed using the Micromedex DrugReax System.
Results The data involved 181 patients (44% male and 56% female): 12% in the range between 65 and 70 years, 79% in the range between 71 and 90 years and 9% of patients older than 90 years. Most patients had between 5 and 10 drugs (69%). The rest of them: 16% of patients had fewer than five drugs, 14% between 11 and 15 drugs and 1% more than 15 drugs. The authors analysed 1348 prescriptions. The therapeutic classes most frequently prescribed were: antithrombotic agent (161 prescriptions, 11.9%), diuretics (129 prescriptions, 9.6%), drugs for acid-related disorders and drugs for the heart (121 prescriptions, 9%). Furosemide (8.0%), pantoprazole (7.0%), acetylsalicylic acid and ramipril (5.3%) were the most frequently prescribed drugs. According to the Micromedex DrugReax database, only the treatments of 34 patients (19%) did not show potential drug interactions. The database responses pointed out 633 potential drug interactions, 47% of total prescriptions: 2% of minor, 78% of moderate and 20% of major severity. This meant that major-severity drug reactions were possible in 74 different prescriptions: ramipril-spironolactone (eight prescriptions) and simvastatin-warfarin (five prescriptions) being the most frequent.
Conclusions The percentage of major-severity potential drug interactions was low. However, in order to improve the quality of healthcare, the key reading of the results was the opportunity to initiate a control procedure to prevent negative effects from the drug interaction. Clinical pharmacists should have a key role, using their expertise in a proactive exchange with the clinical prescriber when the treatment is decided. This might avoid potentially dangerous drug interactions that might lead to therapeutic failure and/or adverse drug reactions. Possible suggestions might include modification of time scheduling for drug administration. Finally clinical pharmacists should also educate patients to promote compliance with the drug administration regimen.

Competing interests None.

GRP057 DOSAGE ADJUSTMENT IN RENAL IMPAIRMENT

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Background The intervention of the pharmacist in the therapy of patients with renal failure can contribute to improve safety, reducing the potential for kidney damage.
Purpose To assess the role the pharmacist plays in the field of welfare safety of patients with renal function impairment.
Materials and methods A retrospective study from January 2011 to June 2011 in a general hospital with 630 beds. Data sources: validated medical prescriptions obtained from ATHOS PRISM program. The authors consider the values of serum creatinine greater than 1.4 ml/dl and estimate the value of each patient's glomerular filtration rate (GFR) by MDRD-4 formula. The choice of drugs that were monitored was performed based on their clinical impact and volume of prescriptions. The reference values for dose adjustment of the selected drugs were obtained from various literature sources: Mensa's Antimicrobial Guide, Sandford Guide to Antimicrobial Therapy and Technical Data Sheet.
Results The authors evaluated the prescriptions of 8367 patients, 961 (11.5%) were patients with impaired renal function. Of these, 240 (24.9%) underwent intervention for inappropriate drug dosage. The interventions were accepted in 105

cases (48.3%) and not accepted by the clinician in 36 (15%). In the rest the outcome of the intervention could not be assessed: in 22.1% because the patient was discharged and in 18.8% because the drug on which the recommendation was made was suspended. The services that accepted our suggestions to a larger extent (in percentage) were surgery (100%), angiology (75%) and geriatrics (63.2%). Drugs with a greater number of accepted interventions were levofloxacin (47 over 105 accepted recommendations, 44.8%), ranitidine (10 over 105, 9.5%) and amoxicillin (8 over 105, 7.6%).

Conclusions It is important to identify and review the treatment of patients with impaired renal function for an appropriate dose adjustment. The drugs that more often have been adjusted are antibiotics, of which the most remarkable for the number of interventions and adjustments has been levofloxacin.

Competing interests None.

GRP058 HIGH RISK DRUGSÖ REORGANISING THE EUROPEAN INSTITUTE OF ONCOLOGY

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10.1136/ejhpharm-2012-000074.58

Background JC Standards impose at hospitals organisation to develop a method to improve high risk drugs safety.

Purpose European Institute of Oncology (EIO) decided to develop this method improving the safety of high-alert drug government in order to reduce the occurrence of medication errors, with an impact on the quality of service provided and the patient quality of life.

Materials and methods The work was structured as follows: (1). Distribution, collection and analysis of a questionnaire on the perception of nurses about high-risk drugs and LASA. (2). Visits to eight units, representative of the care areas, with direct observation of preparation/administration of medications based on prescription. (3). Observation of primary and secondary packaging of 731 drugs in the EIO formulary. A list which shows all the possible confounders drugs (LASA) has been prepared.

Results Data of completed questionnaires (187–86.6% of 216) were revised to highlight the general trend of knowledge at units individual level. From visits were detected 21 findings, of which 15 non-compliance (NC) that have revealed structural problem, incomplete medical prescription, professional incorrect behaviours, lack of standardisation of the process of prescription/medication management, lack of narcotics and electrolyte concentrated procedures knowledge/compliance. Observation and comparison of EIO drugs packaging found that 15.7% of the 731 drugs may be classified as high alert (115) and 17.7% as LASA (130).

Conclusions With these assessments has been defined a general EIO procedure that governs the management of high-alert drugs in order to reduce medication errors and improve patient safety, with an impact on quality of provided service. It 'was defined a list of drugs considered high risk at the EIO (heparin, concentrated electrolytes, insulin, etc..) and what hospital units are authorised for storage. In addition, the high-risk drugs are stored in appropriate red containers and it was defined specific areas for the high alert drugs storage.

Competing interests None.

GRP059 POLYPHARMACY RELATED WITH INCREASED RISK OF HIP FRACTURE IN THE OLDER PATIENTS

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10.1136/ejhpharm-2012-000074.59

Background Polypharmacy and the use of a particular group of drugs including benzodiazepines, neuroleptics, antidepressants, antihypertensives, diuretics, acetylcholinesterase inhibitors and proton pump inhibitors have been associated with the risk of falls and subsequent hip fracture (HF).

Purpose Assess the association between polypharmacy and the use of drugs related to falls and analyse the mortality in older patients with HF.

Materials and methods This is a population-based retrospective case-control study. The case group consists of patients aged≥75 years admitted to a tertiary hospital with HF after accidental fall during the year 2010. 61 patients without HF of internal medicine service were randomised as the control group. To compare comorbidity between both groups Charlson index was used. SPSS was used to estimate update Bayesian OR and 95% credible intervals (CI).

Results 61 patients were admitted with HF. The relationship in the control group was 1:1. Mean age 83.3±4.8 years (60.7% women) for the case group versus 81.97±4.04, p=0.12. The number of drugs consumed was 7.2±3.3 in older with HF versus 4.9±2.1, p<0.05. Statistically significant differences were founded (p<0.05) in: benzodiazepines (OR 3.87, CI 1.77 to 8.46); antidepressants (OR 3.26, CI 1.18 to 9.02) and diuretics (OR 2.58, CI 1.24 to 5.39). The 34.42% of patients with HF died before 1 year, compared to 9.8% in the control group (p <0.05, OR 5.7, 95% CI 2.1 to 15). Mean Charlson index was 4.16 for HF and 3.62 for control group (p=0.14).

Conclusions The risk of HF in the older increases with the number of medications taken and the use of benzodiazepines, antidepressants and diuretics. The mortality in the older with HF is three times higher than the control group, which is consistent with published studies. These studies show death rate among 17–33% after the first year of suffering HF>.

Competing interests None.

GRP060 THE HOSPITAL PHARMACIST AS A MEMBER OF A MULTIDISCIPLINARY TEAM TO MANAGE ANTICOAGULATION BEFORE AND AFTER ELECTIVE SURGERY

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Background Inaccurate anticoagulant reconciliation at the preadmission stage of an elective surgical patient-care pathway can lead to either thromboembolic incidents on admission or could increase the risk of perioperative bleedings. The hospital pharmacist can therefore play an opportune role in the management on anticoagulant therapy around elective surgery.

Purpose To implement an evidence based protocol for managing of oral anticoagulant therapy around elective surgery.

Materials and methods A multidisciplinary team was formed consisting of a haematologist, an anaesthesiologist, a physician assistant, a communication specialist and a hospital pharmacist. A Pubmed search was performed on the following terms: anticoagulant therapy, surgery, and bleeding risk. Studies were reviewed and a protocol was set up. Two flows were made dependant on the anticoagulant therapy of the

patient. A communication plan as well as appropriate materials, such as patient cards, and preprinted prescription was made for implementing the new protocol.

Results Literature studies has lead us to a number of important studies. One of which was a review article by Kearon *et al*.[1] Two main risks are of importance; first the risk for thromboembolic accidents and second the risk for bleeding during surgery. The CHA2DS2-VASc score is leading for determining the risk of thromboembolic events.[2] The risk for bleeding during operation is dependent on the operation and therefore the range of operations were divided into several scales. In case the CHA2DS2-VASc score was four or higher and the bleeding risk during operation was high two different paths were laid out depending on the anticoagulant therapy of the patient. In the Netherlands two oral anticoagulants are used: acenocoumarol and fenprocoumon. In case of acenocoumarol, this therapy is stopped 3 days before the elective surgery and tinzaparine subcutaneous injections are given until 24 h before surgery. When fenprocoumon is used as anticoagulant therapy, fenprocoumon will be stopped 5 days in advance of surgery. The dose of the tinzaparine is dependent on the weight of the patient. After surgery tinzaparine is restarted as well as the acenocoumarol. The tinzaparine is given until the target INR is reached. Information material was made for patients, doctors and healthcare providers, this includes patient information, patient cards and preprinted prescription material for the doctors. At this moment the authors are in the phase of measuring the effects of our interventions.

Conclusions Pharmacy involvement has led to a useful and practical guideline and material for the management of bridging anticoagulant therapy around elective surgery and will therefore improve patient safety.

Competing interests None.

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GRP061 PHARMACIST ACTIVITIES IN THE PHARMACY TECHNICIAN LEAD WARD TOP UP SERVICE

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Background In the Capital Regional Pharmacy in Denmark ward top up service is described according to a contract, where the role of both the pharmacist and the pharmacy technician is outlined. The role of the pharmacist as the academic support for the ward top up service was not well defined, and the result of the pharmacist support has been poorer than expected.

Purpose By development of a model for the pharmacist role, is has been possible to involve the pharmacist in ward top up service successfully. The aim of this project is to document the work done by clinical pharmacist in ward top up service. The pharmacist role in ward top up service has been describes in 'an annual cycle', where each task is outlined in a description. All together 39 tasks are described and evenly distributed through the year. By creating an annual cycle of the role of the pharmacist in ward top up service, each pharmacist is now able to have an overview what is expected and when it is expected.

Materials and methods All pharmacist and pharmacist technicians working with ward top up service where invited to define and debate the future role of the pharmacists as an academic support. In a consensus-conference 39 tasks where defined, each task needed precise description and needed a plan for implementation. To meet that need, the authors developed the annual cycle.

Results It was seen that after implementing the annual cycle the role of the pharmacist was more clearly defined. The pharmacist, both new and senior know what is expected and how they can meet the demands outlined in the contract for ward top up service. Further more is the pharmacy technicians confident with the new role of the pharmacist, and they know exactly what they can expect. Together with the annual cycle, the authors introduced a receipt form to document the activities of the pharmacist in ward top up service. It is useful for the pharmacist to overview the tasks that have been done and future tasks. The receipt form is evaluated every month in the group of ward top up pharmacists together with there leader. The purpose is to continuously work with the role of pharmacist in ward top up service and ensure training a competence development of individual pharmacists.

Conclusions By clearly define the role of ward top up service pharmacist and by introducing described tasks, including a receipt form, the pharmacists now work successfully in ward top up service.

Competing interests None.

GRP062 MEDICATION RECONCILIATION PROCESS IN EMERGENCY DEPARTMENT

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Background Medication reconciliation is a key point of security and improvement to patient care process.

Purpose To describe discrepancies in medication reconciliation process during admission and classify drugs involved in reconciliation errors according to Anatomical Therapeutic Chemical (ATC) classification system.

Materials and methods Prospective, longitudinal study performed from January to September 2011 in a 500-bed university hospital. The pharmacist assisted the emergency department 1 h a day and checked current home medication and emergency prescription. Patients who had programmed admission at that moment were included. Medication information prior to admission was collected from electronic clinical

GRP062 Table 1 Main drug group implicated in reconciliation error

Therapeutic group	N	%
C	235	45.9
Antihypertensives	103	20.1
Hypolipidaemic	60	11.7
Diuretic	32	6.3
N	91	17.8
Antidepressive	34	6.6
Antiepileptics	18	3.5
BDZ	18	3.5
B	66	12.9
Antiplatelet	37	7.2
Oral anticoagulants	6	1.2
A	49	9.6
Oral antidiabetic	16	3.1
IBP	16	3.1
Others	71	13.9

history and patients' interview. Identified discrepancies were commented to physicians to obtain explanation. If it was necessary prescription was filled or/and modified. Quality parameters (discrepancies/patient and errors/patient) and coverage ratio (patients reviewed/admitted) recommended by Sociedad Española de Farmacia Hospitalaria were calculated.

Results 846 patients were included with an average age of 76 (limits: 34–97), 53.1% were men. Were identified 512 discrepancies in 274 patients (1.8 discrepancies/patient), 287 (56.1%) were not justified (considered reconciliation errors). Coverage ratio was 32.4%.

A 63.5% (174) of patients presented at least one error (1.3 error/patient). The main error was incomplete prescription in a 30.1% (154), followed by current drug omission in 11.9% (61), different dose, administration route or frequency in 8.6% (44), wrong medication in 2.5% (13), duplicity 2.1% (11) and interaction in 0.6% (3) cases. Classifying discrepancies by ATC system, the C group presented the highest percentage with a 45.9% (235), the N group 17.8% (91), B 12.9% (66) and A 9.6% (49). The other groups represented 13.9% (71). Main drug group implicated in reconciliation error are detailed in table 1.

Conclusions Medication reconciliation is an important multidisciplinary strategy conducted by pharmacists to improve security in hospitals. A high percentage of patients presented reconciliation errors so it could be necessary that sanitary staff take in consideration its importance.

Competing interests None.

GRP063 THROMBOEMBOLIC EVENTS ASSOCIATED WITH LENALIDOMIDE. A REVIEW AFTER THE EMA ALERT

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Background Lenalidomide is an immunomodulator agent authorised in 2007 by EMA for treatment of multiple myeloma (MM), also used as off-label treatment for myelodysplastic syndrome (MS).

In December 2010 EMA communicated the association between lenalidomide and an increased risk of arterial and venous thromboembolic events (AVTEs), recommending the administration of antithrombotic prophylaxis (AP) and to avoid erythropoietic agents, especially when other risk factors (RFs) were present.

Purpose To assess the incidence of AVTEs and the presence of RFs in patients treated with lenalidomide. To assess treatments with lenalidomide in relation to the EMA's warning.

Materials and methods Observational retrospective study involving the treatments with lenalidomide started between May 2008 and September 2010 in a regional hospital.

Results Sixteen patients required lenalidomide, 14 with MM and 2 with MS. Male/female ratio was 8/8, with a median age of 68.3 years (CI 95% 63.1 to 73.4). The average number of cycles administered per patient was six (2–21). The most frequent RFs were: administration of erythropoietic factors (93.8%), tobacco smoking (75.0%) and prior thrombosis (68.8%). More than 85% of patients had at least two RF. The mean value of maximum haemoglobin levels (Hb) was 12.5 g/dl (CI 95% 11.0 to 14.0). 81.3% of patients received AP with low molecular weight heparins (LMWH) or oral anticoagulants. In this period, three AVTEs occurred (during the second, third and seventh cycle, respectively). These cases presented between three and four RFs but none had Hb>13 g/dl. One of these patients had not previously received AP and the treatment with LMWH was started after the AVTE. Treatment with erythropoietic factors was not discontinued in any case. Lenalidomide treatment was spaced out in one case and stopped in another one.

Conclusions All the patients presented thromboembolism risk factors and most received antithrombotic prophylaxis. The relation between the number of risk factors and thromboembolism events was not found, probably due to the limited size of the population.

Competing interests None.

GRP064 IMPACT OF THE IMPLEMENTATION OF ELECTRONIC PRESCRIPTION ON PHARMACEUTICAL INTERVENTIONS

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Background In order to get a decrease in incidents with impact on safety and improve the effectiveness of the prescriptions, the authors implemented ISOFAR software for electronic prescription.

Purpose To describe the impact of the implementation of electronic prescription in the nature of pharmaceutical interventions recorded in the ISOFAR software.

Materials and methods From November 2009 to February 2010 the authors implemented the electronic prescription with the e-osabide application in the 488 hospital beds. The authors have evaluated pharmaceutical interventions recorded in the ISOFAR software in the period 1 November 2008–31 October 2009 (preimplantation) and in the period 1 November 2009–31 October 2010 (postimplantation). The impact of each pharmaceutical intervention has been assessed and classified according to their impact on safety or efficacy, based on the software.

Results The number of registered pharmaceutical interventions has decreased from 1129 in 2009 to 766 in 2010. This decrease is due, to some extent, to the great effort that this implantation has caused, which made it difficult for us to devote to other activities. There was also a decrease from 94.2% to 74.1% in interventions with impact on safety and an increase from 5.8% to 22.6% in interventions with impact on the effectiveness of treatment.

Conclusions It can be considered that the implementation of electronic prescription has improved security, because of the decrease in incidents with impact on safety and therefore the possibility of potential adverse events, and interventions with impact on effectiveness have increased

Competing interests None.

GRP065 QUALITY RISK MANAGEMENT FOR PREPARED STERILE PRODUCTS IN HOSPITAL PHARMACY

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Background A hospital pharmacy (HP) prepares compounded sterile preparations (CSPs) following the current good manufacturing practice (cGMP) requirements. A quality risk management (QRM) is needed for the assessment, control, communication and review of risk for the quality of medicinal products.

Purpose To assess the quality risk of different CSPs in our HP in order to prioritise the preventive measures implementation.
Materials and methods The failure mode and effects analysis (FMEA) was applied. Risk was defined as the combination of the probability of occurrence of harm (O), its severity (G), and the ability to detect it (D).
Occurrence, severity and detectability value guidelines range 1–10 with the following lowest and highest values:
- Occurrence: very unlikely to occur(1).Very likely to occur(10).
- Severity: not noticeable(1).The item unusable(10).
- Detectability: no detection method(DM) available(1).There is a DM highly effective(10).

They were rated according to our experience. Four CSPs were assessed: total parenteral nutrient solutions (TPNs), analgesia/anaesthesia mixtures, cytostatics and antibiotics preparations. In addition, three failure modes (FM) were evaluated for each CSP according to the compounding process: compounding (C), packaging (P) and sterility (S). Each FM was evaluated for occurrence, severity and detectability. The multiplication of these values leads to the risk priority number (RPN). The total score for the CSPs is the sum of the RPN of each FM. The authors established RPN≤100 for low risk preparations and RPN>100 for high risk preparations.
Results All CSPs except antibiotics preparations have RPN values above 100, thus correspond to high risk preparations. The cytostatics compounding has the highest RPN value, that is, entails the highest quality risk for patients and therefore our efforts will be focused primarily in these products.
Conclusions The application of FMEA as a tool for the QRM provides with a score for each CSPs assessed, what helps classify them according to the potential quality risk that hold, facilitating the prioritisation of future preventive measures and the evaluation of the applied measures.

Competing interests None.

GRP066 EVALUATION OF PHARMACEUTICAL INTERVENTIONS ACCORDING TO DRUG RELATED PROBLEMS IN THE HOSPITAL SETTING

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10.1136/ejhpharm-2012-000074.66

Background Pharmaceutical Interventions (PI) are part of pharmaceutical care process and aim to reduce drug-related negative results through early detection of drug related problems (DRP). They are mainly focused on renal/hepatic adjustment of drugs, and supervision of medicines with narrow therapeutic windows and unconventional regimen features.
Purpose Evaluation of PI in separate departments during the first semester of 2011. This will allow a consistent and uniform record and classification of PI, aiming to raise doctors' awareness for the most frequent prescription-related DRPs.
Materials and methods PI's were recorded on a database (Excel 2007) and classified according to the DÁDER method (Third Revision 2005-University of Granada), accepted as a tool to identify DRPs. DRPs are classified according to: Need: DRP1-Need of additional treatment and DRP2-Unnecessary drug; Efficacy: DRP3-Non-quantitative lack of efficacy and DRP4-Quantitative lack of efficacy; Safety: DRP5-Non-quantitative insecurity and DRP6-Quantitative insecurity.
Results From a total of 1835 PI, 82% were accepted (AC). The DRP's distribution was: DRP1-17, 4%, DRP2-25, 4%, DRP3-2%, DRP4-16, 1%, DRP5-5, 1%, DRP6-33, 5%. Departments were analysed separately because of different specifications. The medicine department had a total of 795 PI, with an acceptance of 80, 4%. The most frequent DRP's were DRP6 (38%), DRP1 (20%) and DRP2 (19%). The surgical department had 470 PI, with an acceptance of 95, 5%. The most frequent DRP's were DRP2 (42,2%), DRP6 (19,9%), DRP1 (18,6%) and DRP4 (17,2%). Intensive care units had a total of 149 PI with 89, 3% accepted, the most frequent being DRP6 (40,4%) and DRP4 (31, 5%). The emergency department had a total of 421 PI with 67% accepted. The most frequent DRP's were DRP6 (37%) and DRP2 (24%).
Conclusions This analysis showed that:
- The pharmaceutical interventions had high rates of acceptance (≥80%)
- The most frequent DRP were related to quantitative insecurity (DRP6), followed by the prescription of unnecessary drug (DRP2), despite some differences between different departments.

Competing interests None.

GRP067 IMPROVING PHARMACOVIGILANCE IN PSYCHIATRY

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Background In the last years, Regione Lombardia, on behalf of the Italian Regulatory Agency (AIFA), promoted some pharmacovigilance projects: our hospital, that since 1980 has become one of the most representative for pharmacovigilance in Italy, is taking part in four projects (FARMAMONITO, FARMAONCO, MEREAFAPS and MEAP). These projects actively involve healthcare professionals in spontaneous ADRs (adverse drug reactions) report. Since ADR to antipsychotic drugs are often under-reported, a collaboration was started, between the Department of Neuroscience and the Hospital Pharmacy.
Purpose Aim of the collaboration is to improve the awareness of the drugs used daily, in particular concerning the indications, uses, and ADRs of antipsychotics, in psychiatrics, psychologists and nurses. Better knowledge of antipsychotics may lead to a faster detection of side effects, helping in appropriate patient care.
Materials and methods The pharmacist, as pharmacovigilance monitor, takes part to briefing at psychiatric ward and to periodic equipe meeting at CPS (community mental health centre): he develops and presents summaries of selected molecules toxicity profile, facilitating and soliciting the ADRs reporting. The pharmacist collects the case information, fills the report form and enters the reactions into the database RNF (Rete Nazionale di Farmacovigilanza) and answers to questions asked by pharmaceutical companies.
Results This collaboration has improved the ADRs attention and report: between 2008 and 2011 the report has increased about two folds. In particular, in 2011, 18 ADRs to antipsychotics were identified (69% not serious, 27% serious). Molecules suspected were haloperidol, olanzapine, risperidone and ziprasidone. Most common ADRs were weight gain, hyperglycaemia, long QT syndrome, sedation and confusion. In the light of the initial results, the collaboration will continue for 2012.
Conclusions This initiative started a collaboration among pharmacists, psychiatrics, psychologists and nurses who provide

appropriate patient care and to ensure treatment safety, detecting early alarm signals to estimate the risk/benefit drug profile.

Competing interests None.

GRP068 REVIEW OF CLINICAL MANAGEMENT PROCESS FOR DRUGS: A SAFETY AUDIT

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Background Adverse events (ADEs) connected with drugs management are 10% of incidents for patients. Among the main causes: poor professional integration, poor quality of information, incorrect procedures and poor recording tools.
Purpose (1) Implement good safety practices in clinical management of medication; (2) identify critical points about use of treatment sheet.
Materials and methods The authors made an observation with incident reporting and subsequent analysis with FMECA to highlight critical steps in drug management process. The FMECA analysis highlighted the following critical factors: quality of information concerning the prescription and management of intravenous drugs, exchange of drugs, verification of effects of drugs. Analysis of the data collected on the incident reporting sheet highlighted problems with: Incomplete or no filling in of the therapy sheet, comprehensibility of the prescription, etc. The improvement plan has allowed us to identify a therapy sheet which meets safety requirements, procedure for use, a list of authorised abbreviations/acronyms. After the application, an audit was conducted about use of new therapy sheet. A team composed of doctors, nurses, midwives and pharmacists, driving by nurse risk manager, has defined some indicators (identification data, allergies, start/end date of therapy, prescriber signature, substance/trade name of drug, dosage, acronyms/abbreviations, medications as needed, writing in pencil, erasures, use of ink for correction) and evaluated the quality of 168 therapy sheet (10% of patients hospitalised in 2009 at surgical department in Castelnuovo Monti Hospital), randomly selected and distributed proportionately for three wards (surgery, orthopaedics and obstetrics-gynaecology).
Results The identification patient data set was correctly reported in 97%; allergies in 78%. The drugs were properly prescribed and signed in 91%, there was a correct description of the dose (quantity, dosage form) in 74%. The prescription for medications as needed (present in 107 patients of 168) was complete in 24% of cases. The signing about administering or not, was evident in 65%. From 3% to 5% of the therapy sheet reported writing in pencil, erasures or inadequate correction. **Conclusions** Although the audit results demonstrated in general a safe use of new therapy sheet, further improvements seem possible. In fact a strong development about to the safety in prescription of drug and in the entire process of clinical management of drug, will be achievable in the future, with the introduction of computer technology.

Competing interests None.

GRP069 IMPORTANCE OF MEDICATION ERRORS IN THE ELECTRONIC HEALTH RECORD

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Background A high proportion of the information about the patients' medication from the electronic health record contains some error. The importance of these errors has not been studied.
Purpose To analyse the importance of the errors contained in the Electronic Health Record EHR relating to patients' usual medication.
Materials and methods The information about medication contained in the EHR-D was analysed including all patients with surgical admission between February and November 2010. The errors taken into account were: medicine omitted (error by default), medicine added (error by excess) or medicine with incorrect dose/regimen. Important errors were considered the ones that affected to target medicines, that were: A) medicines with specific management in surgical patients, and B) medicines that have to be reconciled in the first 24 h of the admission in hospital. The proportion of patients with some errors was determined and the average number of errors, for both, general and important errors.
Results 167 patients were included, whose EHR-D were found registered an average of 7.8 (CI 95% 7.1 to 8.5) medicines. The 79.6% (N=133) of the EHR-D contained some errors, being found an average of 4.2 (CI 95% 3.6 to 4.7) errors/patient. The distribution by type of error was: 2.8 (CI 95% 2.3 to 3.3) errors by excess, 0.4 (CI 95% 0.3 to 0.6) errors by default and 1, 0 (CI 95% 0.8 to 1.2) errors of incorrect dose/regimen medication. The importance of errors affected to the 62, 9% (N=105) of the histories, with an average of 2.3 (CI 95% 2.0 to 2.5) errors/patient, being 1.2 (CI 95% 1.0 to 1.5) by excess, 0.3 (CI 95% 0.2 to 0.4) by default and 1, 2 (CI 95% 1.0 to 1.5) by incorrect dose/regimen medication.
Conclusions Eight out of ten EHR-D contain some error in their registrations of medication, and in six out of ten these errors are considered to be important. Half of the errors found are important ones. The information of the EHR-D should be verified before being used to carry out the reconciliation at the moment of the admission in hospital.

Competing interests None.

GRP070 ANAEMIA IN CHRONIC KIDNEY DISEASE PATIENTS TREATED WITH DARBEPOETIN A

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Background FDA and EMEA recommend haemoglobin (Hb) values above 10 g/dl without exceeding 12 g/dl in patients with chronic kidney disease (CKD) treated with darbepoetin α (Dα) in order to avoid cardiovascular risk.
Purpose To analyse the adherence to the FDA and EMEA recommendations for the use of Dα in the treatment of anaemia in CKD patients.
Materials and methods Retrospective study of CKD patients who were dispensed Dα at the outpatient area of the Pharmacy Department during August–September 2011. Inclusion criteria: patients in treatment with Dα at least during 6 months. The authors evaluated Dα dosage and Hb level in the last four dispensations and identified patients with Hb out of range (10–12 g/dl). Data collected: number of total dispensations, Hb levels in each dispensation, Dα monthly dosage and changes in prescription if Hb level was out of range.

Results 90 patients were treated with Dα, but only 52 fulfilled the inclusion criteria. 59.6% were women, the median age was 78. 76.9% were out of the recommended range. The average of maximum and minimum Hb recorded in this group was 12.7±0,2 g/dl and 10.4±0,7 g/dl, respectively, with a mean dose of 88±12 mcg/month throughout the study period. 160 dispensations were made to this group, 43.1% were associated with Hb out of range, carrying out changes at prescription in 26.1%. Patients who had changes in the prescription had a maximum Hb of 12, 9±0, 5 g/dl and a minimum of 8, 8±1, 1 g/dl, while the rest, maximum and minimum Hb was 12.8±0.3 g/dl and 9.1±0, 6 g/dl, respectively.
Conclusions Changes in prescriptions respond to levels below the recommended interval, while levels outside the upper limits were not modified, so it seems necessary to establish a protocol to guarantee the security of the treatment. Pharmacists could play an important role in controlling laboratory parameters and Dα dosage in order to reduce the number of patients with Hb levels out of range.

Competing interests None.

GRP071 ANTIPSYCOTHIC DRUGS IN DEMENTIA AND ALZHEIMER'S DISEASE: PHARMACOVIGILANCE PLAN IN FLORENCE

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Background The Italian Medicine Agency (AIFA) with a specific directive (Dir. AIFA 28/12/2006) requires the monitoring of off-label prescriptions of the antipsychotic drugs in patients with dementia, used to control personality disorder and agitation symptoms.
Purpose The aim of this study was to define an informed consent by patients with dementia, who are not able to consciously choose, and to monitor adverse drug reactions (ADRs).
Materials and methods Medical record included prescription and treatment follow-up. Pharmaceutical data included prescribed drugs and adverse events. Data record included patient's demographic characteristics.
Results The cooperation between medical team (Neurologists and Geriatricians of Florence) and Pharmacovigilance Centre, has generated an information paper for caregivers and /or patient's family (to explain drug side effects and the reason for seeking consent), an informed consent and a monitoring plan for each patient. Data analysis, lasted from January 2007 to December 2010, were performed every 6 months from Pharmacovigilance Centre. Treated patients were 1632 (622 men and 1010 women), aged from 50 to 103 years (average 76 years). The most prescribed drugs were olanzapine (45.7%) quetiapine (38.7%) and risperidone (7.9%). Identified adverse reactions were 7.9% (129 ADRs of 1632 patients), mainly not serious type and primarily dependent on olanzapine (7.69%) and quetiapine (5.87%). Frequent reactions were: extrapyramidal syndrome, joint stiffness, excessive sedation, akathisia, dyskinesia, confusion and ineffectiveness.
Conclusions Informed consent and information on the risks of antipsychotic adverse reactions are important goals to improve patient safety, especially for those with dementia and Alzheimer's disease. This study is an innovative example in Italy for critical issues resolution because it leads to an integrated therapeutic and diagnostic path.

Competing interests None.

GRP072 MEDICATION-RELATED PROBLEMS AFTER DISCHARGE FROM ACUTE CARE: A TELEPHONE FOLLOW-UP PILOT SURVEY

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Background Transitions of care are risky periods for development of medication-related problems. The authors aimed to identify any problems experienced by patients following an admission to the hospital's Acute Medical Unit and to pilot discharge telephony follow-up. Pharmacist from NHS Direct (our partner for the project) conducted follow-up interviews with selected patients after discharge using their inhouse systems which are set up nationally to handle calls 24 h a day about any health-related matters.
Purpose To describe and quantify medication-related problems in a sample of patients discharged from hospital.
Materials and methods Eligible patients were short-stay admissions (<3 days) to the Acute Medical Unit of the Chelsea and Westminster Hospital. Consented patients had their discharge summary relayed to NHS Direct, who then administered a structured telephone survey 3 weeks after discharge. The pharmacist categorised and attempted to remedy any problems identified. The categories were possible side effects; concordance/compliance; difficulties with packaging; misunderstanding/misinterpretation of directions; other. Responses were fed back to the project team and assessment was made of the potential for harm from their medicines.
Results 54 patients were initially consented; 34 were contacted and 7 were removed from analysis. 20 medication-related problems were identified in 12 patients (44.4%): five potential side effects; five problems with taking medication and four felt that their medication did not suit them. NHS Direct identified one other medication-related problem and three patients received counselling for other medication issues. Only one problem was considered potentially harmful. 19 (70.4%) found the call to be helpful and 25 (88.9%) would like to have a similar follow-up call if admitted to hospital again.
Conclusions Nearly half our cohort was reported to be experiencing medication-related problems, though a low level of potential harm was found. Many patients initially recruited were not able to be contacted by phone. This suggests that although acceptable to those patients who were contacted, before the service can be offered widely methods for targeting need to be explored further.

Competing interests None.

GRP073 HAEMOGLOBIN LEVELS IN PATIENTS WITH ANAEMIA ASSOCIATED WITH CHRONIC RENAL FAILURE IN PREDIALYSIS, TREATED WITH SUBCUTANEOUS ERYTHROPOIETIN

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Background It is necessary to monitor the effect of erythropoietin (EPO) on haemoglobin (Hb) levels to check the efficacy and safety of the medicine. The desirable therapeutic range of Hb according to the product information is from 10 to 12 g/dl and higher or lower levels can damage health. The tolerance, clinical need and urgency required in the resolution of the anaemia varies among patients, however, Hb ≥13 g/dl is associated with cardiovascular events such as thromboembolism, requiring urgent care.
Purpose To determine the proportion of patients with anaemia linked to chronic renal failure in predialysis treated with EPO, with a value of Hb within or outside (lower or higher than) the therapeutic range.
Materials and methods A retrospective study was performed of 155 nephrology patients who collect erythropoietin at the outpatient unit of the hospital pharmacy; duration 1 month. All of them had anaemia associated with chronic renal failure in predialysis and were treated with subcutaneous erythropoietin for at least 4 weeks. The outpatient dispensing program compiles items dispensed per patient, with dates, age, sex, medical record number, diagnosis, amount collected, dosage, department/ward and prescribing physician The last Hb value was obtained for the computerised medical history records and the proportion of patients below and above the therapeutic range was estimated.
Results 139 patients, 61 women (43.9%) and 78 men (56.1%), between 21 and 101 years (mean 68.6). 48.9% (68) of the patients had an Hb within the therapeutic range (mean 11). 22.3% (31) had Hb less than 10 g/dl (mean 9.2 and minimum 6) while in 28.8% (40) it was greater than 12 (mean 13.2 and maximum 15.4).
Conclusions 71 patients (51%) had Hb outside the therapeutic range. It is necessary to monitor the haemoglobin levels to check the safety and efficacy of erythropoietin. It is essential to include all episodes and data in the computerised medical history.

Competing interests None.

GRP074 POTENTIAL HOSPITAL PHARMACISTS' INTERVENTIONS IN ANTIBACTERIAL STEWARDSHIP

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Background Antibacterial consumption has been associated with an increase in the growth of resistant bacterial strains. Hospital Pharmacists play an important role in antimicrobial stewardship strategies, by improving compliance with anti-infective prescribing recommendations.
Purpose To identify real-world situations in which pharmacists can intervene to improve antibacterial patterns of use in Hospital da Luz, Lisbon, Portugal.
Materials and methods Retrospective audit study. All courses of antibacterials for systemic use (therapeutic class J01), prescribed in patients over 18 years-old admitted to Hospital da Luz during January 2011, were extracted from the electronic medical records and analysed. Descriptive statistics were performed.
Results A total of 913 patients were admitted to hospital during the study period, being 81.1% (n=740) prescribed 961 antibacterial courses. Surgical prophylaxis represented 63.7% (n=612) of the courses. The following potential improvement areas were identified:

- In 4.9% (n=47) cases the reason for prescription was not identified.
- Prophylaxis duration was longer than 48 h in 2.1% and between 24 and 48 h in 10.8% courses. A clear distinction between antibacterials prescribed for prophylaxis and therapy was found, except for second-generation cephalosporins (78.3% vs 21.7%), quinolones (24.6% vs 75.4%), and imidazole derivatives (57.1% vs 42.9%).
- Only 3.8% (n=12) of the 349 non-surgical prophylactic and therapeutic antibacterial prescriptions were discontinued after microbiological identification and/or antibiotic susceptibility test results. Parenteral administration represented 73.9% (n=258) of these 349 courses, whereas only 8.4% (n=20) were discontinued due to intravenous-to-oral switch.

Conclusions After an indepth audit process, the following opportunities for pharmacists' interventions to improve the antibacterial pattern of use in our hospital were identified: unclear prescription indication, inappropriate extension of surgical prophylaxis duration, inappropriate selection of the prophylactic antibacterial agent, insufficient microbiological identification follow-up, and scarce intravenous-to-oral switch.

Competing interests None.

GRP075 PHARMACEUTICAL INTERVENTION ASSESSMENT IN CRITICALLY ILL PATIENTS

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Background Patients admitted to the intensive care unit (ICU) are exposed to medication errors twice as compared to other hospital units. Pharmaceutical care in critically ill patients may increase the quality of patient care by reducing medication errors.
Purpose To assess the impact of pharmaceutical interventions (PI) on the health of patients admitted to an intensive care unit.
Materials and methods Study to evaluate PI in patients admitted to an ICU with electronic prescribing. Were obtained from medical records data on age, gender, APACHE-II score at admission. The authors defined the impact of PI such as the presence of negative results, positive or no change in the patient's health, potentially avoided by PI and assessed by the rating scale proposed by Overhage *et al*.[1] The medication error detected with PI undertaken provides the clinical relevance of the intervention, the reason for the intervention preceded the detection of a medication error, measured by classifying Overhage *et al*. modified[2]
Results 25 patients were included, 19 were men, mean age 53.88±16.69 years. 68% of patients had a APACHE-II score less than 10. A total of 35 PI, 1.4 interventions / patient. 71% of the PI made were accepted. In terms of assessing the impact of PI by the rating scale proposed by Overhage *et al*[1], 8.57% were extremely significant (PI avoids a situation that potentially generate extremely serious consequences), 40% very significant (PI prevents actual or potential damage a vital organ), significant 8.57%(PI leads to better patient care), 28.57% something significant (the benefit of the patient is neutral), 14.29% non-significant(only general information or recommendations, not individualised per patient). The clinical relevance of the PI

measured by classifying Overhage *et al* modified[2] was: 5.71% could avoid death (medical error has high potential to produce adverse effects that threaten the patient's life), serious 24.71% (dose of 4 to 10 times higher than normal in a narrow therapeutic index drugs, doses can lead to potentially toxic concentrations...), 28.57% significant lower 31.43%(doses too low for the patient's condition, inappropriate dosage range...), 8.57% absence of error (clarification of the medical order, economic savings).

Conclusions The impact of PI evaluated was mostly significant. Half of the PI had a significant or serious clinical relevance. The authors did not perform any action detrimental to the patient.

Competing interests None.

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GRP076 DURATION AND REASONS FOR CHANGING THE FIRST ANTIRETROVIRAL THERAPY: AN 8-YEAR FOLLOW-UP

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Background Failure of first highly active antiretroviral therapy (HAART) reduces both the duration and the chances of viral control in subsequent regimens, due to cross-resistance and common toxicity between and within classes of antiretroviral drugs.

Purpose To measure the duration of the first HAART prescribed in a population of HIV infected patients and to address factors leading to therapy changes.

Materials and methods Retrospective, observational study which included HIV-infected patients over 18 with no previous HAART and who started their therapy in a regional hospital between 1 January 2003 and 31 December 2008. The follow-up lasted until 31 December 2010. A descriptive analysis was performed and Kaplan–Meier curves were used to assess the duration of the first HAART.

Results 58 patients started a HAART and only in 12 of them (20.58%) no changes had been performed by the end of the study period. Median time until first change of HAART was 509 days, up to 721 days if cases of treatment simplification were excluded from the analysis. Treatment-related adverse events were the main cause for switching therapy (24.14%), followed by treatment simplification (21.42%), and voluntary withdrawal (7%). Immunological, virological or clinical failures were linked to change in only three cases. Most frequent adverse reactions were dyslipidaemia (35.7%), hepatotoxicity (21.4%), and digestive intolerance (14.3%). Study subjects received 18 different initial HAART regimes; most of them (n=32, 55%) started a protease inhibitor-based HAART, followed by non-nucleoside reverse transcriptase inhibitor-based regimen (n=22, 38%) and therapy with three nucleoside reverse transcriptase inhibitors (n=4, 7%). **Conclusions** Duration of the first HAART remains short, especially considering it is supposed to be the longest therapy, since, currently, this treatment is expected to be chronic. Adverse events are the main cause of withdrawal, so their prevention and mitigation should be one of the cornerstones of our activity as pharmacists.

Competing interests None.

GRP077 VARIATIONS BETWEEN PHARMACIST- AND DOCTOR-OBTAINED MEDICATION HISTORIES AND THEIR POTENTIAL SIGNIFICANCE

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Background NICE recommends that pharmacists be involved in obtaining medication histories.[1] Previous studies have shown variations between the medication histories obtained by pharmacists and doctors.[2 3]

Purpose This study aimed to compare the medication histories obtained by both professionals, assess the extent of any variations found and grade their potential clinical significance.

Materials and methods Unintentional variations between pharmacist- and doctor-obtained medication histories were independently assessed by a consultant and clinical pharmacist for their potential to cause patient harm, using the National Co-ordinating Council for Medication Error Reporting and Prevention index. The relationship between variables was investigated using Mann–Whitney U and Kruskal–Wallis Tests.

Results Unintentional variations were identified in the medication histories of 63% of patients. Variations included: drug omission (72%), different dose (17%), different frequency (7%), drug commission (3%) and dose omission (0.7%). 13 patients had >4 unintentional variations. The mean number of medicines being taken was 7, while the mean number of unintentional variations was 3.4. A significant positive correlation was found between the number of medications being taken and the number of unintentional variations. No significant difference in the number of variations per patient across either the different grades or specialties of doctors was found. Up to 13% of variations had the potential to cause patient harm.

Conclusions The study confirms the results of other research which showed that a pharmacist takes more complete medication histories compared to doctors. A more multidisciplinary approach should be taken when admitting patients; this should involve a pharmacist to obtain medication histories. The emergency department is the ideal setting to undertake this process as the maximum impact of involving a pharmacist could be delivered at this early stage of the patient journey.

Competing interests None.

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GRP078 REDUCING MEDICATION ERRORS USING THE PATIENT'S OWN DRUG (POD) SYSTEM AND AN INTEGRATED DISCHARGE PRESCRIPTION (IDP)

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Background Over 50% of all medication errors and 20% of harmful errors occur due to poor communication of information at the interfaces of care.

Purpose To reduce the risk of medication errors on admission and discharge and improve patient safety.

Materials and methods An observational study involving patients admitted and discharged from two surgical wards. 38 patients taking three or more regular medications whose hospital stay exceeded 48 h were selected for each group. Patients enrolled in the control groups received routine pharmacy

service. Patients in the intervention group were enrolled in the POD system and received an IDP on discharge. The POD system involved patients bringing in and using their own medication throughout their stay providing a more accurate medication history. An international index was used for categorising the severity of all errors.

Results Medication errors on admission: 61% of patients in the control group versus 23% of patients in the intervention group; The severity of medication errors in the control group ranged from a minor to severe. Medication errors on discharge: 71% of patients in the control group versus 5% of patients in the intervention group. Errors identified in the control group ranged from minor to severe. Errors in the admission and discharge intervention group were rated as minor. In general: A 68% reduction in medication errors at admission and a 93% reduction in medication errors at discharge were achieved in this study. The mean difference in medication errors between the groups was statistically significant using the unpaired t-test.

Conclusions The study demonstrated that quality improvement procedures such as the POD system and IDP showed a significant reduction in medication errors. The POD system is now routinely used throughout the hospital with plans for the IDP to be used next year.

Competing interests None.

GRP079 PRESCRIBING ERROR REPORTING AND PHARMACIST ORIENTED PREVENTION PROGRAM IN EMERGENCY DEPARTMENT

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Background Due to the nature of emergency department, quantity of medicine used and starting of a newly established emergency medicine residency program in our hospital it was decided to use clinical pharmacist interventions to protect patients from adverse drug events.

Purpose To assess clinical pharmacist intervention impact on reduction of medication errors.

Materials and methods Retrospective evaluation orders of emergency medicine residents from October 2010 to January 2011 were done. The frequency of prescription errors determined by a clinical pharmacist based on patients medical records. Subsequently, weekly educational sessions on prescribing for emergency medicine residents conducted by a clinical pharmacist. Recording errors continued for 4 months period prospectively and statistical analyses compared the results before and after interventions.

Results In a retrospective study The authors evaluated 5320 prescription with total number of 22346 medication ordered. Results indicated 4941(22.1%) ordering errors. After clinical pharmacist intervention the rate diminished significantly to (5.6%) 1276 errors in 5602 prescriptions (22743 medication orders) (P<0.01). Inappropriate drug choice (23%), improper dose(21%), inaccurate dosing interval(19%), drug interactions(16%), misdiagnosis(14%), choosing wrong dosage form(4%), and improper route of administration(3%) were errors before clinical pharmacist interventions. The most frequent errors after intervention were inappropriate drug choice (20%), and drug interactions (18.5%). The rate of other kind of errors were in this order: misdiagnosis (18%), improper dose (18%), inaccurate dosing interval (15.5%), choosing wrong dosage form (6%), and improper route of administration (4%). Inaccurate dosing interval decreased more than other prescribing errors with pharmacist intervention (from 939 to 198 errors).

Conclusions The results show that reduction in prescribing errors was significant after pharmacist intervention. Monitoring of orders and drug therapy education of the physicians seems to be a substantial factor in hospitals which lead to patient safety and rational drug use.

Competing interests None.

GRP080 DEVELOPMENT OF QUALITY OF CARE INTERVENTIONS FOR ADULT BENIGN PATIENTS ON HOME PARENTERAL NUTRITION (HPN). (SUBTITLE) RESULTS OF A TWO-ROUND DELPHI APPROACH

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Background HPN patients deserve professional care as they have to deal with difficult techniques and risk potentially dangerous complications.

Competing interests Ownership Dreesen Mira Advisory board: unrestricted educational grant of the company Baxter.

GRP081 EXCESS DOSING AND BLEEDING EVENTS IN PATIENTS TREATED WITH ABCIXIMAB IN ACUTE CORONARY SYNDROMES

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Background Abciximab (ABX) is indicated as an adjunctive to percutaneous coronary intervention in patients with acute coronary syndrome (ACS). It is considered a high-alert medicine with heightened risk of causing significant patient harm when used in error. Evidence-based guidelines recommend an intravenous administration of a 0.25 mg/kg bolus dose followed by continuous infusion of a weight-adjusted infusion of 0.125 mcg/kg/min (<80 kg) to a maximum of 10 mcg/min for 12 h (≥80 Kg).

Purpose The purpose of this study was to investigate dosing of ABX and its association with bleeding events in patients with ACS.

Materials and methods A retrospective chart review was performed in all patients hospitalised between January and July 2010 at our hospital. Inclusion criteria were: patients >18 years of age, diagnosed with ACS and treated with ABX during their hospitalisation. A database was designed to record patient demographics (age, sex) weight, loading dose, maintenance dose, duration of prescribed ABX and bleeding events.

Results 73 patients diagnosed with ACS were treated with ABX. Median age was 65 (55–73) years old and 78.1% were male. 24.7% of patients were not weighed before ABX administration. All patients who received ABX infusion were treated with a fixed, body weight-independent, dose of 10 mcg/min infused for 12 h (maximum dose) meaning that 28.8% of

patients received an overdose of ABX. 66.7% of them developed a bleeding event compared with 32.8% of patients receiving the correct dose (p=0.016).
Conclusions Overdose of ABX seems to be associated with high risk of developing bleeding events in patients with ACS. Some new procedures have been brought in such as hoists with weighing scales and a table made available containing the appropriate dose and infusion rate for each weight. These facilities could be perfectly applicable to other hospitals. Further analysis should be carried out to determine the effect of other potential risk factors.

Competing interests None.

GRP082 DRUG INTERACTIONS: DETECTION AND PHARMACEUTICAL INTERVENTIONS IN AN OUTPATIENTS UNIT

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10.1136/ejhpharm-2012-000074.82

Background In the pharmacy there is a unit where certain drugs are dispensed to outpatients. Pharmacists provide pharmaceutical care to all patients starting new treatment.
Purpose 1) To identify and classify drug interactions (DIs) in all patients starting any treatment in the outpatient unit of our hospital pharmacy. 2) To carry out pharmaceutical interventions. 3) To identify patients who suffer more frequently from DIs.
Materials and methods Prospective intervention study (January–May 2011) that included patients who started treatment at the outpatient unit of the hospital pharmacy. Data were obtained from the medical prescription and an interview with the patient. To detect and classify DIs the authors used the software 'Lexi-Interact-Online' and the book 'Stockley, Drug Interactions. Third Edition (2009). Data were analysed with SPSS-15.0.
Results Data collection comprised results from 104 patients (39 women, 65 men). Median age 53. SD 20 years (18–92). 187 DIs were detected (incidence 50.96%). 10.16% of the interactions occurred between drugs dispensed in hospital and concomitant home medicines (CHMs). 89.83% of the interactions detected were CHM-CHM. The risk of DI was rated as 'major' (14.43%), 'moderate' (79.14%) and 'minor' (6.43%). The reliability of the DI was 'excellent' (6.95%), 'good' (32.08%), 'reasonable' (57.75%) and 'poor' (3.22%). The mechanisms by which the DI developed were 'pharmacokinetic' (50.26%), 'pharmacodynamic' (35.82%), 'unknown' (12.3%), 'other' (1.09%) and 'mixed pharmacokinetic/pharmacodynamic' (0.53%). 38.46% of patients were polymedicated (≥6 drug). In these patients DI incidence was 87.70% versus a single drug in which DI was 12.3%. Pharmaceutical interventions were: monitoring DI from the outpatient unit in the pharmacy (10.6%), informing doctors (45.45%), advising on administration (31.81%), informing/educating patients (11.36%). Causes of non-intervention: habitual association/DI clinically irrelevant (51.93%), DI beneficial (25.12%), literature reports that there is no action required (12.59%), others (10.38%).
Conclusions 1) The appearance of DIs in patients starting treatment in the outpatient units is common. CHMs should also be reviewed to detect DIs. 2) Every DI must be assessed individually and appropriate pharmaceutical interventions made. Not all DIs are harmful or clinically relevant. 3) Polymedicated patients are a group of special interest because most of the interactions occur in them.

Competing interests None.

GRP083 UTILITY OF DEFINED DAILY DOSE SYSTEM FOR IDENTIFICATION OF ANTIBACTERIAL POTENTIALLY INAPPROPRIATE PRESCRIBED DOSES

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Background Different measurements to assess antibacterial use in hospitals have been described, many of them based on the WHO Defined Daily Dose (DDD) assignments. Although WHO accepts the update of DDDs, 'changes of DDDs should be kept to a minimum and avoided as far as possible'.
Purpose To assess the utility of WHO DDD assignments to: a) measure real-world antibacterial utilisation, and b) label prescribed doses as potentially inappropriate.
Materials and methods All courses of antibacterials for systemic use (therapeutic class J01) prescribed for therapeutic purpose in patients over 18 years-old and admitted during January 2011 were extracted from the electronic medical records. 'Treatment days' was obtained adding one to the difference between the starting and the ending dates. 'DDDs used' per patient were obtained dividing the dose actually used by the WHO DDD assignments. The ratio 'DDD used'/'treatment days' was calculated. Outliers for this ratio were estimated by the IQR rule.
Results A total of 349 antibacterial courses were analysed comprising 1761.79 DDD, and representing 33.8 DDD/100 beds/day. Mean ratio 'DDD used'/'treatment days' was 1.29 (SD=0.76) (range 0.16 to 7.69). This ratio was below one only for penicillins, sulfonamides and lincosamides (doses used were higher than the DDD assignments). IQR for the 'DDD used'/'treatment days' ratio was above two for sulfonamides (IQR=2.53) and glycopeptides (IQR=2.09), identifying them as the two classes where WHO DDD assignments are more deviated from the clinical practice in our hospital. Sixteen extreme (>IQR×3) and 12 mild (>IRQ×1.5) outliers were identified, representing potential inappropriate prescriptions.
Conclusions Except for sulfonamides and glycopeptides, WHO DDD assignments could be used as an alert-generating system for potentially inappropriate antibacterial prescribed doses in our hospital by identifying the outlier prescribed doses. Further analysis is required to exclude a potential systematic inappropriate dosing for these two classes.

Competing interests None.

GRP084 DETECTION OF ADVERSE DRUG REACTIONS BY MONITORING ANALYTICAL PARAMETERS

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Background Alterations in laboratory parameters can be associated with adverse drug reactions (ADRs). Therefore, monitoring parameters may enable early detection and treatment of ADRs.
Purpose To assess the association between laboratory parameters and ADRs in Internal Medicine at a tertiary hospital.
Materials and methods Prospective observational study of hospitalised patients in a section of internal medicine

department during February and March 2011. Every day, a pharmacist recorded drug prescriptions and the following parameters: Na, K, Ca, serum creatinine, glomerular filtration rate (GFR), INR, glucose, haemoglobin, platelets, ALT, AST, bilirubin, GGT, alkaline phosphatase, TSH, T4 and blood digoxin. The causal association between parameters outside the reference range and drugs was analysed using the modified Karch–Lasagna scale.

Results 52 patients (65.4% men) were included; median age 74 years; median hospital stay 7 days. A mean of 2.94 parameters per patient were outside the reference range. An association with drugs was observed in 25.5% of patients. Reduction in GFR, 27.0% (associated with diuretics (41.7%), ACE inhibitors (33.3%), angiotensin II receptor blockers (ARB) (16.6%) and antidiabetics drugs (8.3%)); hypokalaemia, 22.6% (associated with diuretics (50.0%), fluid without potassium (37.5%) and salbutamol (12.5%)); hyperkalaemia, 14.5% (associated with ACE inhibitors (60.0%) and ARB (40.0%)); INR out of range, 10.8% (associated with interactions (66.7%)); hyperglycaemia, 8.4% (associated with corticosteroid (66.7%) and antidiabetic drugs (33.3%)); low blood digoxin during admission, 5.3%; and others, 10.8%. No ADRs led to prolonged hospital stay. In terms of causality, ADRs were classed as possible (52.9%), probable (44.1%) and definite (2.9%).

Conclusions 25.5% of alterations in laboratory parameters were probably or possibly associated with drugs. The most common alterations were as follows: decrease in GFR associated with the use of diuretics, ACE inhibitors and ARB; hypokalaemia due to diuretics; and hyperkalaemia due to ACE inhibitors and ARB. There were no severe ADRs, as these were detected early.

Competing interests None.

GRP085 DRUG-DRUG INTERACTIONS IN PATIENTS ADMITTED TO AN INFECTIOUS DISEASES UNIT IN A TRAUMA HOSPITAL

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10.1136/ejhpharm-2012-000074.85

Background The current complexity of pharmacotherapy in patients with orthopaedic infections increases the risk of drug-drug interactions (DDI).

Purpose The aim of this study is to identify potential DDI (severe/moderate) and its clinical relevance in patients admitted to the infectious diseases unit (IDU) in a tertiary trauma hospital. **Materials and methods** Prospective observational study performed from January 2011 to April 2011 (100 days) in patients admitted to IDU for at least 7 days. The following variables were recorded for each patient from the database of the pharmacy: sex, age and pharmacology treatment during hospital stay.

The laboratory product information and a Spanish DDI database (Medinteract NR) were used to determine potential DDI.

Results The study included 35 patients (25 men and 10 women) with a mean of age of 53 years (range 20–82), an average hospital stay of 21.9 days (range 7–64) and 12.8 drugs per patient. The authors detected 151 potential DDI (21 severe, 130 moderate) in 33 of 35 patients (mean of potential DDI of 4.6 per patient). The most frequent of potentially hazardous associations were: paracetamol/dexketoprofen: 14 cases; rifampicin/paracetamol: 12 cases; dexketoprofen/enoxaparin: 8 cases; insulin/co-trimoxazole: 5 cases; daptomycin/simvastatin: 4 cases, being that one considered a potentially severe DDI. The authors observed one serious DDI with clinical relevance: thrombocytopaenia in a patient treated with leflunomide and metamizole, which was solved by stopping the treatment, and two cases of badly controlled pain in patients treated with rifampicin and paracetamol.

Conclusions The incidence of potential DDI was very high, but only three of them had actual effects on the patient, being just one severe. This is probably due to the proactive role of the pharmacist when is carrying out the validation of the doctor's prescription using an electronic prescribing program. The integration of clinical pharmacist in IDU facilitates prevention and detection of DDI and its complications. It would be recommended to implement computer software for early detection of DDI to notify to the physician these potentially hazardous associations at the time of prescribing.

Competing interests None.

GRP086 TRAINING OF SPANISH STERILE PREPARATIONS TECHNICIANS WORKING IN HOSPITAL PHARMACY: COMPARISON WITH THE REQUIREMENTS OF THE AMERICAN PHARMACOPEA (USP)

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Background The Spanish law indicates that sterile preparations technicians must have a minimum level of education. However, the requirements demanded by the USP are stricter than Spanish law, and, in some ways, stricter than GMP.

Purpose To evaluate the level of training of sterile preparations technicians in Spanish pharmacy services, and compare with the requirements of the USP. Second, to evaluate the level of implementation of other measures assumed by the USP.

Materials and methods The authors conducted a telephone survey with 15 multiple choice questions on the type of hospital, staff responsible for the different preparations (parenteral nutrition (PN), cytostatics (CIT), intravenous mixtures (IVMs), other sterile products (SPs) etc.). The type of training required of personnel to handle these products was investigated. In addition environmental monitoring was evaluated and operator aseptic technique was validated microbiologically. The hospitals surveyed were selected choosing at least one hospital with over 500 beds, and one of fewer than 500 beds from each region.

Results 31 hospitals responded to the survey (three of <100 beds, nine of 100–200 beds, 10 of 200–500 beds, eight of 500–1000 beds, and 1>1000 beds). In most, sterile preparation was performed by nurses (55% of hospitals with PN, 71% hospitals with CIT, 48% hospitals with IVM and 41% of other SPs). The experience of staff assigned to the preparation of sterile products was in all cases greater than 6 months. Only eight hospitals (26%) had an initial training plan. Other aspects covered by the USP, such as environmental control and microbiological control, were performed by 86% of hospitals surveyed. However the aseptic technique was only validated in three hospitals

Conclusions Nurses with more than 6 months experience are responsible for handling sterile preparations in most pharmacy services in Spanish hospitals. The majority of pharmacy services performed microbiological and environmental monitoring on the finished products. However, other aspects related

to the quality of preparation and patient safety such as the accreditation of operator aseptic technique, were almost negligible, which is a clear opportunity for improvement.

Competing interests None.

GRP087 CHANGE OF DOSE OF LENALIDOMIDE IN RELATION TO RENAL FUNCTION: FOLLOWING THE SPC

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Background Lenalidomide was authorised in 2007 by EMA for treatment of multiple myeloma (MM) and is also used for myelodysplastic syndrome (MS) off label. Since lenalidomide is mainly excreted through the urine, renal function monitoring and dose adjustments are required in renal impairment.
Purpose To evaluate modifications in the renal function (RF) in patients with MM and MS and to assess lenalidomide dose modifications in relation to changes in renal clearance as recommended in the summary of product characteristics (SPC).
Materials and methods Observational retrospective study of treatments started in the period between May 2008 and September 2010. RF was classed in four groups: normal (NRF, ClCr: >50 ml/min), moderate worsening (MWRF, ClCr=30–50 ml/min), serious worsening (SWRF, ClCr<30 ml/min without dialysis) and terminal (TRF, ClCr <30 ml/min with dialysis). The lenalidomide SPC recommends dose modifications for the three latter classes.
Results Sixteen patients were found, 14 treated for MM and 2 MS. Male/female ratio was 1:1 and median age 68.3 years (CI 95% 63.1 to 73.4). A total of 98 cycles were administrated, with a median of six cycles per patient (2–21). Renal function was normal in 40 patient cycles, but dose modifications were made in 36.3% due to other adverse effects. Renal function was moderately worse in 49 cycles; dose reduction and spacing out were the most frequent adjustments made (18.4% each one), and no modification was made in 53.1% of cycles. TRF appeared in eight cycles, no adjustment was made in three, the dose was reduced and the interval increased in two (as the SPC recommends) and other modifications were made in three. Dialysis was not needed in any case.
Conclusions As renal damage is often present in multiple myeloma patients (most of our study population), it is vital to monitor kidney function to adjust doses of renally-cleared drugs such as lenalidomide. Despite this, half of the doses that might have been adjusted, were not modified. This would be a potential intervention point for the hospital pharmacist, in order to improve patient safety.

Competing interests None.

GRP088 A PHARMACOVIGILANCE PROJECT IN 'SAN GIOVANNI DI DIO E RUGGI D'ARAGONA' – SALERNO UNIVERSITY HOSPITAL (ITALY): HOSPITAL PHARMACIST IN DEPARTMENT INCREASES PHARMACOVIGILANCE ACTIVITY

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10.1136/ejhpharm-2012-000074.88

Background 'MEREAFaPS Project' is a pharmacovigilance project started in Italy in 2006 with the aim of introduce pharmacists in Emergency Division to collect data on adverse drug reactions (ADR) admissions. In April 2010, Salerno University Hospital joined 'MEREAFaPS Project': a pharmacist reports and supports physician to indentify ADR in Emergency Division.
Purpose The aim of the study is to know if the presence of pharmacist in a department contributes to increase quality and quantity of pharmacovigilance activity.
Materials and methods ADR report forms made in the first 9 months of the project (April-December 2010) were analysed. Some key principles of them were collected: sex; suspected drug which caused reaction and other drugs took in association; description of ADR and their classification in severe, non-severe, life-threatening. They were compared with ADR data of 2009. **Results** 86 forms were analysed, each related to one different patient: 58 patients were woman (67%). 47% of the events were connected to antibiotics, as amoxicillin/clavulanic acid (16 cases), penicillin (13 cases), cephalosporins (11 cases); 35% interested anti-inflammatory as nimesulide (21% of these), propionic acid derivatives (21%), acetylsalicylic acid (14%), ketorolac (11%), steroidal anti-inflammatory (7%). 48 patients didn't take other drugs, but 38 took another one. Skin reactions were 49% of events, while 12% were cardiovascular events, 12% gastrointestinal problems, and 10% were respiratory reactions. ADR not severe were 72%; 28% were severe and 1 case life-threatening. Before the project, in 2009 there was only one ADR report; zero in period January–March 2010.
Conclusions It is evident that the presence of pharmacist in emergency division is an useful tool to increase the number of ADR reports: data confirms that a pharmacist who supports medical staff to signalling ADR should be operative in all hospital departments. However it is necessary an additional analysis on drugs dosages, cases that took another drugs, and their correlation with ADR.

Competing interests None.

GRP089 TIGECYCLINE PRESCRIBING IN SALERNO UNIVERSITY HOSPITAL: SPECIAL FORMS AND MONITORING PREVENT INAPPROPRIATE USE

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10.1136/ejhpharm-2012-000074.89

Background Antibiotic resistance is an emerging and alarming problem in the European Union, considering the high clinical and socio-economic costs, and confirms the widespread inappropriate use of antibiotics. Tigecycline is a semisynthetic glycylcycline bacteriostatic that received approval for the treatment of skin, soft-tissue and intra-abdominal infections. Tigecycline operates by binding the bacterial 30S ribosomal subunit and it is highly active against a wide range of clinically important Gram-positive and Gram-negative aerobic bacteria and anaerobes.
Purpose The aim of this study was to evaluate tigecycline prescribing in Salerno University Hospital by analysis of the special forms introduced in 2010 to limit the inappropriate use of this antibiotic.
Materials and methods The hospital pharmacy supplies tigecycline on receipt of a completed antibiotic monitoring form. Forms from 2010 were retrospectively assessed for appropriate prescribing, adherence to permitted indications and length

of treatment. The monitoring form contains patient details in one section and another part relates to diagnosis, site of the infection and the main reason for tigecycline use. A discussion with a microbiologist or infectious diseases physician is required when tigecycline is not prescribed for its permitted indications. The 2010 data were compared with data from 2009, when a non-specific antibiotic form was used.

Results A total of 220 requests were received in 2010. Intensive care unit (38%), infectious diseases unit (21%), general surgery division (10%) and emergency surgery division (20%) made the highest number of requests for tigecycline; 11 were incomplete. Many gaps (20%) were observed in the diagnosis and period of treatment fields. A pharmacist discussed the off-label use of tigecycline with a microbiologist in seven cases. These results, compared with the 2009 data, showed a general reduction of 30% in inappropriate requests for, and use of, tigecycline.

Conclusions A tigecycline-specific form is an effective tool of clinical governance with which hospital pharmacists can control and decrease the risk of inappropriate antibiotic treatment and development of resistance. The reduction in inappropriate requests confirms this, but the gaps in diagnosis and length of treatment data suggest physicians need more education on the correct use of the form. Moreover this monitoring form could contribute to containing the pharmaceutical costs and it should be extended to other expensive drugs used inappropriately in the hospital.

Competing interests None.

GRP090 THERAPEUTIC TARGET IN PATIENTS WITH DEMENTIA†

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Background In order to reach reasonable therapeutic objectives among geriatric patients, the proper use of the Beers and STOPP-START criteria should be maximised.

Purpose To evaluate optimisation of the use of medicines in patients prescribed antidementia drugs.

Materials and methods The study population included patients who had been diagnosed with dementia, which was defined as patients prescribed ATC N06D medicines. Outpatient pharmacological hospital profiles were reviewed at the time of admission to identify patients who might benefit from patient-centred interventions. Clinical judgement was used to detect potentially inappropriate prescriptions among these patients.

Results Over 1 year (2010), 93 individuals (average age 81.9±3.8 years) were evaluated and prescribed a mean of 8.7±3.7 medicines. Antidementia medicines were documented as follows: 33 (35%) patients were prescribed galantamine, 31 (32%) memantine, 16 (17%) rivastigmine and 15 (16%) donepezil. Eight patients were given memantine in addition to one of the others. In practice, patients with advanced disease are often prescribed additional medicines. In this study, 39 (42%) were prescribed neuroleptics, 45 (48%) antidepressants and 44 (47%) anxiolytics. All three classes were used in combination in 6 (6%) patients, and 17 (18%) were prescribed a two-drug combination of either anxiolytic/antidepressant or anxiolytic/neuroleptic. Four patients in our study were identified as candidates for changing the antidepressant treatment to drugs with a lower anticholinergic potential. Lipid-lowering medicines were prescribed in 32 (34%) patients. This class of drugs may not be warranted for patients diagnosed with dementia, as long-term benefit has not been fully demonstrated. Additionally, five patients were prescribed medicines from the N06BX nootropics and C04AE ergot alkaloids ATC classification; there is have little evidence to support the use of these drugs.

Conclusions By increasing access to therapeutic resources, providers can improve medicines selection and monitoring in patients with complex disease states. As this study demonstrates, future focus is warranted to improve the care of patients with dementia by identifying therapy optimisation strategies.

Competing interests None.

GRP091 PROTOCOL FOR THE CONTROL AND RATIONALISATION OF THE USE OF ALBUMIN IN AVELLINO

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Background Albumin is an essential plasma protein for the regulation of the oncotic pressure. The huge divide between scientific theory and its clinical application has repeatedly limited the control and the effort to rationalise its use. In 2009, our hospital board established a private operational unit of control (N.O.C.), which aimed to regulate prescribing. The evaluation of the appropriateness of the use of albumin produced results that highlighted its inappropriate use. The initial analysis showed that 80% of the prescriptions were incorrect and 30% mentioned an incorrect 'indication'.

Purpose To establish a pathway rationalising the use of albumin in order to spread awareness of the correct use of such a precious substance and reduce its inappropriate use.

Materials and methods The first part of our research evaluated the use of albumin to the extent where the authors could emphasise its inappropriateness. In the second stage of our research The authors analysed several scientific publications and, in collaboration with N.O.C.'s clinics and members, the authors developed a protocol to guide the correct use of albumin. Consequently, The authors also produced a system for requesting human albumin that helps the clinician in charge to choose more appropriate indications.

Results Since this new model has been introduced, the use of albumin has decreased and its off-label use has been sharply reduced. In 2009, about 80% of 4000 prescriptions contained errors. In particular, 30% of the total prescriptions were off-label for their indication, while 24% did not report for the values of albumin required for the calculation of the administered dose. However in 2010 only 10% of the requests had an off-label indication.

Conclusions The new model produced by the hospital board in Azienda Ospedaliera San Giuseppe Moscati, Avellino has successfully abolished the off-label use of albumin and rationalised its use.

Competing interests None.

GRP092 DRUG POISONING: A REASON FOR CARE IN A HOSPITAL EMERGENCIES UNIT

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Background Intoxication by drugs requires often quick attention in the emergency department (ED), so an antidote kit to combat drug intoxication would be helpful.

Purpose To analyse intoxication by drugs treated in the emergency department as a preliminary step to making up an antidote kit.
Materials and methods All patients treated in ED for drug intoxication in a Spanish hospital were included, from January to June 2010. Data collected were: sex, age, cause, measures, days of stay in ED, admission, ward, duration of admission, complications.
Results Data from 137 patients were analysed, 79 females (57.7%), median (minimum-maximum) age was 37 (92–0) years. 77 patients (56.2%) were intoxicated by drugs affecting the central nervous system, 19 (13.9%) by analgesic/anti-inflammatory drugs, 11 (8.0%) by cardiovascular system drugs, 5 (3.6%) by systemic endocrine drugs and the drug(s) involved were unknown in 21 (15.3%) of cases. In 20.4% the intoxication was due to several drugs. 65.0% needed drug-specific treatment. Gastric lavage was necessary in 29.9%. In addition, activated charcoal was administered in 32.1%, flumazenil in 25.5%, naloxone in 4.4% and N-acetylcysteine in 4.4%. Other drugs used were norepinephrine, digoxin-specific antibody (Fab) fragments, a potassium chelator, antiemetics, blood coagulation factors and anticholinergics. The median stay in ED was 1 (0–2) day. 27 patients (19.7%) were admitted and 2 (1.5%) requested voluntary discharge. Of the inpatients, 26.9% were to the psychiatry ward, 19.2% to the critical care unit, cardiology and internal medicine wards, and 15.4% to the paediatric ward. The stay in hospital was 6 (17–0) days. Seven patients had complications related to intoxication (three acute kidney injury, two rhabdomyolysis, two aspiration pneumonia) but none of them died.
Conclusions The analysis of intoxications treated in ED will guide the contents of the antidote kit. It is important to increase the control of drugs that affect the central nervous system.

Competing interests None.

GRP093

IMPLEMENTATION OF A PHARMACEUTICAL CARE PROCESS IN PATIENTS WITH ANAEMIA AND CHRONIC KIDNEY DISEASE IN TREATMENT WITH ERYTHROPOIESIS STIMULATING FACTORS

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Background The authors have implemented a process of pharmaceutical care in the pharmacy hospital in patients with anaemia and chronic kidney disease in predialysis patients in treatment with erythropoiesis stimulating factors (ESF), due to ongoing safety reviews and reports published in the last years.
Purpose Assessing the follow-up of the pharmacy care process.

GRP093 Table 1

Year	2009	2010
Number of patients (Nºp.)	100	79
Nºp. insufficient monitoring of clinical information	31 (31%)	17 (21,5%)
Number of interventions	72	24
Accepted	86% (62)	33% (8)
Rejected	14% (10)	67%(16)
Effective treatment	20	39

GRP093 Table 2

Reasons for intervenning	Number of interventions/year 2009	2010	Recommendations
Hb increases more than 2 g/dl in 4 weeks	9	1	Changing dose or frequency of ESF administration
Hb>12†	29	8	
Hb≥13†	0	3	Discontinuing drug, for safety
Hb<11† to high doses*	34	8	Discontinuing, inefficiency
Beginnings treatment Hb>10†	0	4	Not beginning

*Epoetin α doses>300 units/kg/week or darbepoetin α>1, 5 μg/kg/week.
†Hb levels (g/dl).

Materials and methods The authors have put in place two transverse courts for 7 months in 2009 and 2010, including 100% of sensitive patients. The information was recorded in the Dispensation of Silicon (Grifols) Program. If haemoglobin (Hb) levels were maintained between 10 and 12 g/dl, treatment was considered to be effective.
Results
Conclusions A decrease in the number of patients treated with ESF and the need of interventions was observed. Accepted interventions were fewer also, probably due to an increase in awareness when complying with the recommendations, motivated by the follow-up. It was showed that medical checks were not too close, involving an insufficient monitoring of clinical data and difficulty to establish the effectiveness of many treatments. This data will be reported to nephrology department in order to implement possible solutions.

Competing interests None.

GRP094

PREVENTION OF MEDICATION ERRORS: AN OBSERVATIONAL STUDY

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Background Medication errors represent an important problem of patient safety and have consequences on healthcare services. The authors used an observational national multicentre study to monitor the medicines use process in wards as a tool to control and to prevent these incidents.
Purpose To improve the medicines use process in our tertiary hospital.
Materials and methods The authors first conducted a pre-study to estimate the rate of medication errors in our hospital. In the light of this rate the authors calculated the number of observations required to obtain a representative sample of the population studied. At the same time, The authors checked the prescription validation process in the pharmacy as well as the initial process for prescribing medicines. Then during the months of April–September 2011, the authors performed a prospective, observational, not-disguised study using the modified Barker–McConnell method. The authors observed nurses from when they were preparing patient medicines until administration in the patient's room to detect opportunities for error. The study included all the wards open during this period. Each drug administered to a patient was reported as an observation. Thus, The authors evaluated the complete medicines use process.
Results The authors performed 1167 observations in 297 patients (52.2% were women). The mean age was 72.1 (SD 15.4) (ranges 17–98). 34.1% of patients were over the age of 80. The error rate

was 14.8% (173 errors/1167 observations). The distribution of 173 medication errors detected was as follows: 45.1% omission, 19.6% time error, 8.6% wrong method or administration rate, 6.4% drug not prescribed, 5.7% incorrect dosage (less), 5.2% no nurse checking, 2.3% prescription error and 7.1% others. The most frequently omitted group of drugs was analgesics.

Conclusions The observational method used to monitor drug administration by nurses revealed itself as a good system to study the present state of the medicines use process in the hospital. It helped to identify weak points in the process which should be modified and establish strategies for preventing medication errors and improving patient safety.

Competing interests None.

GRP095 ADHERENCE TO CAPECITABINE CHEMOTHERAPY

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Background Hospital pharmacy departments in Madrid have been required to dispense capecitabine since February 2011 and it represents 38% of prescriptions of oral chemotherapeutics at our hospital. Monitoring adherence may help to prevent treatment failure, avoid adverse effects and reduce the resulting costs.

Purpose The aim of this study was to evaluate adherence to capecitabine.

Materials and methods Prospective observational study, conducted between July and September 2011 in the outpatient unit of a hospital pharmacy department. 30 patients treated with capecitabine, either as monotherapy or in combination with other chemotherapeutic agents, were randomly selected. Each patient was followed up for 2 to 3 months through consecutive interviews. Data recorded: personal details (age, gender, marital status, educational background, occupation), disease variables (tumour type, ECOG performance status, disease onset, concomitant illness), treatment issues (type of treatment, line of chemotherapy, pill burden, duration of treatment, side effects) and drug adherence parameters. A patient was considered to be adherent to treatment if an overall percentage adherence ≥95% was achieved by three indirect methods (dispensing records, pill count and a validated adherence questionnaire (Morinsky–Green test)).

Results 30 patients were included (mean age 65.3 years, 73% men). 50 interviews were conducted (1.7 interviews/patient). Principal medical diagnosis: colon tumours (43%), rectum tumours (27%) and breast cancer (17%). Median pill burden was 9.6 tablets/day (4.8 tablets/dose). Side effects were detected in 26 interviews, 50% of them were hand-foot syndrome. Two patients required dose adjustment as a result. Overall, 28 patients (93%) were considered to be adherent. Two patients (7%) reported some kind of compliance error in one of their interviews. Reasons for non-compliance were forgetting to take treatment and side effects.

Conclusions Adherence to capecitabine in clinical practice is high, despite a high pill burden.

Competing interests None.

GRP096 ACCUMULATION OF DRUGS IN THE HOME MEDICINES CABINETS OF POLYMEDICATED PATIENTS OVER 64 YEARS OLD

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Background The accumulation of drugs can cause errors in taking the medicines and an unnecessary increase in health expenditure.

Purpose To quantify the accumulation of drugs in the home medicines cabinets of polymedicated patients aged over 64 and to assess the associated factors.

Materials and methods Cross-sectional study of polymedicated patients (≥6 medicines in their usual treatment) over the age of 64 admitted to the internal medicine ward in the period from March to July 2011. The authors reviewed the electronic medical record prior to admission, hospital discharge reports and active treatment. Furthermore, The authors interviewed the patient, family and/or care giver to confirm their chronic treatment as well as reviewing the contents of the medicines cabinet in a home visit. The authors considered the patient was accumulating medicines when The authors found either more than one container of at least 3 different drugs or more than 3 containers of the same drug.

Results Of the 52 patients enrolled in the current study, 48.1% accumulated medicines in the home medicines cabinet. Of these, 28.0% accumulated between 3 and 6 drugs, 8.0% between 7 and 9 drugs, 36.0% between 10 and 14 drugs and 28.0% were stockpiling over 14 drugs. In a deeper analysis of the factors that could affect drug accumulation, it was observed that 53.8% of women stockpiled medicines at home compared to 42.3% of men. Distribution by age of those who stockpiled medicines was 30% of 65–70 year-olds, 50.0% of 71–75 year-olds, 41.7% of 76–80 year-olds, 81.8% of 81–85 year-olds and 20.0% in the population aged over 85.

Conclusions

- Almost half of the polymedicated patients together accumulated over 64 medicines in their home medicines cabinets.
- Females had a greater tendency to do this.
- There was a trend to patients stockpiling drugs in line with their age. However, accumulation peaked at 81–85 years old.

Competing interests None.

GRP097 RECONCILIATION OF DISCREPANCIES FOUND IN HOME TREATMENT OF POLYMEDICATED PATIENTS OVER 64 YEARS OF AGE

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10.1136/ejhpharm-2012-000074.97

Background Reconciliation of discrepancies in the patient's treatment may improve the quality of healthcare in a population susceptible to drug errors.

Purpose To analyse differences detected in home treatment after hospital discharge for polymedicated patients (typically ≥6 drugs in their treatment) over 64 years of age.

Materials and methods Cross-sectional study of patients undergoing treatment, over 64 years of age, admitted to the internal medicine ward in the period March to July of 2011. The authors reviewed the medicines documented in the electronic medical records prior to admission, on discharge as well as on the day of home visits (at least 3 weeks after discharge). During the visits, the patient, family and/or carer were interviewed in order to find out the patient's current medicines and to detect possible discrepancies. Discrepancies were considered to be

present when there were unexplained differences between the medicines documented in the electronic medical record and those actually taken by the patient.

Results A total of 52 patients were included in this study and our findings showed that the 92.3% displayed at least one discrepancy in their usual chronic medicines between what was prescribed and taken. The different types of discrepancies detected were as follows: 49.2% of the patients were noted as not taking a drug they had previously been taking (omission), 53.6% were still taking a drug that had been suspended (commission), 73.0% had a difference in dose, route and/or frequency of administration, in 28.9% no substitution had been performed and 11.8% had duplication.

Conclusions Discrepancies between what is prescribed and taken in the chronic treatment of polymedicated patients over 64 years old are a common event, especially those relating to dose, route and/or frequency of administration.

Competing interests None.

GRP098 EVALUATION OF CARDIOVASCULAR DISEASE RISK IN OLDER PATIENTS WITH HIV INFECTION ON ANTIRETROVIRAL THERAPY

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Background The increasing number of older patients (pts) with HIV infection, coupled with the prevalence of cardiovascular disease (CVD) at this age, and the side effects of antiretroviral therapy (ART), mainly related to cholesterol levels, led us to select them as an at-risk population for clinical drug monitoring.

Purpose Assessment of cardiovascular risk in older patients infected by HIV treated with antiretrovirals.

Materials and methods Retrospective study (2010) of HIV-infected older pts (≥65 years) monitored at the infectious disease unit of the author's hospital. Data were obtained from patient medical records, pharmacy medicines database and laboratory test results.

Methods used to evaluate CVD:

- Framingham risk score (FRS): those whose 10-year risk of coronary heart disease-absolute risk (AR) is predicted to be >20% should be considered for treatment;
- Systematic Coronary Risk Evaluation (SCORE): those whose 10-year absolute risk of a fatal cardiovascular event was directly estimated at AR≥10%, if older, should be considered for treatment. Portugal is considered low risk. For female diabetic pts results are multiplied by five, for male patients by three;
- Atherogenic index of plasma (AIP): predictor of cardiovascular risk for pts with index >5.

Results Of 63 pts (48 men), mean age 70.4 (65–84), 15 had diabetes, 4 were smokers and 23 pts presented either one or more CVD risk scales or index: FRS=16; SCORE=17; IAP=9; FRS+SCORE=10; IAP+FRS=4; IAP+SCORE=0; FRS+SCORE+IAP=5. These 23 pts were treated with at least one antiretroviral that induces hypercholesterolemia (seven showed elevated laboratory test results) and hyperglycaemia (12 had diabetes). Antiretrovirals most commonly used: tenofovir+emtricitabine (35), lopinavir+ritonavir (13), zidovudine+lamivudine (9), abacavir+lamivudine (8) and efavirenz (18). Diabetic pts, as well as those with elevated total cholesterol, presented a higher AR.

Conclusions The older population studied presented an increased risk of CVD, confirmed by three evaluation methods, a fact probably also related to ART, since they all had in their therapeutic regimen, one or more medicines that increases total cholesterol and glucose.

Competing interests None.

GRP099 PREVALENCE OF CHRONIC KIDNEY DISEASE IN OLDER PATIENTS WITH HIV INFECTION ON ANTIRETROVIRAL TREATMENT

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Background Renal insufficiency may affect up to 10% of HIV patients as a result of HIV-associated nephropathy (HIVAN), a consequence of HIV replication in the kidney, AIDS-related kidney disease or drug treatment. Tenofovir, atazanavir and abacavir are mainly used, and it is important to consider the potential impact of kidney disease on antiretroviral therapy.[1] [2] The increasing number of older patients with HIV coupled with the prevalence of chronic kidney disease (CKD) in this age group and the side effects of antiretrovirals leads us to select them as an at-risk population for clinical drug monitoring.

Purpose Assessment of kidney function in older patients infected by HIV treated with antiretrovirals.

Materials and methods Retrospective study (2010) of HIV-infected older patients (≥65 years) followed at the infectious disease unit of the author's hospital to identify those with CKD. Data were obtained from patient clinical files, pharmacy drug database and laboratory test results. CKD is defined as either GFR <60 ml/min/1.73 m^2 for ≥3 months or presence of kidney damage (KD) for ≥3 months, with or without decreased GFR, manifest by either pathological abnormalities or markers of KD. Proteinuria (>30 mg/dl) is an early and sensitive marker of KD.[3] The Modification of Diet in Renal Disease equation was used to estimate the GFR (eGFR).[3] The stages (1–5) of CKD are defined based on the level of kidney function.

Results Of 63 patients (48 men) with mean age 70.6 (65–84) and mean serum creatinine 0.99±0.31 mg/dl, 15 were diabetic, 19 had CKD at different levels of kidney function: stage 1=3, stage 2=3, stage 3=11, stage 4=1, stage 5=1. Of this nineteen, 14 were men, mean age 70.9 (65–79), 18 with mean serum creatinine 1.25±0.39 mg/dl and 1 with 10.92 mg/dl on haemodialysis, 12 were being treated with tenofovir, 3 with abacavir and 1 with atazanavir+abacavir.

Conclusions A significant number of this population had a decreased eGFR and had CKD probably due to age, HIVAN, but also to the use of tenofovir, abacavir or atazanavir.

Competing interests None.

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GRP100 DISPENSING ERROR RATE IN A TERTIARY HOSPITAL

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Background The ward drug trolley process is error-prone so therefore pharmacists should take measure to recognise and prevent them.

Purpose To evaluate the rates and types of dispensing errors (DE) during the drug trolley process.
Materials and methods Prospective observational study. Data were collected for 44 working days in 2009 and 2010. The hospital had 350 beds with seven medical and four surgical wards. 84.3% of beds use a unit-dose dispensing system (UDDS) plus written transcription (UDDS-WT) and 15.7% use UDDS plus computerised prescription order entry (UDDS-CPOE). Each day pharmacists randomly selected one or two trolleys and checked them. Dispensing errors were classified as: Type 1: wrong patient, Type 2: omission of drug, Type 3: drug not prescribed, Type 4: Wrong dose, route or dosage form and Type 5: Quantity error. The authors calculated the dispensing error rate (DER) by dividing DE by the opportunities for error (OE: total units dispensed+doses prepared in the drug trolleys).
Results The observations were conducted on 56 drug trolleys (1928 beds): 36 medical and 20 surgical, 14 428 total of doses prepared and dispensed (OE). 137 DEs were detected: 1.46% (2) type 1, 40.15% (55) type 2, 32.17% (44) type 3, 13.14% (18) type 4 and 13.14% (18) type 5. The most frequent errors are type 2 and type 3, related to the prescription changes after the drug trolley process. The DE rate was 0.95% (137 of 14,428). The DE rate in UDDS-WT was 0.91% (117 of 12868) and in UDDS-CPOE it was 1.28% (20 of 1560).
Conclusions The short period of our study and the great difference in the methodology used in other studies hinder the comparison with their results. Although there are almost no differences between our DE rate in the two modalities of dispensing, it was not possible to compare them as the OE varied substantially. Despite the fact that the DE rate was low, recognising the incidence and types of medication errors allows us to analyse the causes to help achieve maximum patient safety.

Competing interests None.

GRP101 COMPREHENSIVE REVIEW OF PHARMACOLOGICAL TREATMENT IN POLYMEDICATED ELDERS

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Background The progressive ageing of the population with associated polymedication is an emergent problem of funding and safety. Many drugs handled by general practitioners (GPs) are initiated by specialists.
Purpose To report on the results of a system used in a health centre in which hospital pharmacists review patients' drug treatments in order to improve prescribing and use of drugs in polymedicated older patients.
Materials and methods Reviewing criteria: >75-year-old patients with >6 prescribed medicines. Hospital pharmacists reviewed primary care (PC) and specialist care (SC) clinical histories and prepared a report, including recommendations, on indication, dose, regimen, duration, interactions, duplications, fulfilment of therapeutic goals, monitoring of adverse effects, dosage adjustment in renal insufficiency, more efficient alternatives, suitability based on STOPP/START criteria and adherence. The doctors were invited to change the prescriptions in the light of this information.

GRP101 Table 1 Treatment modifications

The prescription was justified	59%
Treatment changed to suit patient's current situation	18%
Lab tests were updated	8%
Switched to generic drug	8%
Dose updated	3%
Treatment changed to prevent interaction	2%
Dose adjusted in renal impairment	2%
Duplicate drug stopped	1%
Treatment simplified to improve the adherence	1%

Results Study period: March to September 2011. 31 patients were followed up. Mean age: 83 years (76–99), drugs before the review: 8.9 per patient (pp) (6–15), drugs after: 8.1 pp (0–14), pharmacy recommendations: six pp, 57.1% accepted by the physician, €1500 annual savings.
Conclusions A review of the complete treatment was a valid method, since it detected unnecessary medicines, points of improvement in prescribing and resulted in money saved. The hospital pharmacist collated the drug treatments generated by PC and SC which helped in decision making during the prescription process.

Competing interests None.

GRP102 ACTIVE POLICY FOR SAFE MEDICATION PRACTICE IN A PSYCHIATRIC HOSPITAL: RESULTS AT 3 YEARS

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Background In our hospital the medication process has been computerised since 1995. In 2008, in order to improve safety, an audit was carried out looking at the practices of the pharmacy department (PD) and care units (CUs) in the light of the French health authorities' recommendations.
Purpose To assess progress made against the improvement criteria established after the 2008 audit.
Materials and methods A clinical audit was conducted of 21 CUs and the PD. A set of criteria for improvement was drawn up in order to improve safe medication practices. This includes the development of good clinical practice (GCP) and targeted annual audits with quality indicators. These improvements have been followed up and evaluated each year since 2009.
Conclusions This study has allowed us to harmonise practices and to establish a set of relevant tools in order to improve medication safety. However, these quality indicators need to be continually updated in order to prevent medication errors, particularly due to lack of storage. Drug safety management needs a daily investment from each health professional for it to perform well.

Competing interests None.

GRP103 THE USE OF FAILURE MODES AND EFFECTS ANALYSIS (FMEA) TO REVIEW A MEDICATION INCIDENT REPORTING SYSTEM IN A HOSPITAL

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Background Medication incident reporting systems play a vital role in improving medication safety through the identification of medication incidents/near misses and learning

GRP102 Table 1

Unit	Criteria for improvement	Follow up	Quality indicators: Type	Results: 2009	Results: 2010
CU	Implementation of GCP in storage/preparation	Annual targeted audit	-Correct cutting of blister packs saving identification (name, expiry date)	63%*	50%*
			-Presence of oral tabs without blister packs	37%*	41%*
			-Opening date recorded on solution vials	14%*	20%*
			-Knowledge of the existence of the documentation guideline	94%*	88%*
	Implementation of a single document record for storage/hygiene/expiry-date control		-Compliance rate	82%*	74%*
PD	Implementation of GCP in storage/preparation/dispensing		-Correct cutting of blister packs saving identification -Drugs in unit packaging -Number of dispensing errors	92%** 44%** 7/14528	99%** 44%** 3/16123
CU		Single targeted audit in 2011	-Drug administration in accordance with the medical prescription (68 drug administrations audited)	100%	

*percentage of CUs audited **percentage obtained on a representative sample of the stock.

from them. FMEA is an excellent tool to review a system as it systematically identifies potential problems in a system and makes them transparent on a priority basis before they occur.

Purpose To use failure modes and effects analysis (FMEA) to improve the medication incident reporting system in a hospital.

Materials and methods The prospective risk analysis tool, FMEA, was used by a multidisciplinary team to identify key failures in the original medication incident reporting system. The likelihood of the failure occurring, the severity and detectability of the failure if it occurred were agreed by the team and used to calculate the risk priority number (RPN) of each failure mechanism. Potential failures with an RPN of greater than 45 were targeted in an FMEA action plan which was produced and implemented with the aim of reducing these priority risks. This action plan included the introduction of a new medication incident report form, a new database to record and analyse incidents for trends, a new medication safety newsletter for staff and the production of a key performance indicator to feedback information to management.

Results By implementing the key measures identified in the FMEA process, an overall reduction of 75% was achieved in total risk priority number of the medication incident reporting system.

Conclusions Prospective risk analysis provides a great opportunity for system improvement. The inclusion of a multidisciplinary team at all stages in this analysis ensures a balanced approach to reviewing a system and identifying potential risks. Implementation of the FMEA action plan has lead to a significant risk reduction in the process and resulted in a robust medication incident reporting system in the hospital.

Competing interests None.

GRP104 CLOSING THE GAP Ñ IMPROVING PATIENT SAFETY WITH BETTER DRUG INFORMATION

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Background The problem of poor information transfer exists at the interface between clinical and ambulatory treatment. Patients are not sufficiently informed about their current and future drug treatment.

Purpose To compare knowledge of medicines to be managed at discharge with or without the involvement of a clinical pharmacist.

Materials and methods The amount and depth of information given to the patients about drug treatment started during hospital with and without the intervention of clinical pharmacists were investigated consecutively in a controlled, comparative study at five different hospitals (11 wards). The satisfaction of patients and their general practitioners (GP) with the different style of discharge management was investigated by means of questionnaires.

Results In phase 1 (no involvement of a clinical pharmacist, 847 patients) approximately 50% of patients were prescribed new drugs which were recommended to be continued after discharge. 12% of these patients were not instructed in hospital or in outpatient settings about their newly-prescribed medicines. Even if they were informed about their medicines, 22% of patients were not, or only partially, satisfied. In phase 2 (617 patients), all patients were trained in using their newly-prescribed medicines, so the information ratio rose to 100%. Patient satisfaction regarding the quality of education increased to 89%. Each patient got an illustrated patient-specific medicines plan, which was reported to be helpful by more than 80% of patients. GPs confirmed that their patients were better informed (36% improvement) thus reducing their effort (22% less GP effort required).

Conclusions By involving clinical pharmacists, the gap in patients' knowledge about their medicines was reduced. GPs found their patients better informed and appreciated the reduced time and effort.

Competing interests None.

GRP105 IMPROVED PERFORMANCE FOLLOWING THE DETECTION OF ERRORS IN DRUG STOCKS

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Background In 2009 a checklist was introduced to identify deficiencies in management and control of drugs stocked in

GRP105 table 1

	- 2009	- 2010	- 2011
- **Drugs listed in alphabetical order** - (listed and ordered by active substance instead of brand name)	- 28%	- 25%	- 36%
- **Identification and storage** (wrongly identified with cut blister with no name or expiry date, different doses of the same drug mixed in the same box)	- 28%	- 45%	- 24%
- **Amounts of medicines** (suitable stock levels according to the needs)	- 74%	- 80%	- 84%
- **Refrigerators** (with thermometer in order to control daily temperature)	- 4%	- 51%	- 66%
- **Photosensitive drugs** (quantity of drugs needing protection from light)	- 0%	- 22%	- 60%
- **Controlled drugs** (traceability)	- 58%	- 61%	- 60%
- **Emergency trolley medicines** (completely stocked and well identified)	- 90%	- 94%	- 96%

clinical units. The checklist consists of 10 items: ordering stock drugs, location, identification, storage, thermolabile drugs, photosensitive drugs, emergency trolley drugs, controlled drug regulations, other special drug control and amounts of drugs.
Purpose To analyse the results obtained after an improvement plan to ensure proper storage of drugs in clinical units
Materials and methods Three reviews in 3 consecutive years of 25 drug stocks in wards and operating rooms for adults. The action plan consisted of meetings with nursing staff to analyse the results and identify their needs. It was proposed that all the drug box orders would be made by active substance to avoid errors in the administration. A list was made of the drugs kept in the emergency trolley. The authors explained the controlled drug regulations to the staff and tables were designed showing the correct storage of photosensitive and thermolabile drugs.
Results Improvements were made in six critical points:
There had been an improvement in the quality and safety of drug stocks after the previous pharmacist review, however there were important aspects that needed to improve more.
Conclusions It was decided to draw up an integrated improvement plan with training individualised to the staff involved. A manual will be written that describes how the drug stocks function in clinical units and the powers and responsibilities of the staff in charge of them.

Competing interests None.

GRP106 PHARMACOTHERAPY AND DRUG USE AMONG POOR, INDIGENT AND EMIGRANT PATIENTS IN THE ISLAND OF CRETE, GREECE

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Background The pharmacy of Chania General Hospital (CGH) serves outpatients supported by social services. The pharmacy is informed of the patient, doctor and diagnosis.
Purpose This was a descriptive epidemiology study assessing outpatient characteristics, diagnosis according to ICD-10, and ATC classification of the prescribed drug, for the year 2010.
Materials and methods For the year 2010, the CGH pharmacy dispensed 6309 prescriptions for 837 social services outpatients (61.20% of the total outpatient population prescriptions). This cost €46 8250.18. The prescriptions involved 542 pharmacological substances of different ATC identities in a total of 24 149 drug containers. Every medicine prescribed matched an ICD-10 diagnosis. Thus a database of 12967 registered formulations was analysed out of which in 171 cases the diagnosis was not reported and an additional 784 diagnoses were ICD-10 incompatible.
Results Schizophrenia (F20) was the frequent diagnosis at 14.1%, followed by ischaemic cardiomyopathy – coronary artery disease (I25.1) at 12.9% and affective psychosis (F25.2) as the third most frequent diagnosis (11.10%). 93.93% of the prescribed substances for the dominant diagnosis were central nervous system (CNS) drugs with olanzapine (N05AH03) being the most popular (7.8%). The most common drug prescribed for coronary artery disease outpatients was acetylsalicylic acid (N02BA01) (13.5%) and affective psychosis patients received mostly venlafaxine (N06AA22) (8.9%).
Conclusions Mental illness is highly prevalent in the population of poor indigent and immigrant patients which implies difficulties with social reintegration. Evidence-based positive correlation between acetyl salicylicacid and protection against acute myocardial infarction and sudden death justifies its extended use. These data should be kept in mind when policies for this particular population are reviewed.

Competing interests None.

GRP107 PHARMACIST INTERVENTIONS IN THE SURGERY AREA

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Background Documentation of interventions is vital to a patient's continuity of care and demonstrates the value of clinical pharmacy.
Purpose The aim of this study was to describe and quantify the pharmaceutical interventions in the surgery area.
Materials and methods Prospective longitudinal study of 2-month (June–July 2011) in the surgery area in a 900-bed university hospital. The pharmacist prepares daily pharmacotherapeutic patient history, perform a conciliation of the treatments and validates them. Interventions were recorded in an Access database. Two pharmacists participated in the study.
Results During the study period, 175 pharmacist interventions were performed (2.8 intervention/day) on 61 patients. The 82% were accepted by the medical staff. 43% (75 interventions) were recommendations for sequential therapy, principally over analgesics (56%) and inhibitors of proton pump (23%). The degree of acceptance was 69%. 20% (35) were adjustments to the nutrients and electrolytes composition in the parenteral nutrition. The degree of acceptance was 100%. 19% (32) of interventions were recommendations about antibiotics: 45% switch to the recommend antibiotic, 25% suspend, 20% sequential therapy and 10% dose adjustment. The degree of acceptance was 78%. Finally 18% were others pharmacist interventions such as interactions, adaptation to the hospital's pharmaceutical guide, reconciliation of home treatment.
Conclusions Most interventions were medical staff assistance for to meet the clinical guidelines. So the integration of the pharmacist in clinical units represents an improvement in clinical outcomes and more effective and safe use of medication. The record of pharmaceutical intervention is a useful tool for documenting and evaluating their contribution to the hospital patient care.

Competing interests None.

GRP108 A CLINICAL PHARMACIST-BASED HOME MEDICATION REVIEW OF GERIATRIC PATIENTS

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10.1136/ejhpharm-2012-000074.108

Background The world's population is rapidly ageing and the older are projected to increase from 600 million in 2000 to 1.2 billion in 2025.[1] Medicines-related problems (MRP) are more common in geriatric patients and prescribing drug treatment for older patients is becoming more complex.[2] Home medicines review by pharmacists helps patients manage the medicines and reduces the risk of MRP.
Purpose To assess the knowledge of the medicines, use of prescription drugs, polypharmacy, use of non-prescribed ayurvedic medicines and MRP among geriatric patients.
Materials and methods A prospective study was done by visiting houses in and around HUDCO colony, Manipal, India. A pharmacist interviewed the patients and their carers during a visit and reviewed all medicines used by patients. Data was documented and reviewed for the presence of MRP and the medicines usage pattern. A validated questionnaire was used to assess patient perception of the use of both systems of medicines. The study patients' knowledge of the medicines was assessed using a validated Medication Knowledge Assessment Questionnaire (MKAQ).
Results 219 geriatric patients (≥60 years) were included in the study of which 21% had polypharmacy. A total of 50.2% (110) had medicines-related problems. 64.5% (71) were taking non-prescribed ayurvedic medicines along with allopathic drugs, which was the most common medicines-related problem. Adverse drug reactions 40.9% (45) followed by failure to take the drugs 19.1% (21) were the other problems. Physicians were notified of the existence of potential medicines-related problems. Patients' knowledge of medicines was poor as assessed by recall of name, indications, strength and side effects of medicines. The patients' educational levels and age were found to be negatively associated with knowledge of their medicines.
Conclusions The study confirmed the existence of MRP along with more use and belief in ayurvedic medicines and poor knowledge of medicines among geriatric patients. Pharmacist services help to reduce medicines-related problems and improve care in geriatric patients.

Competing interests None.

GRP109 INTELLIGENT DOCUMENT MANAGEMENT FOR A PAPERLESS HOSPITAL PHARMACY

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Background Hospital pharmacists often waste much time in sorting, labelling, storing and searching pharmacy's documentation.
Purpose To describe a new software application that reduces the time spent sorting documents out, paper waste and physical space for storage, and also allows a fast and efficient document review and control while contributing to a more sustainable environment.
Materials and methods Yerbabuena Software and our hospital pharmacy have been developing a software application based on intelligent document management called 'Paperless Hospital Pharmacy' (PHP) since March 2011. Intelligent document management is the application of semantic technology. This involves three improvements: automatic document classification, Intelligent Character Recognition instead of Optical Character Recognition, and automatic extraction of relevant information from any document.
Results The following types of documents were managed through PHP: delivery notes, invoices, standard operating procedures, requests for inclusion of drugs, medical reports, prescriptions, health warnings and drug approvals. PHP allows multiple information inputs: scanner, email, or directly from the application. Therefore there is no need to print or copy the documents, and the authors save time, paper and space. Typed text, barcodes or any other common codes in healthcare are recognised properly. The system automatically assigns tags to the documents and stores them. They can be searched quickly and easily through a web interface. Searches can be performed by the preassigned tags or by any term in the document. Information is always available, and the authors avoid losing it. Duplicated documents can also be filtered and removed. The authors estimate saving 6 h monthly in archiving and also 38 h in searching for documents with a daily average of 80 patients. PHP can also organise the workflow: The authors can review, approve or sign documents collaboratively in a more efficient way. If a parameter is not satisfactory at any stage, the document returns to a previous one to be reviewed. Secure online access to documents throughout the process is guaranteed.
Conclusions PHP, presented here, provides an efficient and eco-friendly software for document management to worldwide professional pharmacists.

Competing interests None.

GRP110 DEVELOPMENT OF A PHARMACEUTICAL CARE PROGRAMME IN A BONE MARROW TRANSPLANTATION UNIT

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10.1136/ejhpharm-2012-000074.110

Background Pharmaceutical care is a patient-centred practice designed to meet drug-related needs by identifying, resolving and preventing drug treatment problems. Due to the complexity of their pharmacotherapy, haematological patients were the target population with a high risk of drug-related problems (DRPs).
Purpose To develop a pharmaceutical care programme in a bone marrow transplantation unit (BMTU), for severely immunosuppressed patients after bone marrow transplantation or intense chemotherapy.
Materials and methods Prospective study performed from June to September 2011 including patients admitted to the BMTU for whom severe aplasia was anticipated. The pharmacist within the healthcare team collected information after contact with physicians, nurses and patients, on a special data collection sheet. The information collected included demographic data, health problems, laboratory data and drug treatment. Data were evaluated to detect and classify DRPs. Interventions were made if needed.
Results Six patients (66.7% men) were followed for a mean period of 20 days. Twenty-two DRPs were detected before they reached the patient. In accordance with the Third Granada Consensus, DRPs were classified into the following categories: 45.5% a drug adverse event was probable, 4.5% interactions, 9.1% duplications, 4.5% a drug was administered wrongly, 18.2% a health problem was insufficiently treated and 18.2%

the dose, dosage schedule and/or duration was inappropriate. Therapeutic groups mainly involved were: anti-infectives for systemic use (35.3%), antineoplastic and immunomodulating agents (17.6%), alimentary tract and metabolism (11.8%) and respiratory system (11.8%) medicines. Fourteen interventions were made with a 71.4% acceptance rate. Eight DRPs were detected by both physician and pharmacist and thus required no pharmacist intervention. The attending pharmacist detected 175% more DRPs than the physician.

Conclusions Direct interaction of a clinical pharmacist with both the healthcare team and the patient improves patient outcomes, preventing DRPs and solving them before harm is caused. Because of the high-risk drugs involved, preventing DRPs is vital in this specialised unit. DRP detection rates increased when a clinical pharmacist was present.

Competing interests None.

GRP111 EVALUATION OF THE USE OF ADALIMUMAB AND ETANERCEPT IN A TERTIARY HOSPITAL

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Background Adalimumab and etanercept are both anti-TNF drugs used to treat various autoimmune pathologies.

Purpose The purpose of this study was to evaluate the use of adalimumab and etanercept in authorised and unauthorised indications (off label use) and evaluate the effect on finances of the treatments carried out in the latter situation.

Materials and methods A retrospective and observational study was carried out from 1 January 2010 to 30 September 2011, of all patients who started treatment with adalimumab or etanercept in the outpatient dispensing area. Data were obtained through the CAFyDIM program.

Results During the study 111 patients started treatment with adalimumab. Distribution of pathologies was: Crohn's disease (21 patients), psoriasis with arthropathy (21 patients), rheumatoid arthritis (16 patients), ankylosing spondylitis (14 patients), psoriasis (11 patients), juvenile rheumatoid arthritis (7 patients) and ulcerative colitis (5 patients). Off label use: panuveitis (nine patients), Behçet's Syndrome (two patients), undifferentiated seronegative spondyloarthropathy (one patient), polyarthritis associated with ulcerative colitis (one patient), systemic sarcoidosis (one patient), HLA B27 (+) polyarthritis (one patient). The cost incurred by these latter treatments was 132.972€, 4.67% of the total expenditure generated by adalimumab in the study period. 75 patients started treatment with etanercept. Distribution of pathologies was: rheumatoid arthritis (28 patients), psoriasis (21 patients), juvenile rheumatoid arthritis (13 patients), psoriasis with arthropathy (9 patients) and ankylosing spondylitis (4 patients).

Conclusions Etanercept is used in our hospital in approved conditions of use. However, although adalimumab in most cases is used in approved indications, in 13.6% of cases it is used for indications outside the SPC.

Competing interests None.

GRP112 EFFECT OF A SAFETY ALERT IN THE ELECTRONIC PRESCRIPTION PROGRAM: PPI-CLOPIDOGREL INTERACTION†

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10.1136/ejhpharm-2012-000074.112

Background A growing body of evidence suggests that proton pump inhibitors (PPIs) may adversely interact with clopidogrel, diminishing the antiplatelet effect. The potential for increased risk of thrombotic complications warrants cautious use of this drug combination. When concomitant clopidogrel and PPI treatment is considered necessary, pantoprazole or ranitidine may offer a safe choice.

Purpose To analyse the prescription profile and financial impact of an alert that was added to the assisted electronic prescription program (EPP) and is triggered by a prescription for concomitant clopidogrel and omeprazole treatment. A safer choice that is pantoprazole or ranitidine is suggested to assist health professionals.

Materials and methods Retrospective cohort study. Period A (before this alert was added) April–June 2010: pantoprazole was the only PPI included in the hospital's formulary and Period B (after this alert was introduced) April–June 2011: omeprazole and pantoprazole as the low cost and the alternative options respectively for prescribing PPIs. The authors looked at all the clopidogrel prescriptions in both periods of study. Patient code, age (years), gastric protector drug (none, omeprazole, pantoprazole, ranitidine), dose (mg/day) and treatment cost/day data were collected from the EPP. Main outcome and measures: number of patient with PPIs as the treatment for gastric protection and average treatment cost/day. Statistical analysis: OR with its 95% CI and t-test were used to compare the two periods.

Results A total of 360 patients were included in Period A (70% men) with a mean age of 72.2 (IC 95% 70.8 to 73.5) and 327 in Period B (68.9% men) with a mean age of 72.5 (IC 95% 71.2 to 73.8). The change from Period A to Period B was: the percentage of patients treated with a PPI fell from 68.9% to 24.7% (OR=0.15; IC 95% 0.11 to 0.21; p<0.05); the percentage of these patients treated with ranitidine rose from (26.1% to 65.7% OR=5.43; IC 95% 3.91 to 7.54; p<0.05). In Period B physicians ignored the alert in 11.6% of patients. Average cost/day per patient was higher in Period A: 0.21 (IC 95% 0.20 to 0.22) versus 0.05 (IC 95% 0.04 to 0.07; p<0.05)

Conclusions The prescription profile for PPIs was modified by the introduction of the alert. Fewer patients taking clopidogrel are now being prescribed a PPI and a safer drug is used more often. The cost per patient is now lower.

Competing interests None.

GRP113 THE EFFECT OF PHARMACIST INTERVENTION ON PSYCHOTROPIC PRESCRIBING THROUGH CLINICAL MEDICATION REVIEW IN A LONG-TERM CARE HOSPITAL IN DUBLIN

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Background The existence of psychotropic polypharmacy is well established and its detrimental effects on patients in long-term care are irrefutable. In 2009, 88% of long-term patients in the Royal Hospital Donnybrook were on at least one psychotropic medicine, with 59% on three or fewer and 25% on four or more. This level of consumption coupled with a high rate of observed adverse consequences was not conducive to optimum pharmaceutical care. Pharmacists have been shown to be an essential resource for optimum medicines use and safety

and play a vital role in influencing prescribing. Consequently, a medicines review by the pharmacist has been implemented in collaboration with the prescribers.

Purpose The objective was to modify psychotropic prescribing through pharmacist intervention via the clinical medicines review, in order to reduce patient morbidity and increase the quality of life.

Materials and methods Clusters of patients were chosen for the medicines review sessions based on status decline or length of stay. The pharmacist acquired the patients' drug regimen prior to the meeting to facilitate preanalysis. The prescribers and clinical nurse manager then joined the pharmacist on the ward where medical notes and labs were reviewed. The pharmacist conducted a clinical review and made appropriate recommendations from evidence-based guidance such as NICE, STOPP-START and Beers Criteria. These were suggested and substantiated in an attempt to modify patient-specific psychotropic prescribing.

Results Prescribers implemented the majority of recommendations and psychotropic polypharmacy reduced, which infers a tangible transformation in psychotropic prescribing practice. Anecdotal evidence has demonstrated an improvement in morbidity with positive changes in the physical status and behaviour of most patients. An audit revealed a significant reduction in the number of psychotropic drugs prescribed per patient (from 2.3 to 1.7, $p<0.002$) and also a decrease in the total number of medicines per patient (7.1 to 6.0, $p<0.003$) reflecting a decline in side effects suffered. The effect of the intervention has been reinforced by a reduction in the level of admissions to acute care.

Conclusions The effect of pharmacist intervention on psychotropic prescribing through clinical medicines reviews have had an unambiguous impact on the medicines burden of long-term patients in this hospital. This initiative accentuates the value of the clinical pharmacist review and the effectiveness of pharmacist collaboration with prescribers in optimising pharmaceutical care.

Competing interests None.

GRP114 ACUTE HYPERSENSITIVITY SYNDROME CAUSED BY PHENYTOIN: A CASE REPORT

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Background Phenytoin can trigger hypersensitivity syndrome (HS), a rare but potentially fatal complication (incidence of 1:10 000 in new patients).

Purpose To describe a case report of phenytoin HS.

Materials and methods Medical record review and literature search about phenytoin.

Results A 38-year-old man, splenectomised, with a history of seizures after traumatic brain injury. Community treatment was valproic acid (VA): 400–200–500 mg. He was admitted to the intensive care unit presenting with status epilepticus, with normal renal biochemistry and hepatic function. VA level was therapeutic (50.6 mg/l). On admission, he was initially prescribed VA, levetiracetam, propofol and clorazepate, with limited efficacy. Intravenous phenytoin was introduced to treat generalised seizure status. As seizures were controlled and electroencephalography improved significantly, phenytoin was continued orally (100–100–100 mg). Lacosamide treatment (100 mg/day for 2 days then 150 mg/day) was also started. Six days later, he reported generalised rash, fever, liver involvement, and lymphocytosis with normal renal biochemistry. Hepatic function was abnormal, with raised levels of transaminase. Phenytoin level was therapeutic (12.5 mg/l). Physicians requested collaboration from a hospital pharmacist (HP) to identify the cause of the condition. Because phenytoin HS was identified, it was discontinued and high-dose intravenous methylprednisolone and dexchlorpheniramine were initiated. The symptoms of HS responded rapidly to this treatment, with fever reducing, skin rash gradually resolving, transaminase levels becoming normalised and lymphocyte counts within normal ranges. Two days later, the patient was discharged. He has continued with lacosamide treatment (400 mg/day) and the disease is controlled at the moment. This case was reported to Regional Pharmacovigilance Centre.

Conclusions The involvement of a HP can provide all the relevant information for the physician regarding the adverse effects of drugs. In order to prevent future incidents a weekly check is recommended in patients who start treatment with phenytoin.

Competing interests None.

GRP115 SAFE USE OF AUTOMATED DRUG DISPENSING SYSTEM TO IMPROVE MANAGEMENT OF HIGH RISK MEDICINES

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Background Automated drug dispensing systems (ADDSs) are designed for clinical drug management to support safe and efficient medicines management.

Purpose The objective of this study was to develop a strategy to improve the management of high-risk medicines available in ADDSs and therefore patient safety.

Materials and methods Taking into account clinical impact criteria, a list of high-risk medicines was developed based on recommendations of the ISMP and the Spanish Medicines Agency. Drugs with similar or look-alike names or appearance were included in the list to reduce medicines errors. The strategies to improve safety of the medicines were: to store medicines in Cubie pockets restricting access to only one medicine at a time during the removal and refill process, to store in different drawers, to label drawers with alert stickers and use the 'tall man' letter approach to distinguish between potentially dangerous look-alike drug names. An access application was designed to identify potential risk situations, cross matching data from ADDS inventories (drug physical location and type of drawer in each station) with the high-risk medicines list.

Results A total of 1056 medicines included in the ADDS database were reviewed, identifying 154 (15%) high-risk medicines. A total of 651 medicines pairs were identified as having a potentially dangerous similar appearance and 39 look-alike drug names were modified using a 'tall man' letter approach. 15 ADDSs station were reviewed using the Access application and a total of 489 potential risk situation were identified. 73% were resolved by labelling drawers with alert stickers and loading medicines in Cubie pockets. 27% were just labelled because they could not be loaded in a Cubie pocket. 157 drugs that looked similar to one another were also identified and loaded in different drawers in each ADDS.

Conclusions Applying security criteria in ADDS management increased medicines safety, reducing potential for medicines errors during the refill and removal process.

Competing interests None.

GRP116 ANALYSIS OF THE USE OF LINELOZID

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Background Linezolid, an oxazolidinone antibacterial agent, is available for intravenous/oral administration, with activity against Gram-positive bacteria.
Purpose To evaluate the suitability of linezolid prescribing and use, in terms of therapeutic indications (infections of skin and soft tissues and community-acquired and nosocomial pneumonia), sensitivity of the causative organism(s) and the incidence of thrombocytopenia (platelet count <150000 cells/mcl).
Materials and methods A retrospective study included all patients treated with linezolid from January to June 2010 in a 300-bed hospital. The authors recorded the following data: demographic data (number of patients; sex), reason for linezolid treatment, number and type of cultures positive for Gram-positive microorganisms. The suitability of linezolid for use was evaluated according to the indications fpr linezolid in a technical tab. The incidence of thrombocytopaenia was determined in patients whose treatment had lasted longer than 2 weeks.
Results 66 patients were included (59.7% male). The average duration of the treatment was 10.7 days (8.8 to 12.6). 37 patients (56%) were treated with linezolid in line with the approved indications in the technical tab. In 7.6% of patients no blood culture was performed prior to initiation of the treatment. In order to monitor the safety of the treatment, the blood picture was tested on as many patients as possible. Four of these patients developed thrombocytopenia (30.8%).
Conclusions A high percentage of indications for which linezolid is prescribed in our hospital did not apply to those approved in the SmPC. Only in 8% of cases was a blood culture not performed prior to initiation of therapy, as recommended in the SmPC. Haematological toxicity in patients being treated with linezolid for more than 14 days was higher (30.8%) than indicated in the SmPC.

Competing interests None.

GRP117 ISCHAEMIC COLITIS ASSOCIATED WITH BORTEZOMIB: CASE REPORT

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Background Treatment with bortezomib is frequently associated with haematological toxicity. In addition infrequent gastrointestinal disorders such as ischaemic colitis, irritable bowel syndrome and paralytic ileus are described, among others.
Purpose To describe a case of ischemic colitis associated with treatment with bortezomib and to evaluate causality.
Materials and methods The authors report on a woman, 77 years old, diagnosed with multiple myeloma, chronic renal insufficiency and echinococcosis, being treated with enalapril 20 mg/day, bisoprolol 2.5 mg/day, isosorbide 50 mg/day, calcium carbonate 1.25 g/8 h, furosemide 40 mg/day, darbepoetin α 40 mcg/15 days, omeprazole 20 mg/day. In June 2011, she was given fresh treatment with bortezomib 2.2 mg/72 h and dexamethasone 40 mg/week. After the fourth dose, the patient went to the emergency services with abdominal pain and constipation that had been coming on for several days. It was decided to interrupt treatment and she was admitted to the digestion ward. Naranjo's algorithm and Karch–Lasagna's algorithm were used to determine the reason.
Results An urgent colonoscopy showed abundant red stained faecal residue in the descending colon, diffuse mucous with black plaques and surface ulcers which demonstrated severe ischaemic colitis. An abdominal axial CT scan reflected a remarkable oedematous thickening of the colon wall (7 cm) with adjacent frayed fatty tissue related to the colitis diagnosis. After 12 days the patient progressed satisfactorily on conservative treatment having interrupted her standard treatment. When the bortezomib treatment restarted the patient resumed the same medical regimen but very soon she experienced abdominal distension, nausea and vomited bile. Chronic mesenteric ischaemia was diagnosed. After a further 15 days the patient was discharged from hospital and is now trying oral lenalidomide as second line treatment of the multiple myeloma. After applying the causality algorithms, the adverse reaction came out in both cases as definitively due to bortezomib (10 points).
Conclusions Ischaemic colitis is described in the bortezomib technical data sheet as an uncommon adverse event (<0.01%) as reported in postmarketing studies. In the Sistema Español de Farmacovigilancia (FEDRA) Spanish Pharmacovigilance System for Medicines for Human Use 239 bortezomib adverse events are recorded, 44 related to gastrointestinal disorders. Close monitoring of patients showing constipation during their bortezomib treatment is recommended together with notification of possible adverse events not described or listed as uncommon in their severity.

Competing interests None.

GRP118 EVALUATION OF THE POTENTIAL DRUG INTERACTIONS IN PHARMACOTHERAPY OF POST LIVER TRANSPLANT PATIENTS IN ICU

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Background The main recurrent problem after liver transplantation is the rejection of the transplanted organ, which is why immunosuppressants are widely used as post-transplant drug therapy. This drug class has a large number of theoretical potential drug interactions (TPDIs) with other drugs often needed by those patients.
Purpose This work aims to outline the profile of the main TPDIs to which patients undergoing liver transplant surgery are exposed.
Materials and methods This is a cross-sectional, retrospective and observational study. In January of 2011, were collected medical prescriptions of patients admitted to the intensive care unit (ICU) of Hospital de Clinicas – UNICAMP between January and December of 2010. The study included only patients who were hospitalised for more than 24 h, underwent liver transplant surgery, were more than 18 years old, and had their drug prescriptions in the ICU in the medical records available for inspection.
Results The study included 25 patients, an average age of 51.64±11.96, 173 prescriptions were evaluated, an average of

6.92±2.72 prescriptions per patient. The number of TPDIs varied between 1 and 36, an average of 12.48±9.15 per patient. The 312 TPDIs observed in the medical prescriptions were classified according to the Micromedex database as contraindicated (12), major (101), moderate (183) and minor (16). Tacrolimus stood out as the main drug and it was present in 57% of the prescriptions and also in 10 different types of TPDIs.
Conclusions This study helped to design the drug therapy profile used in liver transplant patients in ICU of a Brazilian public hospital, showing that there is a high incidence of theoretical potential drug interactions in prescriptions. The clinical relevance of this work is in its contribution to the prevention of preventable adverse events associated with drug therapy, between them the rejection of the transplanted organ to failure of the immunosuppressive regimen adopted.

Competing interests None.

GRP119 HOW GREAT IS THE CLINICAL IMPACT OF PHARMACIST INTERVENTIONS ON PRESCRIPTIONS?

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Background The public hospital of Aubagne (South of France) records about 15 000 patients each year. New prescriptions are scrupulously examined by pharmacists every day. This routine analysis leads to pharmaceutical notifications (PNs) if any anomalies are detected.
Purpose The aim of this study is to retrospectively analyse the impact of these PNs over 3 months (from July to September 2011) in five clinical departments (internal medicine, geriatrics, pneumology, cardiology and cardiology intensive care).
Materials and methods PNs were added to digital prescriptions during the validation process and therefore could be read at any time by clinicians. They were divided into five categories: indications, inadequate posologies due to physiopathologic characteristics (renal failure, older people), medical interactions, duplicated prescriptions, and clerical errors (inappropriate unit or dosage). Data required to validate the prescriptions were collected on DOME software (stores clinical data, examination records, biological analyses) and THERIAQUE database (stores drug information).
Results 102 PNs were issued out of 722 prescriptions delivered in 3 months, which represents about nine PNs per 1000 prescription lines. At the beginning of the study, the main problem was related to inadequacy of the posology (43.2% of PNs): thanks to pharmaceutical vigilance and collaboration between health professionals, this rate dropped to 15.4% in September. Moreover errors on inappropriate indications decreased from 18.9% to 12.8%, while other indicators did not show significant results. Overall, PN led to modifications of prescriptions in nearly 50% of cases.
Conclusions This study shows how a meticulous examination of prescriptions by pharmacists can be efficient in preventing iatrogenic harm. In the future the authors hope to improve acceptance of these PNs by developing closer links between health teams.

Competing interests None.

GRP120 CRITICAL APPRAISAL OF A NEW MEDICINES PRICING POLICY IN GREEK HOSPITALS

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Background A new regulation has recently given Greek hospital pharmacists the right, through local medicines committees, to directly negotiate medicines prices with the suppliers, instead of using the official prices.
Purpose The aim of this report is twofold: primarily to review the first financial benefits deriving from the new procedure and second to highlight some points that should be considered when evaluating the whole process.
Materials and methods The potential limitation of hospital drug expenditure has been assessed, using the review of the results of the negotiations reported by several hospitals, prices reported in the National Observatory of Prices and current official price lists published by the Ministry for Health and Social Solidarity.
Results In some cases, up to 80% discount on the initial prices was reported, with the average of around 40%. The emphasis has been put on generic and off-patent products. Medicines categories where the biggest discounts have been observed include: antibiotics (eg, meropenem, piperacillin/tazobactam), cytotoxic agents (eg, paclitaxel, cisplatin, carboplatin, gemcitabine), ondansetron, propofol, omeprazole, etc. Larger hospitals seem to be more powerful in the negotiating procedure. However the bed capacity may not reflect the actual consumption, since the type of hospital bed and the distribution per medical specialty should be taken into account as well.
Conclusions It is possible for hospital pharmacists to gain resources by cutting the cost of medicines in hospital care, while ensuring patient safety. The first results reported seem quite positive given the burden of the unfortunate economic conditions; however other considerations should be borne in mind when coordinating such a procedure, for example transparency, patient safety, availability of pharmacoeconomic and bioequivalence studies and all that in respect to the global market rules.

Competing interests None.

GRP121 ANALYSIS OF DRUG SHORTAGES IN A HOSPITAL PHARMACY

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Background Drug shortages are very frequent in recent years. Hospital pharmacy staff lost many hours on research about reasons for shortages or how to purchase drugs from another wholesaler or find therapeutic alternative to avoid consequences for patients.
Purpose To present drug shortages because it is increasing problem which can compromise patient care.
Materials and methods Summary of drug product shortages in period January 2008–August 2011 in which the authors have been collecting data about shortages. The authors define drug shortage as every delay in monthly drug supply. For this presentation medications which were in shortage less then one month and drug which are not registered in Serbia were omitted.
Results Number of drug in shortages were 17, 18, 26 and 42 from January 2008 to August 2011. Unresolved drug shortages were 12, 9, 10, 14 in that period. Therapeutic groups which were mostly involved in drug shortages were antibiotics and cytotoxic drugs. Patients most affected are from haemato-oncology units and ICU. Reasons for shortages were

manufacturing and importation problems, but in most cases The authors did not know details about reasons or expected termination of shortages. As number of shortages is increasing, it is more difficult to find alternative drugs. Number of drugs which had alternative were in percents: 100, 83, 77, 74% from 2008 to 2011. Use of alternative drugs resulted in changes in therapeutic plans and higher costs but without adverse outcomes for patients. Consequences of drug shortages without alternative were delays of therapy. Drugs without alternative were most often cytotoxic drugs. Number of injectable drugs in shortages is increasing and were 6, 8, 15, 17, and it is very troublesome because it is more difficult to find alternative intravenous medication than drug for another routes.
Conclusions Drug shortages is huge and increasing problem. Number of drugs shortages is in increase and in 2011 is twice higher than in 2008. Hospital pharmacist is in position to first know about shortages and to start many actions to diminish damages of patients. Most of interventions were suggestions of similar drugs. Drug shortage is opportunity for hospital pharmacist to be more involved in patient care and hospital drug management.

Competing interests None.

GRP122 INFORMATION TO PARENTS ABOUT PAEDIATRIC HOSPITAL-PRODUCED PREPARATIONS

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Background The compounding laboratory of Ravenna hospital pharmacy produces paediatric preparations prepared individually in response to the lack of preparations for children on the market. In 90% of cases the preparations are for patients at home who often do not have the necessary information about the drug.
Purpose The aim was to write summaries about compounded preparations that provide detailed information, similar to the patient information leaflet accompanying manufactured medicinal products, to be made available to parents of young patients. With this work The authors tried to improve patient compliance and to provide information for the correct use of the drug, its storage, interactions and possible warnings.
Materials and methods Informative summaries were compiled with the help of the technical specifications of drugs and raw materials, BNF for Children, biomedical literature from Medline and Medicamenta. They contain information related to the composition, therapeutic class, as it presents, shelf life, storage, therapeutic indications, how to take it, warnings and possible adverse reactions. The documents are in simple language in order to facilitate the understanding by all patients' parents, who are sometimes foreigners.
Results 52 informative summaries were made about the active ingredients, in different pharmaceutical forms, required in 757 paediatric prescriptions submitted to the laboratory from July 2009 to May 2011. Then telephone interviews were conducted with some of the patients' parents in order to evaluate the usefulness of this work. The authors found that the information most appreciated is that regarding the storage of the drug, how to take it, and, in particular, interactions with non-prescription medicines.
Conclusions Compounding represents a concrete response to the lack of paediatric medicines on the market and hospital pharmacists play an important role in ensuring the patient has full and reliable information.

Competing interests None.

GRP123 ASSESSMENT OF INAPPROPRIATE DRUG PRESCRIPTION IN OLDER PEOPLE THROUGH A SCREENING TOOL

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Background Comorbidity and polypharmacy in conjunction with physiological changes in older people contribute to the well-documented problem of inappropriate drug prescription, a risk associated with an age group.
Purpose To find out to what extent drug prescribing is modified in older patients by using a systems-defined medicine review tool: potential drug-related problems (DRPs) and START (Screening Tool to Alert doctors to Right Treatment)/ STOPP (Screening Tool of Older Person's Prescriptions) criteria, optimising the pharmaceutical validation process to detect inappropriate and omitted prescribed drugs.
Materials and methods A three-month prospective study carried out on 45 patients aged over 70, with 4 or more drug prescriptions, on medium or long hospitalisation in a nursing home with 140 beds. A database was created using all the patient's demographic data along with prescribed drugs, diagnoses and outstanding data from their medical profile. Detected potential DRPs and START-STOPP criteria were set out, differentiating the clinical category for each patient. The authors determined the total potential DRPs found in these patients, the average value per patient and prescription line, the percentage of potential DRPs as defined by START-STOPP criteria, the total of START-STOPP criteria and the average adhered to of each criteria per patient and prescription line.
Results 45 patients included, 69% were women and 31% men, aged 84 on average. Average number of prescription medicines was 6. A total of 171 potential DRPs were identified, averaging 3.8 potential DRPs per patient and 0.62 per prescription line. 147 of the potential DRPs were due to the application of START-STOPP criteria (85.9%) 3.2 and 0.52 was the number of START-STOPP criteria per patient and per prescription line respectively. 48.2% (38 patients) met START criteria (0.26 START/ prescription line) and 51.7% (37 patients) STOPP criteria (0.27 STOPP/ prescription line).
Conclusions The authors found a high number of potential DRPs. START/STOPP criteria resulted in a fast application screening tool to detect and prevent a high percentage of these DRPs.

Competing interests None.

GRP124 IMPLEMENTATION OF A CENTRALISED INTRAVENOUS ADDITIVE SERVICE WITH LIMITED PERSONNEL RESOURCES

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10.1136/ejhpharm-2012-000074.124

Background In many countries the centralised preparation of intravenous medicines is a service provided by hospital pharmacists. Besides cytostatics and parenteral nutrition, the pharmacy in the Donauspital currently prepares about 20 intravenous formulations per day, mostly weight-calculated antibiotics for neonates.

Purpose As the service shall be extended, the need for it and the number of potential preparations have to be assessed.
Materials and methods Over three months all intravenous medicines that were prepared in 50 ml syringes by nurses on three intensive care units (anaesthesiology, medical, paediatric ICU) were recorded. The assessment on the neonatal ICU was stopped since medicines there are not standardised. All intravenous medicines were checked for the right solvent and a literature search was performed on the stability of the drugs in plastic syringes. Nurses were asked if they would appreciate such a service.
Results Nearly 15,000 intravenous preparations were recorded. The most commonly used drugs were midazolam, morphine, clonidine, norepinephrine, heparin and insulin. The prospect of these preparations being provided by the pharmacy was welcomed by the ICU staff, but these numbers would result in 250 syringes being prepared per day (working Monday to Friday), which is not realistic because the staff of the INTRAVENOUS service will probably consist of only one pharmacist working a maximum of 4 h daily. To cut down the number of preparations a risk analysis was made. According to the literature most intravenous medication errors on wards occur with drugs being diluted. If these solutions only were provided by the pharmacy (55% of the recorded preparations), there would be 140 preparations per day. Literature research showed that solutions of these drugs are stable for a least a couple of days, so syringes could be prefilled and stored.
Conclusions Due to the lack of staff it might be possible to implement CIVAS by preparing high-risk intravenous ICU drugs only. Pharmaco-economic considerations will follow.

Competing interests None.

GRP125 TOXIC DEATH-CASE AFTER CAPECITABINE ADMINISTRATION: CASE REPORT AND IMPLICATION OF DIHYDROPYRIMIDINE DESHYDROGENASE DEFICIENCY

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Background Capecitabine is an anticancer agent, pro drug of 5 fluorouracil (5-FU) administered orally and with a narrow therapeutic index, licensed for the treatment of breast and gastrointestinal cancers. 5-FU is metabolised by dihydopyrimydine dehydrogenase (DPD). Patients with a DPD deficiency can experience severe toxicity of 5-FU.
Purpose To evaluate if DPD deficiency investigations were positive for patients who presented severe toxicity following capecitabine administration.
Materials and methods Electronic medical record review (chemotherapy prescription database ONCOBASS®) for toxic death-cases after capecitabine administration to investigate results for DPD deficiency test.
Results The authors identified three toxic death-cases after capecitabine administration. Case 1: 77-year-old man diagnosed in Sep 2008 with colorectal cancer with indication of neoadjuvant chemotherapy who presented signs of major toxicity (grade 4 neutropenia, grade 4 thrombocytopenia, grade 4 mucositis and encephalopathy) two days after capecitabine initiation. After been tested for DPD deficiency, the result was negative. Case 2: 67-year-old woman diagnosed in Sep 2006 with bilateral breast cancer. She received adjuvant therapy for six courses and radiotherapy, which resulted in good response with a patient being without treatment until Dec 2008, when she presented relapse and initiated a course of chemotherapy based on capecitabine. After two courses, the patient suffered signs of severe toxicity (Grade 4 neutropenia, Grade 3 thrombocytopenia, Grade 3 mucositis). The test for DPD deficiency showed that the patient was heterozygous for a mutant DPD allele. Case 3: 78-year-old woman diagnosed in Dec 2008 with metastatic colorectal cancer. She received the first course of Capecitabine and oxaliplatin (XELOX) as first-line treatment. Nine days after capecitabine initiation she presented Grade 2 diarrhoea, Grade 3 mucositis, neutropenia and thrombocytopenia). Investigations showed that she had DPD deficiency.
Conclusions DPD deficiency was tested in all patients with toxic death after capecitabine administration. Pharmacists have an important role in prospective identification of potentially toxic patients in order to reduce the number of patients with severe, life-threatening side effects to capecitabine treatment.

Competing interests None.

GRP126 WEB 2.0 IN THE HOSPITAL PHARMACY

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Background The term Web 2.0 is associated with web aplications that facilitate information sharing, user-centred design, interoperability and using the World Wide Web as a collaboration tool. Information Technology helps to establish effective communication systems to facilitate the work in hospital pharmacy environments.
Purpose Describe the application of Web 2.0 for the hospital pharmacy to improve communication in a decentralised University Hospital.
Materials and methods The communication was difficult and often ineffective until the implementation of Web 2.0 technologies within a hospital pharmacy, with 3 separate hospitals for more than 4 km. The authors established a strategy for improving the quality of communication using online tools: Google groups, Google Sites, Twitter and Facebook.
Results The authors performed 2 Google groups with restricted access for group communication: one for the Pharmacy Department (PDGG) and another specifically for Clinical Pharmacists (CPGG). The PDGG is used for any common notice and the CPGG was to discuss and report on technical issues (including the guard pass the day before). A total of 963 posts in the period October 2008 to October 2011. Also created two Websites with restricted access where there are common sections (secretary of service and quality) and others specific. Thus, in the Pharmacy Department Website, the sections were: welcoming new staff, teaching, standard operating protocols; and in the Clinical Pharmacy Website: Commissions and Committees, Evaluation and selection of drugs, Clinical Pharmacy, Drug Information, Drug Safety and Research. Facebook and Twitter have also been recently incorporated as an additional communication tool.
Conclusions The results show that the Web 2.0 is a suitable tool for collaborative work. This system allows the exchange of relevant information between the Pharmacy Service Staff safely and effectively.

Competing interests None.

GRP127 MONITORING OF PHARMACEUTICAL CARE HEPATITIS C PROGRAM (2007-2011)

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Background Pharmaceutical care(PC) is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.
Purpose To analyse the results of a PC program in patients who are infected with the virus of hepatitis C(HCV).
Materials and Methods Period of study: April 2007-October 2011. It was aimed to prevent, detect and resolve medication-related problems (MRPs) in HCV patients. Phases: First visit: Prescription validation, medical history revision and elaboration of patient medical record. The authors inform patients about adverse reactions, interactions and healthy lifestyle habits. The authors stress the importance of treatment compliance in order to obtain a sustained viral response and how to minimise the side effects. Subsequent visits: Personalised monitoring, detection of MRPs and Pharmaceutical Intervention (PI). The authors establish visiting hours and evaluate the adherence to the pharmacotheraphy. The adherence calculation is done through dispensing registers. The adherent patient endorses the rule 80/80/80:80% of interferon (IFN), ribavirin (RBV) doses and 80% of the treatment time in relation to the genotype.
Results 542 interviews were done in 365 patients under IFN and RBV treatment: oral information 67.16% and both oral and written 32.84%. Face to face interviews 90.22% and telephone ones 9.41%. 27.86% to start the treatment, 69.74% during the treatment, 0.55% by treatment change, 1.66% possible interaction and others 0.18%. Counselling reasons (227), the most frequent were: tiredness 15.86%, mental disorders 11,89%, reaction at the injection site 8.81%, gastrointestinal discomfort 8.81%, pseudo-flu syndrome 8.37%, insomnia 6.61% and pruritus 6.61%. 536 PI were accepted, with recommendations about healthy lifestyle habits and some pieces of advice on medication administration and handling side effects. In 45 times, patients were referred to the specialist doctor.
Conclusions The majority of the patients applied for PC during the pharmacotheraphy follow-up, above all, by side effects related to medication. The interviews with the patients reinforce the information on their pharmacotheraphy in order to minimise side effects and resolve MRPs. The PC program in HCV patients helps to improve the safe use of medications and avoids unnecessary visits to the specialist doctor.

Competing interests None.

GRP128 THE IMPACT OF INTRODUCING OF CLINICAL WARD PHARMACY SERVICES†

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Background The Health System evolution has led to a transformation of roles and tasks traditionally assigned to the hospital pharmacist; he/she is now required to be an integral part of the healthcare team, in order to support both managed treatment and patient safety. The Veneto Oncological Institute IRCCS (IOV) of Padua has been selected as one of the five Italian centres of excellence in oncology taking part in the project sponsored by the Italian Ministry of Health (July 2010–February 2011), aimed at evaluating the contribution made by the continuous presence of a pharmacist in an oncology department. The monitoring and reporting of Near Misses was one of the outcome indicators of the project.
Purpose The aim of the project was to verify the contribution made by the pharmacist in the oncology department in Near Miss reporting.
Materials and methods A record of prescriptions (updated daily) was created to monitor all the following situations that could cause near misses:

- Sending a non-agreed statim prescription – Difficult to read prescription
- Incorrect date – Wrong dosage – Diagnosis not present or incomplete – Non-standardised prescription form

Each situation was evaluated in terms of risk. All high-risk prescriptions associated with a near miss were recorded as non-conforming to our Quality System.
Results A special register was established, in which the different causes of near misses are recorded.
From the creation of the register (October 2010) to 15 February 2011, 50 near misses were recorded classified by event as follows:

- sending a non-agreed statim prescription (17 cases)
- difficult-to-read prescription (20 cases; an incident reporting form was completed for one of them)
- wrong dosage (5 cases)
- mixed up labels (1 case)
- error in calculating the length of cycle (2 cases)
- wrong prescription (2 cases)
- wrong protocol used (3 cases: trastuzumab 2 mg/kg instead of trastuzumab 8 mg/kg)

Since November 1st 2011, prescribing has been computerised. The Oncosys medical record, after 18 months of validation, is the only prescribing system used at the moment in our hospital (IOV) for cancer treatment. Introducing the near-miss register is still in progress so a comparative evaluation of pre and postcomputerisation data was not yet possible. At present a reduction in near misses of up to 60% has been recorded.
Conclusions The recorded cases of near misses have stimulated the development of standardised protocols, computerisation of medical records and increased awareness of potential medicines errors in the physicians and other healthcare staff. The integration of department pharmacists in the multidisciplinary oncological staff significantly contributes to patient safety, ensuring appropriate prescribing and reducing medical errors and adverse drug effects. Moreover, cooperation within a multidisciplinary team enabled the shared setting up of a fully computerised and safe system for diagnosis and treatment.

Competing interests None.

GRP129 MEDICINES RECONCILIATION IN HOSPITAL PATIENTS COORDINATED WITH PRIMARY CARE†

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Background In the literature the authors find many types of reconciliation studies, only at admission, only at discharge or at discharge and later in primary care. The data on discrepancies can vary depending on the professionals performing the reconciliation.

Purpose Our objective was to create a team made up of hospital pharmacists, liaison sisters and primary care physicians to identify and classify the discrepancies at hospital admission, during and after discharge in patients with the same primary health area.
Materials and methods The authors performed a prospective observational study in polymedicated patients admitted to hospital. Patients were interviewed by the pharmacist at admission and discrepancies with treatment found at admission and after discharge were recorded. The discrepancies that required clarification (not justified) were classified depending on whether the drug had been withdrawn, added or modified with no apparent clinical justification regarding the patient's usual treatment. All discrepancies were reviewed later by the primary care physicians.
Results 55 patients were recruited, 48 patients had their medicines recorded at discharge but only 29 could be reviewed in primary care due to death or loss to follow-up. The patients took an average of 8 drugs, 669 drugs were recorded on admission and 480 at discharge. 31.84% (213) and 43.96% (211 drugs) of medicines required clarification at the time of admission and discharge respectively. The largest number of drugs in which discrepancies were found at admission was in the benzodiazepines group (17.58%) while it was proton pump inhibitors at discharge (16.09%).
Primary care disagreed with 4 (1.07%) of the discrepancies classified by hospital pharmacists at admission and 2 (0.75%) of discrepancies classified at discharge.
Conclusions It is necessary to implement measures in hospitals to reduce the number of unjustified discrepancies. These checks can be carried out by hospital pharmacists; reconciliation should be coordinated with primary care for follow-up of patients.

Competing interests None.

GRP130 IMPLEMENTATION OF MEDICINES RECONCILIATION AT HOSPITAL ADMISSION†

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Background Medicines reconciliation processes have successfully reduced drug errors and adverse drug events. In a recent project in the Traumatology ward of our hospital, 59.3% of the patients had at least one unintended medicines discrepancy. Based on this experience The authors decided to implement medicines reconciliation (MR).
Purpose To determine the number and type of pharmaceutical interventions performed after the implementation of the program.
Materials and methods A prospective study carried out between October 2010-October 2011 in a tertiary care teaching hospital. All patients admitted to surgical wards were included. The authors excluded those who could not be interviewed due to language problems and those who were admitted at the weekend. The methodology used in the MR process is the following: within the 24 h of the patient's admission, the pharmacist obtains the preadmission chronic treatment by interviewing the patient or the patient's family/care giver, or from the patient's medical chart and primary care records. This is compared with the treatment prescribed in hospital. All of the discrepancies detected (dose, regimen, route of administration or omission) are discussed with the attending physician to determine whether it was intended in accordance with the patient's condition. If the discrepancy is unintended, appropriate changes are made to the medicines.
Results Upon the implementation of MR, reconciliation was performed for a total of 1464 patients. The wards involved were: General Surgery (637), Traumatology (548), Urology (262) and Vascular Surgery (17). 1390 pharmaceutical interventions were performed, the most frequent being substitution for therapeutic equivalent (34.4%), adjustment of dose for renal insufficiency (24%), change to oral route (9.9%), omission of medicine (7.5%) or duration of treatment (5.5%), among others. The acceptance rate for our interventions was 91%.
Conclusions An MR system was developed with the aim of continuity of treatment at each transition of care and preventing medicines errors.

Competing interests None.

GRP131 EVALUATION OF A COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEM

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Background In a study evaluating polypharmacy in a cohort of older internal-medicine patients in Austria, inappropriate prescribing and adverse drug events (ADEs) were highly prevalent. According to the literature, computerised physician order entry systems (CPOESs) improve medication safety.
Purpose To implement a CPOES and to evaluate its benefit and acceptance.
Materials and methods A study group of 3 clinical pharmacists, 2 cardiologists and a study nurse implemented and evaluated the Rp-Doc CPOES on two surgical, two internal and one neurological ward from November 2009 to April 2010. Depending on the ward, the support given by the study group in entering data into the system was organised differently. The acceptance of Rp-Doc by its users was evaluated by a questionnaire.
Results During the study period, 1259 patients were admitted. The medication of 560 patients (44%) was documented and analysed by Rp-Doc. Depending on the support that was given, Rp-Doc was used more or less (28-65%). Rp-Doc identified potential drug-drug interactions, wrong doses, duplicated medicines, contraindications and inappropriate medicines. In a questionnaire returned by 18 users, the time that was needed to document the data was considered too long, the alert overkill concerning potential drug-drug interactions and the lack of recommendation of alternatives in case a drug was considered inappropriate were criticised. The information regarding dosing, contraindications and drug adjustment in renal failure was appreciated. The majority felt that the system increased their vigilance regarding drug-drug interactions (69%), ADEs (58%), prescribing in the older (50%) and awareness of cost (27%). There was a lack of personal computers, staff and time to really use the advantages of the CPOES.
Conclusions To implement a CPOES successfully, sufficient professional support and adequate infrastructure are necessary. Once implemented, it would improve medication safety

and help to identify those patients who are in greatest need of pharmaceutical care.

Competing interests None.

GRP132 SEVEN REASONS TO PROMOTE CIVAS-ASSEMBLED POINT-OF-CARE ACTIVATED SYSTEMS FOR INFUSION OF LABILE DRUGS INSTEAD OF ON-WARD TRADITIONAL SET METHODS

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Background US recommendations on patient safety support the use of point-of-care activated systems (POCAS) for infusion of labile drugs but this concept is almost unknown in Europe, which mainly uses syringe & needle (SYRNE) or transfer-set (TRASE) methods performed by nurses.
Purpose To identify and publicise the added value of POCAS on quality of care.
Materials and methods The authors conducted 4 different studies in 4 unrelated hospitals to compare POCAS versus the SYRNE method (or TRASE method when available). The POCAS chosen, assembled in our CIVAS facility, was Augmentin 1g phial linked to a 50-mL saline Viaflo bag via a EuroVialMate connector. Reconstitution/administration (n=944) was performed by 44 nurses unfamiliar with POCAS and scored with subjective and objective measurements.
Results All medians were adjusted to 100%-excellence scales so that the SYRNE method (or TRASE method when available) scored 50%. When results were rated on this scale, 7 significant arguments emerged in favour of POCAS: 1) Product quality due to standardised batch production: 92% versus SYRNE (89% versus TRASE), 2) Outsourcing opportunity for small hospitals without PICs-compliant facilities, as encouraged by Belgian health authorities, 3) Patient safety: 94%, due to less risk of bacterial contamination (closed system), 4) Nurse safety: 94%, due to no contact with sensitising drugs and less risk of needle pricks, 5) Intuitive training (3 administrations) and ease of use: 90% (or 89%), 6) Cost containment due to just-in-time reconstitution (15%) and 44% time gain versus SYRNE, 7) Ecological impact: 91% (or 89%), due to no syringe, less metal, less waste and no dioxin production during incineration.
Conclusions The authors recommend POCAS for daily routine infusions of labile drugs.

Competing interests None.

GRP133 DRUG SAFETY MONITORING IN THE NORTHERN REGION OF ZAMBIA

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Background The Copperbelt University Health Services (CBU Health) has been designated by the Pharmaceutical Regulatory Authority (PRA) as its agent for coordinating pharmacovigilance in Copperbelt, Luapula, Northern, North Western and Western Provinces. Adverse drug reactions (ADRs) are the major concern for hospital admissions. Nearly one quarter of the patients are admitted due to adverse drug reactions.
Purpose CBU Health's purpose includes encouraging the reporting of adverse drug reactions (ADRs) as well collecting and collating all ADR reports from health institutions in the five provinces. This report covers our experiences from May 2008.
Materials and methods Beginning in early May this year, CBU Health has been visiting health institutions in the study areas on a monthly basis. Activities include holding discussions with health workers, distributing ADR forms and collecting ADR reports. Once collected these reports are entered into the ADR Register at CBU Health and thereafter causality is assessed. A report is then prepared for the PRA on a quarterly basis. At the PRA, serious ADRs are noted and recommendations made to the Ministry of Health.
Results One hundred and fifty (150) ADRs were collected May – December, 2010. These reports were obtained from twenty-one (21) institutions in the Copperbelt. The reports have all been documented and assessed using the WHO Causality Method. Most of the ADRs reports were caused by antiretroviral drugs (ARVs) and some by antimalarial drugs like artemether/lumefantrine – Coartem. Fifty reports were sent to the Uppsala Monitoring Centre Vigiflow for further analysis.
Conclusions Pharmacovigilance is the science relating to the detection, assessment, understanding and prevention of the adverse effects of drugs. It is an important public health specialty as drug safety awareness can lead to better patient outcomes and reductions in drug-related morbidity. Our results show that pharmacovigilance is becoming an integral part of clinical care in Zambia for patient safety.

Competing interests None.

GRP134 PARENTERAL MEDICATION PREPARATION BY PHARMACY TECHNICIANS ON THE WARD IMPROVES MEDICATION SAFETY

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Background Preparation of parenteral medications is associated with considerable risk that is medication errors and risk of microbiological contamination. In Dutch hospitals parenteral medications are commonly prepared on the ward by nursing staff. In a pilot in the Maastricht University Medical Centre, pharmacy technicians instead of nurses prepared parenteral medications on the ward. For preparation specific protocols per medication in which calculation templates and double checks were included were used and hygienic measures were increased. The effect on medications errors and risk of microbiological contamination was measured.
Purpose To determine the effect of substituting preparation of parenteral medications on the ward by nurses to pharmacy technicians on medication errors as well as on the risk of microbiological contamination. Materials and Methods The study was carried out on two wards of Maastricht University Medical Centre in 2009 and 2010 Medication errors Before and after implementation of the pilot 200 preparations of parenteral drugs were randomly observed by a disguised observer and medication errors were measured. The severity of medication errors was assessed by an independent panel. Risk of microbiological contamination Before and after implementation of the pilot 200 broth simulation preparations were prepared by nurses and pharmacy technicians respectively. Microbiological contamination based on turbidity was identified.
Results Medication errors Medication errors significantly decreased from 40% in parenteral medication preparation by nurses to 1% in preparation by pharmacy technicians ($p<0,0001$). The severity of medication errors decreased and double check significantly increased from 40% to 100%. Risk

of microbiological contamination Risk of microbiological contamination decreased as contaminated broth simulations significantly decreased from 8% to 0% (p<0,0001).
Conclusions Substitution of parenteral medication preparation by pharmacy technicians on the ward instead of nurses significantly reduced medication errors and the risk of microbiological contamination.

Competing interests None.

GRP135 DESIGN, INTRODUCTION AND EVALUATION OF A NEW OUTPATIENT/DISCHARGE PRESCRIPTION FORM FOR BEAUMONT HOSPITAL

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Background In early 2010 traditional, small (102 mm x 178 mm) single copy outpatient / discharge prescription forms were in use in Beaumont Hospital. This raised patient safety and legal concerns. International studies have demonstrated that redesign of prescription forms can improve patient safety.
Purpose The aim of this project was to design and introduce a new outpatient / discharge prescription form to address the patient safety and legal concerns surrounding the traditional form and to evaluate the new form through an audit of the provision of prescriber details and a user satisfaction survey.
Materials and methods A new A4 (210 mm x 297 mm) triplicate prescription form was designed. The new form included copies for the general practitioner and healthcare record. Samples of completed traditional and new forms were audited for inclusion of the prescriber's medical council registration number (MCRN) and contact details. Evaluation included a prescriber survey and a postal survey of community pharmacists. Statistical analysis was performed using PASW.
Results Analysis of the prescription audit revealed that inclusion of the prescriber's MCRN increased from 15% with the traditional form to 76% with the new form (p<0.001). Only 45% of prescribers provided any identification detail on the traditional form but 100% of prescribers provided two or more identification details on the new form (p<0.001).The survey found that 81.3% of prescribers strongly agreed or agreed that the new form was an improvement over the traditional form compared to 100% of pharmacists (p=0.025). Consultants were less likely to agree or strongly agree that the new form was an improvement compared to the non-consultant hospital doctors (NCHDs) (p<0.001).
Conclusion A new A4 triplicate prescription form introduced in Beaumont Hospital was well received by both prescribers and community pharmacists. Prescribers were significantly more likely to include their MCRN and other contact details on the new form compared to the traditional form.

Competing interests None.

GRP136 CONNECTION BETWEEN THE HOSPITAL PRESCRIPTION PROGRAM AND THE PARENTERAL NUTRITION COMPOUNDING PROGRAM

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Background During the parenteral nutrition (PN) compounding process, medical prescriptions must be transcribed in the pharmacy department, where there is an increased risk of medication errors.
Purpose To describe the implementation of the connection between the hospital prescription program and the PN compounding program.
Materials and methods From November to December 2010, an explanatory document was prepared to cover all the products used in the preparation of PN for adult and paediatric patients and the calculations performed to convert the medical prescription in the units of volume for the PN preparation. A second document was developed to collect the data issued by the electronic prescription program (Prescriplant), patient information (history number, name, service, bed, and weight), prescription information (date, time, service, prescribing physician) and information on PN (total volume, nitrogen, glucose, lipids, sodium, potassium, phosphorus, magnesium, calcium, chloride, acetate, zinc, trace elements and vitamins). From January to February 2011, an external provider (Intercath) entered this information in the PN program of the MedicalOne®parenteral database and made the necessary adjustments so that the program could automatically calculate PN.
Results The Prescriplant® program was connected with the MedicalOne®parenteral program. The PN was generated automatically in the MedicalOne®parenteral program using the information obtained from the Prescriplant® program according to previous indications. Tests were performed over a month to validate the calculations made by the program, both for adult and paediatric patients. The necessary adjustments were made, and the calculations that the program did not perform well were corrected.
Conclusions Connection of the Prescriplant® program with the MedicalOne®parenteral program avoids manual transcription of the hospital pharmacist and simplifies the PN compounding process.

Competing interests None.

Technology (including: robots for production, Incompatibilities, drug production and analytics, CRS)

TCH001 PRESCRIBING AND ROBOTIC DISPENSING: THE IMPACT OF TECHNOLOGY ON THE PROFESSIONAL MODEL†

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Background Sunderland Royal Hospital has approximately 1,000 beds, and has operated an integrated electronic prescribing system (EP) since 2001. In September 2009, a robotic dispenser directly linked to EP was installed in the main pharmacy.
Purpose Using electronic prescribing directly linked to dispensing robots delivers a series of benefits in terms of error reduction and efficiency (1)(2). Our aim was to investigate the impact of this on professional practice.
Materials and methods A qualitative survey was undertaken of 8 pharmacists to pilot a semistructured questionnaire. Standard thematic analysis methods (3) were used. Any issue raised by pharmacists was noted and assigned to a theme. This was independently assessed for accuracy (GK). Staff interviewed varied from newly-qualified pharmacists to experienced managers.
Results The results of the survey shown were collated and analysed. The main points are listed in order of positive benefits scored:

- Feeling more empowered on wards 87%
- Availability of relevant patient information 87%
- Enhanced ward-based relationships 75%
- Efficiency of EP + Robots combined 75%
- Improvement in enforcing hospital medicines policies 37%

There was a series of lesser-scoring themes not included for space reasons.
Conclusions The direct linking of a robotic dispensing machine to electronic prescribing, besides increasing efficiency, seems to offer enhancement of professional aspects of clinical pharmacy. Removing mundane aspects of drug supply and policy enforcement allows greater focus on patient-centred activities and enhances professional relationships at ward level. This might in part relate to removal of 'policing' functions of hospital policies because these are done electronically instead of relying on the ward pharmacist. Further detailed work is required to explore the issues raised by this study, and its impact on the professional model. GK = Dr Gulia Karimova, Sunderland Royal Hospital, Sunderland England SR4 7TP.

Competing interests None.

TCH002 FINANCIAL ASSESSMENT OF ASEPTIC PREPARATION FACILITIES IN EUROPEAN HOSPITAL PHARMACIES

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Background The drug manufacturing conditions in hospitals have become increasingly demanding and the use of a Controlled Atmosphere Area (CAA) in the preparation unit is now mandatory.
Purpose To make an inventory of fixtures used for European aseptic manufacturing units; to compare the cost of CAA provided by isolators to CAA provided by Biological Safety Cabinets (BSCs) in order to determine the most economical scheme in hospital and to develop a model to estimate CAA design and operating costs.
Materials and methods 43 hospitals were interviewed (21 French and 22 from four other European countries) by email, telephone and visits over 7 months. A form with 390 items was programmed in VBA (Visual Basic for Applications) to assist with replying. Hospitals were compared according to their location and their type of workstation: BSCII, BSCIII or UDF (Unidirectional Flow) (Group B) and Isolator (Group I). Statistics were generated using the Mann-Whitney test and Monte Carlo modelling.
Results 21 hospitals responded (11 French and 10 foreign). All European preparation units were organised similarly except that in France, isolator use seems more common than in the rest of Europe (73% vs 30% respectively; p=0.0502). Each cost item was compared; only 2 were significantly different: the staff training cost/agent and the cost/m^2 of microbiological control were significantly higher in Group B than in Group I with 3,404 € and 1,731 €/agent respectively (p=0.0028) and 50.46 € and 2.68 €/m^2 respectively (p=0.0017). A synthesis costs program was drafted to calculate an estimate preparation cost. The preparation cost in Group B seemed higher than in Group I (41 € and 30 € respectively in study conditions) although this cost difference disappeared when the annual number of items prepared increased.
Conclusions This pilot study provides data that could be used to optimise resources and save money. A further international study would enable significant results to be obtained.

Competing interests Ownership: GETINGE GETINGE life Science company has taken coverage of B.Dekyndt's travel expenses and Mr Meyer is Marketing Manager for Isolation Technology in GETINGE LIFE SCIENCES Company.

TCH003 MICROWAVE FREEZE-THAW TREATMENT OF CYTOTOXIC AND HAZARDOUS INJECTABLE DRUGS: A REVIEW OF THE LITERATURE FROM 1980 TO 2011

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Background Microwave freeze-thaw treatment (MFTT) of injectable drugs can support the development of centralised intravenous admixtures services (CIVAS).
Purpose The aim of the review was to collect information and results about MFTT of cytotoxic and hazardous drugs.
Materials and methods The scientific literature about drug stability studies was systematically reviewed. The data were presented in a table and described the name of the drug, producer, final concentration, temperature and time of frozen storage, type of microwave oven, thawing power, method of evaluating the concentration and results after treatment or final long-term storage at 2-8°C.
Results From 1980 to 2011, 8 drugs (cyclophosphamide, cytarabine, doxorubicin, epirubicin, fluorouracil, ganciclovir, methotrexate sodium, Mitomycin C) were studied by MFTT and the results were presented in 8 publications. The frozen storage temperature varied from –20°C to – 30°C, the storage time from 11 to 364 days, the microwave power from moderate to

full power. The concentrations were mainly found by High Performance Liquid Chromatography. The 8 drugs were stable during and after the treatment. However, mitomycin needs to be stored at – 30°C. Only 2 research teams have tested the long term stability after MFTT, the first for ganciclovir after 7 days, the second for fluorouracil after 28 days. 6 drugs were tested after one to 11 cycles of refreezing and rethawing, with loss < 5%.

Conclusions This review may help hospital pharmacists to undertake the production of 8 dose-banded ready-to-use injectable cytotoxic and hazardous drugs. Freezing enhances their long-term stability. Validated microwave thawing reduces the time taken to defrost these drugs at the concentrations tested without altering their chemical stability.

Competing interests None.

TCH004 COMPLEXATION'S STUDIES OF CHENODEOXICHOLIC ACID WITH β-CYCLODEXTRINS FOR PREPARATION OF LIQUID AND ORAL PHARMACEUTICAL FORMS

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Background The cerebrotendinous xanthomatosis is a rare metabolic disease with alterations in hereditary of storage lipids (in Italy, 20 confirmed cases). The basic defect of this disorder is the deficit a liver enzyme (sterol 27alfa-hydroxylase), which catalyses the hydroxylation of a sterol intermediate of the biosynthetic way of bile acids, thus causing the accumulation of cholesterol in most tissues. It's characterised by abundant deposits of cholesterol and cholestanol, mostly in the Achilles' heel, lungs, brain and peripheral nerve myelin. In cerebrotendinous xanthomatosis you have stabilisation or improvement of the neurological and systemic clinical conditions as a result of chronic therapy with chenodeoxicolic acid (CDCA). This drug normalises the main metabolic alteration restoring normal cholestanol levels, with a mechanism of feedback inhibition of 27 alfa –hydroxylase.

Purpose The purpose of this work was the preparation and evaluation of the stability of a liquid formulation oral of CDCA for paediatric use (easy to take and pleasant taste) for the treatment of cerebrotendinous xanthomatosis.

Materials and methods To make the formulation was evaluated the solubility of the drug, the ability to form complexes inclusion with β-cyclodextrin, stability after complexation and the correction of taste and smell. The formation of inclusion complexes between the CDCA and β-cyclodextrins has been carried out both by the method 'Freeze-drying' (in water solution and in water solution with ethanol or methanol) and with the method 'Kneading' (solid state). Obtained in the samples was determined the amount of complex formed with the chromatography LC-MS technique. The stability of the dosage form was tested at room temperature, after storage at 3 ° C and -15 ° C using chromatographic techniques.

Results Chenodeoxicolic acid proved insoluble in water but in the form of β-CD complex has a higher solubility. The complex formed between CDCA and β-CD in 1:5 ratio has been shown to be stable for at least 15 days in water solution (r.t.20°C T0=21.32 mg/ml; T1 after 1 week=20.84 mg/ml; T2 after 2 week=20.72 mg/ml; Fridge 3°C T0=21.08 mg/ml; T1 after 1 week=21.13 mg/ml; T2 after 2 week=20.94 mg/ml; Freezer -15°C T0=20.98;T1 after 1 week=21.08 mg/ml; T2 after 2 week=20.82 mg/ml.) The liquid pharmaceutical form was then created by selecting the mode of complexation and solid state using CDCA and β-CD in 1:5 molar ratios. The preparation was pleasant and palatable.

Conclusions The complexation between CDCA and β-CD allowed to make available a liquid pharmaceutical form of pleasant taste, thus improving a good compliance of paediatric patients.

Competing interests None.

TCH005 LONG-TERM STABILITY OF MORPHINE HCL IN 0.9% NACL INFUSION

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Background To extend the range of injectable preparations in a centralised intravenous admixture service (CIVAS).

Purpose To investigate the long term stability of morphine in 0.9% NaCl infusion polyolefin bags (PB) and polypropylene syringes (PS) after storage at 5±3°C, and to evaluate the influence of initial freezing and microwave thawing on this stability.

Materials and methods Ten PB and five PS containing 100 ml of 1 mg/ml of morphine solution in 0.9% NaCl were prepared under aseptic conditions. Five PB were frozen at -20°C for 90 days before storage. Immediately after the preparation and after thawing, 2 ml of each bag were withdrawn for the initial concentration measurements. All PB and PS bags were then refrigerated at 5± 3°C for 58 days during which the morphine concentrations were measured periodically by high performance liquid chromatography using a reversed phase column, naloxone as internal standard, a mobile phase consisting of 5% acetonitrile and 95% of KH_2PO_4 buffer (pH 3.50), and detection with diode array detector at 254 nm. Visual and microscopic observations, spectrophotometric and pH measurements were also performed. Solutions were considered stable if the concentration remains superior to 90% of the initial concentration by regression analysis. The degradation products peaks were not quantitatively significant and were resolved from the native drug.

Results PB and PS solutions were stable when stored at 5± 3°C during these 58 days. No colour change or precipitation in the solutions was observed. The physical stability was confirmed by microscopic and spectrophotometric inspection. There was no significant change in pH during storage. Freezing and microwave thawing didn't influence the infusion stability.

Conclusions Morphine infusions may be prepared in advance by CIVAS, frozen in PB and microwave thawed before storage under refrigeration until 58 days either in polyolefin bags or polypropylene syringes. Such treatment could improve safety and management.

Competing interests None.

TCH006 COMPOUNDING PARENTERAL METHYLTIONINIUM CHLORIDE 1% SOLUTION IN HOSPITAL PHARMACY AND RISK ASSESSMENT OF PREPARATION

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TCH006 table 1

Type of preparation	parenteral preparation	5
Amount prepared annualy(units)	liquid	2
Pharmacological effects of the active ingredients	strong	3
Supply	mainly internal	2
Preparation process	terminal sterilisation	4
Result		240

Background Methyltioninium chloride is an organic thiazine dye.It is used for management of methaemoglobinaemia, also as a visualising agent in surgical procedures, as an antidote for cyanide poisoning. It should be used with caution in patient with severe renal impairment. It is dark green odourless hygroscopic crystals, soluble 1 in 25 of water. A 1% solution has a pH of 3 to 4,5. Methyltioninium chloride is absorbed in the gastrointestinal tract and usually is excreted in the urine. It is administrated intravenously as a 1% solution in doses 1-4 mg per kg body-weight.
Purpose The fact that is lack of Methyltioninium Chloride 1% injection on the drug market in our country, the aim of presented work was to created the conditions to start small scale productions of this formulation and to determinate the risk assessment of the preparations.
Materials and methods Parenteral Methyltioninium Chloride 1% Solution was prepared in the Department for Compounding Sterile Products in our hospital, following established procedure for parenteral preparations and examined the content of Methyltioninium Chloride according the requirement of Ph.Eur.(Ph.Eur.monograph 1132).The preparation was storage protected from light.
Results According to the Standard Operating Procedure, Parenteral Methyltioninium Chloride 1% Solution was prepared aseptically in the laminar flow cabinet and sterilised by autoclaving. The final solution was then submitted to quality control, where a set of selected assays have been defined that ensures both raw material and final product are of assured quality Risk assessment of preparation.
Conclusions With applied technological procedure, it was possible to prepared Parenteral Methyltioninium Chloride 1% Solution in our hospital. The result for risk assessment is higher than 100, so the preparation was considered a 'high -risk preparation', that's why The authors followed GMP Guide to prepare it.

Competing interests None.

TCH007 AUTOMATION BY CLEANROOM ROBOTS IS CLEVER GMP

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Background The traditional process of preparing ready-to-use antibiotics imposes the following challenges: 1) Limited capacity leading to shortage problems, 2) Monotonous repetitive work, 3) High-risk human involvement in large-scale aseptic processing. To address these issues, two collaborating Danish hospital pharmacies have automated the process by introducing cleanroom robots. But is automation the key to success?
Purpose To evaluate the implementation of cleanroom robots in preparing ready-to-use antibiotics.
Materials and methods In 2007, the hospital pharmacies from the Capital Region of Denmark and Odense University Hospital decided to automate the process of preparing ready-to-use antibiotics. Technology was used to maximise compliance with GMP. All qualification and validation tests were completed by the first product release in June 2011.
Results The authors discovered that:
1) Production capacity increased from 150 products per hour to 350 products per hour with equivalent man-hours
2) The monotonous repetitive work was reduced to a minimum
3) Compliance with GMP was optimised by:
- Excluding human interference in class A
- Using dedicated cleanroom robots
- Qualifying robot movement and UDF (unidirectional airflow)
- Manufacturing machine parts in polished 316 stainless steel
- Using vision and image processing for continuous process monitoring
- Fitting probes for particle count

But this was achieved at the cost of:
- a large financial investment (~1 million €)
- a significant delivery time on equipment (~2 years)
- a high demand for qualification and validation (time consuming)
- restricted handling of different materials (eg, vials)

Conclusions The use of cleanroom robots in preparing ready-to-use antibiotics has proven to be clever GMP. Automation requires initial investments and time, but automating the process has increased production capacity and facilitates a healthy work environment. Concurrently, automation made it possible to optimise compliance with GMP on several critical aspects of large-scale aseptic processing.

Competing interests None.

TCH008 DIAGNOSTIC HANDLING OF THE PREPARATION OF EPICUTANEOUS PATCH TESTS REQUESTED BY THE ALLERGOLOGY DEPARTMENT

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Background In epicutaneous patch testing, the substance suspected of being responsible for the skin reaction (contact dermatitis and/or delayed drug reaction) is applied (in excipient) on the skin under occlusion to confirm/rule out a delayed hypersensitivity response. Various epicutaneous patch test batteries are commercially available.
Purpose To develop a work procedure for the Pharmacy Department to meet the demand for epicutaneous patches not commercially available.
Materials and methods The preparation procedure depends on the physical form of the active principle (AP) and the selection of excipient (according to the solubility of the AP). The solubility characteristics of the APs were recorded and The authors searched for commercially-available dosage forms and concentrations of the APs requested and for the pure APs. 1st option: use of pure AP; 2nd option: solid oral dosage form: pulverisation; 3rd option: syrup/drops; 4th option: parenteral form. When the AP was water-insoluble, a lipophilic excipient (vaseline) was used, when it was water-soluble, a hydrophilic excipient (lanolin-vaseline ointment) was used. Finally, the mixture was placed in a labelled 5-mL syringe.

Results The authors evaluated 13 patients during the 10-month study period. The authors prepared 29 types of patch (21% corticosteroids, 14% antiepileptics, 31% antibiotics and 34% other). The authors used the pure product in 6 patches and the commercial dosage form in 23 patches. 8 APs were water soluble and 21 were insoluble or poorly soluble in water. The authors diagnosed two delayed fixed drug exanthema-type reactions (to amoxicillin/clavulanic acid and metronidazole) and one contact dermatitis (from povidone-iodine); these tests were positive at 48 and 96 h.
Conclusions Preparation of epicutaneous patches in the Hospital Pharmacy Department is an effective option to diagnose contact dermatitis and/or delayed drug reaction in cases for which no commercial patch test is available.

Competing interests None.

TCH009 THE DEVELOPMENT OF HOSPITAL MANUFACTURED READY TO USE HEPARIN SOLUTION TO FLUSH CATHETERS

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Background Heparin flush solution is a sterile preparation of heparin sodium with sufficient sodium chloride to make it isotonic with blood. So far heparin was mainly prepared on wards from concentrated solution (25.000 IU/ml) prior to application.
Purpose To streamline the preparation and provide products that meets all the quality criteria. Information about the desired concentrations and quantities of different concentrations of heparin in saline solution were obtained using a 3-month data collection on hospital wards.
Materials and methods A literature search was made and the conclusions of stability studies were respected and obtained monographs were studied. Materials: Heparin Sodium, injectable grade; Sodium Chloride low in endotoxins, suitable for the biopharmaceutical production. Method of preparation: suitable amount of Heparin Sodium and Sodium Chloride are weighed in sterile glass and dissolved in chilled water (20 °C) for injections. After homogenisation the sample for in process control is taken. The solution is then filtered by 0.2 µm membrane filter in 100 ml Asolvex glass bottles and sterilised by steam sterilisation 15 min by 121 °C.
Results The authors have prepared a series of solutions of various content of Heparin Sodium in 9 mg/ml Sodium Chloride solution. Heparin content was measured before and after filtration and before and after sterilisation. Tests were made in accordance with the European Pharmacopoeia chapter 2.7.5. At the same time the pH value and the content of sodium and chloride was measured. All samples were sent for Sterility testing and testing for Pyrogens.
Conclusions Solutions of heparin in concentrations from 1 IU to 100 IU/ml in sodium chloride solution are stable under sterilisation conditions. No significant decrease in heparin activity during autoclaving cycle at 121 °C 15 min was detected.

Competing interests None.

TCH010 INTRODUCTION OF AN AUTOMATED MEDICINES STORAGE AND DISPENSING SYSTEM IN A PHARMACY DEPARTMENT†

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Background The authors wanted to compare the traditional system of dispensing medicines and the new automated Kardex medicines storage and dispensing system.
Purpose To describe the process of introducing an automated Kardex medicines storage and dispensing system in the pharmacy service and to evaluate its use during the first three months.
Materials and methods To prepare for the internal Kardex system drug list The authors excluded from the selection process artificial nutrition, anticancer drugs, thermolabile products, antidotes and areas of medical exclusivity. Each drug was entered into the Kardex system software (Mercurio) with maximum and minimum allowed stock levels, as well as a physical space required for its intrinsic volume and repackaging. The authors started to use the Kardex system for hospital dispensing in December 2010 and the assessment period was three months of active use. The authors used the pharmacy Mercurio and Sinfhos software to acquire and capture data.
Results Initially, the internal Kardex system was used for 62% of all pharmacy drugs. The percentage of free holes was 25.5% in week 3 of activity, decreasing to 9.14% in week 12. The average number of daily prescriptions dispensed and properly completed was 7.6 in week 3 and increased to 38.6 at week 12, whereas the traditional storage system catered for an average of 14.4 orders. The difficulties The authors experienced were mainly due to lack of medicines and lack of repackaged drugs for stock.
Conclusions In spite of the great initial difficulty and the resistance of nursing assistants to the Pharmacy service, The authors consider that the automated Kardex medicines storage and dispensing system offers us advantages. The authors can dispense prescribed drugs and operate Pyxis replacement stations with more efficient management of human resources. The Kardex system software provides information on incidents that arise during dispensing, to make it possible to quantify and analyse our mistakes.

Competing interests None.

TCH011 STOCK HOLDING OF COMPOUNDED CYTOSTATICS Ñ HOW DO SPCS SUPPORT THIS?

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Background Increasing demand for hospital-prepared cytostatics has forced Danish hospital pharmacies to develop solutions which support effective work flow in decentralised and future centralised production units. One way to optimise the logistics is to hold stock of prepared cytostatics for 1-3 months. This requires documentation of extended shelf lives of the prepared products. This can be done in different ways but the authorities' opinion is crucial for the quality. The Danish Drug Agency in spring 2011 stated that stability data for prepared cytostatics should be delivered by the industry and stated in the summary of product characteristics (SPC).
Purpose The aim of this study was to conduct a survey of the shelf lives and the usefulness of the information stated in section 6.3 in the SPCs for 13 selected prepared cytostatics.
Materials and methods The SPCs were identified on www.produktresume.dk and www.ema.europa.eu 5 May 2011.
Results 150 SPCs were identified for 13 cytostatics. The longest shelf life identified for prepared cytostatics was 28 days for doxorubicin, epirubicin, gemcitabine and irinotecan. Great

variation between the minimum and maximum shelf lives for the same drug substance was observed. One of the biggest discrepancies occurred for epirubicin with a minimum shelf life of 'use immediately after preparation' and a maximum shelf life of 28 days after preparation. Apart from a few exceptions the times for which the concentrations are stable, which can be applied to the shelf lives, are not stated in the SPCs. Often no shelf lives for the prepared product are stated but only for the original or reconstituted product, and consistent terminology is lacking in the SPCs.

Conclusions Due to the limited information on shelf lives in the SPCs it is not possible to produce cytostatics in DK for stock; the quality of the SPCs is deficient.

Competing interests None.

TCH012 BATCH OR NAMED-PATIENT PREPARATION: INTRODUCTION OF A DECISION ALGORITHM

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Background One of the tasks of the Pharmacy Department of the CHUV (Centre Hospitalier Universitaire Vaudois) is to supply the hospital with drugs. Medicines not commercially available must be manufactured by the pharmacy. This can be done batch-wise or through named prescriptions for individual patients.

Purpose Batch manufacturing implies a number of principles and constraints such as planning, delays to be taken into account, number of items per batch, final check by the Quality Control Unit and storage and distribution by the Pharmaceutical Logistics Unit. Because these are often incompatible with personalised medicine, it was necessary to define criteria allowing the Manufacturing Unit to decide between batch and individual preparation.

Materials and methods Three pharmacists collaborated to design and develop a decision algorithm meeting the above objective. This algorithm was then introduced and is being applied to all preparations manufactured by the Pharmacy Division.

Results The following criteria were taken into account when designing the algorithm: standardised doses, stability, frequency and number of prescriptions, urgency and costs. A total of 440 preparations were analysed according to the algorithm; 174 have been earmarked for batch production and 266 for named-patient preparation.

Conclusions This algorithm now provides the Manufacturing Unit with an objective tool with which to decide between batch-wise and named-patient classification for new preparations and to review the status of preparations annually.

Competing interests None.

TCH013 INTRODUCTION OF AN AUTOMATED DRUG DISPENSING SYSTEM IN AN INTENSIVE CARE UNIT

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Background In January 2011 the old Xeral-Calde hospital in the city of Lugo moved to new premises. The new hospital management decided to set up an automated storage and dispensing system in the intensive care unit.

Purpose To analyse the automated Pyxis dispensing system in the hospital's intensive care unit (ICU) from the financial and human resources point of view.

Materials and methods A drugs list was established for use in the Pyxis system. Large volume medicines and emergency trolley medicines were not included. They were arranged in the Pyxis by size, frequency of use and safety considerations. A period of 10 days was set aside for training the unit personnel, facilitating the integration of the Pyxis system into the department and involving the whole personnel in the process. To acquire and data capture The authors used the SINFHOS Drugstore management software, the Web Reporting associated with the Pyxis storage system and the hospital collaborated with us over supervision.

Results The average monthly / patient cost in ICU comparing the periods January–March, 2010 (without the Pyxis system) and January–March, 2011 (with the Pyxis system) was reduced by 20.3%. The number of drugs stocked has increased 11.4%, but less space is needed for storage in the unit. The pharmacy staff was required to spend more time on personnel training, each nursing assistant needing about 14 h' more training a week; however nurses working in ICU were able to reduce the time taken for their daily work by an average of two h.

Conclusions Introducing the Pyxis system in the intensive care unit is seen as a step forward in both the ICU and the pharmacy. The main advantages were the decrease in costs assigned to the unit by the reduction of accumulated stock, more information is available about the medicines for each patient and bureaucratic work has been reduced in the ICU, giving staff more time for patient care.

Competing interests None.

TCH014 USE OF COMPUTERS TO IMPROVE EFFICIENCY AND SAFETY OF UNIT-DOSE PREPARATIONS

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Background Unit-dose drug distribution is a medication management system, promoted by ISMETT clinical pharmacy, for optimal pharmaceutical patient care. Suitable software was fundamental to controlling the therapeutic process from prescription to the administration to patients in the care unit.

Purpose The purpose of this study was to demonstrate the efficiency of the software in 2 areas: helping pharmacists do their job and preventing failure of drug administration.

Materials and methods The software used by the pharmacy processes all information about the patient and the injectable medicines prescribed in the electronic clinical chart. A label is generated for each preparation and all information (patient's name, date of birth, identification code, unit, room, drug, dose, dilution, expiry date, rate of administration and storage conditions) is printed. A barcode is used for the last check before administration. Then technician prepares the daily batch of injections under pharmacist supervision.

Results From January to September 2011, 75000 preparations were made (average of 275 per day). 31% were continuous infusions and 69% were bolus including antibiotics (46%), gastroprotectives (12%), cardiac stimulants (9%), antihypertensives (5%), antiarrhythmics (1.5%), hypoglycaemics (7%), anaesthetics (6%), antithrombotics (5%), antifungals (2%), antivirals (1%), other (8.5%). This software supports the pharmacist in providing the right drug to the right patient in the right dose and dosage form by means of the electronic interface with the

clinical chart data. Moreover the time taken for preparation was reduced by 40% and no errors were found in label data. Batch preparation also reduced waste.

Conclusions The system adopted increased the overall quality level enabling patients' treatment to be matched to their real needs. Software provides a fundamental support for drug management and allows the elimination of labelling errors. This leads to better drug monitoring (several reports are generated) and reduced costs (reduction of the time spent on management).

Competing interests None.

TCH015 EFFECT OF BAR-CODE TECHNOLOGY ON THE SAFETY OF CYTOSTATIC DRUGS ADMINISTRATION

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Background Serious medication errors are common in hospitals and often occur during order transcription or administration of medication. To prevent such errors, technology has been developed to verify medications by incorporating bar-code verification technology within an electronic medication-administration system (bar-code eMAR)

Purpose Incorporate an electronic system of validation and control of cytostatic drug administration using bar codes and an electronic medication-administration system (eMAR).

Materials and methods Bar-codes wristbands have been used to identify patients and The authors acquired PDAs as eMAR, which were connected to e-prescribing program by the hospital WIFI. After having received the medication sent from Pharmacy Department the cytostatic drugs administration circuit in day hospital consists of: the nurse scan the bar codes printed on patient's wristband, automatically drug information about medicines to be administered appears on the screen of the PDA (patient data, route, speed and time of administration, sequence order, components, and number of administrations). After scanning the bar code on the patient's wristband the nurse scan the bar code on the medication's labels of cytostatic drugs. Validated variables by the scan are: patient, drug administration sequence, start and end times. If the dose being scanned corresponds to a pharmacist-approved medication order and the patient is due for this dose, administration is automatically documented. However, if the dose does not correspond to a valid order, the application issues a warning.

Results During the first month and a half since its introduction, this system has been used in 202 oncology-haematological patients (24.3% haematology, 75.7% oncology patients), 486 medication orders scanned (28.8% haematology and 71.2% oncology) and 1522 doses identified (14.2% haematology and 85.8% oncology). Because the eMAR imports medication orders electronically from either the physician's order entry or the pharmacy system, its implementation may reduce transcription errors. Possible detected errors: incorrect order of administration, already administered drug and selected drug that does not belong to scanned patient. During study period The authors detected: 4 cases of incorrect administration order, 2 cases of already administered drug and 9 cases of selected drug that does not belongs to scanned patient.

Conclusions The implementation of bar-code medication-verification technology embedded in an eMAR in an onco-haematological day hospital act as an additional safety net in medication administration and in patient safety. This system also improves treatment efficiency and achieve a greater inter-disciplinary collaboration.

Competing interests None.

TCH016 HOSPITAL FORMULATIONS FOR THE TREATMENT OF NON-ALBICANS VULVOVAGINITIS

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Background As vaginal flucytosine is not commercially available, it is necessary to prepare this formulation in the Pharmacy Department.

Purpose To describe the preparation of flucytosine 15.5% (FLUCY15.5), and flucytosine 17% + amphotericin 3% (FLUAM) creams for vaginal use and their efficacy in the treatment of Candida glabrata and Candida tropicalis.

Materials and methods FLUCY15.5 was prepared as follows: Twenty-eight 500 mg capsules of flucytosine (Ancotil) were opened into a mortar and the contents crushed. The powder was mixed with glycerine to form a paste. Cold Cream was added up to 90 g. It was blended until smooth.

The procedure for preparing FLUAM was: Thirty-one 500 mg capsules of flucytosine were opened into a mortar and the contents crushed. Then 2.7 g of amphotericin B powder were added and mixed with glycerine to create a paste. Acuagel was added to a total weight of 90 g. It was blended until smooth. An expiry date of 14 days was given, although according to the Spanish Pharmacopoeia the stability of these formulations is 3 months. Vaginal applicators were used to apply the cream intravaginally.

Results A 36-year-old woman with vulvovaginitis (positive culture for C. glabrata resistant to itraconazole and sensitive to amphotericin B, flucytosine, fluconazole and voriconazole in January 2009), was treated with oral and intravenous fluconazole, vaginal ketoconazole, intravenous voriconazole and vaginal boric acid. However, in February 2009 the culture was still positive. The physician prescribed 5 g/day vaginal FLUCY 15.5 for 14 days. For preparation details see materials and methods. After this treatment, the culture became negative (April 2009). Unfortunately, in March 2010, the patient again developed pain and vaginal itching. Culture of vaginal discharge was positive for C. tropicalis. The physician prescribed 5 g/day vaginal FLUAM and oral fluconazole 50 mg/day for 14 days. It was prepared as indicated above. After this treatment, the culture was negative (April 2010).

Conclusions Local treatment with flucytosine and amphotericin B was effective against vaginal infections caused by non-albicans Candida species.

Competing interests None.

TCH017 ACTIVITY AND MICROBIOLOGICAL MONITORING OF ISMETT'S GALENIC LABORATORY

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Background Intravenous sterile galenic preparations allow unit dose personalised therapy for patients. The assurance of sterile preparations, especially in a transplant centre that treats immunocompromised patients, must be guaranteed

by dedicated rooms and equipment, qualified personnel and application of aseptic techniques.
Purpose The goal of the study is to evaluate the activity and safety of the pharmacy compounding laboratory.
Materials and methods Ismett hospital has about 90 beds and an average of 2000 patients / year.
Compounds sterile medications in a laminar flow hood in our class 10,000 clean room guarantee safety and quality products by following Italian rules of good manufacturing (NBP), Good Manufacturing Practice (GMP) and microbiological testing incorporate on a regular basis. Intravenous galenic preparations were monthly tested for determination of aerobic / anaerobic bacteria and bacterial endotoxins by Lymulus Amebocyte Lysate test. Environmental, surface and personnel were tested every three months.
Results 75,000 intravenous preparations were performed from January to September 2011, with an average of 8322 monthly and 275 daily doses. 31% continuous infusions and 69% bolus, (46% antibiotics, 12% gastroprotectors, 9% cardiac stimulants, 5% antihypertensives, 1.5??% antiarrhythmics, 7% hypoglycaemics, 6% anaesthetics, 5% antithrombotics, 2% antifungals, 1% antivirals, 8.5% others). Environmental samples, personnel hands and galenic preparations were always negative (100%). 25% of the surface samples were positive for coagulase-negative staphylococci, oryzihabitan Pseudomonas, Sphingomonas paucimobilis, Sphingomonas spp and Acinetobacter spp, micrococci and Alternaria fungi. Consequently some strictly corrective measures have been adopted to avoid positive surface samples.
Conclusions Considering the large number of daily preparations, periodical microbiological monitoring is essential to take the necessary corrective measures to reduce microbial load and ensure the quality and sterility of preparations.

Competing interests None.

TCH018 MICROBIO: A WEB-BASED PROGRAM FOR PROCESSING AND EVALUATION OF MICROBIOLOGICAL CONTROLS ON ASEPTIC DISPENSING

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Background According to the Dutch GMP-hospital pharmacy directive (1) three types of microbiological controls are required when aseptic dispensing is performed: 1. microbiological monitoring of the air in the working area, the gloved hands of the operator and the work surface at the critical place in the laminar airflow cabinet; 2. microbiological validation of the operators through media fill runs; 3. validation of the aseptic process by repeating the procedures with an appropriate broth.
Purpose To develop a web-based program for data of microbiological controls on aseptic dispensing for Dutch hospital pharmacies for: simple processing of environmental monitoring data; trending of environmental monitoring data; comparing individual data with other hospital pharmacies nationwide.
Materials and methods The web-based program MICROBIO was designed in collaboration with an expert group of hospital pharmacists. Participating hospital pharmacies collected microbiological control data and entered them into the program. Limits for microbiological contamination are based on EU-GMP recommendations (2).
Results Currently 49 of 80 Dutch hospital pharmacies use MICROBIO.
More than 85% of the microbiological controls on monitoring comply with the results (air 87%, gloved hands 90%, work surface 86%).
Conclusions MICROBIO is a standardised tool which fully supports processing data and evaluation for all three types of microbiological controls and presents them in diagrams and histograms.
The results show that the directive on aseptic dispensing in GMP-hospital pharmacy is met. Literature 1. Aseptic dispensing. In GMP-hospital pharmacy. The Hague: Dutch Association of Hospital Pharmacists; 2005; www.nvza.nl. 2. The rules governing medicinal products in European Union. Volume 4. Good manufacturing practices. Medicinal products for human and veterinary use. Annex I. Manufacture of sterile medicinal products. European Commission, revision May 2003.

Competing interests None.

TCH019 OVERALL EQUIPMENT EFFECTIVENESS: A PRODUCTION WORK TOOL APPLIED TO A PARENTERAL NUTRITION ROBOT IN A UNIVERSITY HOSPITAL

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Background 'All in one' parenteral nutrition bags are prepared in our University Hospital by a robot. Overall Equipment Effectiveness (OEE) is an indicator usually used in pharmaceutical industry to monitor and optimise the use of machines.
Purpose In the context of optimisation of resources in hospitals, the production activity of the parenteral nutrition bags was studied using this tool allowing the continuous evaluation of resources.
Materials and methods The OEE has been determined for the robot Exacta-Mix 2400® over 2 years (2009 and 2010) (Baxa Corporation, Englewood, USA). Quality, availability and performance levels were calculated after measuring production data: planned production time, operating time, ideal cycle time of neonatology and paediatric bags and total number of bags per day.
Results Regarding production data, the operating time increased from 67 to 90 min between 2009 and 2010, the ideal cycle time of paediatric bags increased from 4.9 min to 7.4 min. Total pieces per day decreased from 12.2 to 9.9. The quality level was 100% in 2009 and 2010, that is all bags were in accordance with Good Manufacturing Practice guidelines such as electrolyte identity and content, uniformity of mass and of content. The availability level calculated as operating time / planned production time, increased by 7.3%. The performance level calculated with ideal cycle time, operating time and total pieces per day, decreased by 43.7%. The OEE calculated as availability x performance x quality, decreased from 36.6 to 18.7%.
Conclusions The drop of OEE between 2009 and 2010 indicates a decrease of the production effectiveness, particularly due to the decrease of the performance level (generally influenced by small stops and reduced speed). This indicator allows us to select quality and performance improvement actions.

Competing interests None.

TCH020 CHEMICAL CONTAMINATION DURING THE PREPARATION OF CYTOTOXICS: A MULTI-SITE SIMULATION STUDY

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Background Although an effort is always made to reduce contamination, traces of cytotoxic drugs can be found in the environment. External surfaces of vials can be a source of contamination, but the operators themselves also contribute to this problem during manipulation.
Purpose To quantify the chemical contamination generated by a large panel of operators during a standard preparation process, using a non-toxic tracer in a multi-site simulation.
Materials and methods Preparation was simulated voluntarily by operators in Swiss hospital pharmacies. Each operator had to reconstitute 3 vials of quinine diHCl powder (200 mg) with 5 mL of water and dilute them in 3 saline solution infusion bags (50 mL). A standard procedure was used, using only one 10 and one 20 mL syringe, 2 needles and 15 gauze compresses, creating a worst-case scenario. Contamination on vials, bags, gloves and compresses was analysed by a validated fluorimetric method (λ_{ex}=345 nm, λ_{em}=448 nm, LOD (limit of detection) =0.3 ng/mL or 15 nL and LOQ (limit of quantification) =1 ng/mL or 50 nL at pH 3.0).
Results Sixty-two operators in 24 hospitals (1 to 5 per hospital) participated in the study. 95% of operators contaminated at least one object. Mean total contamination was 78 µL (0 to 596 µL). Compresses were the most contaminated items (mean 72 µL, 0 to 592 µL). Contamination also occurred on gloves (0.2 µL, 0 to 59 µL), bags (0.7 µL, 0 to 24 µL), quinine vials (0.2 µL, 0 to 16 µL) and water vials (0.02 µL, 0 to 0.8 µL).
Conclusions A simple validation protocol for chemical contamination, using a non-toxic tracer, enables the ability of operators to avoid spillage to be checked. It demonstrated wide variability between operators in a multi-site survey. Such a simulation tool is of the utmost importance in the context of the operator's initial and continuing training and qualification.

Competing interests None.

TCH021 CYTOTOXIC SURFACE CONTAMINATION IN 24 SWISS HOSPITAL PHARMACIES

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Background Exposure to cytotoxic drugs is a risk to healthcare professionals. To improve safety, most hospitals have introduced centralised preparation of cytotoxics, but the infrastructure and protective measures can vary between places. To determine the performance of confinement methods, it is important to benchmark the contamination levels between similar structures.
Purpose To establish an overview of chemical surface contamination by cytotoxic drugs in a large panel of Swiss hospital pharmacies.
Materials and methods A sampling campaign was conducted voluntarily in Swiss hospital pharmacies. At each site, wipe samples were collected in the preparation and logistics areas (most collection spots were common to all pharmacies, but each site could choose a few points of interest to itself). Chemical surface contamination of 10 cytotoxic agents (cyclophosphamide, ifosfamide, gemcitabine, doxorubicin, epirubicin, irinotecan, methotrexate, etoposide phosphate, cytarabine and vincristine) was determined by a validated wiping procedure and LC-MS/MS analysis.
Results Twenty-four hospital pharmacies (out of 46 contacted, 52%) participated in the study: 12 to 29 wiping samples were collected in each site. The surface contamination was generally lower than 100 ng per 100 cm^2, with wide variability between sites. In 2 pharmacies, no contamination at all was detected. The heaviest contamination (> 30 µg) was found on a CATO keyboard. Preparation areas (especially work benches, objects inside the safety cabinets and cleanroom floors) were more contaminated than logistics areas. Ifosfamide, cyclophosphamide and cytarabine were the drugs detected in the highest quantities.
Conclusions Despite recommended safe handling practices, workplace surface contamination was observed. Most contamination was confined to manipulation areas, reducing the risk of exposure for operators. Possible correlations between structural and/or organisational characteristics and the level of contamination will be evaluated.

Competing interests None.

TCH022 MICROBIOLOGICAL STABILITY OF VIALS USED IN CYTOSTATIC COMPOUNDING

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Background Phial sharing would lead to great savings in cancer therapy. Although physicochemical data support this practice frequently, microbiological stability is of concern.
Purpose To assess microbiological stability of vials in cytostatic compounding when a closed-system drug transfer device (CSTD) is used.
Materials and methods Cytostatic compounding process was simulated using 100 ml TSB culture media vials. Three batches (eight vials each) were elaborated by different technicians. Handling was conducted inside a biological safety cabinet and using PhaSeal system (CSTD). Usual garbing for cytostatic compounding was used. At day zero, vials were diluted (5 ml of sterile water). Thereafter, on days 1, 4, and 7, seven millilitres of phial content were removed using a 10 ml syringe and 13 ml were transferred to a 100 ml empty bag. Vials were stored outside the clean room. Work surface and gloves were sampled at the end of each day by applying Tryptic Soy Agar (TSA) contact plates. All samples were incubated for two weeks (20-25°). Contamination was defined as visual turbidity. Contact plates were incubated one week at 37°.
Results No microbiological growth was detected in any of the 24 vials after 7 days of storage and 9 manipulations of each phial. 96 syringes and 96 bags were incubated. None were contaminated either. Samples from the work surface remained clean. Only one plate from the gloves was contaminated with two colony-forming units of gram positive cocci. Microorganisms did not reach the solution supporting the fact that PhaSeal® encourages a proper aseptic technique. Absence of contamination after storage and handling has also been reported previously using traditional needle-based methods. However, the use of CSTD

as in our study represents best current practice in cytostatic compounding where operator protection is a cornerstone.
Conclusions An aseptic technique using PhaSeal® maintains phial's sterility over time and handling, allowing substantial savings. Results will be validated in a larger study that is ongoing.

Competing interests None.

TCH023 EVALUATION OF SURFACE CONTAMINATION WITH EIGHT ANTINEOPLASTIC DRUGS IN PREPARATION AND ADMINISTRATION AREAS IN POLISH HOSPITALS

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Background There is a lack of awareness of contamination levels on surfaces in Polish hospitals and pharmacies where antineoplastic drugs are handled. No studies so far have evaluated the surface contamination with these hazardous drugs in Poland.
Purpose To evaluate the surface contamination with 8 antineoplastic drugs in 4 Polish hospitals in the pharmacy (pharmaceutical preparation) and on the ward (use).
Materials and methods Wipe samples were taken from 5 comparable surfaces in the pharmacy (workbench inside biological safety cabinet (BSC), floor in front of BSC, checking counter inside and outside the preparation room, refrigerator door) and 5 similar surfaces on the ward (checking counter at nurses' station, lid of cytotoxic waste container, top of patient armchair, floor under the drip infusion stand, phone). The samples were analysed using LC-MS/MS for surface contamination with cyclophosphamide, docetaxel, etoposide, 5-fluorouracil, gemcitabine, ifosfamide, methotrexate, paclitaxel.
Results 37 of the 40 surfaces sampled were contaminated with at least one substance (92%).The most contaminated surfaces in preparation areas were: workbenches in BSC (total: 8.21 ng/cm^2), floors (5.43 ng/cm^2), checking counters (3.63 ng/cm^2). The administration areas with the highest total contamination were: floors (145 ng/cm^2), top of patient armchairs (10.76 ng/cm^2) and phones (3.71 ng/cm^2). Two pharmacies with the highest number of drug preparations had significantly less cytotoxic drug contamination than the other pharmacies. The most common surface contaminant in all pharmacies was identified as gemcitabine (on 80% surfaces) but the highest concentration was found of ifosfamide. 26 surfaces (17 in 4 wards; 9 in 2 pharmacies) were contaminated with drugs that were not used on the day of sampling. This old contamination shows that the cleaning procedures must be improved as well as the preparation procedures.
Conclusions Measurable amounts of at least one agent were detected on almost all of the sampled surfaces in the preparation and administration areas in all hospitals investigated. The level of surface contamination was significantly higher in wards than in pharmacies.

Competing interests None.

TCH024 PREPARATION OF CAPSULES FOR INDIVIDUAL PATIENTS: VALIDATION OF THE OPERATOR'S ACCURACY

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Background Preparation of capsules is common in hospital pharmacy when an adapted dosage is not available on the market. According to the Good Manufacturing Practices, validation of processes and operators are essential to ensure the quality of preparations.
Purpose To evaluate and validate the operator's accuracy during the manual process of capsules preparation. Materials and Methods Operators had to manually prepare, without using mannitol carmine, 3 batches of 100 capsules. Each 250 mg capsule (size 2) contained 6 mg of phenylephrine used as a tracer. Ten capsules in critical points of the capsule filler (2 in every corner and 2 in the centre) were analysed according to the European Pharmacopeia (uniformity of mass and content). Phenylephrine was determined by a validated capillary electrophoresis-UV method. Results were analysed considering the operator's experience based on the years of experience and the frequency of execution (low, medium and high).
Results Forty-two batches were produced by 14 operators (11 technicians and 3 pharmacists). Mass uniformity: all batches were conform. The mean mass (±SD) was 247.5 mg (±3.8). The mean mass obtained by the operators with low (n=6), medium (n=4) and high (n=4) experience were 244.6 (±2.4), 247.9 (±2.3) and 251.6 mg (±2.7), respectively (r^2=0.60). Content uniformity: 6 batches (14%) were not conform. 9/14 operators (64%) passed the test for 3/3 batches, 4/14 (29%) for 2/3, and 1/14 (7%) for 1/3. The mean content for low, medium and high experience was 95.6 (±3.0), 96.9 (±2.1) and 97.0% (±2.5) of the target concentration, respectively (r^2=0.06).
Conclusions All operators displayed adequate skills to uniformly fill capsules, with a trend to a better performance by experienced operators. However, insufficient homogenisation of the mixture was observed, independently of the experience. Further studies are needed to evaluate different systems from producing consistent mixtures.

Competing interests None.

TCH025 STUDY OF CHEMICAL STABILITY OF AN IN OIL FENRETINIDE MICRODISPERSION VEHICLED IN RIGID CAPSULES THROUGH CFS1200 Æ TECHNOLOGY

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Background In a double-blind, breast cancer chemoprevention trial in young female subjects with a genetic predisposition (BRCA1\2 mutation), the Hospital Pharmacy of the European Institute of Oncology developed a fenretinide formulation (not commercially available retinoid). The formulation consists in an oily microdispersion of fenretinide, encapsuled in Licaps by an automatic capsule filling and sealing system called CFS1200®.
Purpose The aim of this study is to demonstrate the chemical stability of the formulation for 18 months.
Materials and methods Hygroscopicity test, test for mechanical strength, dissolution test up to six months and content uniformity test at 6,12 and 18 months by HPLC/UV (capsules have been stored at room temperature in open bottles) have been performed. The HPLC/UV method is described below: -Operating temperature=15°C; -Column=Agilent Zorbax Eclipse XDB C18-150*4.6-5 µm; -Mobile phase A= methanol-water-acetic acid(700:300:3); -Mobile Phase B= methanol-

water-acetic acid(950:50:3); -Gradient: start at 15% of mobile phase B; 40 min=100% mobile phase B; -Acquisition-time: 50 minutes; -Reconditioning-time: 10 minutes; -Flow rate: 1, 5 ml/min; -λ=35 nm; -Loop: 10 microlitres.
Results Hygroscopicity tests (water exchange at different RH) and mechanical strength test gave results in accordance with the specifications. The use of pepsin in dissolution medium made it possible to overcome the cross-linking issue between excipients and the gelatin capsule shell. The final results of the dissolution test after 6 months of storage were within specifications. The HPLC/UV method is robust and accurate. Linear responses were obtained in the considered concentration range(r^2=0.99). The chromatogram contains up to 11 integrable peaks, of which the largest one is fenretinide (peak 9), peaks 7,8 and 11 are known impurities, while the sum of all the other impurities is 0,158%. There was no significant difference between the average concentration of the analyte in the capsules at 18 months(98.43%), and the fresh internal standard (quantitative deviation=4.82%).
Conclusions In oil fenretinide microdispersion, encapsulated in a nitrogen atmosphere using CFS1200® technology, is stable for at least 18 months.

Competing interests None.

TCH026 DRUG STABILITY DETERMINATION BY VARIABLE-PARAMETER KINETIC EXPERIMENTS

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Background The effect of environmental parameters on drugs stability is a very important piece of information in pharmaceutical field. It often requires a detailed kinetic investigation to have quantitative data on the dependence of the reaction rate constant on a physical parameter (temperature, pH, ionic strength, metal ions concentration, etc.). The common way consists in following many times the reaction, by a suitable analytical instrument for different values of a parameter and for each required parameter with a considerable expense of time and chemicals. The continuous introduction of new drugs made it necessary to develop faster analytical methods for the evaluation of their stability.
Purpose In this contribution the authors show a variable parameter method for the determination of drug stability based on a generalisation of non-isothermal analysis that takes advantage of the capabilities of modern data collecting and processing system.
Materials and methods The used method consists in carrying out kinetic experiments while varying, in a known way, the value of a physical parameter and in obtaining, trough a single experiment run, the entire dependence of the rate constants on that parameter. The experimental apparatus was made up of routine instruments and data were automatically collected and processed using commercially available software.
Results Many drugs, in solution, were analysed: acetylsalicylic acid, indomethacin, rolitetracycline, diltiazem, piroxicam and cinnoxicam following the reacting species using various analytical instruments: UV-vis spectrophotometer, fluorimeter, conductometer, polarimeter and HPLC. Validation was performed, in the same lab, by comparison to results obtained from traditional method experiments with measurements of accuracy, precision, linearity and detection limit. The results are in good agreement with those obtained using constant-parameter kinetic runs, moreover, being the results obtained in a fast way, through a simple mathematical treatment, are subjected to a minor statistical uncertainly.
Conclusions Variable parameter kinetics was an important method for the studied drugs and it can be easily used for all drugs when drug stability investigation is required.

Competing interests None.

TCH027 CENTRALISED PREPARATION OF INTRAVENOUS DRUGS IN THE PHARMACY DEPARTMENT: WHAT ARE THE OPTIONS?

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Background The preparation of intravenous drugs by nurses results in many drug-related errors. Centralised preparation in the pharmacy department enables INTRAVENOUS infusions to be prepared more safely.
Purpose The objective of this study was to undertake a feasibility study of different preparation scenarios for an 815-bed hospital (which uses computer-assisted prescribing):
- Manual centralised preparation for all intravenous drugs
- Automated centralised preparation for all intravenous drugs
- Centralised preparation of ready-to-use syringes for selected drugs.

Materials and methods The theoretical number of preparations was estimated. The hourly spread of the preparations over a day was established. For each scenario the following criteria were studied:
Number of FTE (full time equivalents) required for pharmacists and pharmacy technicians, organisational problems, costs, feasibility depending on the drugs' stability.
Results The first two scenarios were not realistic: the benefit/ risk ratio was insufficient, organisational problems would often occur, some drugs are not stable enough and the cost was too high. In such scenarios The authors would have to make over 200 preparations per hour during the peak period. However, the third scenario: centralised preparation of ready-to-use syringes should be encouraged for particular drugs: insulin, heparin, anaesthetics. The concentration should then be standardised. Buying a pump or a syringe-filling machine depends on the number of preparations being made. The financial balance is reached, with the construction of a dedicated preparation unit, when the annual number of preparations made exceeds 22,000 ready-to-use syringes (quality control costs not included).
Conclusions Setting up a dedicated preparation unit to make ready-to-use syringes for drugs with a narrow therapeutic index would improve the quality and improve patient safety.

Competing interests None.

TCH028 MICROCALORIMETRY: EARLY IDENTIFICATION OF BACTERIAL INFECTIONS†

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Background Microcalorimetry is an experimental technique that allows us to determine, with great sensitivity, the energy released during any process or transformation.

Purpose To determinate the applications of microcalorimetry as a method of early identification of bacterial infections.
Materials and methods A Calvety-type microcalorimeter was used, which maintains a constant temperature of 37 degrees centigrade. Samples of Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa were prepared at different concentrations (10^6, 10^5, 10^3 and 10 CFU/ml). Digested Soy-casein liquid culture was used as the culture medium. 7 ml of culture medium was injected into the control cell together with 1 ml of physiological saline, and 7 ml of culture medium was injected into the test cell. Both cells were placed in the microcalorimeter and left to stabilise for approximately an hour and a half. After this time, 1 ml of the test concentration was injected into the test cell.
Results By plotting heat voltage difference versus time, we obtain the characteristic bacterial growth curves of S. aureus, E. coli and P. aeruginosa at different concentrations. Analysing the thermograms obtained, The authors assumed that each bacterium has its own growth profile that repeats at all the concentrations studied, so that The authors obtained a 'thermal fingerprint' that allow us to identify the bacteria within the first 24 h of culture. Moreover, The authors observe that the time until the signal starts is greater when the concentration decreases, but in any case in less than 10 h The authors can identify the presence of bacteria in the culture medium, even for less concentrated samples (10 CFU/ml).
Conclusions Microcalorimetry allows us to determine the presence of bacteria in the sample in less than 10 h. In addition, each species of bacterium has its own growth profile which allows it to be identified in the first 24 h of culture, allowing treatment to be started early and tailored to the sensitivities of the causative agent.

Competing interests None.

TCH029 NEW GALENIC FORMULATION BASED ON MECHLORETAMINE FOR TOPICAL TREATMENT OF MYCOSIS FUNGOIDES

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Background The treatment of mycosis fungoides (MF), the most common form of primary cutaneous lymphoma T cells, depends on clinical staging. In the presence of lesions in patch/plaque the use of phototherapy, retinoids, immunomodulators and radiotherapy is common in the early stages and in the presence of disseminated nodular lesions the use of systemic chemotherapy.
Purpose The possibility to have a preparation of topical chemotherapy available, which can be used alone or in combination with other treatments, could be an important therapeutic option. Thus topical formulations of mechlorethamine with characterisation and evaluation stability were developed. The authors then proceeded to the evaluation of the clinical activity and the tolerability of the topical preparation based mechlorethamine 0.02% in the treatment of plaque and nodular lesions of MF. Materials and Methods Various lipophilic and hydrophilic formulations were prepared and characterised. Mechlorethamine 0.02% in Aquaphor ointment base was identified and characterised for chemical and microbiological stability for clinical investigation. After informed consent, 6 patients, median age 67 years (48 -88), whose disease had relapsed after chemotherapy were treated. The galenic preparation was applied daily for the treatment of 11 lesions, 5 days / week for up to 3 weeks. The response was evaluated after treatment using the RECIST criteria.
Results The use of mechlorethamine has been improved in order to obtain a new preparation technique in consideration of instrumental resources available in a hospital pharmacy and the difficulty of handling cytostatic drugs for topical formulations. 11 lesions were treated, a partial clinical response was obtained in 5 and a complete response in 2. In all the cases, the treatment was well tolerated, 2 patients developed short-lived erythema / oedema peri-lesional. There was no evidence of systemic toxicity.
Conclusions Based on these preliminary results, topical application of mechlorethamine has been well tolerated and associated with good clinical activity. The encouraging results obtained in this preliminary phase encouraged us to continue the study on a larger number of patients.

Competing interests None.

TCH030 CONTENT ANALYSIS OF UK MEDIA COVERAGE OF PHARMACOGENETICS

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Background In recent years, the analysis of media dialogue has been recognised in the literature as an important aspect within the area of health research. As patients are becoming increasingly self-educated via the media, it is important to know how the media portray information on PGx to the public.
Purpose To explore, through systematic content analysis, the trends in UK newspaper coverage of pharmacogenetics in general and the potential benefits and risks of pharmacogenetic testing in particular.
Materials and methods A purposive sample of the 10 UK highest circulation national daily newspapers and their Sunday equivalents was investigated, through Jan 2001-Dec 2010. The LexisNexis database was used to identify and retrieve full text articles from electronic archives. A standardised coding frame was developed to facilitate consistent data extraction and analysis. The main researcher manually coded the entire set of relevant newspaper articles while a second independent researcher reassessed a random sample (24%) of the articles in order to estimate the overall reliability of the coding process.
Results Of the 233 articles captured by the search terms, 83 articles met the study inclusion criteria and thus were included in the final detailed analysis. The mean inter- coder κ score was 0.84, indicating good agreement. The vast majority (98.8%) of the articles stated at least one benefit of the application of pharmacogenetics, while only 34.9% of the articles mentioned at least one risk. Overall beneficial effects were mentioned 5.5 more frequently than risks ($p<0.001$). There was a marked unequal distribution of articles in broadsheet versus tabloid newspapers ($P<0.001$). There was a positive correlation between the size of the article and both the number of benefits and risks stated ($P<0.01$).
Conclusions The study demonstrated that pharmacogenetics is a topic of only marginal interest to UK newspaper editors. The majority of articles emphasised the benefits of pharmacogenetics testing while under-reporting the risks whereas a 'balanced assessment' is required to allow readers to make informed decisions. This trend of reporting highlighting that

journalists have special responsibilities in conveying information (both sides of the story) to the public since readers may make important decisions based on what is presented. One side of a story is not sufficient for the reader; If the benefit is overstated, the public expectation for cure or health improvement may be inflated and unrealistically raised. The opposite is also an issue that is if a risk is overstated, this may generate unnecessary anxiety which could reflect adversely on patient behaviour.

Competing interests None.

TCH031 THE COMPLETE AUTOMATION AS THE NEW FRONTIER OF ONCOLOGY DRUG COMPOUNDING

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Background The pharmacy laboratory of oncology drugs compounding of the University Hospital of Ancona runs about 20000 preparations per year. Thanks to the collaboration with Loccioni Group, the process of work automatisation started in 2007 with the introduction of a first robot for chemotherapy compounding. The following years were devoted to develop and validate the system, increase the number of drugs handled and enlarge the productivity. At the end of 2009 a new generation of robotised system was introduced into the Pharmacy with the objective of setting the first totally automated laboratory by the end of 2010.
Purpose To evaluate the work of the last four years.
Materials and methods The 2007-2009 data are analysing by combining the APOTECAchemo database with the clinical database of the Pharmacy. Since 2010, the two database were merged into the same platform in order to make the data mining much simpler.
Results The authors starting with 5 active ingredients in September 2007 and now APOTECAchemo handles 56 oncology molecules, which correspond to more than 160 different vials. The production rate of the system passed from 3400 in 2008 to 6600 in 2009 and 16300 in 2010. In the first 9 months of 2011 The authors already produced 14200 units and The authors expect to overcome 19000 preparations delivered by the end of 2011.
Conclusions The automated production of the cancer therapies is a matter of fact: the percentage of work daily covered by automation was around 80% in 2010 and is about 95% at the moment (Oct 11). 100% of the therapies compounded with the robot are certified and each compounding step is fully traced. This represents also an important protection of the work under the pharmacist's responsibility.

Competing interests Advisory board: Dr. Demis Paolucci is the scientific head of Loccioni humancare (APOTECAchemo manufacturer). He has been involved in the project since the beginning thanks to the free-of-charge collaboration public-private.

TCH032 THE PERFORMANCE IMPROVEMENTS OF THE 3RD GENERATION ROBOT FOR THE AUTOMATED COMPOUNDING OF ONCOLOGY DRUGS

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Background The collaboration established in 2007 between the Oncology Pharmacy of the University Hospital of Ancona and the Loccioni Group was aimed at implementing, validating and integrating the robotised system for the chemotherapic drugs compounding in the day-to-day pharmacy activity. Currently the Oncology Pharmacy is almost totally automated (95%) and Loccioni has its clinical site for the continuous engineering. During this 4-year period, the constant implementation gave rise to three generations of robot with the final version ApotecaChemo released late in 2009. The authors had the chance to experience all three generations and to validate the tough work done to increase efficiency, ergonomics and user-friendliness.
Purpose The objective of this work is to analyse the performance of the third generation robot and to compare it with the previous ones.</p>
Materials and methods Data were obtained from the robot database. An other advantage of automation is related to the data mining. Every step is measured and traced, providing a huge amount of information helpful for both performance statistics and process re-organisation. In this case, The authors compared production rate and the preparation time of specific drugs in standard protocols along the years.</p>
Results The average preparation time of a fluorouracil bag of a CMF protocol halved from 303 to 156 s with the 3rd generation robot. Similar trend is recorded for a methotrexate bag (CMF) and an epirubicin bag (FEC), whose preparation time passed from 276 to 127 s and from 565 to 253 s respectively. The improvement is even more significant for other drugs like gemcitabine, which is about 80%.
Conclusions This technology has developed rapidly reaching high production rate. Nowadays, ApotecaChemo performances are comparable to those of the manual activity, with the added values of a quali-quantitative certification of each preparation compounded.

Competing interests None.

TCH033 IMPROVING THE EFFICIENCY, SAFETY AND SECURITY OF CONTROLLED DRUGS INVENTORY MANAGEMENT WITH THE PYXIS C11 SAFE SYSTEM

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Background Current manual inventory management systems for controlled drugs are time-consuming and error prone. The Pyxis C^{11}Safe is a computerised controlled drugs system. Evaluation of this technology using a structured observational methodology to assess efficiency, safety and security is required to support adoption.
Purpose To compare the efficiency, safety and security of the Pyxis C^{11}Safe system with the current manual systems for controlled drugs using 'time and motion' observational methods.
Materials and methods Pre and postimplementation methodology was adopted.

- Stage 1: Map the process and quantify existing processes.
- Stage 2: Develop 'best practice model' using Pyxis C^{11}Safe; procedures are simulated, documented and implemented.
- Stage 3: Conduct a time and motion study of existing and new processes to evaluate aspects of efficiency, safety and security using an independent observer.

Results Controlled drugs inventory practices were process-mapped and standardised in an acute care government hospital. An independent observer then conducted a time and motion study of the manual system, over a one month period. The time taken to complete a range of transaction types (receipt, distribution, discharge dispensing, returns

and destruction) were recorded for 680 transactions. A best practice model for Pyxis C[11]Safe was developed, simulated and refined. Pharmacy staff were trained and the Pyxis C[11]Safe procedures implemented with 350 transactions observed and timed. Statistically significant time saving (20%, p=0.0001) was identified in the processing of controlled drug prescriptions distributed to patient care areas (5 min 3 s with Pyxis C[11]Safe vs 7 min 11 s for existing processes). Non-significant time savings were demonstrated in other transaction types.

Conclusions A structured observational methodology has facilitated the assessment, and demonstrated significant efficiencies, of the Pyxis C[11]Safe system compared to the current inventory management systems for controlled drugs.

Competing interests Ownership: – Advisory board: an unrestricted grant from CareFusion supported the conduct of this study; Board of directors.

TCH034 PROTEOMIC APPROACH TO INVESTIGATING THE MOLECULAR INTEGRITY OF INFLIXIMAB AFTER RECONSTITUTION AND DILUTION IN TYPICAL HOSPITAL CONDITIONS

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Background The active substance of Remicade is infliximab. It is a chimeric human-murine monoclonal antibody directed against tumour necrosis factor α (TNFα), manufactured from a recombinant cell line. Remicade is presented as powder for concentrate for solution for infusion (100 mg/phial), to be reconstituted with water for injections, diluted with saline and thereafter administered via intravenous infusion.

Purpose The purpose of this study was to investigate the suitability of a proteomic approach using MALDI-TOF mass spectrometry to test the molecular integrity of infliximab when reconstituted and diluted in the usual hospital conditions.

Materials and methods Infliximab was reconstituted in water for injection (10.0 mg/ml) and diluted with NaCl 0.9% solution (2.0 mg/ml and 0.5 mg/ml). 10 µL of the samples containing the antibody were reduced with DTT and alkylated by iodoacetamide in darkness for 30 min and they were digested by trypsin at pH 8.5 for 4 h at 37°C. The digest was loaded onto the MALDI target plate using 5 mg/ml α-cyano-4-hydroxycinnamic acid in 0.1% trifluoroacetic acid, 50% acetonitrile as the matrix. Each digest was analysed five times by MALDI-TOF mass spectrometry using a Voyager DE-PRO (Applied Biosystems) in positive reflector mode.

Results The peptide fingerprint map (PFM) of the infliximab was obtained for the reconstituted sample and for the diluted samples right after their preparation. In this way, the molecular integrity of infliximab can be described and characterised.

Conclusions This proteomic approach for the analysis of infliximab is suitable to be used in a long stability study of the antibody reconstituted, diluted and stored refrigerated (4°C) and frozen (-20 °C) since possible changes in the antibody structure could be detected by changes in the corresponding PFM. This study stability is currently being performed by our research group.

Competing interests None.

TCH035 STABILITY OF DOCETAXEL INFUSIONS

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Background According to the manufacture, docetaxel infusions should be used within four h at room temperature (<25°C).

Purpose To determine the stability of intravenous mixtures (IVM) at a concentration of 0.7 mg/mL in 0.9% sodium chloride prepared from three different specialties generic docetaxel at room temperature and refrigerated

Materials and methods In vertical laminar flow hood two IVM were prepared for each specialty (docetaxel Teva® 80 mg/2 mL, docetaxel Actavis® 20 mg/mL and docetaxel Hospira® 10 mg/mL), diluted in 0.9% sodium chloride 100 mL (Grifols Physiological saline Fleboflex®) at a final concentration of 0.7 mg/mL, one of which is kept at ambient temperature and the other kept refrigerated (2-8°C). In each of the IVM, was taken an aliquot of 0.5 mL at 0, 24, 48, 72, 96 and 120 h for the determination of docetaxel. The concentrations are expressed as a percentage of the remaining concentration with respect to the initial concentration obtained immediately after preparation of each of the IVM. The determination of the concentrations of docetaxel was performed using high performance liquid chromatography (HPLC). The authors used a Merck-Hitachi® HPLC System, consisting of a pump, an autoinjector system, a UV detector and an integrator in the form of software. The authors used the following chromatographic conditions: stationary phase C18 column (5 µm 150 mm x 4 mm), mobile phase: water and acetonitrile (48:52) both of HPLC grade. The flow was set at 1 ml/min. The retention time is 5.5 min. The wavelength used by the UV detector is 233 nm.

Results None of the IVM analysed, turbidity or precipitation was observed. The percentages of the remaining concentrations of docetaxel in the IVM compared to the initial concentration were: 99.4-102.5, 100.3-104.2, 98.3-102.4, 97.6-102.2, 100.7-103.3% at 24, 48, 72, 96 and 120 h respectively in both IVM stored at room temperature and under refrigeration. Additional peaks were not seen in any chromatogram from test samples.

Conclusions The physicochemical stability of docetaxel at the conditions used both room temperature and refrigerated, is at least 120 h, allowing us to reuse the vials for intravenous administration through centralised preparation in intravenous therapy unit in the Pharmacy Service.

Competing interests None.

TCH036 DEVELOPMENT AND VALIDATION OF A METHOD TO STUDY THE MIXTURE DAPTOMYCIN/HEPARINE IN RINGER LACTATE BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

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Background In patients with infection related to catheter (IRC) is needed to consider several aspects that will lead both the managing and treatment of them. When the retention of the catheter is advisable it is necessary to apply technologies of sealed antibiotic. With that aim, the mixture daptomicine/

heparine prepared in ringer lactate solution has been proposed to be used.

Purpose The purpose of this research has been to study the mixture daptomicine/heparine sodium prepared in ringer lactate solution since no information upon its chemical and physical compatibility has been found in the consulted bibliography. A high performance liquid chromatography method (HPLC) has been developed following the International Conference on Harmonisation guidelines (ICHs) for this purpose.

Materials and methods The chromatographic separation was performed in a C-18 column. Due to the complexity of the mixture, it was necessary to apply a gradient in the mobile phase to achieve complete separation of the compounds, also to get separation from the degradation products of daptomicine. The started mobile phase composition was water /acetonitrile containing 0.1% of trifluoroacetic (60%:40%). The entire compounds were separated in 10 min. The detection was performed using a Diode Array Detector.

Results The linearity, accuracy, reproducibility, robustness and specificity of this HPLC method have been validated following the ICH guidelines. In fact, the HPLC method considered the degradation products that were detected when the mixture was submitted to accelerated stress conditions. The method was optimised to ensure that degradation products will not interference in the determination of daptomicine/heparine when analysing the mixture. Recoveries higher than 90.0% of the initial concentration were found when analysing the mixture daptomicine/heparine in ringer sodium lactate in preloaded syringes in a long term stability study (15 days).

Conclusions The method here propose has been validated following the ICH guidelines to be used as indicating-stability one. Thus, it has been used in the stability study of the mixture daptomicine/heparine in ringer sodium lactate in preloaded syringes since no information has been previously published about its chemical and physical compatibility. This study has demonstrated the stability of the mixture during the time tested (15 days).

Competing interests None.

TCH037 STABILITY OF TWO METHOTREXATE ORAL FORMULATIONS

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Background Pharmaceutical industry does not always provide suitable preparations for paediatric population. In these situations formulations should be developed for small scale compounding in hospital pharmacies, especially when cytotoxic drugs are involved.

Purpose Some guidelines for non-sterile pharmaceutical compounding preparations (eg, USP797) recommends in absence of stability information, an expiry date of 14 days under refrigeration for liquid preparations. The aim of the study is to develop a methotrexate oral formulation that yields stable for at least 25 days, an adequate period for three weekly administrations of one chemotherapy cycle.

Materials and methods Two formulations of 2.5 mg/ml were prepared by dissolving respectively tablets or injectable solution of methotrexate with Ora-Plus and Ora Sweet SF mixed in a 1:1 ratio. Preparations packed in amber coloured bottles were kept at 2-8° C. Samples were taken at 1, 7, 15, 25 days, and were analysed for appearance, pH, microbiological growth and methotrexate concentrations by Fluorescense Polarisation Immunoassay (FPIA) and ultraviolet-visible spectroscopy (UV-S) at 370 nm only with the solution (no supported for suspensions). Assays were specific for methotrexate (without cross-reactivity with metabolites) and calibrated with a known concentration. A stability study has been performed on these two formulations. Samples were diluted 1/100 with Xsystems Dilution Buffer. In FPIA was also performed the 1:100 dilution protocol of TDx/TDxFLx analyser.

Results Both formulations show stability for at least 25 days, with remaining content of methotrexate of 98.76% in suspension and 97.06% (FPIA) or 96.20% (UV-S) in solution. Appearance assay (no odour or colour changes), pH (5.0) and microbiological growth (negative) in all samples were appropriate and similar for both formulations.

Conclusions Methotrexate can be extemporaneously prepared in suspension or solution and stored at least 25 days under refrigeration without significant degradation. For paediatric patients who cannot swallow tablets, these formulations provide an accurate and suitable option for administering oral methotrexate.

Competing interests None.

TCH038 DEVELOPMENT OF AN ELISA ASSAY FOR THE DETERMINATION OF THE ANTIBODY INFLIXIMAB IN HOSPITAL CONDITIONS OF USE

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Background Infliximab (Remicade®) is a chimeric human-murine antihuman tumour necrosis factor (TNF) monoclonal antibody (75% human; 25% murine). It is composed of human constant and murine variable regions. It is produced by a recombinant cell line cultured by continuous perfusion. Infliximab binds to the soluble and transmembrane forms of tumour necrosis factor α (TNFα) and inhibits binding of TNFα with its receptors. It is approved for patients with rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis and ulcerative colitis. People with certain diseases have too much TNFα that can cause the immune system to attack normal healthy parts of the body. Thus, Infliximab can block the damage caused by too much TNFα.

Purpose The purpose of this research has been to develop an ELISA assay for the quantification of Infliximab when reconstituted in sterile water for injection to give final concentrations of 10.0 mg/ml, 2.0 mg/ml and 0.5 mg/ml.

Materials and methods A direct and non-competitive ELISA test has been developed to determine Infliximab. This inmunometric test has been based the use of coated ELISA plates with Infiximab. The plates were incubated overnight at 4°C using samples of the reconstituted Infliximab diluted appropriately in buffer carbonate/bicarbonate pH 9.6 0.1 M to give final concentrations between 1.0 and 500.0 ng/mL. Blocker was then added and incubated for two h at 37°C. Then plates were incubated 30 min after the addition of antihuman IgG peroxidase conjugated to the sensitised Infliximab plates. At the end of the incubation period the substrate (OPD o-phenylenediamine dihydrochloride) was added to each well. The reaction terminated by addition of sulphuric acid (1.0 M). The absorbance was obtaining by subtracting the measurements at 450 and 620 nm using a 96-well plate reader and the results

analysed using the XFluor4 software. Statistical data treatment for the validation of the method were performed using Stagraphics Plus 5.1 software.
Results The Infliximab ELISA method has been validated in terms of coating reproducibility, dynamic range of the assay including the estimation of the calibration function, accuracy (as recovery), intra e inter assay precision (as %CV), and sensitivity (as detection and quantification limits). Specificity was not included in the validation, since no cross-reactions are expected when analysing reconstituted Infliximab.
Conclusions The method here propose is ready to be used in further long term stability studies of Infliximab reconstituted in sterile water for injection to give the hospital conditions of use.

Competing interests None.

TCH039 CYTOTOXIC SURFACE CONTAMINATION IN A ROBOTIC SYSTEM COMPARED WITH MANUAL PREPARATION

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Background The preparation of cytotoxic drugs involves an occupational risk of contamination by aerosolised drug or contact contamination. To work with a robot could be an option to reduce risk to the operator, assuming that automation causes less contamination than manual preparation on a workbench.
Purpose To compare the surface contamination with cytotoxic drugs during automated preparation and manual preparation.
Materials and methods The contamination level of 5 predetermined areas in the CytoCare cabinet was investigated with swab tests by a known method (Schierl R *et al*). Samples were analysed by gas chromatography-mass spectrometry or inverse voltammetry after UV digestion. In the first series, 15 bags of 5-FU and 15 bags of platinum-containing cytotoxic drugs were prepared over two consecutive days. All surfaces were swabbed before (directly after the cleaning procedure) and after the preparation process. A second series was prepared and in addition the outer surface of each bag was swabbed. In parallel, the surface contamination during the manual preparation was studied. 15 bags of 5-FU and 15 bags of platinum-containing cytotoxic drugs were prepared over two consecutive days. 4 particular areas of the laminar air flow, the gloves of the technician and all bags prepared were swabbed by the same method.
Results Contamination with cytotoxics was observed in the working area of the CytoCare and on the outer surface of several automatically compounded products. The contamination levels were similar or higher in the robot to those in the manual preparation process.
Conclusions The cleaning procedure of the CytoCare turned out to be insufficient and must be improved. Further investigations are necessary to identify the origin(s) of the contamination and reduce them.

Competing interests None.

TCH040 PILAR COMPARISON BETWEEN MANUAL AND AUTOMATED PROCESSES IN THE PREPARATION OF INTRAVENOUS MIXTURES

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Background Automated systems have shown increased efficiency and safety in preparation processes and quality control of intravenous mixtures (IVMs).
Purpose To evaluate the differences, in terms of efficiency and safety, between manual and automated processes in the preparation and quality control of IVMs.
Materials and methods Comparative descriptive study of manual versus automated IVMs preparation (IV Station robotic system). The procedures for the manual workflow and the automated system were compared. Quality control procedures for the final product were also compared.
Results The manual process comprises five stages: 1) Preparing the relevant material (eg, drugs, solvents, consumables, packaging material) 2) Checking the material gathered 3) IVM production (following the relevant standard operating procedure) 4) Packaging and labelling of the final product 5) Quality control of the final product by a different member of staff: drug and solvent (name, volume), label (patient, drug and dosage, solvents, volume, infusion rate, storage conditions, batch, expiry date, visual inspection, packaging). The automated process includes five stages: 1) Preparing the materials specified in a software-generated list 2) Loading and automatic material checking by optical recognition and barcode checks 3) IVMs preparation and gravimetric control of intermediate components (eg, vials) and final product through a robot-integrated precision balance 4) Automatic labelling and downloading of final product 5) Label check and visual inspection of final product by nursing staff.
Conclusions Although preliminary results show the same number of steps for both processes, the robotic system achieves 60% automation of the quality control. Optical and barcode recognition, gravimetric control and automated labelling represent the main advantages of the robotic system compared with the manual preparation and also the best guarantees for the IVMs production process. Robotic systems give added value to production in terms of efficiency and safety.

Competing interests None.

TCH041 SAFER LABELLING OF PREPARED MEDICINES: INTRODUCTION OF COLOUR AND GRAPHIC DESIGN ELEMENTS TO MANAGEMENT SOFTWARE

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Background Patient safety is one of the most important subjects today. The correct differentiation of labels of all products is one of the first steps in this objective.
Purpose To describe the introduction of colour and other graphic design elements into the labelling of prepared medicines to improve the identification and differentiation of preparations, and thus improve patient safety. To introduce label design management software in order to design labels to differentiate between these elements.
Materials and methods A cycle of improvement has been introduced in the pharmacotechnology area, initially identifying products whose labels could potentially pose a risk to the patient. Then colour combinations, pictograms and graphic design resources were chosen that allow their differentiation. Changes in the software were introduced using Microsoft Access.
Results The authors identified the following groups of formulations in which differentiated labelling would improve

safety in use: treatment of drug dependence, combination eye drops for eye infections and dry eye, intravitreal and intracameral injections, dermatology and gynaecology preparations that may have a caustic effect. Graphic resources and colours were selected that facilitate the differentiation of the products within each category. For treatment of drug dependence labelling in the same colour as the prepared dishes highlights differences in dosage and active ingredient. In combination eye drops different colours were selected for each active series (vancomycin, ceftazidime or amikacin, voriconazole, autologous serum, acetylcysteine and cyclosporine). For preparations for intracameral administration combined colour printing and differentiation of the format of letters were introduced. Finally in the caustic products R phrases were introduced with corresponding R pictograms. Each model was created as a template tag in management software so it could be used in other preparations. The production schedule was modified so that the pharmacotechnology area can print labels for each preparation, automatically including batch, expiry date and other legal requirements.

Conclusions Graphic design elements are intended to facilitate identification of the product and improve patient safety. It is now necessary to incorporate this functionality into software management in the pharmacotechnology area.

Competing interests None.

TCH042 PROTEOMIC APPROACH TO INVESTIGATING THE MOLECULAR INTEGRITY OF RITUXIMAB WHEN DILUTED IN TYPICAL HOSPITAL CONDITIONS

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Background The active substance of MabThera is rituximab. It is a genetically engineered chimeric mouse/human monoclonal antibody which binds specifically to the transmembrane antigen CD20. It is currently indicated for the treatment of several follicular lymphomas. MabThera is available in single-use vials containing 100 mg/10 ml and 500 mg/50 ml concentrate for solution for infusion.

Purpose The purpose of this study was to investigate the suitability of a proteomic approach using MALDI-TOF mass spectrometry to test the molecular integrity of rituximab in its pharmaceutical presentation form and diluted in typical hospital conditions.

Materials and methods Rituximab (100.0 mg/10 ml) was diluted with SSF (to 4.0 mg/ml and 1.0 mg/ml). 10 µL of three types of samples containing the antibody were reduced with DTT and alkylated by iodoacetamide in darkness for 30 min then digested by trypsin at pH 8.5 for 4 h at 37°C. The digest was loaded onto the MALDI target plate using 5 mg/ml α-cyano-4-hydroxycinnamic acid in 0.1% trifluoroacetic acid, 50% acetonitrile as the matrix. Each digest was analysed five times by MALDI-TOF mass spectrometry using a Voyager DE-PRO (Applied Biosystems) in positive reflector mode.

Results The peptide fingerprint map (PFM) of rituximab was obtained for the three types of samples (100.0 mg/10 ml and the dilutions) immediately after their preparation. In this way, the molecular integrity of rituximab could be described and characterised.

Conclusions This proteomic approach to the analysis of rituximab is suitable for use in a long stability study of the antibody diluted with SSF and stored refrigerated (4°C) and frozen (-20 °C) since possible changes in the antibody structure may be detected by changes in the corresponding PFM. This stability study is currently being performed by our research group.

Competing interests None.

TCH043 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY ASSAY OF AMIODARONE CAPSULES

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Background Amiodarone has been widely dispensed as capsules prepared in the pharmacy department for paediatric patients. A stability study was performed with these capsules to determine their expiry date. However the European Pharmacopoeia High Performance Liquid Chromatography (HPLC) method was not performed because of a worldwide shortage of acetonitrile at the beginning of our stability study.

Purpose The purpose was to develop a HPLC assay of amiodarone capsules that did not use acetonitrile.

Materials and methods The authors developed the assay on a chromatographic system consisting of a Spectra-Physics Analytical HPLC chain. The column used was a C18 (120Ä, 250 mm x 4.6 mm, 5 µm). The mobile phase was 0.01 M phosphate buffer pH 2.30 + methanol (17/83 v/v) with a flow rate of 1 ml/min. The sample injection volume was 20 µL. The analysis time was 15 min. The validation study was performed according to ICH. The chromatography parameters (retention time, number of theoretical plates, tailing factor, capacity factor) were calculated to study the system suitability test. Specificity (interference from mannitol, excipient), linearity, precision (repeatability and intermediate precision) and accuracy checks were performed.

Results In chromatographic conditions, amiodarone retention time was 7.47 minutes. The capacity factor and the number of theoretical plates were respectively 1.34 and 5,313. The tailing factor did not exceed 1.5. No interference from mannitol could be observed at 242 nm. Within the assay range, amiodarone concentration was linearly related to absorbance at 242 nm. The repeatability and the intermediate precision were demonstrated because relative SD was less than 2%. The method is accurate because the 100% value was within the confidence limits.

Conclusions The method developed in this study has the advantage of being simple, precise, accurate and convenient. This method is applicable for qualitative and quantitative amiodarone capsules. The results are accurate and precise and confirmed by statistical parameters.

Competing interests None.

TCH044 STABILITY OF PHARMACY-PREPARED VANCOMYCIN AND CEFTAZIDIME-FORTIFIED ANTIBIOTIC EYE DROPS AND SOLUTIONS IN POLYPROPYLENE SYRINGES: A REVIEW

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Background The treatment of endophthalmitis is usually instillation of fortified antibiotic eye drops and/or intraocular

injections of ceftazidime and vancomycin. Hospital pharmacies have to make these ophthalmic preparations to mitigate the lack of commercially-available medicines and store them to manage urgent requests. Numerous studies have been carried out to determine the stability of these preparations.
Purpose A literature review of studies concerning the stability of eye drops and prepared intraocular injections of ceftazidime and vancomycin.
Materials and methods Research was based on references such as Trissel's stability of compounded formulations, Handbook on injectable drugs, or databases such as Scopus. Various criteria were listed depending on the study: the concentration of the solution, the solvent, the conditions of storage and the duration of stability. Studies are classified in summary tables, one for each drug.
Results 18 studies were found for ceftazidime and 22 studies for vancomycin. Two studies stand out and the formulations they recommend seem to be most suitable for long term storage. The first one concluded that 6 months' stability for syringes for intraocular injection of vancomycin at 10 mg/mL and for ceftazidime at 22.5 mg/mL could be obtained by freezing at -18 °C. The second one settled on a stability of 75 days for vancomycin eye drops at 50 mg/ml in glucose 5% and for 50 mg/ml ceftazidime in sodium chloride 0.9% by freezing at -20°C.
Conclusions Freezing enables standardised hospital preparations to be stored for long periods, which makes it possible to build up a useful stock and as a result to resolve the problem of urgent care. Thanks to this review the pharmacists can choose the best option, in consultation with the medical teams (in particular for the choice of the solvent) and respond to situations in which urgent treatment is required.

Competing interests None.

TCH045 STABILITY OF CEFUROXIME SOLUTION IN POLYPROPYLENE SYRINGES: A REVIEW†

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Background Endophthalmitis is a rare but serious postoperative infectious complication following cataract surgery. According to the Agence française de sécurité sanitaire des produits de santé (AFSSAPS) recommendations 2011 there is a preventive treatment to minimise it, consisting of the administration of an intracameral injection of 0.1 ml of cefuroxime 1 mg/0.1 mL, after uncomplicated surgery. This treatment is not marketed and must be prepared within a hospital pharmacy.
Purpose To perform a literature review of studies concerning the stability of cefuroxime ocular solutions.
Materials and methods A review of the literature found 14 references, contained in Trissel's stability of compounded formulations, Handbook on injectable drugs, or databases such as Scopus. Various criteria were listed depending on the study: the concentration of the solution, the solvent, the conditions of storage and length of stability.
Results The studies were classified in a summary table. Concentrations can range from 7.5 to 60 mg/mL; the different diluents may be sodium chloride 0.9% (NaCl 0.9%), Balanced Salt Solution (BSS) or water for injections; preparations may be stored in the freezer at temperatures ranging from -21 °C to -10 °C or in the fridge at +4 °C; the expiry ranges from 24 h to one year. The hospital pharmacy of Nancy University Hospital makes series of syringes of 0.2 mL of cefuroxime 10 mg/mL in sodium chloride 0.9% in 1 mL graduated polypropylene syringes. These hospital preparations are produced once a week and stored at +4°C. Freezing assures stability of at least one month. So a cefuroxime solution of 10 mg/mL at -21 °C may be stored for 28 days in BSS or for 4 months in NaCl 0.9%.
Conclusions The mode of storage in the Nancy University Hospital should evolve to increase the length of time for which its preparations are stable. The best way to preserve for a long time is freezing.

Competing interests None.

TCH046 CALCIUM CARBONATE CAPSULES PRODUCTION WITH AN AUTOMATIC ENCAPSULATOR IN THE GALENIC LABORATORY OF THE HOSPITAL PHARMACY OF ASL CN2

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Background Calcium carbonate capsules is a drug used in the hospitals with nephrology-department but it doesn't exist like industrial drug in Italy. Normally is acquired by external companies like food-integrator or produced in galenic laboratories with manual encapsulators. In this paper a survey on a recent study to optimise the use of the automatic-capper ZANASI-LZ-64-Tecnofarma (ACZT) is presented. Galenic laboratory of ASLCN2 is equipped of ACZT.
Purpose Formulation of apt calcium carbonate mixture to ACZT; Realisation of procedures for the use of ACZT and its calibration; pharmacoeconomic study.
Materials and methods In order to choose the optimal mixture a comparison between manual-mixing in mortar and an automatic-mixing with rotary-body mixer is taken into account. A sliding-test FUXII on different mixtures has also been performed. Finally the samples obtained varying the mechanical parameters of ACTZ were tested (uniformity-mass-test FUXII) to obtain 500 mg capsules. A pharmacoeconomical study to compare internal production costs and external provisioning costs is also presented.
Results In the experimental conditions manual-mixing is comparable and preferable to the automatic-mixing and can avoid dangers of powders *sequestration* for this purpose a new mortar mixing powders procedure is elaborated. No mixtures obtained with calcium carbonate glidants and lubricants has entered in the parameters for fluency because the angle of rest is higher than 35°; The authors have chosen the light calcium carbonate thanks to its angle of 33°. An update of the standard laboratory procedures with the operating instruction of ACZT, extraordinary-ordinary maintenance, extraordinary-ordinary cleansing has been done. Thanks to that is possible to reduce the cost of the produced capsules, of 1.491€.
Conclusions ACZT is an uncommon technology for galenic laboratory and has huge potentialities. The production of the calcium carbonate capsules could satisfy the requirements of Piedmont hospitals for orphan drug production.

Competing interests None.

TCH047 STABILITY INVESTIGATIONS OF GALENIC PREPARATION-STERILE MULTIDOSE LIDOCAINE HCL 2% ANAESTHETIC GEL

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Background The sterile multidose anaesthetic Lidocaine HCl 2% gel that is extently applied in the most of our hospital wards is a galenic preparation from our hospital pharmacy. The authors have formulated our own prescription and producing process and proved that the extemporaneous preparation met the requirements regarding pH, content of the active substance and sterility. With determination of the microbiological integrity and shelf live of this preparation The authors wanted to ensure safe use of this preparation.

Purpose To correctly determine microbiological integrity and expiring date of the preparation.

Materials and methods On the samples of 13 series of prepared and kept at the room temperature (cca. 25°C) one, two and three years, of sterile multidose anaesthetic Lidocaine HCl 2% gel The authors performed quantitative analysis tests-1. extraction with chlorophorm and 2. anhydrouse titration with perchloric acid. On the same samples The authors performed sterility tests. Of each serial 3 samples were examined and the average value were analysed. Tests (according USP 31.Ed, Chemical tests and assays) of the content of lidocaine HCl for shelf life examinations were done at Control and analytical laboratory at the Department for infusion solutions production in our hospital. Sterility tests were performed in the microbiological department of Centre for public health, Bitola. Ingredients used for this preparation were: powder Lidocaine HCl (Sigma – Aldrich, USA, USP),Carboxymethylcellulose Na, high viscosity (Sigma-Aldrich, USA, USP), Aqua sterillisata (our hospital Department for infusion solutions production, Ph.Eur).

Results Quantitative examinations of lidocaine HCl in the series of samples indicated that the average content of the active substance meets the pharmacopoeial requirements within an one year period. The numeric results of all examinations will be presented on the poster at the congress. Average pH=6.7 and meets the pharmacopoeal requirements too. Sterility control tests confirmed the sterility for one year too.

Conclusions The authors formulated our own prescription and producing process for sterile multidose anaesthetic Lidocaine HCl 2% gel with expiring date of one year in the hospital pharmacy of the Clinical hospital in Bitola and The authors ensured safe use of this preparation.

Competing interests None.

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

DSL001 THE USE OF DC BEAD PARTICLES LOADED WITH DOXORUBICIN FOR THE TREATMENT OF NON-RESECTABLE MULTIFOCAL HEPATOCELLULAR CARCINOMA

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Background The use of DC Bead particles loaded with doxorubicin (DCBP-D) in hepatic chemoembolisation (HC), is presented as a first line option for non-curative treatment of multifocal hepatocellular carcinoma (MHC) in an intermediate-advanced state in patients with unresectable tumours without vascular or extra-hepatic dissemination.

Purpose

- To describe the use of DCBP-D administered by HC in the treatment of non-resectable MHC, making sure that this use is compatible with scientific evidence.
- To describe risk factors associated with MHC and the toxicity profile derived from treatment.
- To calculate the expense of one cycle of HC.

Materials and methods Descriptive and retrospective study which took six months (January-June 2011) of patients treated by HC with DCBP-D for their MHC. The results of tests were taken from patients' medical histories. The doxorubicin dose and the size of the particles were taken from the database of the centralised unit where cytostatics are made within the pharmacy department.

Results 12 patients (10 men) with an age average of 64 (44-81) (median=63) were included in the study. All patients were diagnosed with non-resectable MHC. 5 patients, (41.6%) got MHC as the result of alcoholic cirrhosis. In another 4 patients (33.3%) the MHC was produced secondarily after infection by VHC. 1 patient got the MHC directly from VHB infection, (8.3%). 2 patients (16.6%) were considered to have mixed MHC (viral- alcoholic). In 66.6% (8 patients) the treatment was started while they were awaiting a liver transplant, while in the other 4 cases it was used as palliative treatment. Patients were divided according to the Child-Pugh classification: 5 patients (41.6%) in group A, and 5 in group B (41.6%). It was impossible to determine the state of 2 patvients. According to the Okuda classification: 4 patients were in stage I (33.3%), 3 patients were in stage II (25%) and 1 patient in stage III (8.3%). In 4 patients, the classification could not be determined. As to the doses received: In 8 patients (66. 6%), maximum doses of 150 mg of doxorubicin were employed in particles of 100-300 µm and 300-500 µm. (Cost per cycle: 1266 €).

In 4 patients (33.3%) 75 mg of doxorubicin was given in particles 100-300 µm. (Cost per cycle: 633.19€). The total number of HC was 13. In 25% of the cases, postembolisation syndrome appeared after the chemotherapy, but it was solved without complications.

Conclusions The use of DCBP-D was adjusted to the right indication in all cases. The main risk factor associated with CHC was alcoholic cirrhosis. On the whole HC was well tolerated. Mild postembolisation syndrome was the only complication arising from treatment. The average cost of this treatment was 14559.57€.

Competing interests None.

DSL002 USE OF CARBETOCIN IN ELECTIVE CAESAREAN SECTIONS

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Background The Pharmacy and Therapeutics Committee (PTC) decided to evaluate the use of carbetocin following a request by the Obstetrics and Gynaecology department.

Purpose To evaluate the use of carbetocin in elective Caesareans.

Materials and methods A retrospective, observational study was undertaken over 14 months (March 2010–April 2011). The following variables were recorded: date of request and date of Caesarean, age of patient, elective Caesarean or not, urgent or planned Caesarean and bleeding risk factors.

Results During the period of study, 134 patients were treated, average age of 34 years (21–45). In 87.31% of the cases (117) carbetocin was used for an elective Caesarean and in 12.68% of the cases (17) for urgent Caesareans. Of the 117 elective Caesareans, 63.43% (72) were planned Caesareans, whereas 38.46% of these Caesareans (45) had no type of planning. 59.70% of the requests (80) included some bleeding risk factor as opposed to 40.29% of the requests (54) that undertook treatment without any risk factors. The bleeding risk factors involved in the use of carbetocin were: 27/129 multiple births, 21/129 previous uterine surgery, 3/129 premature sac breaking, 3/129 previous haemorrhage, 6/129 myomas, 4/129 multiparity, 5/129 macrosomia, 5/129 treatment with anticoagulants or thrombocytopenia and 1/129 polyhydramnios. In 5 cases the information was not available.

Conclusions

1. Carbetocin was requested for 134 patients as opposed to the 180 proposed by the Service of Obstetrics and Gynaecology.
2. A standard form is required for prescribing carbetocin, which includes requesting the bleeding risk factors, in order to obtain information from the physicians.
3. Due to the complexity of the case histories, an evaluation of the efficacy of carbetocin needs the review of clinical histories as well as the analysis of the incidents of postcaesarean bleeding.

Competing interests None.

DSL003 MAINTENANCE OF AN UNBROKEN COLD CHAIN THROUGHOUT THE PREPARATION OF AZACITIDINE (VIDAZA) INJECTION SYRINGES.

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Background Azacitidine (Vidaza) is a powder to be made up into a suspension for injection whose stability, after reconstitution, does not exceed 45 min at room temperature. This is a very short time considering that the drug is prepared in the pharmacy department and injected in another department. This stability can extended up to 22 h if the preparation is made and kept between 2 and 8°C (Vidaza EPAR EMEA/H/C/000978 -II/0009).

Purpose The authors here describe a method for preparing Vidaza injection syringes that ensures an unbroken cold chain, from preparation to storage.
Materials and methods Our chemotherapy preparation unit is equipped with two Isocyt Freja rigid isolators (Getinge). Sterile DPTE (Double Door Leaktight Transfer) containers can be safely connected and disconnected to these isolators without breaking containment. Sterile anticancer drug vials that should be stored between 2 and 8°C after opening are put in such containers
Vidaza is administered daily for 7 days. On the first day The authors sterilise all the materials needed for the first and the second injection (drug phial(s), syringes, water for injection vials). On the next day the sterile products are put in a sterile container and placed in our refrigerator. The following days: 1/ The authors sterilise and put in a container what is necessary for the next day's injection. 2/ The authors use the previously sterilised, cold-stored medicine, material and solvent for the current day's injection. And so The authors proceed until the end of the cycle (from day 2 to day 7).
Results All the Vidaza injection syringes for a given day are prepared at the same time, sealed in sterile bags and stored between 2 and 8°C. The cold chain is uninterrupted throughout this process and The authors can ensure 22-h stability for our Vidaza injection syringes. So when the patients come back (day 2 to day 7), their injection syringe is already prepared and given to them immediately.
Conclusions Going from 45-min stability to 22-h stability is a huge improvement. This makes us more flexible towards the patients' consultation hours: they can come at any time during the day, the syringes are waiting for them. It has really improved the way patients are taken care of in the Haematology Department. The authors should also mention that it greatly helped us optimise the chemotherapy production flow.

Competing interests None.

DSL004 THE EFFECTIVENESS AND SAFETY OF PEGINTERFERON ALFA-2A IN PATIENTS WITH CHRONIC HEPATITIS C ON HAEMODIALYSIS

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Background Hepatitis C (HCV) virus infection is the most common cause of liver disease in patients on haemodialysis (HD). It's a very serious and difficult health problem in these patients because of increased mortality. It reduces the chance of a kidney transplant and reduces the quality of life. The Hepatitis C virus is a RNK virus from the Flaviviridae family. For the treatment of Hepatitis C PEGASYS, peginterferon alfa-2a is recommended, which is a covalent conjugate of recombinant alfa-2a interferon.
Purpose To evaluate the efficacy and safety of using peginterferon alfa-2a (Pegasys) in our hospital.
Materials and methods A retrospective descriptive study of patients treated with peginterferon alfa-2a for periods of 6 years (2005-2011). The information was obtained from medical records. The following data were recorded: age, sex, diagnosis, treatment, dose, laboratory test (alanine aminotransferase-ALT), AST, anti-HCV with micro Elisa and HCV-RNK with the PCR. The safety profile was evaluated by type of side effect.
Results 32 patients were treated with Pegasys (29 men and 3 women); average age of 49.91 (32-70) years; the dose administered was 135 mcg/week SC (subcutaneous) over a period of 48 weeks. After the treatment, 30 patients had undetectable HCV-RNK, however 2 of them became again HCV-RNK positive, 6 months after the treatment. In these patients treatment with peginterferon alfa-2a was repeated successfully. In 2 patients the treatment was discontinued after 12 weeks due to absence of early virological response. The main side effects were muscle pains, fatigue, fever and anaemia (anaemia in our patients was corrected with erythropoietin).
Conclusions The treatments were effective and safe for our patients. Pegasys showed efficacy in 30 out of 32 patients. The side effects did not stop treatment; it was well accepted by our patients. Pegasys remains the drug of choice in treating patients with hepatitis C, for effectiveness and safety.

Competing interests None.

DSL005 SIMPLIFICATION OF ARV TREATMENT WITH LOPINAVIR/RITONAVIR: CLINICAL ASSESSMENT AND FINANCIAL IMPACT

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Background Simplification of antiretroviral treatment (ART) is a very useful therapeutic tool to facilitate adherence and prevent or reverse some adverse effects.
Purpose To monitor patients with simplified ART to assess clinical response, adherence and the financial savings of the simplification.
Materials and methods The authors selected patients who were given simplified ART in 2010 with the combination lopinavir/ritonavir. For each patient the ART before simplification, the CD4 cell count and viral load were analysed. The authors also noted the reason for the initiation of simplified ART and dispensing records from the Pharmacy department were used to calculate the adherence. The cost savings were calculated by comparing the cost of the patient's last ART and the cost of the simplified ART, using the official laboratory price and the number of prescriptions dispensed.
Results 20 patients were included in the study. 90% of them had been taking at least two antiretroviral regimens before starting the simplified treatment. All patients completed at least 6 months with an undetectable viral load (<50 copies/mL) before starting simplified ART. In 100% of the cases, the reason for simplification was greater immunological and virological control of the patient. The viral load at 3 months of treatment remained undetectable in all patients. There were no adverse effects or dropouts, the adherence was above 90% in all cases and all patients had a good immune status. Regarding the financial impact of ART change, the difference between the old ART and the new simplified regimen was found for each patient. The overall cost of the simplified ART was 83,506€. If patients had continued with the previous ART, the cost would have been 159,189€. Therefore, the cost saving resulting was 75,683€.
Conclusions Simplified ART with lopinavir/ritonavir is a regimen with significant cost savings and no loss of virological efficacy or adverse effects.

Competing interests None.

DSL006 CARBOXYPEPTIDASE RESCUE AFTER HIGH-DOSE METHOTREXATE

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Background High-dose methotrexate may cause acute nephrotoxicity because it is mostly excreted by the renal route. Carboxypeptidase G2 is an enzyme that hydrolyses methotrexate rapidly to the inactive metabolites DAMPA and glutamate. The criteria that justify the use of carboxypeptidase in the hospital studied are: methotrexate plasma concentration >10 µM/L, 48 h after administration or increase of creatinine by 100%, 24 h after infusion.
Purpose The aim of this study was to check that carboxypeptidase was being used correctly according to the hospital's criteria and to evaluate patient response to treatment.
Materials and methods Retrospective study of patients who received carboxypeptidase in the last five years. The data collected were: diagnosis, age, doses of methotrexate and carboxypeptidase, methotrexate and creatinine plasma levels.
Results Eighty patients were treated with high dose methotrexate (5 g/m^2) and 8 of them (10%), diagnosed with acute lymphoblastic leukaemia, needed a rescue with 50 IU/kg of carboxypeptidase 48 h after infusion. The mean age was 8.87 years (3-13).
The mean time to recovery renal function was 7.28 days (4-17) after administration of carboxypeptidase.
Conclusions All patients fulfilled at least one of the two criteria that justified carboxypeptidase administration. This drug offers an alternative rapid route for methotrexate elimination. The role of the pharmacist is important to ensure proper use of carboxypeptidase due to the high cost of the drug.

DSL006 table 1

	- METHOTREXATE LEVELS (µM/L)		- CREATININE LEVELS (mg/dL)		
PATIENT	- Before carboxy-peptidase	-24 h after carboxy-peptidase	-Before metho-trexate	- After metho-trexate	- 24 h after carboxy-peptidase
- 1	- 57.27	- 6.39	- 0.47	- 2.54	- 2.66
- 2	- 56.69	- 3.88	- 0.33	- 2.48	- 2.49
- 3	- 91.25	- 8.37	- 0.69	- 1.50	- 1.50
- 4	- 29.96	- 5.67	- 0.40	- 2.61	- 2.48
- 5	219.09	- 0.77	- 0.50	no data	no data
- 6	- 40.48	- 9.44	- 0.80	- 4.01	- 4.73
- 7	- 51.32	- 6.87	- 0.32	- 1.94	- 1.90
- 8	- 45.49	- 9.23	- 0.42	- 2.21	- 4.33

Competing interests None.

DSL007 THE TREATMENT OF HEREDITARY ANGIOEDEMA: A REPORT OF TWO CASES

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Background Hereditary angioedema (HAE) type I is a rare genetic disorder, autosomal dominant, caused by a deficiency of the enzyme C1 inhibitor (C1INH). It is characterised by recurrent and unpredictable episodes of oedema primarily affecting the extremities, face, throat and intestinal wall and may jeopardise the patient's life if not treated properly. Available treatments for acute attacks are icatibant acetate (IA) given subcutaneously (sc), fresh plasma and C1INH esterase (CE) (a foreign substance – likely to result in antibodies), both given intravenously.
Purpose To describe our experience in the treatment of acute episodes of HAE in two patients (siblings) from our health area.
Materials and methods Retrospective observational study. Period: January 2008 – September 2011. Data source: medical history, Sinfhos® software. Data: age and sex, prophylactic treatment, number of crises and accident and emergency (A&E) visits, acute treatment, efficiency, safety and cost.
Results Two siblings (male and female, 33 and 31 years old respectively) with no prophylactic treatment, had poorly-controlled symptoms and poor tolerance. Between them, the two came to the A&E 19 times, presenting attacks with laryngeal oedema. 11 were treated with CE; in 3 cases a second dose was needed and in another one 4 doses. IA was already available in the hospital; the last 4 outbreaks were treated with a single dose of this agent with complete resolution of symptoms. There were no adverse effects with either drug.
Conclusions In all episodes treated with IA, the outbreak was resolved with a single dose. The SC route of administration of the IA allows self-administration in a crisis if laryngeal oedema is not involved. The haematological safety profile, storage at room temperature and that it isn't a foreign substance represent additional advantages of IA against haematological derivatives. The average price of treatment with CE was € 1060.78 and with IA € 1692.29.

Competing interests None.

DSL008 DEVELOPMENT OF ANTIVIRAL TREATMENT OF CHRONIC HEPATITIS B OVER THE PAST SIX YEARS

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Background Chronic infection by Hepatitis B virus (HBV) affects more than 350 million people worldwide. Recently, there have been significant advances in the understanding of this disease, a new diagnostic tool that can accurately determine the activity of HBV replication, the identification of mutations involving resistance to antiviral drugs and clinical studies that have evaluated the efficacy and safety of new drugs against HBV. All these developments have led to changes in treatment recommendations of international clinical guidelines such as the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL).
Purpose To describe how the prescription of antiviral drugs against HBV has changed in an outpatient dispensing service in a community hospital.
Materials and methods Retrospective observational study of antivirals dispensed against HBV in not co-infected patients in an outpatients department over the last six years.
Results The number of patients increased from 32 patients in 2006 to 59 in 2011. The percentage of patients treated with antiviral drugs in this period was as follows (see table).
Data show an increase in the percentage of patients treated with entecavir and tenofovir, and a decrease in lamivudine and adefovir. The approval of entecavir and tenofovir in 2006 and 2008 respectively, and new recommendations in clinical guidelines, are the reason for this change. Both AASLD and

DSL008 table 1

	LAMIVUDINE	ADEFOVIR	ENTECAVIR	TELBIVUDINE	TENOFOVIR
2006	90.6%	25.0%	0.0%	0.0%	0.0%
2007	75.6%	34.0%	4.8%	0.0%	0.0%
2008	67.4%	39.0%	10.8%	0.0%	4.3%
2009	46.4%	30.3%	23.2%	1.7%	17.8%
2010	41.3%	19.0%	25.4%	1.6%	50.6%
2011	32.2%	8.4%	25.4%	0.0%	55.9%

* Note that a patient can take several drugs over a year or a combination of two drugs during the same period.

EASL recommend avoiding lamivudine, telbivudine and adefovir as first line treatment in treatment-naive patients since they have a low genetic barrier, and avoiding adefovir because it is a weak antiviral.

Conclusions The prescription of antiviral drugs against HBV in our hospital has changed during recent years in response to new recommendations and clinical guidelines. Further changes in HBV treatment are expected, so more prospective studies are needed to ensure safe and effective pharmacotherapy.

Competing interests None.

DSL009 STUDY OF HYPERSENSITIVITY REACTIONS TO TAXANES IN IN AND OUTPATIENTS WITH CANCER

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Background The taxane-class agents (paclitaxel and docetaxel) have been among the most important cancer chemotherapy drugs in the past several years. They are microtubule-stabilising anticancer agents which causes mitotic arrest in metaphase. Hypersensitivity reactions may occur in some patients receiving infusions of taxanes.

Purpose The purpose of this study was to examine the proportion of chemotherapy patients who used taxane compounds during their treatment who developed symptoms of hypersensitivity reactions in order to determine the likelihood of hypersensitivity developing and develop procedures to minimise the risk to the patients.

Materials and methods The dataset consisted of 30 (59% female and 41% male) patients with ages varying between 29 and 82, who had hypersensitivity reactions during their inpatient or outpatient chemotherapy treatment in VKF American Hospital between December 2008 and May 2011. By investigating the adverse drug reaction reports of these patients The authors separated out the cases that were believed to be the result of treatment with taxanes.

Results Of 30 cases of possible hypersensitivity reactions, 55% were considered to be the result of taxane treatment. 7 of these cases arose from paclitaxel, whereas the remaining 9 cases occurred during docetaxel infusion. The proportion of docetaxel-related cases was 56.25% of taxane reactions. Among these, one of them was mild, 7 of them were medium and the remaining one was classified as severe. Among the paclitaxel-related cases, 3 of them were classified as mild and the remaining 4 as medium impact. No meaningful relationship was found between the diagnosis of cancer and the severity of the hypersensitivity reactions.

Conclusions The authors concluded that decreasing the infusion speed of the premedication rather than increasing the amount of antihistamine or corticosteroid might be more effective in preventing hypersensitivity reactions due to taxane compounds. The authors informed the physicians and decided to lengthen the infusion time to at least 30 min and to give 30 min resting period between the premedication and chemotherapy. After implementing the new procedure, no hypersensitivity reactions were reported during the control period between July 2011 and September 2011. In addition, in order to treat hypersensitivity reaction symptoms quickly, emergency kits have been programmed into the Pyxis automated systems in the departments where our chemotherapy patients are treated. The authors expect to provide the necessary medicines as fast as possible with minimum human error. The performance monitoring and development phases of both processes still continue at our hospital.

Competing interests None.

DSL010 ANTIRETROVIRAL PRESCRIPTION PROFILE AND ADHERENCE TO GUIDELINES

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Background A national HIV study group publishes yearly recommendations for antiretroviral therapy (GESIDA) in Spain.

Purpose To describe the differences between GESIDA in 2010 and 2011 (GESIDA-2010; GESIDA-2011). To analyse the antiretroviral therapy (ART) prescription profile (PP) in treatment-naïve patients for 2010 and 2011(PP-2010; PP-2011) and evaluate the adherence to GESIDA.

DSL010 table 1

		PP-2010 (GESIDA-2010)		PP-2011 (GESIDA-2011)		*PP-2010 (GESIDA-2011)	
WITHIN GUIDELINES	PREFERRED	43	88%	28	83%	40	81%
	ALTERNATIVE	5	10%	0	0%	3	6%
OUTSIDE GUIDELINES	OUTSIDE	1	2%	8	17%	6	13%

- – * Adherence of PP-2010 to GESIDA-2011.
- In 2010 98% of treatments adhered to GESIDA-2010; however in 2011 adherence to GESIDA-2011 fell to 83% ($\alpha<0.003$).
- It seemed as though some doctors were still following the 2010 guidelines in 2011, since 88% of treatments were in line with PP-2010 and only 83% were in line with PP-2011. Furthermore, PP-2010 preferred therapies (recommended by GESIDA-2010) were used more than GESIDA-2011 recommended treatments in 2011, verging upon significance ($\alpha=0.05$).

Materials and methods Eighty-five treatment-naïve patients (49(2010) and 36(2011)) were included in a retrospective observational study of ART and laboratory/microbiology parameters (January 2010 – September 2011), in a 450-bed tertiary hospital. The latest GESIDA guidelines (January 2010 and January 2011) were reviewed. Excel 2007 and SPSS Statistics 19 were used for statistical analysis.
Results There were slight differences in ART between GESIDA-2010 and GESIDA-2011 according to the new investigation carried out during 2010, but none of them seem to be reflected in PP-2011, as there were non-significant differences in all aspects of treatment. The main difference was the reduction in the number of recommended treatment combinations (16 to 9). While GESIDA-2010 allowed antiretroviral drugs to be combined relatively freely, GESIDA-2011 narrowed it to only certain combinations. Looking at patients with a CD4 count in the range 350-500, in general, and leaving exceptions aside, GESIDA-2010 recommended not starting treatment while GESIDA-2011 considers the patients as treatable. In our study, 12% started in 2010, while 23% started in 2011(RR≈2).
The table below shows the adherence of the prescription profile to GESIDA.
Conclusions The results suggest that the prescription profile seems to adhere more to the previous year's recommendations (GESIDA 2011 adherence: PP-2010(87%); PP-2011(78%)). The high percentage of adherence of PP-2010 to the 2010 guidelines could be partly explained by the freedom of therapeutic options available under it at that time. GESIDA is a reference for ART, and when it is published once a year, prescribers should update their practice in line with it.

Competing interests None.

DSL011 CHANGES IN THE USE OF ANTIFUNGALS ON A HAEMATOLOGY WARD

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Background The antifungals are among the pharmacological groups that contribute more to the increase in the number of drugs used each year in Spanish hospitals. One of the strategies adopted to contain the increase in pharmaceutical waste is the agreement of departments to optimise the use of drugs.
Purpose To analyse the changes in the trend towards using antifungals of the Haematology department in a tertiary hospital, after the creation and introduction of a protocol for use of those drugs was agreed as an objective for 2011.
Materials and methods A descriptive study was made of all the antifungals used by the Haematology department between January-September, performing a comparative analysis 2010-2011. The differences in use of groups of antifungals were found in terms of the number of defined daily doses (DDDs) used, as well as in the financial repercussions.
Results The number of antifungals purchased annually by the Haematology department decreased by 20.9%, compared with the overall decrease in the hospital of 22.04%. An increase in the use of echinocandins was noted, the number of DDDs prescribed increasing by 2.88%, Caspofungin being the most used (73.5%). The total DDDs of azoles decreased by 5.93%, oral voriconazole being the drug used less (-33.19%), while an increase in the use of posaconazole was observed (80.18%). The polyene antifungals experienced a higher reduction in use, the DDDs used dropping by 55.49%. The financial repercussions of this reduced use in the Haematology department represented a decrease in the amount of this pharmacological group of 102,200.68 €, contributing 31.36% of the savings achieved by this department in the hospital's total drugs bill.
Conclusions The objective agreed for 2011 has modified the trend in antifungal use in the Haematology department. The decrease in the use of polyene antifungals has been the change with the most effect. These modifications have contributed to containing pharmaceutical waste in our hospital.

Competing interests None.

DSL012 EVALUATION OF HOSPITAL DRUG EXPENDITURE

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Background The expenditure on drugs represents a significant part of hospital budgets.
Purpose To analyse changes in hospital pharmaceutical expenditure in HCU 'Lozano Blesa' during 2006-2010.
Materials and methods Retrospective study of drug consumption over five years. Data were collected from distribution of hospital pharmaceutical expenditure (drugs and classification of drugs by ATC group). Data source: Dominion program from the pharmacy department.
Results The growth of hospital pharmaceutical expenditure during the 5-year period was 60.1% with a median increase per year of 12.9%. The main drugs by cost in this period were: adalimumab (5.9%), tenofovir/emtricitabine (3.2%), trastuzumab (3.0%), etanercept (2.9%), infliximab (2.8%), bevacizumab (2.7%), docetaxel (2.5%), rituximab (2.1%). The percentage increase in consumption by 2010 compared to 2006 in most drugs consumed was: tenofovir/emtricitabine (479.9%), infliximab (106.3%), bevacizumab (355.6%), adalimumab (281.52%), rituximab (38.03%), trastuzumab (15.74%). This increase was due to the increased number of indications, patients and a change in the patterns of HIV treatment choice. In 2010 the main ATC groups by cost were: L04AA (Selective immunosuppressants) (14.5%); L01XC (Monoclonal antibodies) (10.2%); J05AR (Antivirals for treatment of HIV infections, combinations) (6.8%); L01XE (Protein kinase inhibitors) (5.0%); J05AE (Protease inhibitors) (4.1%).
Conclusions An increase in hospital pharmaceutical expenditure was observed during the study period. The largest increases were observed in the main drugs consumed by cost. Selective immunosuppressants, monoclonal antibodies and antivirals for treatment of HIV accounted for a high percentage of hospital pharmaceutical expenditure.

Competing interests None.

DSL013 EFFICACY AND SAFETY OF RITUXIMAB IN COMBINATION WITH CHEMOTHERAPY IN THE TREATMENT OF NON- HODGKIN'S LYMPHOMA

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Background Chemotherapy, radiation and autologous bone marrow transplant are conventional standard therapies in

Non-Hodgkin's lymphoma (NHL). Nowadays the introduction of monoclonal antibodies has enhanced the specificity of treatment, reducing the toxicity and presenting synergism with conventional chemotherapy.

Purpose To compare rituximab efficacy and safety in combination with CHOP chemotherapy (cyclophosphamide, adriamycin, vincristine and prednisone) in the treatment of NHL in our hospital, with that published in the literature.

Materials and methods Retrospective observational study of 116 patients diagnosed with NHL who received chemotherapy with R-CHOP (rituximab-CHOP) between January 2005 and December 2010. The authors reviewed the medical history (100%) and the data were analysed using SPSS predictive analytics software. Were recorded: demographic data (age, sex); efficacy (complete response (CR), partial response (PR), overall response rate (ORR), progression and relapse, overall survival (OS) and event free survival (EFS)); toxicity (haematological and non-haematological).

Results 53.5% of patients were male and mean age at diagnosis was 59 years. The authors obtained an ORR of 80.2% (71.3% CR and 8.9% PR). 14.8% of patients did not respond, and 5% had an unknown response. The progression and relapse rates were 18.8% and 17.8% respectively. Projected median OS for responding patients was over 30 months and EFS after one year was 70.3%. Neutropenia, anaemia and thrombocytopenia rates were reported as 15.8%, 12.4% and 2.3% respectively. Infusion-related reactions were reported in 1.95% of patients, 72.2% during the first session. The detected rate of infection was relatively low, and 3.5% of all infections were microbiologically documented.

Conclusions The results obtained were comparable to those of published studies in the literature for the treatment arm with R-CHOP in randomised patients (GELA NHL-95.5 study group, U.S. Intergroup Study, Mabthera International Trial MINT study). Neutropenia rates were higher than those found in the study of McLaughlin *et al*, while the other cell lines the results were similar.

Competing interests None.

DSL014 RECORDING MEDICINES ADMINISTRATION ERRORS BEFORE INTRODUCING NEW TECHNOLOGY

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Background Drug administration is one of the most important stages in the medication process. New technologies are being developed to improve patient safety. The majority of studies focus on administration errors, but evaluation of the impact of administration technology on error rates has lagged behind implementation.

Purpose

- To classify and quantify the errors in the medication administration record (MAR) before implementing an electronic drug administration record.
- To identify the main causes of MAR errors.
- To compare MAR errors detected in a surgical and a medical ward.

Materials and methods An observational and prospective study in a surgical and a medical ward lasting 37 days. Both of them had computerised prescription order entry and an automated dispensing cabinet (ADC). MAR errors were classified according to the taxonomy defined by the Ruiz-Jarabo 2000 group. MAR errors were detected through chart reviews, checking that the administration chart matched the prescription. The day following administration, the pharmacist collected all the information and recorded it on a data sheet.

Results The authors analysed 1,185 doses from 68 patients. The error rate was 15.4%. The most common type of error was failure to record administration (93%). The main cause was procedural failure (66.3%), 52.7% due to incorrect withdrawal of medicines from the ADC. Error rates were higher on the surgical ward (19.5%) than the medical ward (9.4%). This difference was statistically significant ($p < 0.001$).

Conclusions

- Failure to record administration was the most common type of MAR error. The main cause was procedural failure, due largely to incorrect withdrawal of medicines from the ADC. There is a need for safe strategies that will reduce errors associated with ADC processes.
- MAR errors were more common on the surgical ward.

Competing interests None.

DSL015 DRUG AVAILABILITY: CONSIDERATIONS FOR THE HOSPITAL PHARMACIST

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10.1136/ejhpharm-2012-000074.198

Background Hospital pharmacists play a key role in formulary decision-making. As a part of that role, it has become important to consider the assurance of drug supply for their institutions, as adequate drug availability is a growing global concern. With drug shortages, both physicians and pharmacists need to consider less desirable options including rationing drugs, delaying critical treatments, and utilising less efficacious medications. Regulatory agencies are striving to develop processes to address drug shortages, including rapid notifications. While this may aid healthcare providers in managing shortages, it does not address their ability to maintain continuous supply. Pharmaceutical and biotechnology manufacturers face operational efficiency challenges, placing stable supply to patients at risk.

Purpose Utilising biologics as an example, this report highlights critical supply chain parameters that pharmacists should consider when evaluating a manufacturer's ability to maintain and deliver a continuous supply of medications.

Materials and methods Through examples, key considerations for ensuring drug availability in the complex environment of manufacturing and distribution challenges are outlined.

Results Key factors that can enable biologic manufacturers to ensure continuous supply of high quality products to patients include: 1) integration of global manufacturing and distribution information systems that link patient demand to production scheduling; 2) qualification of suppliers and dual sourcing of raw materials; 3) redundant manufacturing capabilities and strategic capacity management; 4) maintenance of strategic safety stocks to minimise impact of manufacturing delays/interruptions; and 5) active management of robust and secure cold chain distribution networks. These factors require leveraging resources, both financial and human, to ensure that approved drugs are available through normal operations, and during periods of supply shortages.

Conclusions In conclusion, it should become an integral part of the hospital pharmacist's role to understand and take into consideration how a manufacturer manages drug supply when weighing formulary decisions.

Competing interests Ownership: Employed by Amgen Owns Amgen stock Advisory board: No Board of directors: No

DSL016 TREATMENT SCHEMES: FROM TRIPLE THERAPY TO MONOTHERAPY IN HIV PATIENTS: ANALYSIS OF THE EFFICACY AND SAFETY

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Background The simplification of a triple antirretroviral treatment(TAR) to a monotherapy in patients with viraemia controlled by prolonged periods and without previous failure with a protease inhibitor(PI), is an strategy which can decrease the TAR toxicity.
Purpose To analyse the efficiency and safety since the establishment of the naive TAR until the monotherapy with PI.
Materials and methods Retrospective study during 9 months(January-September 2011) of the pharmacotherapeutic history of the HIV patients in treatment with PI in monotherapy during at least 6 months until the naïve TAR which withdrawn medication in the Pharmacy service of the hospital. Efficiency variables: viral load(LV) and CD4 re-count and security variables: appearance of adverse reaction to medication(ARM).
Results Of the 120 patients in triple TAR simplified to monotherapy with PI 19%. 59% men and 41% women. Average age 49 years. 18% started naive TAR with PI in association (18% VL>1000 copies/ml, 45% CD4<350 cells/ml), 50% reduced the VL in a logarithm and 68% of the patients abandoned the TAR. In the following scheme of TAR at 54% were prescribed PI in association (32% VL>1000 copies/ml and 32% VL<50 copies/ml, 40% CD4<350 cells/ml), 77% reduced the VL in a logarithm and for the good control of the disease 50% of the patients were simplified the TAR to PI in monotherapy. To the 91% of the patients lopinavir was prescribed as PI in monotherapy(68% VL<50 copies/ml, 36% CD4<350 cells/ml), 77% maintained the LV undetectable. A total of 26 ARM were detected: 31% of the reverse transcriptase inhibitors(TI) no similar nucleoside, 29% of inhibitors of the TI similar nucleoside, 27% PI.
Conclusions The establishment of the PI in the triple therapy as well as in monotherapy suppose an increase of the efficiency (reduction of the VL and CD4 or undetectable viral load) and safety of TAR

Competing interests None.

DSL017 ADHERENCE TO ORAL THERAPY IN ONCOLOGY – IMPROVING THE QUALITY OF PATIENT CARE. FROM LA SPEZIA, ITALY

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Background In oncology, oral treatment and the revised use of traditional drugs have brought major changes in treatment management. Non-adherence to treatment can reduce the effects, constitute a potential risk of toxicity and a waste of resources. Our expenses for oral treatment now constitute over 30% of the overall cost of cancer treatment.
Purpose Our Oncology Department and Hospital Pharmacy have devised a programme for cancer patients undergoing oral treatment that includes visits by a specialist before each treatment cycle, provided directly by the hospital pharmacists, and ongoing toxicity monitoring. The aim of this report was to evaluate patient adherence to treatment.
Materials and methods Data regarding all the breast cancer patients treated orally (capecitabine and/or vinorelbine) by ASL5 between 2009-2010, taken from patient records and prescriptions analysed retrospectively.
Results There were 61 patients with an average of six cycles each and an average duration per cycle of 21.6 days. Three patients (5%) dropped out for unknown reasons. The others suspended treatment because of disease progression (40%), causes related to the treatment (38%) and disease stability (17%). The patients were divided into three groups based on the number of cycles undergone (<=3, 4-6, >6). The average cycle lasted 21, 22 and 23 days respectively. The first group included the three lost patients. In the first and last group 58% and 6%, respectively suspended due to toxicity, while 8% and 65% of drop-outs respectively were due to disease progression.
Conclusions The patients attended regularly, adherence and persistence were good. The programme improved the quality of care and reduced costs. Adherence to oral treatment in oncology could be improved by better selection of the patients. Predictive factors regarding compliance could be identified and organisational aspects optimised to encourage regular attendance; patient education and monitoring by the whole team could be improved.

Competing interests None.

DSL018 REVIEW OF TREATMENT WITH ZOLEDRONIC ACID 4 MG

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Background Zoledronic acid is a bisphosphonate indicated for the prevention of skeletal-related events in patients with advanced malignancies involving bone and treatment of hypercalcaemia of malignancy. According to data sheet Zometa isn't recommended for patients presenting with severe renal impairment (CrCl <30 ml /min) prior to initiation of therapy. Following initiation of therapy, serum creatinine should be measured and the dose adjusted according to creatinine clearance value. Treatment should be withheld if renal function deteriorates.
Purpose To assess the technical suitability of treatments with zoledronic acid 4 mg (Zometa) in terms of indication and dosage adjustment according to the renal function of patients in the Oncology Department of a General Hospital.
Materials and methods The authors performed a retrospective study (January 2009 to December 2010) in which creatinine values of patients were collected (n=83). Renal clearance was calculated by the Cockcroft-Gault formula in each case to evaluate the renal function status and see if dose adjustment was necessary. The authors also collected demographic data and the diagnosis to check that the indication for the drug was correct.
Results

- In 28.91% of patients, serum creatinine values were not obtained before the first dose.

- 30.12% of patients (60% women and 40% men) required a dose adjustment sometime during the treatment. Of these, 68% were older than 65.
- 24.09% of patients experienced a worsening of renal clearance at some point during treatment, 25% of which was bad enough to require dose adjustment in subsequent administrations.
- One of the patients received two doses separated by a time interval below the minimum (3-4 weeks).
- The main diagnoses were: breast cancer (45.78%), lung (19.27%) and prostate cancer (16.86%).

Conclusions The authors concluded that it is important to introduce a standard procedure for the use of zoledronic acid 4 mg and assess the need for dose adjustment as the data sheet recommends, considering the possible adverse effects that the treatment can produce.

Competing interests None.

DSL019 IMPLEMENTING RECOMMENDATION Ñ AN ONGOING MULTIDISCIPLINARY QUALITY PROCESS

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Background The Regional Drug and Therapeutics Committee of Region Zealand are implementing rational pharmacotherapy within hospital and primary care, by recommending drugs that are rational for use in concern of particularly effectively, safety and totally drug expense for hospitals and primary care. After discharge from the hospital the GP tend to continue the drug chosen at the Hospital, hence the use at the hospitals affect the use in the primary care. To the hospitals oxycodone is only marginal more expensive than morphine but in primary care oxycodone is substantially more expensive.

Purpose To implement the recommendation of morphine instead of oxycodone, and thereby reduce the total drug expense for the healthcares system at Region Zealand.

Materials and methods The implementing was made step-by-step with follow-up. 1. Written information to the hospital wards and the GP, with advice to remove oxycodone from the standard assortment, and how to change patient treatment to morphine. 2. Dialogue with the wards by clinical pharmacist toward final agreement of removing oxycodone from the wards standard assortment. Written advice in the medical journal of every patient still treated with oxycodone. 3. Every 3rd-month a status report is made to the GP and the wards, with the data of their actual oxycodon consummation. 4. The Regional Drug and Therapeutics Committee follow the total consumption of oxycodone and strategy for further or repeated intervention is made.

Results One year after the start of implementation, the amount of morphine used (DDD) is increased from 25% to 50% in the hospitals and from 38% to 44% in primary care. The drug expense for the total healthcare system is thereby reduced by 7%. The implementation is still in process.

Conclusions The step-by-step quality implementation is successful to implement recommendation.

Competing interests None.

DSL020 AN ALTERNATIVE TREATMENT FOR CANDIDA INFECTIONS WITH NIGELLA SATIVA EXTRACTS

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Background Nigella sativa is a herb from the Mediterranean region with antidiabetic, bronchodilator, antioxidant, hepatoprotective, lipid lowering, anti-inflammatory and analgesic properties.

Purpose This study aimed to reveal the antifungal activity of aqueous, methanolic and chloroform extracts obtained from the plant seeds, compared with the effect of traditional antifungals.

Materials and methods Using standard mycological diagnostic methodology The authors isolated and identified 20 strains of Candida albicans from pathological products collected from patients hospitalised in different departments of the Craiova Emergency Hospital. Aqueous, methanolic and chloroform extracts were made from the seeds of Nigella sativa, in decreasing dilutions, in which Wattman filter paper discs were soaked and dried and then used to achieve the antifungal graph by using the Kirby-Bauer diffusion technique. Simultaneously, the testing was repeated using standard antifungal disks (Becton Dickinson) and the two sets of results compared. The antifungal effect was assessed by measuring the diameter of the inhibition zone, noting the concentration per disk.

Results The results show that methanolic extracts of Nigella sativa have the strongest antifungal effect followed by the chloroform extracts. Aqueous extracts showed no antifungal activity.

Conclusions The research shows treatment with natural products in a good light as an alternative for treating fungal infections. The authors envisage Nigella sativa extract enhancing the effect of conventional therapy.

Competing interests None.

DSL021 VALGANCICLOVIR: AN OPTION IN THE TREATMENT OF CYTOMEGALOVIRUS DISEASE IN HAEMATOLOGICAL PATIENTS

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10.1136/ejhpharm-2012-000074.204

Background Ganciclovir (Cymevene) has traditionally been the drug of choice for the treatment of cytomegalovirus infections; it should be administered intravenously because it has low bioavailability. The development of the highly bioavailable prodrug, valganciclovir (Valcyte) has provided an oral option for cytomegalovirus infections.

Purpose The authors evaluated valganciclovir as an alternative in sequential therapy in haematology patients treated with ganciclovir (off-label use).

Materials and methods This was a retrospective observational study lasting 2 years (July 2009–July 2011). The authors included all hospitalised haematology patients who had been treated with ganciclovir. Data were collected: age, sex, haematology disease, ganciclovir (dosage and duration), previous treatment, switch to valganciclovir and date of discharge.

Results The authors included 23 episodes of treatment with ganciclovir involving 21 patients, 9 women and 12 men with median age of 52 years. The most common haematology disease was non-Hodgkin's lymphoma (9 patients) followed by acute myeloid leukaemia (5 patients). 21 episodes of treatment

began with ganciclovir 5 mg/kg every 12 h, an induction regimen, then 7 were changed to ganciclovir 5 mg/kg every 24 h, a maintenance regimen. At discharge, 8 patients continued with ganciclovir, 6 (75%) switched to valganciclovir, 5 patients at 900 mg/12 h and 1 patient at 900 mg/24 h. 1 patient was switched to valganciclovir 900 mg/24 h during hospitalisation, treatment continued at discharge. The ganciclovir was discontinued in 12 patients and they were switched to foscarnet (Foscavir) because ganciclovir was associated with leucopenia.

Conclusions Valganciclovir can be the oral alternative to ganciclovir in treatment of cytomegalovirus infections in haematology patients; it does not require hospitalisation for administration. The main limitation on the use of ganciclovir was leucopenia. The use of alternatives such as foscarnet was required in the treatment of cytomegalovirus infections.

Competing interests None.

DSL022 ANALYSIS OF DABIGATRAN PRESCRIBING

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10.1136/ejhpharm-2012-000074.205

Background Dabigatran is indicated for primary prevention of venous thromboembolism (VTE) in adult patients undergoing surgery for total hip or knee replacement.

Purpose To analyse the prescription and adaptation to the approved indications for dabigatran in a tertiary hospital.

Materials and methods Retrospective observational study lasting 12 months (January 2010-December 2010) which included patients treated with dabigatran.

Results During the study period, 236 interventions were made for which dabigatran treatment was suitable (94 hip and 142 knee replacements). Dabigatran was prescribed in 11 patients (9 women and 2 men), mean age 61 years (36-77): 5 for hip replacement, 2 for knee replacement, 1 for partial femoral neck fracture and 3 patients had not undergone prosthetic intervention. Dose adjustment was necessary only in two patients aged over 75 years: a 77-year-old woman treated with 110 mg/day and a 76-year-old man with 150 mg/day. Only in 63.63% of cases (n=7) did the prescription conform to the approved indications.

Conclusions Despite being newly introduced to the hospital's formulary, it is necessary to remark that one third of the prescriptions did not conform to the approved indications for use in the hospital. Therefore, it is necessary to create and disseminate standard rules for use in the medical wards. This will increase adherence to the recommendations of use, reduce prescribing errors and establish corrective actions for them.

Competing interests None.

DSL023 EXPERIENCE WITH USING INTRAVENOUS CLONIDINE HYDROCHLORIDE IN THE CRITICAL CARE UNIT OF A TERTIARY HOSPITAL IN SPAIN

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10.1136/ejhpharm-2012-000074.206

Background Clonidine hydrochloride is an α-2 agonist whose approved indication in the summary of product characteristics is as an antihypertensive; nevertheless other indications could be possible.

Purpose To examine the 'off label' indications of clonidine in critical care patients on mechanical ventilation, in a tertiary hospital. To describe the procedure to obtain intravenous clonidine hydrochloride in our hospital, since it is not marketed in Spain.

Materials and methods Retrospective study of the use of intravenous clonidine in continuous infusion, for critically-ill patients, in the first six months of 2010. The Selene and Picis programmes were used to analyse computerised clinical histories.

Results A total of 18 patients were treated with clonidine. In 16.7% of the cases, it was used as antihypertensive, and in the remaining 83.3% cases, its use was 'off label'. In 33.3% of the cases, it was used to control withdrawal symptoms, in 27.8% to prevent withdrawal when removing sedation, in 16.7% to contribute to sedation and in 5.5% to treat delirium. The range of doses used in intravenous perfusion was 0.3-9 mcg/Kg/h. The average length of treatment was 6.8 days. In 94.4% of patients, it was used in combination with other sedatives; it was used as monotherapy in only 5.5% of the cases. It was combined with propofol in 77.7% of cases, with midazolam in 33.3%, with fentanyl in 22.2%, with remifentanil in 22.2% and with morphine in 11.1% of cases. 27.7% of the patients responded with hypotension and 0.05% with bradycardia. Acquisition of intravenous clonidine in Spain must be through importation from abroad or by requesting it as a 'special' from accredited pharmacies. The authors acquire it produced in small amounts in this way in concentrations of 0.15 mg/ml and 0.4%, 5 ml ampoules.

Conclusions In our patients, intravenous clonidine hydrochloride has been shown to be a useful drug for controlling tolerance to, or withdrawal from, sedative and analgesic drugs in critically-ill patients undergoing mechanical ventilation.

Competing interests None.

DSL024 ASSESSMENT OF TRASTUZUMAB USE IN ADJUVANT THERAPY

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10.1136/ejhpharm-2012-000074.207

Background Trastuzumab is indicated for the treatment of patients overexpressing HER2 in metastatic breast cancer and HER-positive early breast cancer.

Purpose This study aimed to evaluate the use of trastuzumab in an adjuvant setting, in the Hospital Garcia de Orta.

Materials and methods This evaluation, carried out in September 2011, included all early-stage breast cancer patients who started trastuzumab in 2008 or 2009. Data source: medical records and patients' prescriptions from the cytostatic unit in the pharmacy department. Each patient was evaluated on six factors of poor prognosis (age < 50 years; invasion of lymph nodes; absence of oestrogen and progesterone receptors; tumour size > 2 cm; disease staging ≥ GIII and overexpression of the HER2 receptor).

Results This study included 32 women with an average age of 49.5±11.4 years (33-75 years). Twenty-five women were clinically well (78.1%), 2 (6.3%) had metastases and 5 (15.6%) died. All patients had at least one factor of poor prognosis (overexpression of HER2). Only 1 patient had 1 poor prognosis factor, 6 had two factors of poor prognosis, 12 patients had 3, 9 patients presented 4 and 4 patients had 5 factors for poor prognosis. Statistically significant differences were found between the patients who were clinically well and those who

developed metastatic disease or died, for the number of poor prognosis factor present at the time of trastuzumab prescription ($p<0.05$). Of all the poor prognosis factors, disease staging was the one that showed statistically significant differences between the 2 groups of patients ($p<0.001$).

Conclusions The literature refers to disease staging as the most accurate estimate of prognosis in breast cancer. Based in our study, disease staging was also the factor of prognosis that best predicted the result of trastuzumab therapy.

Competing interests None.

DSL025 PHARMACOECONOMIC CONSIDERATIONS ON TREATMENT OF MULTIPLE SCLEROSIS: IMPORTANCE OF COMPUTERISATION AND ROLE OF THE DAILY DOSE RECEIVED

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10.1136/ejhpharm-2012-000074.208

Background In Italy, four parental formulations are currently approved for Multiple Sclerosis: interferon-β 1a (Avonex and Rebif), interferon-β 1b (Betaferon and Extavia) and glatiramer (Copaxone). In this study the appropriateness of the prescription, patient compliance and pharmacoeconomic profile were evaluated for each drug.

Purpose The aim of this study was to test a particular database, FarmaDDSS, designed to follow patients through the hospital pharmacy where they receive the prescribed dose. This approach allows us to calculate important drug use parameters such as Received Daily Dose (RDD), Prescribed Daily Dose (PDD).

Materials and methods In order to monitor prescriptions for drugs, a database was created, called 'FarmaDDSS', to enter drug use data such as RDD, PDD, appropriateness of the prescription, patient compliance and physician compliance. Economic considerations were made depending on the daily used dose of study drugs. The following data were loaded in the FarmaDDSS database: patient demographics, drug used, dosage and date of delivery of the drug.

Results There were 117 patients in this four-year study. RDD and PDD and related costs were calculated for each drug. The RDD values, calculated over four years, between 2007 and 2010, for Avonex, Betaferon, Extavia, Rebif 22 and 44 were 4.65, 3.92, 19.75, 9.05 and 18.82, respectively. Appropriateness of the prescribing and patient compliance were approaching the figure 1, thus showing a good clinical profile for all drugs except for Rebif. Calculating the cost per RDD, the most expensive drug seems to be the Rebif with a cost of € 36.00 per day.

Conclusions It is very important to use the RDD as parameter of pharmacoeconomic valuation because it represents a more reliable indicator than the DDD. In this case the computerisation plays an important role in following the patient, especially in this type of pathology.

Competing interests None.

DSL026 THE QUANTITY AND QUALITY OF PATIENTS' OWN MEDICINES BROUGHT TO HOSPITAL DURING ADMISSION

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Background Patients' own medicines (POMs) are medicines that patients have obtained in the community setting and bring to the hospital when admitted. Literature suggests that using POMs has benefits to the patient and the hospital that include improving the accuracy of admission prescriptions and continuity of care as well as reducing medicine costs. Nonetheless the quality and the practice of using POMs have been poorly investigated.

Purpose To evaluate the quantity and quality of POMs to assess the disadvantages and benefits of using them.

Materials and methods Clinical pharmacists in 4 wards comprised of 3 acute care wards and 1 geriatric ward at 3 different hospitals in Denmark evaluated POMs for quantity and quality. The POMs were evaluated on their appearance, container, labelling, identification, storage conditions and expiry date. POMs were defined suitable for use if the medicine was intact, labelled with patient ID, in original container, had visibly not exceeded the expiry date, appeared clean and the contents could be verified. Current policies in Zealand Region allow POMs to be used if they meet the above criteria and if no suitable substitute (generic or equivalent) is stocked in the hospital.

Results During March 2010 to July 2011 529 patients were assessed by the clinical pharmacist. According to medicines histories the patients took 4600 medicines (including over the counter medicines and supplements) averaging 8.7 per patient. A total of 60% patients (315) brought POMs, equivalent to 44% (2035) of the medicines from the medicine history to the hospital. The majority of the POMs were suitable for use according to the criteria set, although only a small percentage were actually used under the criteria that no suitable substitute was available.

Conclusions More than half of patients bring their own medicine to the hospital and the majority of POMs are suitable for use. Only a small proportion are actually used since substitution is often possible.

Competing interests None.

DSL027 ALLOCATING THE COST OF THE MEDICINES AFTER IMPLEMENTING AN AUTOMATED DISPENSING SYSTEM†

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Background Our 450-bed general hospital had a unit dose dispensing system in 100% of inpatient wards until July 2010, when an automated dispensing system (ADS) incorporating most of the medicines was introduced in the Large Burns Unit (LBU).

Purpose To quantify the variation in drug expenses allocated per patient after introduction of an ADS in the LBU and to identify the products mainly affected by this change. Materials and Methods To quantify the variation in the expenses allocated, The authors compared two equal periods of four months, before the introduction of the ADS (September-December 2009) and four months after (September-December 2010). The authors used the average book price to calculate the cost of the Unit, by adding the cost of stock replenishment and unit dose medicines dispensed in the case of the first period and extracted from the ADS in the case of the second period.

Results In the period prior to ADS implementation, Unit expenses were 53,037 euros of which 45.43% were allocated to the patient. After ADS implementation, the Unit cost 50,732 euros to run, of which 73.33% were allocated per patient. Of the 68 products that went from dispensing stock to ADS, the ones

that mainly affected the change in the medicines expense allocation per patient were: sulfadiazine (47.5%), midazolam (8.5%) atracurium (5.8%), propofol (5.5%) and ketamine (4.3%).
Conclusions The medicines that mainly affected the change in the allocation of medicines belong to the D06, N05, M03 and N01 ATC classification groups in financial terms:, these were traditionally dispensed by replenishing stock. This has represented a significant reduction in the Unit stock. The ADS improve the allocation per patient of medicines expenses, including special units with prior unit dose dispensing, which enables the pharmacist to increase the level of knowledge about drug use in the Unit.

Competing interests None.

DSL028 DESIGN OF THE MEDICINES STORAGE AREA IN HOSPITAL WARDS

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Background It is important to know the preferences of the users on the design of the medicines storage area to optimise resources and avoid errors that reach the patient.
Purpose To find out the preferences of the chief nurses on the design and functioning of the medicines storage area in hospital wards
Materials and methods The authors interviewed 25 chief nurses from May to June of 2011. They were asked to name the most important characteristics that a medicines storage area needs to have. Then they had to rate them (1 to 10) according to the importance.
Results A total of 15 specifications were grouped in 4 categories: Classification, Stock and replacement, Safety and Structure. The most requested specifications were the following: 1.-Medicines arranged in alphabetical order (9.37, Classification) 2.-Medicines included and stocks suitable for the needs of the hospital ward and daily replacements (9.36, Stock and replacement). 3.- Medicines containers should be labelled with the name of the drug and the trade name (9.25, Safety). 4.- Big and legible labels (9.10, Safety). 5.- Medicines classified by route of administration (9.02, Classification). 6.- Medicines storage area located near the nurses' work station (8.94, Structure). 7.-Visual code (symbols or colours) on the label to indicate the medicines close to expiry, route of administration, storage conditions, high risk medicines, etc. (8.75, Safety). 8.- The logistics department should provide daily information about replacing the medicines and the reasons for the lack of medicines (8.67, Stock and reinstatement). 9.- More versatile medicines containers (8.46, Structure) 10.-Logistics department should review the expiry date of the medicines every three months (8.00, Stock and reinstatement).
Conclusions The safety dimension was the most valued. The most frequently mentioned categories were safety and structure.

Competing interests None.

DSL029 SIMPLYING THE MANAGEMENT OF PATIENTS WITH BIPOLAR DISORDER AND/OR SCHIZOPHRENIA WITH EXTENDED-RELEASE QUETIAPINE AS ADJUNCT TREATMENT

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DSL029 table 1

Mean Data (Range)	Admission	Discharge
Number of tablets	5 (1-11)	9 (4-15)
Number of doses	5 (1-11)	8 (5-12)
Number different drugs	3 (1-6)	5 (3-8)
Dosage (mg) at discharge	-	624 (200-1200)

Background Lack of adherence leads to frequent emergency visits and an increased number of hospital readmissions. Several studies have shown that once a day dosing (simplification of treatment (ST)) may improve adherence.
Purpose To assess ST at discharge, with initiation of, or change to, extended release quetiapine (QXR) in patients admitted to a psychiatric unit diagnosed with bipolar disorder (BD) and/or schizophrenia (SCH).
Materials and methods Retrospective study (February 2010-April 2011) of QXR prescription in BD and/or SCH from the admission and discharge reports. ST: reduction of one or more drugs and/or two or more tablets/times a day. Each administration of drops was equivalent to one tablet.
Data were measured at admission and discharge:
- number and types of drugs, doses and tablets.
- QXR dosage at discharge.

Results 18 patients (8 men) aged 25-67 years (mean 44 ±12 years) in 19 admissions (16 BD, 3 SCH). 4 were excluded, all with BD, because QXR was discontinued.
Type of drug at discharge: Antipsychotics: 93% had an antipsychotic other than QXR (mainly clozapine), 80% had more than 2 and 40% over 3. 20% reduced the number of antipsychotics. Benzodiazepines: 47% increased the number of different benzodiazepines and 13% got a decrease. Antidepressants: only 1 patient had antidepressants, related to a reduction of antipsychotics. Mood stabilisers: 33% had at least one at admission, and 60% more than one. Other: 60% were taking more 'other medicines' at discharge, 78% due to starting lithium. The treatment was simplified in 20% of patients: 1 patient reduced the number of drugs and tablets, 1 the number of doses and 1 the number of drugs.
Conclusion The proportion of patients with ST was very low in our series.

Competing interests None.

DSL030 ERYTHROPOESIS-STIMULATING AGENTS – STUDY OF THEIR USE IN CANCER PATIENTS

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Background Anaemia is common, occurring in 30-90% of cancer patients. Erythropoiesis Stimulating Agents (ESAs) have shown to be effective in the correction of anaemia in oncohaematology.
Purpose To assess the use of ESAs in cancer patients and the adherence to the 2011 ASCO guidelines on the use of epoetin and darbepoetin in adult patients with cancer.
Materials and methods A retrospective study into the use of ESAs in cancer patients was performed over nine months. Patients were located by reviewing the dispensing records supplied by the unit dose and outpatient software in the pharmacy department. Data collected were: age, sex, diagnosis, chemotherapy schedule, ESA dosage, haemoglobin level

at baseline and after 6 to 8 weeks. The degree of adherence to guidelines was assessed for the items: anaemia related to chemotherapy, haemoglobin <10 g/dl before ESA, continuing treatment beyond 6–8 weeks in the absence of response (1–2 g/dl increase in Hb).
Results 82 patients were included (61% female), mean (±SD) age was 62±18. The most common cancer locations were lung and breast. The most common chemotherapeutic agents were carboplatin and paclitaxel. 7 patients were treated with epoetin 30000 IU weekly, and 75 with darbepoetin (5.3% 150 mcg weekly or 94.7% 500 mcg every 3 weeks). Titration was performed only for one patient and the drug was changed for two patients. The mean (±SD) baseline haemoglobin was 9.93±0.56 mg/dl. Response was obtained in 53.6% of patients. Degree of adherence: 95.1% of patients were treated with chemotherapy, baseline haemoglobin was <10 g/dl in 56% of patients and 17% continued treatment in the absence of response.
Conclusions The ESA most commonly used was darbepoetin 500 mcg every 3 weeks. ESAs were effective in half of patients. In accordance with guidelines most patients had concomitant chemotherapy. However pharmacists face an important challenge in seeking to improve other aspects that have been evaluated.

Competing interests None.

DSL031 'WHAT ARE THE ROOT CAUSES OF RETURNED MEDICINES IN HOSPITAL PHARMACY?' A LEAN APPROACH.

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Background In CHU Mont-Godinne, physicians prescribe medicines through a CPOE system and medicines are then delivered on an individual patient basis by the pharmacy. The amounts are generated according to a 'limit date system'. The pharmacy faces the problem of considerable amounts of medicines returned.
Purpose To determine the root causes of medicines being returned to a hospital pharmacy.
Materials and methods The study was conducted on the 'Respiratory & Oncology' ward and focused on all medicines returned in relation to 31 patients who had been admitted to the unit for a period of 5 weeks. Currently, one out of four medicines supplied to the 'Respiratory & Oncology' ward is not administered to the patient and is returned to the pharmacy. Cause analysis was conducted retrospectively and according to a lean approach. It is a structured process used to improve process cycle time through the identification, reduction and elimination of process waste and non-value-added activities. First, The authors determined for each medicine returned to the pharmacy the step of the medication use process where the problem originated: the prescription, dispensing by the pharmacy, picking operation by nurses, administration to the patients and management. Then for each of these steps The authors identified more specific reasons why it had been returned.
Results 1754 returned medicines were analysed. The three main root causes of returned medicines were: a discharge date not recorded in the CPOE system (22.86%), inappropriate use of electronic prescribing (10.15%), late capture of a known discharge date (7.98%).
Conclusions To reduce the number of returned medicines, health professionals using the CPOE systems must be trained appropriately. Once the discharge date of the patients is known, it is imperative to record this information as quickly as possible in the software.

Competing interests None.

DSL032 SAFETY OF SUNITINIB IN RENAL CELL CARCINOMA

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Background Renal cell carcinoma (RCC) represents only 2-3% of all cancers. Sunitinib is a standard initial therapy in advanced and metastatic renal cell carcinoma.
Purpose A retrospective review was performed to assess the safety of sunitinib in RCC.
Materials and methods RCC patients undergoing sunitinib treatment and follow-up for at least one month were included. Variables: sex, age, nephrectomy status, histology, risk group, metastatic sites, sunitinib starting dose, % adverse events (AEs) from Common Terminology Criteria for Adverse Events (CTCAE version 4.0), % grade 3-4 AE, % starting dose reduction, % extra week rest period and % colony stimulating factors (CSF) used for toxicity management. Statistical analysis by SPSS 18.0.
Results 19 patients were analysed: 73.7% male, median age 62 years, 94.7% previously nephrectomised (78.9% radical nephrectomy and 15.8% partial nephrectomy), median time to sunitinib treatment 60.5 months. By histology, 79.0% was clear cell carcinomas. Grouped according to their risk (57.9% of patients could be assessed for risk): 15.8% were assessed as favourable, 26.3% intermediate and 15.8% unfavourable. Median metastatic sites were 3, sorted by frequency: lung 68.4%, liver 47.4%, soft tissues 26.3%, bone and pleura 21.1%, brain, skin and heart 10.5%. Starting dose of sunitinib were 68.4% 50 mg/day, 26.3% 37.5 mg/day and 5.3% 25 mg/day administered for four consecutive weeks and followed by a two-week rest period. 100% patients reported at least one AE. The most frequent AEs were asthenia 11.6%, neutropenia or thrombocytopenia 10.7%, hypertension or diarrhoea 9.9%. Grade 3-4 events were neutropenia 4.1%, anaemia 2.5%, bleeding 1.6%, hypertension, hand-foot syndrome or diarrhoea <1.0%. In addition, one case of toxic hepatitis and a cerebral oedema event were reported. Median cycles sunitinib received were 4.3. Toxicity management consisted of dose reduction 38.4%, extra week rest period 57.6%, no patients required CSF as filgrastim or epoetin α.
Conclusions With sunitinib, adverse events such as hematologic toxicity, asthenia, hypertension and gastrointestinal events were common. Toxicity management included dose reduction or additional rest period.

Competing interests None.

DSL033 TREATMENT WITH MONOCLONAL ANTI-TNF ANTIBODIES

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Background The monoclonal anti-TNF antibodies infliximab and adalimumab and etanercept are equally effective in rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and inflammatory bowel disease. Poor persistence with, and adherence to, biologicals can undermine

the effectiveness of these drugs. There are no standardised methods for tracking persistence with, and adherence to, biologicals.

Purpose The aim of this study was to evaluate the patient adherence to treatment through the compliance ratio. The cost of treatment per day was also calculated for each drug.

Materials and methods The study was carried out in 2010. The following data were loaded in the database in use at the pharmacy, FarmaDDSS: patient demographics, drug used, dosage and date of delivery of the drug. So, it was possible calculate the drug use parameters Received Daily Dose (RDD) and Prescribed Daily Dose (PDD) for comparison with the Defined Daily Dose (DDD). Patient adherence to treatment was calculated as the ratio of RDD to PDD.

Results Of the 207 patients treated in 2010, 52 had etanercept, 102 adalimumab and 53 infliximab. The RDDs were 6.4, 3.9 and 7.2, respectively. The PDDs were 7,11, 3,00 and 3,78. Appropriateness (RDD/DDD) and adherence (RDD/PDD) were 0.9 for etanercept, 1.3 for adalimumab and 1.9 for infliximab. The cost per RDD was € 33.47, € 50.00 and 39.94, respectively.

Conclusions Etanercept and adalimumab showed a good clinical profile. Infliximab appears to betaken at twice the dose. It's very important to follow the patients by developing an outcomes research system. The use of a dedicated database such as FarmaDDSS can facilitate the measurement of rates of persistence with, and adherence to, biologicals.

Competing interests None.

DSL034 ANALYSE THE IMPACT OF HOSPITAL SUPPLY OF ORAL CHEMOTHERAPY AGENTS IN A OUTPATIENT UNIT

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Background Oral chemotherapy agents are medications that were dispensed in pharmacies usually but since the entry into force of an order regional president in January 2011 became hospital dispensing.

Purpose To analyse the economic and healthcare impact of the inclusion of oral chemotherapy agents in a outpatient dispensing unit.

Materials and methods The study period runs from 23th January to 30th September, 2011. During this period, 16 chemotherapy agents have been acquired and dispensed in our unit: anagrelide, capecitabine, cyclophosphamide, chlorambucil, dasatinib, erlotinib, gefitinib, hydroxyurea, imatinib, lapatinib, melphalan, sorafenib, sunitinib, nilotinib, tretinoin, temozolomide. For the economic analysis estimates the cost of which has led to the introduction of oral chemotherapy compared to other outpatient dispensations of haematology, oncology and urology, which are the units that consume such medicines data were obtained through the computer application outpatient dispensing (DIPEX) and management software (Sinfhos), was also evaluated consumption of each active ingredient included.

Results During this period, the number of patients who where dispensed oral chemotherapy were 388; it's means the 26,7% of patients attending in the outpatient unit. Consumption in this period for each area not including the dispensing of oral chemotherapy was: Haematology: 691,586.9€; Oncology: 280,038.23€; Urology: 27,754.74 € and consumption at the same time and each area including the dispensing of oral chemotherapy was: Haematology: 1,428,089.71€; Oncology: 907,203.66€; Urology: 96,641.97€. Representing an increase of 48.42% in consumption of Haematology, a 30.86% in Oncology and a 28.72% in Urology. The most dispensed drugs were: capecitabine 12,74%, dasatinib 9,48%, erlotinib 12,28%, imatinib 25,21%, lapatinib 5,25% and sunitinib 10,13%. Nobody was joined the staff to reinforce the outpatient unit.

Conclusions 16 new oral chemotherapy agents were acquired during this period, this has meant an overall increase in consumption of 243.43%, The drug is highest cost was imatinib. The number of patients increased by 26,7%, a very important increase of work without increase in the staff budget.

Competing interests None.

DSL035 FINANCIAL IMPACT OF ORAL VINORELBINE USE IN A REGIONAL HOSPITAL

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Background The advantages of orally active chemotherapy make it a valuable option for treating cancer patients.

Purpose To assess the use and cost of oral vinorelbine (OV) in a regional hospital.

Materials and methods A retrospective descriptive study carried out from January 2009 till September 2010. The authors report on all the patients who were treated with OV during the period of study. The authors checked the following information: sex, age, diagnosis, previous and subsequent chemotherapy regimens, chemotherapy regimen, mean dose, patient-related cost and overall cost.

Results The authors studied 21 patients (80.9% men and 19.1% women) with a mean age of 68.1±8.9 years. 15 patients were diagnosed with non-small cell lung cancer (NSCLC), 3 with breast cancer (BC) and 3 with prostate cancer (PC). 40% of patients with NSCLC had previously been treated with cisplatin-paclitaxel or cisplatin-gemcitabine whereas 60% had been treated with cisplatin-vinorelbine or vinorelbine alone. With regard to the other diagnoses: 3 patients with BC had been treated with paclitaxel-anthracycline and 3 patients with PC had been treated with paclitaxel-carboplatin. For the current treatment, the distribution of treatments was the following: a) OV monotherapy (6), b) OV associated with cisplatin (6), c) docetaxel monotherapy (2) and c) without treatment (7). The chemotherapy regimens with OV were: 60 mg/m2, on the 1st and 8th day every 21 days (71.4%); 60 mg/m2, on the 1st and 8th day every 21 days the first cycle and 80 mg/m2, on the 1st and 8th day every 21 days in the following cycles (14.3%); 60 mg/m2, on days 1, 8 and 15 every 28 days (14.3%). Average dose of OV was 110.4±13.6 mg with an average number of prescriptions dispensed of 4.7±2.7. Only 9 patients had received prior intravenous vinorelbine. Patient-related cost was 1,314.08 € and overall cost was 14,454.96 €.

Conclusions In our hospital, OV was used in accordance with the guidelines except that the absence of intravenous vinorelbine first in 42.8% of patients should be justified. Although the cost of OV is high it is justifiable because it avoids indirect costs.

Competing interests None.

DSL036

PROPHYLAXIS OF EMESIS INDUCED BY HIGH EMETOGENIC CHEMOTHERAPY: A COMPARISON BETWEEN CLINICAL PRACTICE AND TREATMENT GUIDELINES

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Background According to European Society for Medical Oncology (ESMO) guidelines (2011), the preferred treatment for acute emesis induced by highly emetogenic chemotherapy (HEC) consists of the administration of a 5HT3 receptor antagonist (granisetron, ondansetron or palonosetron) and dexamethasone, plus aprepitant (known as triple therapy, TT). In the Anticancer Drugs Unit of Careggi Hospital (CH) of Florence, the ancillary treatment included in chemotherapy protocols is managed by using software shared with physicians. In this way the ancillary therapies can be modified at the time of prescription.

Purpose The aim of the study was to verify the correspondence between emesis treatment guidelines and the real clinical practice in our hospital wards.

Materials and methods Antiemetic medicines administered in CH wards in a two-month period (April-May 2011) were assessed using the treatment management software. Of particular interest were the days in which cisplatin was used at a dose higher than 50 mg/m² (alone or in association with other antineoplastic drugs), dacarbazine at all doses and combinations, and cyclophosphamide and anthracyclines included in breast cancer protocols.

Results In the reference period, 137 days' treatment with HEC were performed. Cisplatin administration was associated with TT in 42.4% of cases (dexamethasone 8-32 mg), and in the remaining 57.6% treatment with dexamethasone (16-20 mg) associated with a 5HT3-RA (mainly granisetron 3 mg) was preferred. Dacarbazine was administered as part of TT (palonosetron plus aprepitant) in 17.4%. In the majority of cases (82.6%) it was used only with palonosetron. Finally the TT regimen was given only in 1 out of 15 days' therapy during cyclophosphamide and anthracycline treatment.

Conclusions The availability of the chemotherapy management software allows us to have information about drug consumption. Our study shows that antiemetic prophylaxis for HEC is not always prescribed according to international guidelines.

Competing interests None.

DSL037

PROSPECTS OVER THE INTRODUCTION OF AN ELECTRONIC PRESCRIBING SYSTEM ASSOCIATED TO AN AUTOMATED SYSTEM OF DRUG DISPENSING

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Background According to the safety strategies proposed by National Quality Forum, Institute for Safe Medication Practices and SESCAM, in 2009, the introduction of an electronic prescribing system associated to an automated system of drug dispensing (EPS&ASDD) was started in some clinical units of a general hospital.

Purpose To assess, before its introduction, the views of the medical and nursing staff regarding the EPS&ASDD.

Materials and methods In January 2011, before EPS&ASDD was extended to the Oncology, Digestive and Cardiology Units (35 beds), The authors took through an anonymous and voluntary questionnaire the views of the potential users, including:

- A section to asses the introduction (positive, negative or indifferent).
- Six sections with multiple choice (nothing, little, enough or much) to evaluate handling, safety, time and prescription support, considering positive answers enough and much.

Information gathered: sex, age, professional status. Analysis of results: Excel® database.

Results 100% participation (18 doctors, 11 nurses). 75.9% found the introduction of EPS&ASDD positive (all nurses, 61.1% doctors). Users who considered positive each aspect:

Conclusions Nurses evaluated EPS&ASDD better than doctors in all items. The perception of an increase of patient safety and easy handling were the best valued aspects. The opinions of the users are a good tool in order to introduce improvements in EPS&ASDD.

Competing interests None.

DSL037 table 1

		SEX		AGE			PROFESSIONAL STATUS	
	GLOBAL	MEN	WOMEN	>50	30-50	<30	Doctors	Nurses
Easy handling	69%	75%	66.7%	100%	64.2%	50%	90.9%	55.6%
Increase of patient safety practice	79.3%	75%	81%	100%	78.3%	50%	72.2%	90.9%
Decrease of medication errors	79.3%	75%	81%	100%	78.3%	50%	72.2%	90.9%
Decrease of medication related problems	82.8%	75%	87.5%	100%	78.3%	100%	72,2%	100%
Decrease of global time dedicated to patient	31%	37.5%	28.6%	50%	26.1%	50%	27.8%	36.4%
Increase on prescription quality (only doctors)	44.4%	50%	40%	100%	30.8%	50%	--	--

Drug information (i. Anti-infectives, ii. cytostatics, iii. others)

DGI001 CONSUMPTION OF INTRAVENOUS IMMUNOGLOBULINS IN CLINICAL HOSPITAL CENTER OSIJEK 2006-2010

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Background Retrospective analysis of the use of intravenous immunoglobulins (IVIG) in our hospital. On the National Drug List The authors find immunoglobulins 0.5 g/10 ml, 2.5 g/50 ml and 5 g/100 ml. Prices were constant during the period 2006-2010, 240 kn/g and 459.6 kn/g.
Purpose To determine the costs of IVIG and the largest consumers (clinics/wards) over a four-year period in the hospital.
Materials and methods Retrospective analysis of data obtained by computer program. Financial costs are given in kunas (1kn=7.5€), and consumption of IVIG in grams.
Results The costs of IVIG were: 257062.09 kn in 2006, 455430.52 kn in 2007, 476072.30 in 2008, 702350.48 in 2009 and 763276.67 in 2010. Total consumption of IVIG in 2006 was 1257 g, 2097g in 2007, 1979.5 g in 2008, 2729 g in 2009 and 3018 in 2010. The largest consumers were Anaesthesiology: 75 g in 2006, 150 g in 2007 and 2.5 g in 2009 and 2010; Immunology: 210 g in 2006, 240 g in 2007, 480 g in 2008, 550 g in 2009 and 580 g in 2010; Haematology: 32.5 g in 2006, 476.5 g in 2007, 131 g in 2008, 130 g in 2009 and 20 g in 2010; Haemodialysis – 2.5 g in 2006, 5.0 g in 2007 and 2008 and 100 g in 2009; Paediatrics: 377 g in 2006, 289 g in 2007, 804.5 g in 2008, 1110.5 g in 2009, 1861 g in 2010; Neurology – 450 g in 2006, 840 g in 2007, 400 g in 2008, 781 g in 2009, 575 g in 2010.
Conclusions In the given period costs for IVIG increased by 270%, while consumption went up by 240%. The largest consumers were the Paediatrics Clinic, Allergology and Immunology, followed by the Neurology Clinic, whose consumption oscillated. The Anaesthesiology and Haematology wards consumed decreasing amounts of IVIG.

Competing interests None.

DGI002 MANAGEMENT OF RESTRICTED ANTIBIOTICS

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Background Attempts are made worldwide to restrict and control antibiotics because of rising concern about problems of antibiotic resistance.
Purpose The purpose of this research was to develop policies and guidelines for the process of prescribing antibiotics to determine the patients who use restricted antibiotics and plan their treatment.
Materials and methods Last year, a multidisciplinary subcommittee was constructed of members of the infection control committee. The committee first listed the restricted antibiotics in the hospital formulary and found this added up to 13% of all drugs in the list. It was decided to enlist the benefits of technology. 'Pyxis drug consoles' were programmed to provide a batch report which lists all the patients who use restricted antibiotics and the pharmacy sends these lists to the email group of the infection control committee every morning. A special investigator group was created in 2011 that consisted of an infection doctor, an infection nurse, a pharmacist and a microbiologist. An 'antibiotic usage form' was created by the group and filled in for each patient for one month. All patients who used antibiotics were visited three times a week and data were collected from their charts.
Results After visits, evidence of 552 occasions of antibiotic usage was collected and evaluated via the STATA program. The authors noticed that 45% of administrations were inconvenient during treatment, 62% inconvenient usage in prophylaxis. The causes of inconvenient usage of restricted antibiotics in prophylaxis; 63% reported it was 'unnecessary', 6% said it was 'completely unnecessary', 3% 'too broad a spectrum antibiotic' was used, 2% insufficient spectrum antibiotic. In empiric administration; 33% was completely unnecessary, 10% stringing it out was unneccesary, 9% too broad spectrum, 7% insufficient antibiotic spectrum.
Conclusions The list of antibiotics that were being used inappropriately was determined and classified according to the department using them. The multidisciplinary approach has increased the awareness of the healthcare professionals of the antibiotic resistance problem.

Competing interests None.

DGI003 SAVINGS MAY BE OBTAINED BY SELECTING NON-INFERIOR ALTERNATIVES INSTEAD OF ERTAPENEM

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Background Ertapenem (Invanz) was the third carbapenem approved by European Medicines Agency. It is mainly used for the treatment of polymicrobial infections. Nonetheless, while ertapenem enjoyed market exclusivity period of time, generic alternatives are now marketed, so Invanz is the most expensive option. Moreover, there is no evidence to show that this brand is better; non-inferiority studies are required for licensing approval.
Purpose The aim of this study was to evaluate what The authors would have saved if The authors had used alternative brands of ertapenem, shown to be non-inferior by the scientific literature and antibiograms. No data have been published since the alternative generic drugs were commercialised.
Materials and methods Observational, retrospective study, carried out in a General Hospital. All patients treated with at least one dose of ertapenem were evaluated from January to June 2011. Information was obtained by reviewing clinical histories. The clinical justification for each case, antibiogram and duration of treatment were recorded. Afterwards, the costs of ertapenem treatment and the cheaper non-inferior alternatives were estimated according with the Antimicrobial Treatment Hospital Guidelines.
Results 90 patients were identified: 51 intra-abdominal infections, 9 diabetic foot infections, 9 prophylaxis of surgical site infections, 7 urinary tract infections, 6 cases of community-acquired pneumonia, 8 other infectious. 87 patients (96.66%) treated with Invanz could have been treated with other antimicrobials. 79 patients (90.80%) could have been treated directly with a non-inferior generic drug. Over six months, the money spent on ertapenem could have been reduced by 84.72%.
22,265€ were spent because of Invanz treatments. The alternative non-inferior generics would have cost 3,400.13€: 2,662.3€ piperacillin/tazobactam +215.73€ amoxicillin/clavulanic +309.12 imipenem +35.1€ cefoxitin + 177.88€ other minority cases according to the antibiogram.

37,730€ could be saved each year if a non-inferior generic were selected instead of ertapenem.
Conclusions Instead of using ertapenem, other non-inferior generic alternatives could obtain significant savings.

Competing interests None.

DGI004 THE MEDICAL RECORD AS AN INSTRUMENT FOR MONITORING OFF-LABEL USES AND DRUG RELATED PROBLEM: THE EXPERIENCE AT THE MONDOVI HOSPITAL

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Background The medical record is a document that accompanies the patient from his admission to the hospital. This document contains the objective examination, the patient's history, diagnostic activities practiced and therapy. Its compilation must be timely and must reflect the real situation. It is a valuable tool for testing and monitoring for use off label drugs in a hospital setting.
Purpose Since you use off label in a hospital is still virtually unknown. The hospital pharmacy, on the recommendation of the Health Department ASL CN1, began a sample monitoring of medical records of patients admitted to the hospital of Mondovi in the year 2010.
Materials and methods To quantify the problem of off-label prescriptions, which should be authorised by the Internal Pharmaceutical Care Commission, The authors have analysed medical records of the Internal Medicine, Hospital of Mondovi, who admits patients with multi-pathologies, often with complicated clinical situation and therefore represents a valid sample for an initial analysis.
Results During 2010 The authors have examined 50 medical records. This study showed that 36% of them have off label prescription drugs and the cases analysed are related to:
1. Pantoprazole vials administered for longer than 15 min with a consequent loss of efficacy (15%);
2. Antibiotics prescribed without an indication in antibiogram doing that can cause serious bacterial resistance (40%);
3. Levoxacin administered in a dose of three times a day (5%);
4. Tigecicline used at a dose of 100 mg for two days (5%);
5. Fosfomicine not used for therapy of cystitis but for therapy of infection in immunocompromised (8%);
6. Tramadol prescribed for chronic pain relief sublingual vials(10%);
7. Rasburicase vials administered for longer than 30 min with a consequent loss of effectiveness (9%);
8. Pantoprazole 40 mg tablets prescribed to prevent peptic ulcer discharge (8%).

The analysis also revealed possible interactions between drugs (ex pantoprazole and iron gluconate with a probable decrease in the bioavailability of iron) and some dosage error (proton pump inhibitor with a full stomach, statins in of award administration and outside evening time, Bisoprolol in the treatment of heart failure with high doses once instead of a gradual increase, prednisone induction treatment with lower doses of 20-30 mg with possible ineffectiveness of therapy).
Conclusions The study clarifies that off-label prescriptions are still widely used in hospital practice. In addition to the purely regulatory issue the fundamental problem is health of patients, in fact use a drug outside the indication in the data sheet does not ensure safety, quality and efficacy guaranteed by registration studies. The figure of the clinical pharmacist to the bed of the patient during the therapy setting is crucial, as the guarantor of the appropriateness prescriptive.

Competing interests None.

DGI005 ANALYSIS OF CARDIOVASCULAR EVENTS OR DIABETES MELLITUS DURING ANDROGEN DEPRIVATION THERAPY IN KOREAN PROSTATE CANCER PATIENTS

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Background ADT (Androgen Deprivation Therapy) is widely used as prostate cancer treatment which suppresses serum testosterone and inhibits the cancer cell growth. Since people with prostate cancer have relatively high 5-year survival rate, chronic diseases such as cardiovascular disease (CVD) and diabetes mellitus (DM) may impact their quality of life and overall survival more than those of patients with other cancer types. Recently, possible adverse effects of ADT have been issued which may be associated with an increased risk of CVD and DM.
Purpose The possible association between ADT and CVD or DM has not been fully studied in Korean men with prostate cancer, and the purpose of the current retrospective observation study is to investigate this association.
Materials and methods The study included 546 patients treated with ADT and 262 patients treated with radical retropubic prostatectomy (RRP) at the National Cancer Center in Korea from January 2001 through December 2008. Study subjects were those who have node-negative localised and advanced localised prostate cancer. After excluding patients with a history of radiation therapy, node-positivity, evidence of metastasis and pre-existing CVD and DM, 96 patients treated with ADT and 90 patients with RRP were remained for the analysis. The data on these patients, followed-up until December 2010, were retrospectively reviewed from electronic medical records (EMR). To test the difference in the incidences of CVD or DM between RPP and ADT groups, exact logistic regression analysis was performed due to the small number of incidences. Baseline variables including age, body mass index, family history of CDV or DM, history of smoking and T-stage were examined to check the imbalance between two groups. Variables that were significantly imbalanced between groups were considered in the multivariable logistic regression, and variable selection method based on exclusion criteria of p-value at 0.1 was performed to obtain the final model. All reported p-values are two-sided and the criterion for significance was p-value less than 0.05. All statistical analyses were performed using R statistical software, version 2.12.
Results Newly developed CVD or DM were found in 7 out of 96 patients in the ADT group, and 1 out of 90 patients in the RRP group. The incidence of CVD or DM was higher in ADT group than RRP group, but it failed to reach statistical significant at 0.05 with the observed p-value=0.066. Subgroup analysis based on different treatment drugs (LHRH agonists + antiandrogen (AA), or each alone) revealed that the incidence of CVD or DM was higher in the combination of LHRH agonists and AA group (odds ratio=2.05; 95% CI 1.01-4.12; p=0.043). However, it was not significant in LHRH agonists alone, and AA alone groups.
Conclusions In conclusion, our study found that there is a tendency of increased CVD or DM in Korean men with prostate

cancer treated with ADT compared to RRP, however, it failed to reach statistical significance. Considering the limitations of the retrospective observation study, including possible selection bias, further well-designed prospective studies are needed to thoroughly assess the impact of ADT on CVD or DM in patients with prostate cancer, and as recommended by Food and Drug Administration (FDA) and Korea Food and Drug Administration (KFDA), careful monitoring of prostate cancer patients treated with ADT who have pre-existing CVD or DM is required.

Competing interests None.

DGI006 EFFICACY AND SAFETY OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS

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Background A novel target for the treatment of rheumatoid arthritis (RA) is cytokine interleukin-6 (IL-6), a key pro-inflammatory cytokine in RA contributing to both the articular and systemic manifestations of the disease.
Purpose To describe the efficacy and safety of tocilizumab, an IL-6 receptor antibody, in RA.
Materials and methods Retrospective review of all patients treated with tocilizumab since its market launch between November 2009 and April 2011 in a regional hospital. Data collected from the management system software were: age, sex, treatment duration, previous treatments with biologicals, acute phase reactants (erythrocyte sedimentation rate (ESR), C-reactive protein (CRP)), laboratory findings and adverse events.
Results 12 patients (10 women, 2 men) were included. Mean age was 52 years (range 35 – 69). Mean treatment duration was 8 months (range 2-18). 10 patients had previously been treated with biotherapy (4 adalimumab, 2 etanercept, 1 adalimumab and abatacept, and 3 patients with 3 biologicals). Evolution of median acute phase reactants as efficacy end points was:
ESR: 62.5% reduction (from 32 mm/h at the beginning of treatment to 12 mm/h at the end of the study). CRP: 86% reduction (from 12.6 mg/L to 1.8 mg/L). Hepatic transaminases, lipid parameters and neutrophils were normal. 4 of 12 patients discontinued tocilizumab treatment (1 for lack of efficacy, 2 for adverse events and 1 for another reason). Adverse events were facial hyperaemia and dysaesthesias in arm and fingers.
Conclusions In this study tocilizumab showed a positive benefit-risk ratio in RA.
Major limitations were low number of patients and lack of long term safety data.

Competing interests None.

DGI007 FREQUENT INTERACTIONS BETWEEN CHEMOTHERAPY AND COMMUNITY-DISPENSED DRUGS IN A CONTINUOUS SCREENING PROGRAMME

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Background A previous retrospective study into drug-drug interactions between anticancer agents administered in our hospital and drugs dispensed in community pharmacy identified a prevalence of clinically relevant interactions of 18%. Based on these findings The authors developed a continuous screening programme for all chemotherapy patients.
Purpose To identify drug-drug interactions between cytotoxic agents and community pharmacy-dispensed medicines prior to the start of chemotherapy, and to develop clinical rules for their management.
Materials and methods Prior to chemotherapy, a medicines review was performed on the current medicines list from the community pharmacy. Both ambulatory and inpatient oncology patients were included from June 2010 until September 2011. 365 patients were screened in total 412 times.
Results 80 potentially relevant interactions were observed in 57 patients (16%). The most frequent interactions, their possible clinical effects and proposed management were: A) coumarin with cytostatics (n=17), resulting in possibly increased anticoagulation. Clinical management involves additional INR (international normalised ratio) checks. B) protease inhibitors with anthracyclines and Vinca alkaloids (n=13) resulting in possibly increased toxicity. Management consists of prophylactic GCSF (granulocyte colony-stimulating factor) and monitoring for neuropathy. C) ciprofloxacin with anthracyclines, podophyllotoxins and oxazaphosphorines (n=8), leading to reduced exposure to fluoroquinolones. In the case of prophylactic treatment, no action is needed, whereas in therapeutic use, switching to another antibiotic should be considered. Overall, 24 interactions involved CYP-inducing or inhibiting co-treatment. In 11 of these, a switch to a non-CYP-affecting drug was feasible. In 3 cases, antiepileptics or antidepressants were involved, requiring additional monitoring of serum levels. These results warrant timely interaction screening, preferably days before the start of chemotherapy.
Conclusions The high prevalence of potential drug-drug interactions between anticancer agents and community-dispensed drugs makes clear the need for optimal medicines surveillance and data exchange between the hospital and the community.

Competing interests None.

DGI008 ASSESSMENT OF ANTIDOTE STOCKS IN HOSPITALS OF THE ITALIAN REGION EMILIA ROMAGNA

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Background The Department of Pharmacy of the University Hospital of Ferrara (AOUFE) has been appointed Regional Centre of Reference for the supply of some antidotes by the Region Emilia Romagna (RER). In order to assess their availability, a qualitative-quantitative assessment of antidotes available in regional hospitals was carried out.
Purpose The authors looked particularly at antidotes supposed to be used within 30 min, (type A antidotes) which should be available in all hospitals.
Materials and methods All 17 regional hospitals were asked for information about the kind and the quantity of antidotes stocked. The number of potential poisoning victims treatable with the quantity in stock was calculated based on the maximum dosage.
Results All 17 regional hospitals provided the required information with the following results. Of the 27 type A antidotes The authors investigated, the stock for the maximum treatment of one patient was the following: 2 antidotes (activated charcoal, ipecacuanha) were available in 16 hospitals; 4 antidotes (atropine sulphate, calcium gluconate, physiostigmine and protamine

sulphate) were available in 15 hospitals, and methylene blue was available in 14 hospitals. Eleven type A antidotes (pyridoxine, hydroxocobalamin, sodium bicarbonate, dantrolene, calcium folinate, polyethylene glycol 4000, $MgSo_4$, diazepam, Fuller's earth, digoxin-specific antibodies, polyethylene glycol 4000, fomepizole) were available in fewer than 10 hospitals. Glucagon was not present in any hospital to treat a patient.

Conclusions Quantities of some antidotes available in regional hospitals were not sufficient to treat a single patient. This was the case for fomepizole, digoxin-specific antibodies and Fuller's earth among type A antidotes, and for Prussian blue, dimercaprol and pralidoxime among type B antidotes. Therefore, the need to provide many regional hospitals with higher stocks of antidotes is recognised.

Competing interests None.

DGI009 EFFICACY AND SAFETY STUDY OF CETUXIMAB ASSOCIATED RADIATION THERAPY IN ADVANCED CARCINOME OF THE HEAD-NECK

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Background The current approach to advanced head and neck squamous cell carcinoma (AHNSCC) is based on the combination of radiotherapy (RT) and chemotherapy. Recent introduction of monoclonal antibody cetuximab as a radiosensitiser agent has made a significant advance in the treatment of this pathology.

Purpose To evaluate the efficacy and safety of cetuximab in combination with RT in the treatment of AHNSCC and compare our results with those reported in the pivotal trial.

Materials and methods Observational, descriptive and retrospective study. It was followed in patients with AHNSCC who started treatment with cetuximab from 2007 to 2010 in our centre.

Results The authors reviewed 36 patients, 27 men (75%) and 9 women (25%), with an average age at baseline of 66 years (range 35-85). The most common tumour localisations were: 12 oral cavity (33.3%), 9 tongue (25%) and 7 larynx (19.4%). Of all patients, 20 (55.5%) underwent surgery prior to treatment. Patients received a median of 5 administrations (range 1-10) for 38 days (range 1-77). In 25 patients (69.4%) the tumour was stable and in 11 (30.6%) it progressed with a median TTP of 5.1 months. Respect to the toxicity associated with cetuximab-RT, 25 patients (69%) developed some adverse events. Skin toxicity was the most frequent with 16 patients affected (44%), followed by 14 patients with mucositis (39%). 7 (19%) patients The authors had to discontinue treatment and 3 (8%) required hospitalisation.

Conclusions The results obtained are similar to those of the pivotal trial. In our case The authors got worse results in TTP. This may be because the ideal conditions of clinical trials differ from clinical practice. Likewise, the median cycles which received cetuximab in the pivotal trial were over, which could also influence the therapeutic efficacy. The percentage of patients with side effects is high, but it was only necessary to discontinue treatment in a small number of them.

Competing interests None.

DGI010 HEALTH ECONOMICS ANALYSIS OF PEGFILGRASTIM IN THE PROPHYLAXIS OF FEBRILE NEUTROPENIA (FN) IN ITALY

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Background FN is a serious side-effect of myelotoxic chemotherapy. G-CSF prophylaxis decreases FN incidence and reduces related morbidity and mortality.

Purpose Evaluate the budgetary impact of primary (PP) and secondary prophylaxis (SP) of pegfilgrastim for the Italian NHS in two scenarios: first when increasing pegfilgrastim use in PP and SP from the 2011 patient share to the estimated 2013 share; and second when shifting all usage to only PP pegfilgrastim.

Materials and methods A decision-analytic model calculated the budget impact. Costs considered were: direct G-CSF healthcare costs, G-CSFs administration costs and costs of FN-related events. G-CSF costs were calculated by using the maximum selling price to hospitals. Filgrastim biosimilar lower costs and filgrastim branded cost were considered together by using a weighted average cost based on market shares. Prophylaxis strategies included in the first scenario were filgrastim, pegfilgrastim, lenograstim and antibiotics; estimated pegfilgrastim PP use increased from 12.8% (2011) to 15.7% (2013) and SP use increased from 8.5% (2011) to 10.5% (2013). Chemotherapy regimens included CHOP(R) for non-Hodgkin's lymphoma (NHL); and AC-T, TAC and TC for breast cancer. Annual incidence of NHL and breast cancer (stage II and III) was estimated by applying incidence rates from the German Krebregister to the Italian population.

Results A negative budget impact value represents a cost reduction. Regarding NHL (N=10,800), the budget impact for the first scenario was €-261 K for CHOP and €-255 K for CHOP-R. The budget impact for the second scenario was €-2,76 mio for CHOP and €-2,55 mio for CHOP-R. For stage II breast cancer (N=14,970) the budget impact for the first scenario was €-370 K for AC-T, €-236 K for TAC and €-234 K for TC, while the budget impact for the second scenario was €-1,82 mio, €-396 K and €-2,33 mio, respectively. Stage III breast cancer (N=1,950) followed the same trend as stage II.

Conclusions In our budget impact model, a prophylaxis strategy including pegfilgrastim as PP or SP reduced costs for the Italian NHS in breast cancer and NHL.

Competing interests Ownership: Amgen Dompè SpA, Italia

DGI011 VALUE OF HOSPITAL PHARMACISTS SERVICE IN THE OPTIMISATION OF CAPECITABINE USE

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Background On November 12, 2009, the Valencian Health Agency ordered that certain drugs formerly available from pharmacies would from now on only be available from hospital pharmacies.

Purpose The aim of this study was to evaluate the economic impact derived from the change of dispensation of capecitabine (Xeloda ©) from the pharmacies to the hospital Pharmacies.

Materials and methods The authors analysed data of the dispensations of capecitabine made in pharmacies during 2009 and compared them with those obtained from our hospital electronic prescription program during 2010. There was no variation in the number of oncologists prescribing during both periods. Since the publication of the law, all oral

cytostatic prescriptions were validated by hospital pharmacists using the same criteria as used for intravenous drugs, and the exact number of tablets needed for each cycle was dispensed.

Results During 2009, 42 patients were treated with capecitabine dispensed by pharmacies for an amount of 276,845 euros with an average annual cost of 6,752 euros per patient. During 2010, 72 patients were treated with capecitabine dispensed by the Hospital Pharmacy Service, each visit they were only given the exact number of tablets until the next cycle, for an amount of 105,215 euros with an average annual cost of 1,461 euros per patient.

Conclusions Adjusting the dose prescribed according to the patient's weight and optimising the number of tablets dispensed has decreased from 486,164 theorist euros in 2010 (6,752 euros / patient per 72 patients) to 105,215 euros, meaning a final annual saving of 380,929 euros (a whole decrease of 78.3%). The hospital pharmacist plays an important role in validating the clinical use of drugs and evaluating the economical impact of new therapies.

Competing interests None.

DGI012 BE CAREFUL OF SODIUM INTAKE IN SOME DRUGS! EXAMPLE OF EFFERVESCENT PARACETAMOL FOR HYPERTENSIVE OR HEART FAILURE PATIENTS

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Background The World Health Organisation's(WHO) recommendations for hypertension or heart failure is to reduce sodium intake to less than 2g (which equals 5g of salt). A link between raised blood pressure and sodium excipient content of soluble or effervescent analgesic has been previously reported[1]. Paracetamol 500 mg effervescent is the drug referenced in our hospital that contains more sodium (412.4 mg). It was prescribed to only a few patients, according to their preference or to nasogastric tube carriers.

Purpose The aim of our study was to evaluate the use of effervescent paracetamol by patients suffering of hypertension and heart failure and find solutions to decrease it. **Materials and Methods** The authors made a retrospective study over a period of one year by selecting all the patients in our hospital with a prescription of effervescent paracetamol, with Pharma ® 's software (computer Engineering).

Results A total of 42 patients took effervescent paracetamol. The dosage most prescribed was 3g per day, the equivalent of 6 tablets of 500 mg each. This corresponds to an amount of 6.3 g of salt, more than the maximum recommended by the WHO and regardless of the recommended daily amount of food and other drugs. This amount increases to 8.4 g for a dose of 4g per day! 19 patients (45%) were also taking an antihypertensive or medicine against heart failure. The solutions implemented in our hospital were to provide information in multidisciplinary meetings, displaying the amount of sodium in data sheet on the software to alert doctors at the time of prescription and writing pharmaceutical notifications when prescribing effervescent paracetamol for an hypertensive or heart failure patient. Finally, a lyophilisate tablet of paracetamol (negligible sodium level) was referenced.

Conclusions This study was used to realise some effects of the prescription of effervescent paracetamol for hypertensive or heart failure patients. Four measures to reduce this consumption have been set up and a future audit will estimate their possible impact.

Competing interests None.

DGI013 DO HIV/HCV CO-INFECTED PATIENTS NEED HAEMATOPOIETIC GROWTH FACTORS EARLIER THAN NON-CO-INFECTED DURING HCV TREATMENT?

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Background Hepatitis C treatment (HCVt) with peg-interferon and ribavirin is limited by haematological side-effects. Haematopoietic growth factors (HGF) allow to maintain standard antiviral doses in order to achieve sustained virological response in hepatitis C (HCV) infected patients.

Purpose To evaluate if HIV/HCV co-infected patients need HGF earlier than non-coinfected during HCVt. Clinical and haematological characteristics of HCV-infected-patients receiving HGF were compared between HIV+ vs HIV-.

Materials and methods Retrospective study in a third level hospital including all patients on HCVt that needed HGF between January 2008 and February 2011. Data: HIV-co-infection, age, gender, HCV-genotype, HCVt, haematological parameters, HGF. Statistical analyses: χ^2 and Fischer exact test for dichotomic variables and t-student and 'U' Mann-Whitney tests for continuous variables.

Results 132 patients. 33(25%) HIV+. Characteristics HIV± versus HIV-:

- Age: 50.3± 7.6 versus 52± 11.1 p=0.412
- Male: 26(78.8%) versus 58(58.6%) p=0.039
- Genotype(G): G1: 17(51.5%) versus 66(66.7%), G2: 2(6.1%) versus 2(2%), G3: 10(30.3%) versus 18(18.2%), G4: 4(12.1%) versus 10(10.1%), non-typeable: 0(0%) versus 3(3%).
- All patients received ribavirin. All HIV+ received peg-interferon α2a. HIV- received 88(88.9%) peg-interferon α2a and 11(11.1%) peg-interferon α2b.

Patients on HGF (HIV± vs HIV-). Erythropoietin: 26(78.8%) versus 78(78.8%). Filgrastim: 15(45.5%) versus 33(33.3%). Both: 8(24.2%) versus 12(12.1%). Days until erythropoietin initiation 76(32-124) versus 103(57-192) (p= 0.15). Days until filgrastim initiation 92(58-124) versus 97(48-224) (p= 0.72)

Conclusions HIV/HCV co-infected patients did not initiate HGF earlier than non-co-infected, although a tendency to a shorter period of time until starting erythropoietin was observed. A greater percentage of HIV+ seemed to need the use of both, erythropoietin and filgrastim, although it was not significant. Haematological parameters at the beginning of HCVt and HGF were similar in both groups.

Competing interests None.

DGI013 Table 1 Haematological parameters

	HCVt* initiation		HGF* initiation		
	HIV+	HIV-	HIV+	HIV-	
Haemoglobin (g/dL)	14.6± 1.60	14.4± 1.56	9.2± 1.31	9.8± 1.07	Erythropoietin
Leucocyte count (cel/mcL)	4,566± 1,417	4,581± 1,356	1,694± 480	1,718± 371	Filgrastim
Neutrophil count (cel/mcL)	2,333± 992	2,530± 956	663± 159	661± 207	

*P=NS

DGI014 PANITUMUMAB FOLLOWING CETUXIMAB: A RETROSPECTIVE POSITION

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Background There are two highly selective antibodies to the epidermal growth factor receptor (EGFR): cetuximab (Ig G1 chimeric molecule) and more recently panitumumab (fully humanised IgG2 molecule). Not much information is available about the sequential use of these EGFRs.
Purpose To analyse chemotherapy treatment with EGFR in those patients treated with panitumumab following cetuximab and to describe the reason for that change.
Materials and methods Retrospective study including patients treated with panitumumab following cetuximab during 2009 and 2010. Information was obtained using an Oncofarm database. The authors reviewed clinical histories and collected age, sex, diagnosis, line treatment settings, before chemotherapy was administered, mono or combination treatment, number of cycles administered, wild type KRAS, adverse drug events and reason for change from cetuximab to panitumumab.
Results Data from 12 patients were studied (mean age 65 years, 83% men). 75% patients had metastatic colorectal cancer (mCRC) and 25% head and neck cancer (in these patients treatment with panitumumab is an off-label indication). In 25% of patients, panitumumab was administered in combination (17% taxol, 8% taxol-carboplatin, 8% FOLFOX, 8% FOLFIRI). Panitumumab was administered as 4th line treatment. Reasons for change were: 25% cutaneous toxicity, 16% progression, 16% toxicity and progression, 8% convenience for patients (cetuximab weekly vs panitumumab every fifteen days) 8% suffered hypersensitivity reactions. All patients had wild-type KRAS and treatment with panitumumab was stopped after an average of 6 cycles because of cancer progression.
Conclusions There are not too many patients to whom panitumumab was administered following cetuximab. This sequential treatment was related to progression of the illness and toxicity. There is no evidence to assess whether panitumumab following cetuximab could avoid cancer progression. However, more studies are needed.

Competing interests None.

DGI015 SURVEILLANCE OF SURGICAL SITE INFECTION

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Background Nosocomial infections are one of the most relevant cause of morbidity and mortality; also, they markedly contribute to increment the cost of healthcare. The most frequent are the infections following surgery or invasive medical procedures for example cross-contamination. Monitoring and prevention of the sources that are involved in the development of the nosocomial infection is performed at the Antonio Cardarelli Hospital of Naples which provides the corresponding corrections.
Purpose Aim of the project Surveillance of surgical site infection is the promotion of the prophylaxis guidelines and the control of the Healthcare-Associated Infections.
Materials and methods Within this project the role of the Pharmacy is to enable the targeting of the patients using specific antibiotic-based therapies. The project foresees the recording and the screening of the clinical folders of all the patients which underwent to surgery between the year 2010/2011 in Operative Units of Cancer surgery, Gastroenterology surgery, Gynaecology, Emergency Neurosurgery and Orthopaedics and Knee Surgery. All the antibiotic therapies followed by the patients either for the prophylaxis or for the treatment of possible postsurgical infections, are registered in specific schedules. Subsequently, the collected data, especially the one related to the prophylaxis, are compared with the standard corporate protocols and inserted in the regional documents.
Results The choice of the antibiotic prophylaxis is mostly not comparable with the corporate protocols, usually because antibiotics used for the treatment of serious infections are favoured to the detriment of the one applied for surgical prophylaxis. Moreover, the administration times should be reviewed because often they are longer than those provided by the guidelines.
Conclusions Once the critical issues have been emphasised and the specific corrections applied, a reduction in infections should be achieved, resulting in benefits not only in term of therapies optimisation but also in the reduction of the healthcare costs.

Competing interests None.

DGI016 CALCIUM GLUCONATE AND MAGNESIUM SULPHATE IN THE PREVENTION OF SENSORY NEUROTOXICITY ASSOCIATED WITH THE USE OF OXALIPLATIN

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Background The use of calcium and magnesium reduces both the incidence and time of development of peripheral sensory neurotoxicity, oxaliplatin-limiting toxicity.
Purpose To determine the effectiveness of calcium gluconate and magnesium sulphate in preventing sensory neurotoxicity associated with the use of oxaliplatin.
Materials and methods Retrospective observational study of patients diagnosed with colorectal cancer treated with oxaliplatin + 5-fluorouracil (5-FU) and calcium folinate or capecitabine plus oxaliplatin for the years 2009-2010, with oxaliplatin treatments of 85 mg/m2 every 14 days or 130 mg/m2 every 21 days, respectively. All received 1 gram of calcium gluconate and 1.5 grams of magnesium sulphate of 15% diluted in 250 ml glucose 5% before and after oxaliplatin administration. In all cases, the oxaliplatin infusion time was 2 h. Symptoms of chronic or cumulative sensory neurotoxicity (SNT), graduated according to the scale of the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE v3). The primary end point was the percentage of patients with grade 2 or higher SNT at any time during or after oxaliplatin-based therapy.
Results The authors included 48 patients. The mean age was 63.62 years (50% men and 50% women). The primary tumour was colon in 70.8% of cases (33.3% adjuvant and 37.5% metastatic) and rectum in 29.1% (16.7% adjuvant and 12.5% metastatic). A total of 33 patients received oxaliplatin regimens of 85 mg/m2 every 14 days, while 15 patients received oxaliplatin regimens of 130 mg/m2 every 21 days. 12.5% patients (6/26) presented SNT=2 (none grade > 2), with a mean cumulative dose (±SD) of 878.33±205.88 (mg/m2) and an average of 10.33±2.42 cycles received. In 83.3% (5/6) of cases was necessary to reduce the dose of oxaliplatin administered.

Conclusions The low incidence of SNT=2 or higher (6 patients and none, respectively) of our study support the neuroprotective activity of the Ca/Mg.

Competing interests None.

DGI017 COST ANALYSIS OF HIV TREATMENT AND DRUG-RELATED ADVERSE EVENTS WHEN FIXED-DOSE COMBINATIONS OF ANTIRETROVIRALS (FDCAS) WERE STOPPED, VERSUS CONTINUATION WITH FDCAS

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Background The launch of a generic form of lamivudine (g3TC), included in several fixed-dose combinations of antiretrovirals (FDCAs), led to considering switching stable patients from lamivudine and emtricitabine-containing FDCAs to separate components including the less expensive g3TC. The Balearic Islands Public Autonomic Health Service ordered, in July 2010, that FDCAs be administered as separate components. In August 2010 they allowed FDCAs to be resumed.
Purpose To assess the cost differences of antiretroviral treatment and adverse drug events management between patients whose FDCAs were discontinued compared to those who maintained their FDCA treatment.
Materials and methods An independent retrospective cost analysis was performed at Son Llatzer Hospital. A total of 75 patients underwent the substitution of their FDCAs to single agents. The authors chose 150 patients matched by gender and type of FDCAs who did not stop taking their FDCAs. For both groups of patients, resource use related to adverse drug events management and drugs administered were collected. The study period assumed for cost calculations was the mean days that patients stayed with the replacement for FDCAs (120 days). An alternative analysis was performed considering the extra appointments (medical visits and analytical procedures) required to monitor those patients whose FDCAs were switched to separate components. Unit costs (€, 2011) were obtained from a Spanish database.
Results Considering the cost of managing antiretroviral treatments and drug-related adverse events, the administration of the components separately increased the total cost by €0.75 per patient per day compared with the FDCA strategy. When the cost of any extra appointments was considered, the total cost increased by €3.6 per patient per day during the study period.
Conclusions Unfortunately stopping FDCAs led to an increase in healthcare expenditure, not the hoped-for decrease.

Competing interests None.

DGI018 STABILITY OF BORTEZOMIB 1 MG/ML SOLUTION IN POLYPROPYLENE SYRINGES-APPLICATION TO THE DAILY PRACTICE OF A CENTRALISED UNIT

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Background Bortezomib is used in the treatment of myeloma. The manufacturer gives a 8 h stability in syringes and André et al (Ann Pharmacother 2005; 39: 1462-1466) gives a 5 days at 5°C.
Purpose The objective was to evaluate the stability of a 1 mg/ml solution stored over 35 days in polypropylene syringes in order to prepare in advance standardised doses without any risk of losing the syringes if the administration is cancelled.
Materials and methods Four syringes were prepared after reconstitution of 3.5 mg of bortezomib with 3.5 mL 0.9% sodium chloride. Two were stored under refrigeration (2-8°C) and two at room temperature. Criteria of stability were defined as retention of at least 95% of the initial drug concentration and as percentage of degradation products below 1%. After a visual inspection, samples of each syringe were analysed after preparation and on days 2, 4, 7, 14, 21, 28, 35 with a stability-indicating high-performance liquid chromatography validated method according to ICH guidelines
Results No physical changes were observed during the study period. Under refrigeration, solution retained over 95% of the initial bortezomib concentration until day 35. Three degradation products appeared, corresponding to 0.4% of total peaks areas. At room temperature, the bortezomib concentration stayed over 95% until day 28, and six products of degradation reached 3% at day 35. Solutions of bortezomib 1 mg/ml in 0.9% sodium chloride were stable for 35 days at 2-8°C and for 14 days at room temperature.
Conclusions Stability for 35 days at refrigerated storage (2-8°C) enables a new organisation of the Centralised Unit in our pharmacy and allows the preparation of syringes in advance, in standardised doses without any risk of losing money, because of the possible conservation and reallocation of a syringe which injection would be cancelled. The immediate availability reduces considerably the waiting time of the patient in the wards.

Competing interests None.

DGI019 DETECTION OF DRUG INTERACTIONS BETWEEN PROTEASE INHIBITORS AND PRESCRIBED TREATMENT IN PRIMARY CARE

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Background Drug interactions between protease inhibitors and treatment prescribed in primary care may compromise the efficacy of antiretroviral treatment or cause serious adverse reactions.
Purpose To identify potential interactions that may occur in patients treated with protease inhibitors (PIs) and other prescription drugs from Primary Care (PC).
Materials and methods All patients treated with PIs in the hospital pharmacy department were included. Each patient was checked to see if they were taking regular medicines that interact with PIs. Data were obtained by auditing the PC Digital Health Record. Based on the available literature, 3 types of interactions were established: drug combination contraindicated or not recommended (type A), potential interaction that may require close monitoring or changing dose (type B) and no clinically significant interactions (type C).
Results At the time of the study, 285 patients were treated with PIs. 89% showed no clinically relevant interactions with drugs prescribed from PC. Type A interactions were detected in 17 patients (6%), and type B in 13 patients (5%). The interaction most often observed was the combination of atazanavir

and proton pump inhibitors in 8 patients (type A interaction that can cause reduction in plasma levels of atazanavir over 70%). Another type A interaction observed was salmeterol/fluticasone with various PIs in 3 patients (FDA has contraindicated this combination because of risk of QT prolongation).
Conclusions There were some disagreements between the hospital and PC treatment, several interactions found may compromise the efficacy of antiretroviral treatment or cause serious adverse reactions. In an effort to improve the situation, The authors are going to consult the specialists in the most serious cases and promote communication between PC and Hospital regarding HIV patients.

Competing interests None.

DGI020 EFFICACY OF INTRAVENOUS IRON III SUCROSE IN DECREASING THE NUMBER OF TRANSFUSIONS IN PATIENTS WITH COLORECTAL CARCINOMA NOT DEMONSTRATED

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Background Improving the haemoglobin levels preoperatively leads to a reduction in transfusions required. Intravenous iron III sucrose (IVI), with a good safety profile, represents a new therapeutic option for the treatment of anaemia.
Purpose To determine whether IVI administration in postoperative colorectal cancer (CRC) decreases the number of transfusions required.
Materials and methods Retrospective case-control study in patients undergoing CRC surgery in the years 2008, 2009 and 2010, matched by age (±3 years), sex, type of surgery, tumour stage and surgical approach.
Variables recorded: sex, age, tumour location, tumour stage, type of surgery, surgical approach, haemoglobin prior to surgery (Hbs) and at discharge (Hbd), number of transfusions after surgery (Ts) and doses of IVI received. Statistical analysis: Pearson's χ^2 test or Fisher's exact test and Student's t or Mann-Whitney test using SPSS 15.0. software.
Results The number of patients was 342, of which 104 were paired into 2 groups of 52 patients (G1-IVI treated and G2-IVI untreated), 33 men and 19 women per group, with a mean age of 70.9±11.1 and 70.6±10.9 years, respectively. Tumour location in both groups: rectum (25/22), left colon (15/17), and right colon (12/13). Tumour stage in both groups: III in 36.5%, 0 in 26.9%, IV in 13.5%, I in 11.5% and II in 11.5%. Type of surgical procedure in both groups: anterior resection of rectum in 36.4%, left and right colectomy in 28.8% and 21.2%, respectively. Surgical approach: 92.3% by laparotomy and 7.7% by laparoscopy. Hbs was 12.3±1.6 g/dl (G1) and 12.8±1.9 µg/dl (G2)(p=0.133), and Hbd was 10±1.1 g/dl (G1) and 10.6±1.2 µg/dl (G2)(p=0.012). Ts was 3±1.6 (G1) and 3.3±3 (G2)(p=0.682). 28.8% and 30.8% in groups 1 and 2, respectively, were transfused (p=0.830). The mean dose of IVI was 592±445 mg.
Conclusions Administration of IVI does not appear to decrease transfusion requirements, possibly because bone marrow physiologically requires a period longer than the hospital stay to increase haemoglobin levels. Additional studies are needed to show more clearly the value of IVI.

Competing interests None.

DGI021 EFFECT OF PARENTERAL GLUTAMINE SUPPLEMENT ON BLOOD ALBUMIN LEVELS

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Background Glutamine is an amino acid with several functions. It acts as a precursor of protein synthesis, regulates the transport of nitrogen between organs and tissues, and is involved in active cell replication. Several studies have found a significant increase in albumin levels in patients receiving parenteral nutrition supplemented with glutamine.
Purpose The aim of this study is to compare differences in blood albumin levels between patients receiving glutamine-supplemented parenteral nutrition and patients receiving non-supplemented parenteral nutrition.
Materials and methods Observational study performed from 01/01/2010 to 31/12/2010. Study population: Surgical patients who started parenteral nutrition during the study period and whose blood albumin level had been assessed. Patients were divided into two groups: 1. Glutamine group: patients receiving parenteral nutrition supplemented with glutamine for 7 days. 2. Control group: patients receiving parenteral nutrition without glutamine supplement. The authors recorded blood albumin levels at the start of parenteral nutrition and after 7 days. The authors calculated the variation in albumin levels in both groups and applied the *t* test to identify significant differences between groups. Data were collected from the software used to prepare parenteral nutrition (Multicomp ®) and from the application used to record clinical laboratory data (IntraLAB ®). The statistical analysis was performed using SPSS ® version 15.
Results The study group comprised 30 patients and the control group 30 patients. The mean increase in albumin level was 0.457 g/dl in the glutamine group and 0.180 g/dl in the control group (p=0.003).
Conclusions The authors found statistically significant variations in albumin levels in favour of the group receiving glutamine-supplemented nutrition. Further controlled studies are needed to confirm this finding.

Competing interests None.

DGI022 TOLVAPTAN: ØHOW IS IT USED?

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Background Tolvaptan is an orally active vasopressin V2-receptor antagonist used to treat hyponatremia associated with congestive failure, cirrhosis, and the syndrome of inappropriate antidiuretic hormone (SIADH). Hyponatremia (< 135 mmol/l) is a predictor of death among patients with chronic heart failure and cirrhosis. Current therapy for acute and chronic hyponatremia is often ineffective and poor tolerated.
Purpose Our aim is to analyse the use of the drug, benefit and adverse effects, checking if the prescription complies with the guidelines and accuracy of the dosage.
Materials and methods The study was conducted between March-August 2.011. Patients with a tolvaptan prescription

were reviewed: analysis, diagnose and admission's reason, treatment duration, evolution and possible side-effects.
Results 14 patients (57% male) received tolvaptan in the study period. Average age was 69.28 (55-88) years. Location of patients among the clinical units was, 28% Cardiology department, 21.4% Geriatric department, 14.3% Hepathology and other units (Internal Medicine, Oncology and Critical Care Unit). Main diagnoses were 28.6% hyponatremia, 28.5% heart failure. Treatment duration was 13.6 (3-51) days and starting dose was 15 mg/24 h, only in 2 patients dose was increased to 30 mg. Another patient began with 30 mg/24 h and dose was increased to 60 mg/24h. Average pretreatment parameters: serum sodium concentration SSC: 125.1 (113-129) mg/dl, creatinine: 1.41 mg/dl (0.41-3.07), glucose: 125.14 mg/dl (113-139) and potassium 4.55 mg/dl (3.2-5.6). Average post-treatment parameters: SSC: 135.3 (129-143), creatinine: 1.36 mg/dl (0.54-3.20), glucose: 135.3 mg/dl (129-143) and potassium 4.21 mg/dl (3.2-5.2). No adverse events due to treatment were registered. Exitus: a critical patient, a terminal cancer patient and 2 85-year-old patients. Mean cost of the treatment: 1.214 €/patient (260-4431) €.
Conclusions Tolvaptan is used in our patients to treat hyponatremia (not secondary to SIADH) and optimises sodium serum levels. The treatment diminished successfully the admission time and improved the clinical situation without adverse events.

Competing interests None.

DGI023 STUDY OF RITUXIMAB COST AND ITS OFF-LABEL-USE

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Background Rituximab is used in Non-Hodgkin Lymphoma (NHL), Chronic Lymphocytic Leukaemia (CLL) and Rheumatoid Arthritis (RA). Moreover, it has other uses which are not included in Technical Data Sheet (TDS).
Purpose To analyse the off-label-use of Rituximab and estimate the global cost of Rituximab treatment.
Materials and methods Retrospective and descriptive study, in which all patients who received Rituximab between January and June, 2011, are included. The list of patients, dose and number of cycles administered were extracted from the *Oncogest*® program. From the electronic medical record (*Selene*® Siemens 5.1.0.1) the following were obtained: sex, age, diagnosis and prescribing services. The total cost was estimated by summing the sale price corresponding to the total dose for each patient.
Results Number of patients: 79; Male: 54.4%; Female: 45.6%; Average age: 61.3 years (range: 16-87). In 67 patients (84.8%) the diagnosis were described in TDS: NHL 46 (52.8%), CLL 19 (24.1%) and RA 2 (2.5%). In 12 patients (15.2%) the indication was not included in TDS, among these the most frequent use was Idiopathic Thrombocytopenic Purpura (ITP) (4 patients). The departments which most frequently prescribed Rituximab were: Haematology (78.5%) and Oncology (11.4%). The average dose per chemotherapy cycle was 697 mg and the average number of cycles per patient was 3.1. The total cost of Rituximab was €408 370 and the average cost per patient was €5 169. The cost of approved treatments responded for 84% of the total cost (€342 889).
Conclusions Rituximab was mostly used in label conditions, mainly in NHL treatment. Label use was associated with the highest cost of Rituximab. Moreover, the average cost per patient with CLL proved to be higher than all other approved uses, because the total doses administered, as well as the number of cycles, were higher. The most common diagnosis off-label-use was ITP.

DGI023 table 1

DIAGNOSIS	AVERAGE COST PER PATIENT (euro, €)
CLL	7 476
NHL	4 157
AR	4 800

Competing interests None.

DGI024 USE AND EFFECTIVENESS OF PALIVIZUMAB ON PREVENTING BRONCHIOLITIS DUE TO THE RESPIRATORY SYNCYTIAL VIRUS

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Background In healthy infants, bronchiolitis is usually a self-limited disease. But children with some risk factor have greater frequency and severity of bronchiolitis.
Purpose To describe the use and effectiveness of palivizumab on preventing bronchiolitis due to respiratory syncytial virus (RVS) from October 2004 to April 2010.
Materials and methods Our hospital follows the Paediatric Spanish Society guidelines to determine whether the palivizumab prophylaxis is indicated. In addition, our hospital makes a campaign to fight respiratory infections with the families of all infants. The data were taken from AS-400 software program (single dose and drug management) and Global Clinic (medical reports).
Results 170 patients were treated with palivizumab during the period. 6 of them needed hospitalisation because of bronchiolitis. In 3 of these the infection was due to RVS: 2 patients with haemodynamical unstable congenital heart disease under 24 months, and 1 premature less than 29 weeks of gestation and under 12 months old at the start of RSV bronchiolitis season risk. 367 children, who did not perform our criteria for the administration of palivizumab, were born before 35 weeks of gestation. 19 of these were hospitalised because of bronchiolitis, 7 of them due to RVS. In hospitalisation cases due to bronchiolitis by RVS the length of hospitalisation was 3, 8 and 9 days, with an age of 10, 5 and 20 months, respectively. Children who didn't receive palivizumab were hospitalised 3, 6, 6, 7, 8, 8 and 14 days (median 7), with 22, 6, 10, 2, 2, 2 and 1,5 months old (median 2), respectively. No case needed the hospitalisation in paediatric Intensive Care Unite (ICU). The average annual cost of palivizumab treatment was 115,087.71¤.
Conclusions If the prophylaxis with palivizumab was made in the subgroup of patients who are considered highly recommended to receive prophylaxis against RSV, it could be used with criteria of greater efficiency, more suitable with available data of clinical efficacy and pharmacoeconomic studies

Competing interests None.

DGI025 ADHERENCE, APPROPRIATENESS AND EFFECTIVENESS OF HAART IN HIV PATIENTS TREATED AT THE 'AMEDEO DI SAVOIA' HOSPITAL

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Background 'Amedeo di Savoia' Hospital is the regional centre in Piedmont for HIV infection diagnosis and treatment. A multidisciplinary team, Infectiologists, Pharmacists, Nurses, and Psychologists are working to optimise the clinical and therapeutic path of HIV-positive patients, to increase the efficacy and tolerability of HAART and to reduce its costs.
Purpose To focus on a process to measure the adherence to, and appropriateness of, HAART treatment in order to identify ways to increase the efficacy of the treatment.
Materials and methods The analysis was performed with 2094 HIV-positive patients (110 of whom were treatment-naive), whose HAART treatment was dispensed every 2 months, over a period of 22 months (1/11/2009-31/08/2011). The authors assessed each switch in treatment in terms of reasons and cost variations. Appropriateness was assessed by comparing prescriptions with registered indications. Adherence was calculated by measuring the 'pharmacy refill' as: days' supplies between refill dates/(duration of interval + 60 days) x 100.
Results Antiretroviral treatment switches were made in 322 patients because of adverse drug reactions, treatment failure or simplification:

- In 45% of cases treatment switch led to a saving (25% of switches saving more than 20%)
- In 55% the cost of treatment increased (of which 33% by more than 20%)
- 118 (0.06%) patients received non-appropriate HAART prescriptions compared to registered indications.

These prescriptions are now being discussed in Local Pharmaceutical Committees in order to create specific protocols.
Adherence estimated is measured on:

- 1.738 (83%) patients in treatment with NNRTI or NRTI: 54% are patients with >95% adherence, only 1% with <40% adherence;
- 1196 (57%) treated with PIs: 46% are patients with >95% adherence, only 2% with <40% adherence.

Conclusions Assessing the result of switching treatment has demonstrated no substantial variations in terms of costs; adherence results are in line with literature data. These studies together with appropriateness analysis are important to verify the effectiveness of HAART.

Competing interests None.

DGI026 STUDY OF USE OF TIGECYCLINE IN TREATMENT OF COMPLICATED INTRA-ABDOMINAL INFECTIONS

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10.1136/ejhpharm-2012-000074.246

Background The polymicrobial nature of complicated intra-abdominal infections makes these infections particularly challenging to treat. The initial selection of antimicrobial therapy is therefore extremely important.
Purpose The authors assessed the use of tigecycline in treatment of complicated intra-abdominal infections.
Materials and methods A retrospective observational study was made about patients with complicated intra-abdominal infection treated with tigecycline in a Intensive Care Unit from November'07 to December'10. The authors checked: age, sex, APACHE II at admission, aetiology of infection, posology, antibiograms, duration of the treatment in days, clinical recovery and death.
Results During the study, 97 patients were included: 64 men and 33 women. The mean age was 58,5±17,7 years. With regard to the aetiology of infections, 64 patients were diagnosed of secondary peritonitis, 27 of abscesses and 6 presented tertiary peritonitis. The microorganisms more frequently identified were gram-negative bacilli (Escherichia Coli found predominantly) and gram-positive cocci (Enterococcus spp.)The average in the scale APACHE II was 16,5 ±7 points. The percentage of patients at admission with sepsis and septic shock was 43,3% and 56,7%, respectively. All the patients received the first dose of 100 mg followed of 50 mg every 12 h for intravenous route. The average duration of the treatment was of 9,5±3.75 days. Clinical recovery occurred in most patients (80,7%). The death rate was 27,8%, which was lower than expected, according to the scale APACHE II (36,7% expected). With regard to the safety, serious adverse effects associated to tigecycline were not registered.
Conclusions Our finding shows that tigecycline was effective and safe in complicated intra-abdominal infections when it was used according to authorised conditions (dosage and indications)

Competing interests None.

DGI027 ANALYSIS OF DRUG ALLERGIES IN THE HOSPITAL 'PAOLO GIACCONE' IN PALERMO

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Background Allergies to drugs and xenobiotic compounds constitute a large part of the iatrogenic effects induced by therapy. It was desired to evaluate the skin reactions of patients in the period July 2010-February 2011 who had regular admission to the dermatology Unit at the Company, classifying them on the ground of event, involved body area and therapeutic class of drugs.
Purpose Study the incidence of Allergies to drugs at Policlinico Paolo Giaccone.
Materials and methods The data was derived from analysis of the first cycles delivered in accordance with law 405/2001 and subsequent verification with the data recorded on patient records.
Results 72 adverse drug reactions were detected. The sample consisted by 35% men and 65% women classified into three age groups 0-30 years (28%) 31-50 (24%) and over 51 years (48%). It is possible to have more detailed information for only 53 adverse reactions among the 72 considered. The authors wanted to investigate the habits of patients and, among 53 cases analysed, 17 cases were smokers, 31 were non-smokers and 5 cases were not recorded. As regards taking of alcoholic beverages, 10 patients regularly consumed alcohol, 34 were abstinent and for 9 the datum was not available. The main clinical manifestations observed were erythema (41 cases), oedema (9 cases), pruritus (34 cases), erythema more other (5 cases), other (3 cases). Events against the trunk were 21 with a prevalence of pruritic erythematous pomfoidi lesions; in the face were two manifestations such as angioedema; in the limbs were 19 events with pomfoidi itchy rash lesion, 6 of which also affect the trunk. It was registered 21 demonstrations against the trunk, with a prevalence of pruritic erythematous pomfoidi lesions; 2 events against the face (angioedema), 19

manifestations against the limbs with erythematous pruritic pomfoidi events among these 6 also interested the trunk, 11 against trunk and face, 2 against face and limbs and 3 against trunk, limbs and face. Classes of drugs that presented major adverse effects were FANS due to ketoprofen (17 cases) followed by nimesulide, ibuprofen and diclofenac with 5, 3 and 2 respectively, followed by analgesics-antipyretics drugs (paracetamol in the foreground followed by metamizole) and ASA on a par with food supplements and lipolytic substances. 47% of adverse reactions was attributable to a single product, 49% to groups of 2 or more drugs, the remainder has not been possible to identify the cause.

Conclusions Given the stochastic nature of the allergic event it was not possible to uniquely identify a relationship between the habits of life of patients and the occurrence of adverse reaction. It is important to point out how the events are more represented for wider access medicines for which it would be necessary to propose awareness-raising and information campaigns for all users who access the structure in order to disadvantage the misuse.

Competing interests None.

DGI028 USE OF VINFLUNINE IN UROTHELIAL BLADDER CARCINOMA

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Background Vinflunine is a vinca alkaloid indicated as monotherapy for the treatment of patients with advanced or metastatic carcinoma transitional cell urothelial tract after failure of prior treatment that included platinum compounds.

Purpose To analyse the use of vinflunine in a 600-bed hospital.

Materials and methods Retrospective study of patients treated with vinflunine from February 2010 to April 2011. Data were collected from Oncofarm ® software, medical records of patients and dispensing program to outpatients.

Results The authors studied 6 patients: 5 men and 1 woman, mean age: 67 (52-80) years. 4 had distant metastases (M1) at diagnosis and 2 showed no metastasis (M0). As first lines: 2 patients received carboplatin-gemcitabine scheme, with an average of 7 cycles; 2 received carboplatin-gemcitabine with an average of 7 cycles; 1 received 2 cycles of carboplatin-gemcitabine, followed by 4 cycles Gemcitabine; 1 received 5 cycles of cisplatin-gemcitabine, followed by 2 cycles of carboplatin-gemcitabine and 3 cycles of gemcitabine alone. As a second line: 3 patients received Vinflunine an average of 4 cycles; 2 received paclitaxel with an average of 4 cycles, and 1 received 8 cycles of cisplatin-gemcitabine. As a third-line: 2 patients received Vinflunine with an average of 5 cycles and 1 received 3 cycles of paclitaxel, following by a 4th line with 1 cycle of vinflunine. The use of vinflunine regimen in 2 patients was due to progression of liver carcinoma, in 2 to cerebral progression, in 1 to lung and bone progression, and progression in 1 to lung, liver and pelvic node. No patient received other subsequent treatment lines, 3 died of disease progression, 1 is currently being treated with vinflunine and 2 with symptomatic treatment.

Conclusions Vinflunine was used in all cases correctly according to its indication, and may be an alternative for patients with advanced transitional cell urothelial tract carcinoma.

Competing interests None.

DGI029 A FATAL EVENT IN A PATIENT RECEIVING IPILIMUMAB FOR METASTASIC MELANOMA: CAUSALITY ANALYSES

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Background Ipilimumab has been approved to treat patients with late-stage melanoma and it has been associated with potentially fatal immunological adverse effects due to T cell activation and proliferation.

Purpose To analyse the causality of a fatal Suspected Serious Adverse Reaction (SSAR) related to ipilimumab in a patient diagnosed of unresectable stage IV metastatic melanoma (MM).

Materials and methods A 73 years old patient who received ipilimumab for a MM developed serious refractory diarrhoea with fatal outcome which was reported as a SSAR to treatment. Clinical records were reviewed and chronology of events and concomitant medication were built to analyse temporal sequence. Causality algorithms were applied that considered timing, effect of withdrawal, re-exposure and alternative explanations.

Results The patient was first diagnosed of Non-Hodgkin's Lymphoma, but after a biopsy of liver metastasis, a primary MM was diagnosed. He received first-line dacarbazine treatment, but was switched to second-line with ipilimumab due to the onset of tumorous fever. After two doses of ipilimumab, grade 3 diarrhoea appeared. Based on the recent description of immunologically mediated colitis, a SSAR report was issued by the caring physicians, and unsuccessful corticosteroid treatment was started. Empirical antibiotic treatment to cover possible pseudomenbranous colitis was also unsuccessful. Finally, a bowel biopsy diagnosed severe cytomegalovirus colitis. Despite ganciclovir treatment the patient died shortly after. Systematic approach to causality assessment concluded low suspect for ipilimumab, but probable causality of previous immunosuppressive chemotherapy.

Conclusions Secondary diarrhoea to ipilimumab treatment has been recently described, but a causality analysis could have considered other alternatives to explain patient's symptoms and cover potential alternative causes. Causality algorithms for SSARs can be a useful clinical tool for helping in clinical decisions.

Competing interests None.

DGI030 BEVACIZUMAB-IRINOTECAN COMBINATION IN THE TREATMENT OF GLIOMA

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Background Patients with recurrent malignant gliomas, such as glioblastoma multiform and anaplastic astrocytoma, have a poor prognosis. Repeat surgery may not be feasible, because of tumour infiltration, and additional irradiation has limited control on further tumour growth and would potentiate neurological toxicity. Treatment options are limited. The association of an angiogenesis inhibitor with a classical cytotoxic -bevacizumab plus irinotecan – is one of the options used by the neuro-oncologists.

Purpose Evaluate the effectiveness of combination bevacizumab and irinotecan in recurrent malignant gliomas.
Materials and methods Retrospective analyse of patients with gliomas treated with bevacizumab/irinotecan. Data source: medical records and patients prescription from the cytostatic unit in pharmacy department. The following variables were analysed: sex, age at diagnosis, diagnosis, previous treatment received, number of cycles and dose. Disease progression was evaluated by MRI.
Results This study included 16 patients (7 females, 9 males) with a mean age at diagnosis of 45,75±9,75 years (range 29-60). The principal diagnosis was glioblastoma multiform (68,7%). Bevacizumab/Irinotecan was used in second-line treatment in 9 patients (56,2%) and in third-line setting in 7 patients (43,8%). Fifteen patients did radiation therapy with concurrent Temozolomide (TMZ) before Bevacizumab/Irinotecan, and all patients had undergone prior surgical resection. The mean number of cycles of bevacizumab/Irinotecan was 7,9±5,5 (1-16). Disease progression, was observed in 12 patients (75%) and 4 are still in treatment. Considering the patients who already stopped treatment, the calculated time to disease progression, based on the duration of bevacizumab/irinotecan treatment, was 22,4 weeks. (Time to disease progression described in the literature: 23,0 weeks).
Conclusions Preliminary results with Bevacizuman/Irinotecan in the treatment of patients with high grade gliomas are similar the results observed in the literature and encouraging in poor prognosis disease in malignant glioma.

Competing interests None.

DGI031 EFFECTIVENESS OF 5-AZACITIDINE IN PATIENTS DIAGNOSED WITH MYELODYSPLASTIC SYNDROME

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Background Myelodysplastic syndromes (MDS) are a heterogeneous group of clonal haematopoietic neoplasms, characterised by the presence of morphological and functional alterations in different haematopoietic cell lines and anaemia, leucopenia and thrombocytopenia. 5-Azacitidine (AZA) is a hipomethylating agent indicated for the treatment of adult patients, who are not eligible for haematopoietic stem cell transplantation with intermediate-2 and high-risk MDS, according to the International Prognostic Scoring System (IPSS).Its effectiveness was evaluated in 3 studies conducted by the Cancer and Leukaemia Group B.
Purpose This study aims to evaluate the effectiveness of AZA in patients diagnosed with MDS, outside the scope of CT.
Materials and methods Results are taken from a retrospective observational study, including all patients with MDS treated with AZA 75 mg/m2 subcutaneously in our Hospital, during the period November 2007-April 2011. The World Health Organisation (WHO) criteria for diagnosis (bone marrow examination and cytogenetics studies) and classification of MDS were used. Response to treatment was assessed using the International Working Group (IWG 2006) criteria: overall response (complete and partial remission), stable disease, time of transformation to acute myeloid leukaemia (AML), overall survival, cytogenetic response and hematologic improvement.
Results Data collection comprised results from 16 male and 9 female with a median age of 68,72 (±12,52) years. The average time to diagnosis of MDS was 22.56 (± 22.11) days. The number of blasts in bone marrow of patients at the time of diagnosis was on average 11%. An intermediate-2/high IPSS risk was documented in 76% of the patients, an intermediate-1 IPSS risk in 24%. The most frequently used dose was 75 mg/m2 subcutaneously, 12% of the patients required dose adjustment. The mean number of administered cycles was 9 (±6,08). 68% of patients had high transfusion requirement. Overall response was achieved in 29,16% of patients, stable disease in 33,34%, cytogenetic response in 48% and transfusion independence in 25%. The rate and the time of transformation to Acute myeloid leukaemia (AML) was 20,83%. The median overall survival was 32 months (95% CI 10.72-53.29) and the median time to AML transformation in 23 months (95% CI 21.54-24.4).
Conclusions Results demonstrate that 5-azacitidine is an effective drug in the treatment of MDS, outside the scope of CT, which improves overall survival, quality of life and delays AML transformation.

Competing interests None.

DGI032 CARDIAC MONITORING OF THE ADMINISTRATION OF TRASTUZUMAB AT THE PORTUGUESE INSTITUTE OF ONCOLOGY OF COIMBRA FRANCISCO GENTIL, EPE

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Background Cardiotoxicity is a recognised adverse effect of trastuzumab. Cumulative doses of chemotherapy (CT) with anthracycline, low left ventricular ejection fraction (LVEF), old age, high body mass index, constitute risk factors to consider. Measurement of LVEF by radionuclide angiography (MUGA) or echocardiogram must be carried out.
Purpose Aim of this retrospective study was to define the tolerability and safety of patients with breast carcinoma treated with trastuzumab at the IPOCFG, EPE, according to the recommendations of The National Cancer Research Institute.
Materials and methods Patients treated with trastuzumab at the Day Hospital (DH), between January 2009 and August 2011. Data collected using the computer application Oncofarm® and SIGEHP®.
Results A total of 253 patients, 96.8% breast carcinoma and 3.2% inflammatory breast carcinoma; 52.2% left breast, 43.1% right breast and 4.7% both; average age: 55 years (28-79); average weight: 68 kg (42-110). Total mastectomy: 44.3%; conservative surgery: 55.7%. Average treatment time: 328 days (1-2806). Treatment was palliative in 62.4% of patients, adjuvant in 33.6% and neoadjuvant in 4%. Previous CT regimens: FEC (57.7%), Docetaxel (31.2%) and Docetaxel/Epirubicin (29.2%). Hormonal therapy prescribed to 10.7% of patients; 52.2% held radiotherapy; 28.5% hypertension controlled with medication; 485 values obtained by MUGA: 17.9% of LVEF were < 55%, of which 27.6% were ≤50%.
Conclusions The trastuzumab is, nevertheless, well tolerated. The main recommendations of The National Cancer Research Institute include: monitoring scheme that defines baseline and heart function during treatment; intervention strategies with cardiovascular therapeutic; simplified rules for start, stop and discontinue trastuzumab; and multidisciplinary approach to the treatment.

Competing interests None.

DGI033 RISK ASSESSMENT ASSOCIATED WITH NATALIZUMAB TREATMENT

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Background Progressive multifocal leukoencephalopathy (PML) is an opportunistic viral infection of the central nervous system that usually leads to death or severe disability. In patients receiving natalizumab treatment, some independent risk factors are associated with an increased risk of PML: duration of treatment (especially beyond 2 years), the use of immunosuppressive agents (eg, mitoxantrone) before receiving the drug and the presence of antibodies to JCV.
Purpose To calculate the estimated risk of developing PML in patients being treated with natalizumab in Garcia de Orta Hospital.
Materials and methods A literature search was performed to determine the relative risk of developing PML for the different factors being assessed. Patients with multiple sclerosis on natalizumab treatment in June 2011 were evaluated regarding the risk of developing PML.
Results This evaluation included 13 patients with multiple sclerosis on natalizumab treatment, 10 of whom were females (76.9%), with a mean age of 37.0±4.5 years (18-56 years). Five patients (38.5%) had been treated with natalizumab for over two years, three (23.1%) had been taking immunosuppressive agents prior to natalizumab and seven (53.8%) had a positive result for JCV antibodies. Regarding the risk of PML, 4 patients had no risk factors (PML risk=0.19‰), 5 patients had only one risk factor (PML risk=1.37‰), 2 patients accumulated 2 risk factors (PML risk=4.3‰) and 2 patients had all three risk factors in analysis (PML risk=7.8‰). The presence of the 3 risk factors increases the risk of PML by 41 times in MS patients treated with natalizumab when compared with an absence of risk factors.
Conclusions This analysis helped determine which patients had an increased risk of developing PML, allowing the Neurology department to assess the risk-benefit of natalizumab treatment more objectively.

Competing interests None.

DGI034 EXPERIENCE WITH THE SAFETY OF ALBUMIN-BOUND PACLITAXEL IN METASTATIC PANCREATIC ADENOCARCINOMA

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Background Nanoparticle albumin-bound paclitaxel (nab-paclitaxel) is a protein-bound derivative of paclitaxel with improved solubility over conventional paclitaxel. This allows a shorter infusion time, reduces the risk of hypersensitivity reactions and eliminates the need for premedication with dexamethasone, dexchlorpheniramine and ranitidine.
Purpose The aim was to determine the off-label use and evaluate the toxicity of, and tolerance towards, nab-paclitaxel in patients with metastatic pancreatic adenocarcinoma.
Materials and methods Retrospective observational study of two patients with metastatic pancreatic adenocarcinoma treated with nab-paclitaxel. Data were collected from the cytostatics software Oncofarm, patient histories and record of tests performed with Omega3MIL software.
Results Patient 1: A seventy-six year-old woman, diagnosed with pancreatic adenocarcinoma cT3cN0M1 (hepatic cells) in February 2011, started first-line treatment with gemcitabine-oxaliplatin x 5 cycles. In April 2011, biochemical and hepatic progression, second-line treatment with capecitabine-erlotinib x 3 cycles. In July 2011, biochemical and clinical progression, third-line treatment with nab-paclitaxel 100 mg/m^2 and gemcitabine 800 mg/m^2 days 1, 8 and 15 every 4 weeks. Received 3 cycles in total until progression of the disease in October 2011. The patient developed second-degree lymphopenia and anaemia. Patient 2: A fifty-eight year-old man, diagnosed with pancreatic adenocarcinoma pT3pN1(7/19) M1 (lung, retroperitoneal ganglion and hepatic cells). Head-pancreaticoduodenectomy was performed. In December 2009, first-line treatment with gemcitabine-oxaliplatin x12 cycles followed by gemcitabine monotherapy x11 cycles. In December 2010, progression in lungs and liver. Started second-line treatment with capecitabine-erlotinib x5 cycles. In May 2011, pulmonary and hepatic progression. Started third-line treatment with nab-paclitaxel 100 mg/m^2 days 1, 8 and 15 every 4 weeks. The patient had received 5 cycles and was continuing treatment at the time of writing. First-degree anaemia was observed.
Conclusions The patients tolerated the treatment well. They did not develop any severe adverse reactions associated with nab-paclitaxel. Peripheral neuropathy, neutropenia and hypersensitivity reactions were not observed. No doses of the drug needed to be omitted or postponed.

Competing interests None.

DGI035 THE USE OF INTRAVENOUS LINEZOLID†

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Background Linezolid is an antibiotic approved for treatment of nosocomial pneumonia (NP), community-acquired pneumonia (CAP) and complicated skin and soft tissue infections caused by Gram-positive bacteria susceptible to linezolid.
Purpose To determine the use of intravenous linezolid in a 400-bed general hospital, where its use is only sanctioned for:
- NP due to methicillin-sensitive and methicillin-resistant S. aureus (MSSA and MRSA) or methicillin-sensitive S. pneumoniae.
- CAP due to methicillin-sensitive S. pneumoniae or MSSA.
- Skin and soft tissue infections with MSSA or MRSA, S. pyogenes or S. agalactiae.

Materials and methods One-year retrospective study (2010). Data were obtained from: clinical records, Savac and Selene programs and laboratory tests. The case report form used had the following items: diagnoses, bacterial culture, indication, dose, duration, concomitant antibacterial treatment, previous treatment with glycopeptides and adverse effects, creatinine level and possibility of oral administration.
Results Sixty-seven episodes corresponding to 52 patients whose mean age was 60.7 years. Episodes were reviewed from: intensive medicine (68.3%), surgery (15%), internal medicine (6.6%), other (10.1%). Only 17.3% of patients used the drug according to indications for which it is restricted according to the hospital protocol. Non-indicated uses included: pneumonia not matching the above conditions (20.3%) and postoperative

abdominal abscess (20.3%). In 100% of cases bacterial culture was performed, and its use was justified in 19% of cases. The recommended dose was used in 95% of cases. Mean duration of therapy was 9.7 days. Significant concomitant antibiotics were: piperacillin-tazobactam (29.2%), meropenem (25.2%), cefepime (8%), and amikacin (8%). 41.6% had been treated previously with glycopeptides. Mean creatinine was 0.8 mg/dL.

Conclusions There is low compliance with the authorised indications. Those treated the longest (11.5%) had blood toxicity. Almost half could have been treated orally at the same dose (100% bioavailability).

Competing interests None.

DGI036 EFFICACY AND SAFETY OF THE USE OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS

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Background Tocilizumab (T) is a new biological agent for the treatment of rheumatoid arthritis (RA).

Purpose Our purpose was to review the response to, and safety of, tocilizumab.

Materials and methods Retrospective and descriptive study in a University hospital. All patients with RA being treated with tocilizumab (since the drug was included in the hospital's formulary) were selected. Period of study: December 2009-May 2011. Data collected: demographics, diagnosis, previous treatments, duration of treatment with tocilizumab, concomitant treatment, response (Clinical criteria: pain, inflammation of the joints (DAS28), morning stiffness, as defined by the Spanish Society of Rheumatology (SSR), adverse events (AEs) and cost. All data were collected through the pharmaco-therapeutic profile and by reviewing the medical chart.

Results 12 patients (8 women) with seropositive rheumatoid arthritis were included, mean age: 53.42±14.93 years. Median time from diagnosis of RA: 9.17±6.23 years. Mean duration of treatment: 8.25±5.46 months. All patients received tocilizumab due to progression after other treatment. 41.67% of patients received tocilizumab as a second-line, 25% as a third-line, 33.33% as a fourth or more line. 25% of patients took T-MTX, T-Leflunomide (8.34%) and without concomitant disease-modifying antirheumatic drugs (66.67%). 75% of patients took corticosteroids concomitantly. Dosage: 8 mg/kg/ 4 weeks. 11 patients had any type of response to T after 3 cycles (their subjective symptoms improved). Only 2 patients had DAS28 data (3.04 and 2.08) after 3 cycles. In 2 patients the treatment was stopped: 1 lack of response and 1 AE. The most frequent AEs: 3 cases of hyperlipidaemia that required statin therapy (1 required to stop T and was notified to the National Pharmacovigilance Center),1 grade II neutropenia. T treatment has cost €97,167 since December 2009. Average cost/patient was €8,097. Annual cost of treatment/patient €12,087.

Conclusions T is a therapeutic alternative to use when conventional therapies have failed. T is well tolerated but cholesterol levels should be monitored during treatment. To assess the response with the available data is difficult because DAS28 was not collected according to SSR recommendations. Pharmacists should get involved in evaluating the tolerance and the cost-effectiveness of this type of drug.

Competing interests None.

DGI037 ASSESSING THE QUALITY OF ANTIBIOTIC PRESCRIBING AT DISCHARGE FROM HOSPITAL

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Background Infectious diseases, mainly respiratory diseases, are one of the main reasons for hospital admissions. So an appropriate antibiotic prescription at discharge (APD) after these episodes of hospitalisation may have important clinical repercussions.

Purpose To assess the quality of APD.

Materials and methods Descriptive, observational, retrospective study over 3 months carried out in an Internal Medicine Short Stay Unit of a 400-bed hospital. It included patients discharged from an interdisciplinary medicines reconciliation program (June-August 2010). The authors reviewed all discharge information and collected data relative to demographics (sex, age), clinical picture (allergies, diagnosis), antibiogram (sample, microorganism isolated) and APD. To evaluate the quality of APD, The authors use these indicators: adherence to the Primary Care Pharmacotherapeutic Guide (PCPG), prescription by International Non-proprietary Name (INN), rate of prescription errors (PEs) (= (number of PEs/ total antimicrobial prescriptions)*100) and use (empirical/non-empirical). The authors considered the following to be PEs: mistakes in the dose/frequency/duration of treatment, omission of any of these or incomplete prescriptions.

Results 41.2% of patients were prescribed at least one antibiotic at discharge (n= 35, 5 of them with 2 antibiotics). Patient characteristics: 54% male, 75±13 years, 8 patients with a known history of drug allergies (4 to antibiotics such as penicillins, cephalosporins and/or fluoroquinolones). Amoxicillin-clavulanic acid was the most frequent antimicrobial agent prescribed (47.5%) and then, the third-generation cephalosporin cefditoren (17.5%) and the fluoroquinolone levofloxacin (17.5%). As to the clinical diagnosis, 71.4% of patients suffered respiratory infection (48% caused by COPD/asthma exacerbation). Microbiological cultures (sputum, blood, urine) were only assessed in 31.4% of the patients and half of them were positive, isolating a variety of microorganisms (Streptococcus viridans, Escherichia coli, Streptococcus pneumoniae, Haemophilus influenzae, Candida albicans, Aspergillus fumigatus, Morganella morganii, etc.). Regarding the quality of APD: 64.1% adhered to the PCPG, 24.4% prescribed by INN, PE rate=4.8%, 84.3% was empirical use.

Conclusions A review the use of antibiotics in hospital is a necessary tool to assess quality of prescription and to promote the rational use of drugs.

Competing interests None.

DGI038 BENDAMUSTINE IN LYMPHOMAS: A REVIEW OF ITS USE

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Background Bendamustine is an alkylating agent recently approved in several European countries for non-Hodgkin's lymphoma (NHL) refractory to rituximab (R).

Purpose To describe bendamustine use in lymphomas and review safety in our clinical practice.

Materials and methods Retrospective study carried out during 2010. The following data were collected: sex, age, previous treatment, bendamustine dosage, treatment duration, % adverse reactions (ARs), % colony-stimulating factor required and reduction of the initial dose of bendamustine.
Results 7 patients received bendamustine: 71.4% male, age 53.9 at the beginning of bendamustine treatment. 42.8% Hodgkin's lymphoma (HL) and 57.2% NHL, 50.0% were mucosa-associated lymphoma tissue (MALT) and 50.0% follicular NHL. An average of 3 treatment lines were used before bendamustine was used. In NHL patients (n=4), first-line treatment was CHOP±R; several schemes were used in the second line (BEACOPP-14, DHAP). Bendamustine was used as third line: 50% combined with rituximab and 50.0% in monotherapy. There were no standard dose criteria for bendamustine: 90 mg/m2 (2 patients), 100 mg/m2 and 120 mg/m2 one each. In HL patients (n=3), 2 patients received ABVD followed by bone marrow transplant and 1 patient BEACOPP-14 at first. In second and third-line treatment different schemes were administered (BEACOPP-14, GEMOX, DHAP and CNOP). As the fourth line bendamustine was requested as off-label at 110-120 mg/m2. In this study, bendamustine treatment was continued for 22.85 weeks (95% CI 19.11 to 26.60). The most common AR was haematological toxicity (85.7%); grade 3-4 neutropenia appeared in 9.5% and anaemia in 4.8% of patients. Use of colony-stimulating factor and epoetin alfa were essential in 71.4% patients; it was not necessary to reduce the dose of bendamustine. Other ARs were fatigue 14.3%, fever, nausea or vomiting 9.5%.
Conclusions Experience with bendamustine in Hodgkin's and Non-Hodgkin's lymphoma in our institution is limited. Haematological toxicity is common and can be managed with colony-stimulating factor.

Competing interests None.

DGI039 ESNEE PROJECT: STRATEGY FOR THE EXTENSIVE REVIEW OF THE LITERATURE ON EXCIPIENT TOXICITIES

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Background Excipients are used to facilitate the manufacturing of dosage forms and maintain the stability of medicines in the face of chemical and microbial challenges. The lack of neonatal safety information exposes these patients to the risk of specific adverse reactions unexpected from adult experience.
The European Study of Neonatal Excipient Exposure (ESNEE) consortium was created in order to improve experience on this topic. A systematic review of excipient safety and kinetics in humans and juvenile animals has been planned.
Purpose This study aimed to develop and validate a systematic and standardised search strategy for collecting relevant information about excipients.
Materials and methods 8 metadatabases were selected: PubMed, Scopus, Biosis, Inchem, AcTOR, Toxseek, International Pharmaceutical Abstract. Search focus was on the toxicity, safety and pharmacology of chemicals. An individual search strategy was developed for each resource.
Results Search strategy was developed using propylene glycol as a model. The systematic database review included 5 steps:

- definition of inclusion/exclusion criteria,
- source identification,
- adaptation of search strategies to each source,
- data assessment,
- database creation/use,

Inclusion and exclusion criteria were: English language, chemical product name (CPN) (not a derivative) mentioned in the abstract and its safety and/or toxicity on animal or human subjects evaluated; the CPN not cited as an example or used as a solvent in admixture, or for analytical matters. Boolean search strategy was not selective enough leading to too many irrelevant hits. Section Headings (SHs) search was more structured and narrowed the search without losing information. SHs had to be defined for each database. The relevance of abstracts was estimated independently by two pharmacists, using the inclusion/exclusion criteria. Articles identified will be assessed by experts in toxicology/pharmacokinetics before implementation into the ESNEE database.
Conclusions In future excipient monographs will summarise the data retrieved. They will provide the missing information needed to improve the safe use of drugs and drug formulations in neonates.

Competing interests None.

DGI040 OFF-LABEL USE OF RITUXIMAB IN A GENERAL HOSPITAL

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Background The therapeutic indications for rituximab are: Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.
Purpose The aim of this study was to review the off-label use of rituximab in our hospital.
Materials and methods Retrospective study of rituximab in off-label indications from October 2009 to June 2011. Data collected: age, sex, diagnosis, posology, number of doses planned and administered and cost of treatment.
Results Rituximab was used for 21 patients (76.1% women) with a mean age of 39.3 years (11-71). The indications were antisynthetase syndrome (dermatomyositis), autoimmune encephalitis, nephrotic syndrome, neoplastic cerebellar syndrome, pemphigus foliaceus, acquired haemophilia A, acute renal rejection (2), autoimmune thrombocytopenic purpura (ITP) (2), systemic lupus erythematosus (SLE) (5) and neuromyelitis optica (6). Posology varied according to the indication. SLE and antisynthetase syndrome: 1 g every 14 days, 2 doses. Nephrotic syndrome, ITP, pemphigus foliaceus, haemophilia A and neuromyelitis optica: 375 mg / m2 intravenous once weekly, 4 doses and in the last indication there is an option of retreatment with 2 doses of 1000 mg depending the CD19 count. Neoplastic cerebellar syndrome: 375 mg/m2 intravenous every 28 days, 4 doses. Acute humoral rejection: 500 mg (single dose) for 1 patient once weekly, 4 doses for the other patient. 14.2% of patients didn't start treatment with rituximab and 72.2% received the planned total doses. Only 1 patient received 2 doses as a retreatment for neuromyelitis optica. The off-label use of rituximab meant a cost of 90,638 €.
Conclusions Rituximab is widely used in autoimmune pathologies as a therapeutic alternative in patients who have failed conventional treatment, although its use is not supported by large clinical trials. The high cost and its wide use warrant large randomised controlled clinical trials to demonstrate its efficacy.

Competing interests None.

DGI041 IMPROVEMENTS IN THE ACCESS AND AVAILABILITY OF GUIDELINES FOR THE ADMINISTRATION OF MEDICATION IN THE NURSESÍ UNITS OF OUR HOSPITAL.

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Background The nursing staff has the responsibility of administrating drugs correctly to the appropriate patients. Sometimes, the access to information about giving medication, the stability and compatibility of medicines, is not adequate.
Purpose Improving the availability of information about giving medication in the nurses' units
Materials and methods Up to date bibliography about guidelines for the administration of drugs was researched on the internet. Using these key words: *Guidelines; administration; Internet – intranet*. Standard guidelines for the administration of medication available on each of the floors of our hospital were referred to.
Results The first step has been to create access, on the hospital's intranet which enables nurses to search a basic drugs database in our community of Castilla y León (Remedios®) and another to the guidelines used at the Reina Sofia University Hospital and Hospital Son Espases, which are both available in PDF format. The authors have also made the guidelines of parenteral drugs of the Hospital University of Salamanca (www.ismp.es) available in paper format. This information is being reinforced with talks and leaflets given by the pharmacy staff in the hospital nursing units about on-line resources. The pharmacy staff are frequently reminded about the availability of a pharmacist from 8 a.m to 10 p.m every day (in the pharmacy The authors have specific books about drug administration like Trissell, Stockley, Martindale, CD stabilis; Medimecum; Spanish Guidelines about drugs administration; Micromedex; and selected Internet sites.
Conclusions The patient safety unit together with the pharmacy services and nursing management have improved access and availability of administration guidelines of medication and have also improved the information available about medication on different wards. In this way nurses have been helped to take decisions about the correct administration of drugs which are prescribed by doctors and validated and dispensed by pharmacists.

Competing interests None.

DGI042 EXPERIENCE WITH DUODENAL LEVODOPA INFUSION IN ADVANCED PARKINSON'S DISEASE IN OUR HOSPITAL

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Background Continuous levodopa delivery by enteral infusion is an alternative to deep brain stimulation and subcutaneous apomorphine to control motor fluctuations and dyskinesia in advanced Parkinson's disease (PD).
Purpose The objective was to describe the efficacy and safety of levodopa duodenal infusion (LDI) in patients with advanced PD.
Materials and methods The authors carried out a retrospective descriptive study in which The authors included patients with PD who started continuous daily LDI through percutaneous endoscopic gastrostomy (PEG) from October 2010 until October 2011. LDI has been introduced in our hospital for advanced PD treatment in patients who have tried all oral medication, have family support and do not have dementia. The patient data were obtained from their clinical histories. The authors evaluated the improvement in the motor fluctuations and dyskinesia and reduction in off-time. The adverse events were assigned to 3 categories: related to the treatment, related to the PEG and related to technical problems with the infusion device.
Results Three patients were included in the study (mean age of 69.7 (range 54-78) years, 33.3% male). The average disease duration was 20.3 (17-23) years and Hoehn & Yahr (H&Y) staging 3-4. LCI was used as monotherapy. Dosing of LCI was adjusted to the needs of each individual patient. The total accumulated follow-up time was 17 months (2-12). All our patients showed an improvement of fluctuations, increased on-time without dyskinesia and a reduction in the duration of the off periods. One of them was in stage 4 on the H&Y scale and improved to stage 3. In terms of complications, there was one due to PEG positioning and failures in the infusion system.
Conclusions LCI is a useful treatment to reduce motor fluctuations and dyskinesia for patients with advanced PD in whom motor fluctuations and dyskinesia were inadequately treated with traditional oral medicines. The procedure was in general well tolerated and complications were related to the infusion system and dopaminergic effects but could easily be managed. Our conclusions were limited by the modest number and size of the study. New evaluations are needed.

Competing interests None.

DGI043 EVALUATION OF THE USE OF TOLVAPTAN IN A SPANISH TERTIARY HOSPITAL†

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Background Tolvaptan is the first oral antagonist of the vasopressin V2 receptor, indicated in adult patients with hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone hypersecretion (SIADH).
Purpose To evaluate the use of tolvaptan in a Spanish tertiary hospital.
Materials and methods Retrospective observational study of the use of tolvaptan from November 2009 to October 2011. The authors identified patients who had received treatment with tolvaptan during the study period. A data collection sheet was designed on which was recorded: diagnosis related to hyponatraemia, age, gender, dose, duration of treatment, serum sodium when the treatment with tolvaptan was initiated and time until normalisation of serum sodium.
Results Four of the 15 patients identified (mean age of 68±17.8 years; 60% males) were admitted to the Internal Medicine ward, 4 to Gastroenterology, 4 to Cardiology, 1 to Endocrinology and 1 to Nephrology. Four patients had hyponatraemia related to oedematous decompensation secondary to liver disease, in 4 the cause was heart failure, while 6 patients were diagnosed with SIADH and in the other 2 patients, hyponatraemia was

secondary to the use of drugs. The dose usually used was 15 mg/day, although 5 patients took 30 mg/day and in one case, the maximum dose specified in the summary of product characteristics (SPC), 60 mg/day, was reached. The duration of treatment varied from 3 to 7 days or 1-2 months in patients on Internal Medicine and Gastroenterology, to 6 months in Endocrinology, Nephrology and Cardiology patients. 6 patients died due to their severe clinical situation. No side effects related to tolvaptan were recorded.

Conclusions Our results agree with the tolvaptan clinical trials, that it appears to be safe and effective in the treatment of hyponatraemia refractory to other treatments. Although there were no side effects related to tolvaptan, it is likely that some of the adverse effects described in the SPC may have been masked by the patient's clinical status.

Competing interests None.

DGI044 TARGETED ANTICANCER TREATMENTS

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Background Targeted anticancer treatments (TATs) are drugs or other substances that act on a specific target or biological pathway associated with tumour growth and dissemination. These treatments can be used alone or in combination with chemotherapy in first-line, refractory, or relapsed settings.

Purpose To evaluate the use of TAT in adult onco/haematological patients treated in our hospital and to estimate the financial impact of these treatments.

Materials and methods Retrospective study of adult onco/hematological patients treated with TAT from February 2011 to September 2011. Literature was reviewed to define the drugs classified as TAT. Data were obtained from: pharmacy management program, hospital oncology software and outpatient pharmacotherapy history. Variables studied were: TAT, number of patients, chemotherapy protocols (used in combination with chemotherapy or monotherapy), treatment cost.

Results 1788 active patients received chemotherapy during the study period of whom 536 (29.98%) were in treatment with some TAT. The distribution of patients being treated with each drug was the following:

TATs were used in combination with conventional chemotherapy in 268 patients and in 301 patients as monotherapy. Cost of TAT was 6,357,299.55 euros which represented 73.15% of total cost of all chemotherapy treatments (8,690,640.4 euros).

DGI044 table 1

TAT (drugs)	Nº patients (%)
Alemtuzumab	1 (0.19)
Bevacizumab	110 (20.52)
Cetuximab	80 (14.93)
Ipilimumab	4 (0.75)
Panitumumab	5 (0.93)
Rituximab	76 (14.18)
Trastuzumab	104 (19.48)
Dasatinib	10 (1.86)
Erlotinib	49 (9.14)
Gefitinib	6 (1.12)
Imatinib	53 (9.90)
Lapatinib	20 (3.73)
Nilotinib	6 (1.12)
Sorafenib	8 (1.49)
Sunitinib	22 (4.10)
Bortezomib	15 (2.80)

Conclusions Targeted treatment is a widely used cancer treatment option. Most of the financial cost of cancer treatment is related to TATs so these drugs should be selected and used correctly according to hospital protocols.

Competing interests None.

DGI045 ORAL ANTICANCER AGENTS: A PROSPECTIVE PILOT STUDY OF A PATIENT EDUCATIONAL SURGERY RUN BY A PHARMACIST AND A NURSE

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Background There has been a remarkable growth in approved oral anticancer agents (OAA) in recent years. This situation involves the pharmacist as a key part of the interdisciplinary team ensuring the safety and an adequate knowledge of the treatment with OAA. This may enhance compliance and reduce adverse events. A patient educational surgery was established by a team of a pharmacist and a nurse (PESPN).

Purpose To describe the first PESPN patients. To compare the number of calls received by the continuing oncology care unit (COCU) before and after the establishment of PESPN.

Materials and methods Prospective observational study from 2010 to present in a tertiary hospital. The authors included all patients initiating OAA. The information tools employed were validated leaflets about each drug, others leaflets related to symptoms management and personalised treatment calendars. Furthermore, The authors checked potential interactions between OAA and other concomitant treatment. Data collected: demographics, family support, KI (Karnofsky index), comorbidities, disease, staging, treatment type, information support, concomitant medicines, interactions prevented, number of phone calls received by the COCU.

Results 34 patients. No. (%): women: 20 (60.6%); age (mean 66.5+/-15.2); family support 28 (84.8%); KI 90-100%: 28 (84.8%); comorbidities: 20 (60.6%); disease: breast 14 (42.4%), lung 9 (27.2%), CNS: 8 (24.2%), colon: 2 (6.1%); stageIV: 32(97.0%); metastatic: 23(69.7%), adjuvant: 10 (30.3%); indication for OAA: progression by imaging: 15 (45.5%), first-line treatment: 13 (39.4%), biochemical progression: 3 (9.1%), patient preference: 2 (6.1%), pathological progression: 1(3.0%); OAA: vinorelbine: 11(33.3%), capecitabine: 8 (24.2%), temozolomide: 8 (24.2%), topotecan: 3 (9.1%), erlotinib: 2(6.1%), gefitinib 1(3.0%); information tools: OAA leaflets: 31(93.9%), personalised calendar: 4(12.1%), others 3(9.1%); concomitant medicines: 32 (97.0%)(mean 3.8+/-2.2); complementary medicine: 2 (6.1%); total interactions: 6(18.2%); erlotinib-omeprazole:3(9.1%), erlotinib-acenocoumarol: 1(3.0%), capecitabine- acenocoumarol (3.0%), valproic-temozolomide: 1(3.0%). Phone-calls received by COCU: year 2009:1320 versus year 2010:1087 (17.7% reduction).

Conclusions The typical patient profile was a woman with metastatic breast cancer initiating OAA after imaging progression. The treatment most dispensed was vinorelbine and the patients were given information leaflets specifically about the OAA. Almost all patients were on concomitant medicines and potential interactions were prevented. There was a significant reduction in the number of telephone inquiries received by COCU.

Competing interests None.

Pharmacotherapy: Pharmacokinetics and Pharmacodynamics (including: ADE, TDM, DUE)

PHC001 DVT PREVENTION IN SURGICAL PATIENTS IN STIP GENERAL HOSPITAL 2010

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Background There is high incidence of DVT after major surgical intervention. Thromboprophylaxis get a critical component in this patient.
Purpose The aim of this study is to show LMWH are effective prophylactic agents for prevention of DVT in high-risk patients who underwent major surgical intervention.
Materials and methods 374 patients (168 male and 206 female, 16–80 years old) undergoing major surgery. All of them had high risk of DVT. The interventions were made with general anaesthesia. Preoperative they were treated with LMWH 'ENOXAPARIN' 40 mg. sc, 12 h before the intervention, and postoperative with the same dose. The mean duration of prophylaxis was 7-10 days, depends of length of hospitalisation. The patients were monitored for the TP, APTT and PT.
Results 374 patients were hospitalised on the surgery department, 206 female and 168 male with a different diagnosis and high risk of DVT. Postoperative hospitalisation lasted 8 days. In this period the patients got 'ENOXAPARIN' 40 mg. sc once a day in the morning. Every third day the patients were monitored for TP, APTT and PT and the values were normal. Patient mobilisation was made first day after surgery. One female the third day after intervention died from pulmonary thromboembolism. Two of them got leg oedema, and one got leg redness. Only one male got allergic reaction.
Conclusion LMWH appears to be effective for prevention of DVT and safe in high-risk patients undergoing major surgical procedures. Laboratory monitoring is not needed for DVT prevention. Risk of side effects is minimal and LMWH are save of bleeding. LMWH may be useful in treatment of DVT in therapeutics aims.

PHC002 MEASUREMENT OF METHOTREXATE IN CEREBROSPINAL FLUID BY FLUORESCENCE POLARISATION IMMUNOASSAY IN PATIENT WITH MEDULLOBLASTOMA

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Background Medulloblastoma is one of the most frequent malignant brain tumours in infancy. Conventional treatment is based on combined radiotherapy and chemotherapy after surgical resection of the tumour. The chemotherapy consists of combinations of various anticancer agents, including methotrexate. Methotrexate is administered in intravenous infusion at high doses combined with intrathecal injection at low doses. The use of fluorescence polarisation immunoassay (FPIA) to monitor blood methotrexate levels is widely validated, but there have been few studies on its application to analyse cerebrospinal fluid (CSF) concentrations of this drug.
Purpose To analyse cerebrospinal fluid (CSF) concentrations of methotrexate by fluorescence polarisation immunoassay (FPIA) in patient with medulloblastoma.
Materials and methods A 22-month-old female diagnosed with medulloblastoma underwent intensive chemotherapy. The regimen was three two-month courses of chemotherapy with methotrexate and other anticancer agents. The patient has received one complete course to date. In the first week, 2 mg of methotrexate were administered intraventricularly via Ommaya reservoir for four days, followed by intravenous cyclophosphamide for three days. In week 3, 2 mg of intraventricular methotrexate was administered in combination with a 24-h intravenous infusion of 2.7 g methotrexate and INTRAVENOUS infusion of vincristine on day 1 and was administered alone on day 2. The treatment in week 5 was identical to that in week 3. Finally, in week 7, the patient received 2 mg of intraventricular methotrexate daily for four days followed by intravenous carboplatin and etoposide for three days. Methotrexate CSF samples were drawn before the first intraventricular injection and at 24 h after each intraventricular administration. CSF methotrexate levels were determined by FPIA using an Abbot TDX analyser.
Results CSF methotrexate levels were measured with the following results: week 1, day 1: 14.26×10^{-6} M, day 2: 218×10^{-6} M, day 3: 0.75×10^{-6} M, day 4: 0.33×10^{-6} M; week 3, day 1: 0.05×10^{-6} M, day 2: 2.96×10^{-6} M; week 5, day 1: 0.02×10^{-6} M, day 2: 2.16×10^{-6} M; week 7, day 1: 0×10^{-6} M, day 2: 1.46×10^{-6} M, day 3: 0.94×10^{-6} M, and day 4: 1.07×10^{-6} M; the mean value was 1.38×10^{-6} M. Values on day 1 of each cycle were obtained prior to the intraventricular injection and were determined solely to confirm the virtual absence of methotrexate before initiating the next intraventricular administration cycle; therefore, day 1 values were not considered in the calculation of the mean CSF concentration. Values on days 1 and 2 of week 1 were excluded from our analysis because the same route was used for the intrathecal injection and subsequent CSF sample extraction; therefore, the corresponding samples were contaminated.
Conclusions FPIA proved to be a reliable method to measure CSF fluid methotrexate concentrations, within published ranges, although further studies are required to verify these findings.

Competing interests None.

PHC003 EFFECT OF INFUSION TIME ON THE PHARMACODYNAMIC PROFILING OF MEROPENEM IN CRITICALLY ILL PATIENTS WITH PSEUDOMONAS AERUGINOSA INFECTIONS

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Background Severe infections in critically ill patients due to P. aeruginosa require timely and appropriate antibiotic treatment. Pharmacokinetics (PK) and pharmacodynamics (PD) both affect dosing antibiotic regimens. The minimum inhibitory concentration (MIC) becomes a PD surrogate for microbiological cure for the combination of infecting bacteria and drug. Monte Carlo simulations facilitate theoretical forecasting of the probability of PK/PD targets being attained. Regarding carbapenems, the PK/PD index to be optimised is the time for which the free serum drug concentration exceeds the MIC: $fT^{SS}>_{MIC}$.
Purpose To use Monte Carlo simulations to evaluate the appropriateness of extended intravenous infusions (EIs) of

meropenem (MEP) in patients critically ill with P. aeruginosa infections.

Materials and methods For each dose regimen (MEP 1 g intravenous q8h-q6h and different lengths of infusion), 5000 PK profiles were simulated (NONMEM v.6) based on previous PK data and creatinine clearance (CLcr). A range of MICs was studied: S ≤2 mg/L, I 4 mg/L and R >8 mg/L, according to the EUCAST cut-off for P. aeruginosa for MEP. The likelihood of target attainment (PP_{50}: $fT^{SS}_{>MIC}$>50%), was calculated for each EI while keeping the interdose interval of 6h, 8h or 12h.

Results In patients with CLcr 80 mL/min and MICs ≤2 mg/L, high doses of MEP 1 g intravenous for 30 min/6h were needed to reach the goal (PP_{50}>90%). For higher MICs, this high dose was clearly inadequate (eg, MIC=4 and 8 mg/L PP_{50} were 76.5% and 38.8%, respectively). The PP_{50} could be markedly increased by using longer EIs (eg, for MIC=4 mg/L PP_{50}=85.2%, 94.8% and 100% for EIs of 1h, 2h and 3h, respectively). Lower MEP doses could be prescribed without loss of efficacy (PP_{50} 89.7%, 95.1% and 99.1% using MEP 1 g intravenous/8h for 1h, 2h and 3h, respectively), for MICs ≤2 mg/L. The length of infusion had less effect on PP_{50} in moderate/severe renal impairment. For MIC≤2 mg/l, PP_{50} remained >90% while Clcr=40 ml/min for q6–8 h.

Conclusion The probability of attaining PP_{50} for a given MIC rises as long as the infusion time increases. MEP administered as an EI (3h) might increase the likelihood of a favourable microbiological and clinical outcome in ICU patients when P. aeruginosa. has a high MIC.

Competing interests None.

PHC004 ATORVASTATIN: EVALUATION OF DRUG USE

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Background Statins reduce the risk of death, myocardial infarction and stroke in patients with coronary heart disease and others at high cardiovascular risk**.**

Purpose Currently atorvastatin is one of the top 5 most costly medicines at King Fahd Medical City; therefore a drug use evaluation was conducted to assure adherence to the National Cholesterol Education Program recommendations.

Materials and methods A retrospective randomised chart review analysis was conducted between the periods of May to June 2010 for a total of 107 patients on atorvastatin treatment.

Results Out of 107 patients who were evaluated, 41% were males and 59% females. Our data showed that the baseline lipid profile was not obtained in 23% of patients and baseline liver profile in 43% of them. Only 52% of patients had their LDL cholesterol controlled sufficiently within the target based on recommended guidelines; while, 26% of them did not reach the target and 22% had no lab results despite being on atorvastatin treatment. Targets were specified based on the patient risk factors although risk factors for hyperlipidaemia were poorly documented.

Conclusions Our data suggested poor documentation of risk factors in patients' files. Moreover, patients did not meet their targets of LDL levels and a correlation was found that the higher the risk of coronary heart disease, the lower the percentage of subjects meeting their targets. This finding was revealed as adherence to the recommended target in only 52% of patients which is an alarming number. In addition, dosing adjustments and other antihyperlipidaemic medicines were not fully used.

Competing interests None.

PHC005 ADVERSE DIGESTIBILITY EFFECTS, DRUG-FOOD INTERACTIONS AND LONG-TERM SAFETY OF PROTON PUMP INHIBITORS

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Background Gastric acidity is mandatory for pepsin activation, bactericidal effect, secretin and pancreatic enzymes' release. PPIs (proton pump inhibitors) change gastric pH permanently to >3-4.

Purpose The aim of this work is to assess the impact of permanent high gastric pH on absorption and bioavailability (except of CYP450-interactions) and to recommend nutrition support options.

Materials and methods A systematic online literature research was performed on usual platforms. Recommendations rely on a multidisciplinary focus group assessment.

Results Risk factors assigned to long-term inhibition of gastric acidity arise from

· cleavage-resistance of peptide and glycosidic bonds
· mucosal degeneration and leak
· loss of bactericidal action

and comprise

· bacterial overgrowth
· community and hospital-acquired pneumonia
· childhood asthma related to PPI treatments of mothers in pregnancy
· sensitisation to food allergens in the older and in pregnant women (progesterone slows down gastric emptying)
· deterioration of lactose intolerance, celiac disease, atrophic gastritis, rheumatoid arthritis, diabetes mellitus
· modified bioavailability
o malabsorption of micronutrients, for example vit C and B12, folate, Zn, Fe, Mg, Ca
o lower bioavailability, for example ketoconazole, itraconazole, posaconazole, (not: voriconazole), atazanvir, cefpodoxime, cinnarizine, enoxacin, dipyridamole
o higher bioavailability, for example nifedipine, digoxin, penicillins, erythromycin, alendronate.

To prevent these complications, the focus group recommends:

· **alternative antacids, step-down, intermittent and on-demand strategies:**
o $MgCO_3$ and H_2-antagonists have a shorter onset and time of pH>3-4 than pantoprazole 40mg (median pH=3.7, pH>4 for 10.8h) or esomeprazole 40mg (median pH=4.7, pH>4 for 16.1h).
· **to avoid high allergenic food**
o that is **c**rustacean, eggs, fish, milk, peanuts, soybeans, tree nuts or fruits, and wheat
· **buffering, pepsin replacement, stimulation of digestion and peristalsis**
o Carbonated beverages, quinine water, aperitifs, appetisers, and bitter substances (amara)
o Prokinetic agents (domperidone, bromopride, metoclopramide, quinine, erythromycin)
o Mucosal protectors (curcumin, quercetin, alginates, pectins, glycyrrhizin)
o Melatonin (regulates digestion and has structural similarity to omeprazole)

o Pepsin in HCl preparations
· **nutrition and dietary approach combined with physical activity**
o High-fibre-, low-fat-, low-carb diet · **reassessment of pharmacotherapy**
o Weak acids (pK_a<4.5) lose their undissociated state required for diffusion across membranes.
o Absorption is impaired by membrane-bound CYP3A4,5,7 and efflux transporter P-gp.
(a log-conc-diagram, structure formula, tables of relevant drugs and nutrients, as well as references are provided on the poster)
Conclusions PPI safety profiles are troubled by risk factors arising from inappropriate long-term use. Drugs may be more bioavailable as a result of mucosal hyperpermeability, or less bioavailable as a result of altered dissociation. Care should be given to substrates with pK_a<4.5. At least children and pregnant women should prefer alternatives to PPIs.

Competing interests None.

PHC006

BEHIND CYP450 INTERACTION TABLES Ñ THE EFFECT OF GENDER AND AGE ON PHARMACOKINETICS

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Background Interaction tables are restricted to unspecified isoenzymes of the families CYP1, CYP2, and CYP3. Data on gender impact has been required by the FDA only after 1993.
Purpose The aim is to assess the effect of gender and age on pharmacokinetics and to explain inconsistent data reported so far.
Materials and methods A systematic online literature research was performed on the usual platforms. 168 references could be evaluated.
Results·Ontogeny, peri- and postnatal phase: CYP450 inducibility begins in the earliest embryonic stage and reaches high rates before birth. Drugs are not distributed freely to all parts of the body in newborns. Childhood: preadolescent fasting boys absorb 35.2%, girls 45% of an oral iron loading dose. This explains the higher prevalence of iron anaemia in boys aged 11-15 (12.1%) compared to equally aged girls (6.1%). Adulthood: mean gastric fasting pH is 2.15 for men and 2.8 for women corresponding to a fivefold H^+ activity in men. Women secrete gastrin and bicarbonate at the moment of substrate afflux, men more steadily. Gastric emptying, small intestine motility and colon transit times are downregulated by oestrogen and progesterone. In men, isoenzymes CYP1A2, CYP2C9, CYP2E1 are more active (CYP1A2 up to 40-fold), in women CYP3A4,5,7, CYP2A6, CYP2B6, and CYP2D6 (CYP2D6 only in the fertile phase). CYP3A4,5,7 activity depends on the menstrual cycle and peaks before ovulation and in pregnancy. Hepatic and intestinal P-gp (permeability glycoprotein) is expressed more in men than in women. Confused reports arise if the authors do not account for any mutually opposed effects of P-gp and CYP3A4,5,7. Pharmacokinetics change markedly in pregnancy due to slow motility, haemodynamics, cardiac output, etc. Incomplete protein digestion due to PPI treatment in pregnancy is a documented risk factor for predisposition to immune responses and asthma of the child (5.6% vs 3.7% in the untreated population). Copper absorption is higher in women aged 20-59 (71%) than in men of the same age (64%). This difference between the genders does not exist in the 60-83 age range.
Conclusions Inconsistent data arise from crossed effects of co-localised P-gp and CYP3A4,5,7. Thus, only studies involving drugs that are not transported by P-gp are appropriate in CYP3A4,5,7 studies and vice versa. Interaction tables are limited tools. They do not distinguish between special patient groups or age ranges and thus need improvement.

Competing interests None.

PHC007

GENETIC RISK FACTORS FOR TYPE 2 DIABETES MELLITUS AND RESPONSE TO SULFONYLUREA TREATMENT

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Background Following the identification of alleles that increase the risk of type 2 diabetes mellitus (T2DM), models have been developed to identify high-risk subjects. The authors hypothesise that these risk alleles affect the treatment response to oral antidiabetic drugs.
Purpose To investigate whether genetic risk factors for T2DM are associated with response to sulfonylurea (SU) treatment.
Materials and methods Patients starting treatment with SUs (tolbutamide, glibenclamide, glimepiride, gliclazide) with T2DM were recruited from 4 primary care centres. Data were retrieved from the electronic patient records. Primary end point was achieving stable SU dose defined as the 1st period of ≥270 consecutive days without dose adjustment, initiation of other SU, insulin or metformin. Secondary end points were stable dose of prescribed SU, and time to stable SU dose. 20 SNPs (Single nucleotide polymorphs)consistently associated with T2DM in 19 genes were selected: TCF7L2, KCNJ11, HHEX/IDE, SLC30A8, CDKAL1, CDKN2A/CDKN2B, IGF2BP2, KCNQ1, PPARG, FTO, NOTCH2, WFS1, JAZF1, THADA, CDC123/CAMK1D, TSPAN8/LGR5, ADAMTS9, HNF-1β, MTNR1B. A genetic risk score per patient was calculated based on the number of risk alleles. The χ^2-test was used to compare the primary end point between groups scoring differently for genetic risk.
Results The mean genetic risk score was 19.0 (95% CI 18.7-19.4) in our T2DM population (n=207). The genetic risk score was negatively associated with achievement of stable SU dose: 84.7% of the patients in the low risk group (n=59) achieved a stable dose versus 74.1% and 62.3% of the patients in the intermediate risk (n=81) and high risk group (n=62; p=0.004). No significant effect of the genetic risk score on the stable SU dose achieved during this study was found. Carriers of more than 17 T2DM risk alleles showed a marginally significant increased time to stable dose (hazard ratio: 0.81; 95% CI, 0.75-1.01, P=0.058).
Conclusion Patients with an increased genetic risk of T2DM are less responsive to SUs.

Competing interests None.

PHC008

COMPARATIVE BIOAVAILABILITY STUDY OF ORAL FORMULATIONS OF IMIPRAMINE TABLETS IN HEALTHY VOLUNTEERS

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Background Plasma levels of imipramine vary widely between individuals. They are probably due to genetic polymorphism and inter-individual differences in the metabolism of imipramine.
Purpose The objective of this study was to obtain pharmacokinetic data and compare the relative bioavailability of generic imipramine 25 and 50 mg tablets (Sobhan Pharmaceuticals, Iran) with the reference product (Tofranil, Ciba Geigy Pharmaceuticals, England).
Materials and methods Fourteen healthy male volunteers received a single oral dose (100 mg) of the generic and reference formulations following overnight fasting in a double blind, randomised, crossover study. Blood samples were collected and the plasma concentrations of imipramine were determined by using a rapid and selective reverse phase high-performance liquid chromatographic (HPLC) method. Plasma data was used to evaluate relative bioavailability and other pharmacokinetic parameters such as AUC, C_{max}, T_{max}, etc.
Results The mean peak plasma concentration (C_{max}) of imipramine for different tablet formulations, A (reference) and B (test), were 95.83±14.00 ng/ml (A_{50}), 144.33±30.17 ng/ml (A_{25}), 112.70±9.31 ng/ml (B_{50}) and 141.00±26.86 ng/ml (B_{25}) at 3.25±0.24 h (A_{50}), 2.83±0.24 h (A_{25}), 3.25±0.25 h (B_{50}) and 2.90±0.28 h (B_{25}) respectively. The mean $AUC_{0-\infty}$ of the different formulations, A and B, were 511.22±58.99 ng h ml^{-1} (A_{50}), 770.49±132.40 (A_{25}), 512.9±75.82 (B_{50}) and 821.06±159.00 (B_{25}).
Conclusions Statistical analysis showed no significant differences between the various pharmacokinetic parameters of the different formulations. The 90% CI for the mean ratios (the test against the reference formulation) of the C_{max}, AUC_{0-24} and $AUC_{0-\infty}$ were within the FDA requirements (80-125%). There was a significant difference between the dissolution rates of the different dosage forms ($p<0.001$). Results of this study showed that despite of a lower dissolution rate, the generic formulation of imipramine tablets are bioequivalent to the reference product with respect to the rate and extent of absorption.

Competing interests None.

PHC009 COST-UTILITY ANALYSIS FOR INDUCTION OF LABOUR WITH DINOPROSTONE

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Background Taylor and Armour assessed consumer preferences for two methods of induction of labour. This made it possible to conduct a cost-utility analysis; so far no study has been published including the quality of life parameter.
Purpose To investigate whether dinoprostone vaginal gel or slow release pessaries have a better incremental cost-utility ratio (ICUR) for induction of labour.
Materials and methods The authors used a simulated decision tree for cost-utility analysis, which has been described before; and took into account all end results and drug adverse reactions. For each of the options there were 108 arms in the model. The perspective was the hospital. Time horizon was less than a year so it was not necessary to discount cost or utilities. Population studied consisted of nulliparous pregnant women with Bishop score ≤4. Disutilities and the probabilities of events were extracted from reference studies. Cost (€ 2011) included the form of dinoprostone, treatment of ARD (Absolute Risk Difference, adverse drug reactions), inputs and personnel cost for administration, and DRG (diagnosis related group) for each event. The authors tested scenarios in univariate, bivariate and umbral sensitivity analysis. A cohort of 10000 for each alternative was tested in stochastic analysis.
Results In deterministic analysis, ICUR was –0.916 €/QALY. Total cost for dinoprostone gel was 3416.64€ and 8815.45 QALY; versus 2838.81€ and 9446.53 QALY for the pessary. Cost utility ratio for dinoprostone gel was 0.387 €/QALY and for the pessary 0.362 €/QALY. Univariate sensitivity analysis had the same result: the best option was dinoprostone pessaries. Umbral analysis showed cost of dinoprostone pessary over 877 €. Probabilistic sensitivity analysis, 2000 Monte Carlo simulations, showed an ICUR of -0.918 (SD: 0.004) €/QALY. For all simulations, dinoprostone pessaries dominated.
Conclusions For ripening of the cervix in nulliparous women, 10 mg of dinoprostone pessary is a better cost-utility option than two doses of 0.5 mg of dinoprostone endocervical gel,

Competing interests None.

PHC010 CHANGE IN RESPONSE TO CLOPIDOGREL AFTER SWITCHING FROM OMEPRAZOLE TO PANTOPRAZOLE

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Background Clopidogrel is an approved antiplatelet agent used in the treatment of atherothrombotic disease. Proton pump inhibitors (PPIs) are often prescribed in combination with clopidogrel. The use of omeprazole is associated with decreased antiplatelet activity and adverse clinical outcomes of clopidogrel because of cytochrome P450 (CYP) 2C19 interaction.
Purpose The authors investigated the effect of switching from omeprazole to pantoprazole on the clopidogrel response expressed as the platelet reactivity index (PRI) measured by vasodilator-stimulated phosphoprotein phosphorylation.
Materials and methods Clopidogrel users (N=25) switched from omeprazole to pantoprazole and were given pantoprazole 40 mg daily for this prospective, prepost cohort study. Data collected were age, clopidogrel indication, PRI results, comorbidities, comedication and CYP2C19 genotype (*2, *3 mutations). Primary end point was PRI of clopidogrel which was measured on the day before switching and after at least three weeks of pantoprazole use.
Results Clopidogrel users taking pantoprazole had a significantly lower mean PRI than during the omeprazole period (difference PRI 4.6%; 95% CI (CI95) 1.0-8.2%; P=0.015; figure 1). The mean PRI was also significantly higher in CYP2C19*2 allele carriers compared to the wildtype CYP2C19 group during omeprazole (difference PRI 16.7%; CI95 3.7-29.7%; P=0.014) and pantoprazole use (difference PRI 17.4%; CI95 2.4-32.5%; P=0.025).
Conclusions In this study switching from omeprazole to pantoprazole resulted in better clopidogrel response. Patients with variant CYP2C19 alleles had a significantly higher clopidogrel PRI when using omeprazole or pantoprazole compared to wildtype patients. If a PPI is indicated, clopidogrel users should use pantoprazole instead of omeprazole.

Competing interests None.

PHC011 DORIPENEM VERSUS IMIPENEM IN VENTILATOR-ASSOCIATED PNEUMONIA: A COST-EFFECTIVENESS ANALYSIS

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Background Ventilator-associated pneumonia (VAP) has high impact on costs and resources at hospitals worldwide. Correct antibiotic use could reduce mortality and decrease length of stays. Acquisition cost of doripenem is higher than imipenem but has better health outcomes.
Purpose A cost-effectiveness analysis of doripenem versus imipenem in empiric treatment of VAP. **Materials and methods** A simulated decision tree for cost-effectiveness analysis was performed It took into account rescue antibiotic therapy and all end results, include mortality and drug adverse reactions. The authors considered separately the main seven microorganisms causing VAP in our country and the rest were considered together. Population studied consisted of 10,000 simulated patients–in Intensive Care Unit with empirical treatment for VAP (64 outcomes each one). The analysis used the hospital perspective and a time horizon lesser than a year. Probabilities of event and VAP aetiology were extracted from clinical trials and database respectively. Costs (€ 2011) included the antibiotic options (Doribax® and Generic imipenem), rescue treatment, length of stay, administration supplies and personnel costs, and DRG (diagnosis-related groups) cost for each event. Different scenarios were tested in deterministic and stochastic sensibility analysis.
Results In deterministic analysis, ICER for 10,000 patient was –12,755.63 €/patient survived. Total cost were 8,693.03 €/patient and 9,063.59 €/patient for doripenem and imipenem respectively. Patient survived in each group were 9,711.14 for doripenem and 9,420.63 for imipenem. Univariable sensibility analysis had almost always the same result as the base model. However in the two scenarios it was up to threshold (20,000€): imipenem had similar length of stay than doripenem and when considered methicillin-sensitivity *Staphylococcus aureus* as single microorganism causing the infection. Probabilistic sensibility analysis, 2,000 Monte-Carlo simulations, showed an RCEI of – 391,762.10 (SD: 350,012.96) €/patient survived. Up than 80% simulations, imipenem was dominated.
Conclusions Doripenem is a better cost-effectiveness option than imipenem for VAP empirical treatment.

Competing interests None.

PHC012 ADJUST DOSES OF ANTIBIOTICS IN ACUTE RENAL FAILURE: THE ROLE OF HOSPITAL PHARMACIST

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Background Many clinicians, unassisted by reference books, are unable to make the required dose adjustment of antibiotics needed when a patient has renal insufficiency. Dosage adjustment to renal function is an important aspects of rational antibiotic prescription. The hospital pharmacist plays an important role in validating the clinical use of drugs.
Purpose Evaluation of the Pharmacy Department recommendations about antibiotic dose adjustment in patients with serum creatinine greater than 1.2 mg / dl.
Materials and methods From April 1 to September 15, 2011, hospital pharmacists reviewed all the prescriptions containing amoxicillin-clavulanate, levofloxacin, vancomycin, gentamycin, tobramycin and amikacin. Glomerular filtration rate (GFR) was estimated for patients with serum creatinine greater than 1.2 mg / dL, using the MDRD-4 formula (Modification of Diet in Renal Disease). The Pharmacy Department conducted dose adjustment if the glomerular filtration rate was less than 60 ml / min. Surgical day hospital patients were excluded because of the short length of stay.
Results During the study, Pharmacy Department looked through 1939 creatinine values. Antibiotic dose adjustment was required in 47 cases (2.4%). The number and percentage of patients with each one of the antibiotics evaluated was: amoxicillin-clavulanate 738 patients (38.1%), levofloxacin 507 patients (26.1%), vancomycin 279 patients (14.4%), gentamycin 248 patients (12.8%), tobramycin 140 patients (7.2%) and amikacin 27 patients (1.4%). The mean glomerular filtration rate observed was 32.3 ml/min. All the pharmacists recommendations were accepted.
Conclusions Pharmaceutical intervention had improved antibiotic pharmacotherapy of patients with acute renal failure.

Competing interests None.

PHC013 CLINICAL EFFICACY OF BIOSIMILAR FILGRASTIM IN FERNANDO FONSECA HOSPITAL, PORTUGAL

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Background Given that biosimilar products are not generic products, a switch from filgrastim to a biosimilar filgrastim could be considered a change in treatment. Due to the nature and variability of manufacturing processes for biopharmaceuticals, biosimilar filgrastim has the potential to result in differences between safety and efficacy when compared with its reference product. Phase III studies have demonstrated their bioequivalence in terms of clinical efficacy and safety profile. Clinical efficacy was demonstrated by comparing the two products in three ways: duration of severe neutropenia, in which severe neutropenia was defined as absolute neutrophil count (ANC) < 0.5 $x10^9$/l (DSN), time to ANC recovery (defined as ANC > 3 $x10^9$/l) (TAR), mean number of injections (MNI). Other end points were also used.
Purpose To evaluate biosimilar filgrastim efficacy in the Hospital Fernando Fonseca clinical setting during its first six months of use.
Materials and methods This was an observational, transversal, non-randomised, retrospective study. Two assessment periods were created: October 2010 – March 2011 (filgrastim data) and April 2011-September 2011 (biosimilar filgrastim data). The authors called each unit of data entered, which was the act of dispensing the product, an episode. Within each period, The authors identified four types of dispensing settings: non-oncology inpatient dispensing (NOI); oncology inpatient dispensing (OI); prophylactic outpatient oncology dispensing (POO); treatment outpatient oncology dispensing (TOO). End points for each of these settings were: NOI and OI: DSN and TAR; POO – percentage of treatments and mean number of injections; TOO – percentage re-treatments and MNI.

Results Filgrastim data In NOI there were 8 valid episodes with mean DSN =1.8 days and mean TAR=4.4 days; in OI there were 4 episodes with mean DSN =3 days and mean TAR=6 days; in TOO there were 80 episodes with no re-treatments (0%) and MNI=2.6; in POO there were 113 episodes in which 3 were treatments (2.7 %) and MNI= 3.6. Biosimilar filgrastim data In NOI there were 23 valid episodes which translates as mean DSN =2 days and mean TAR=4.4 days; in OI there were 9 episodes with a mean DSN =3.5 days and mean TAR=5.8 days; in TOO there were 53 episodes with 1 re-treatment (1.9%) and MNI=2.5; in POO there were 108 episodes in which 5 were treatments (4.6%) and MNI=3.9.
Conclusions According to our results there were no significant differences in terms of clinical efficacy between the two filgrastims. Moreover, there were no reports of differences in the safety profile. Given the fact that there was a tremendous reduction in hospital expenditure with biosimilar filgrastim this alternative provides a highly cost-effective option.

Competing interests None.

PHC014 EFFECTS OF CLINICAL DECISION SUPPORT ON THE TDM OF GENTAMICIN AND VANCOMYCIN IN NEWBORNS

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Background The dosing scheme for gentamicin and therapeutic drug monitoring (TDM) of gentamicin and vancomycin in newborns were evaluated as very heterogeneous in our institution. Once daily dosing (ODD) of gentamicin and trough levels measurement is recommended for most patients to ensure efficacy and reduce blood sampling. Guidelines were developed and implemented as a clinical decision support system.
Purpose To evaluate dosing practices, blood sampling and therapeutic levels.
Materials and methods Retrospective case– control study (01.2010-12.2010 and 04.2008 – 03.2009) in newborns (< 28 days of life) receiving either gentamicin or vancomycin before and after implementation of guidelines. Chart analysis criteria (mean +/-SD (Fisher's exact, Wilcoxon rank sum tests)): % of ODD gentamicin dosing schemes, % of peak levels, mean number of levels sampled, % of therapeutic levels (trough level: gentamicin ≤1 mg/l; vancomycin: 5–10 mg/l).
Results Gentamicin: 132 (cases) versus 102 (controls) totalling 134 patients were included (mean gestational age: 33.8±5.4 versus 34.6±5.2 weeks, p>0.05). After guidelines had been implemented, an ODD scheme was used (97.7 vs 61.6%, p<0.001). Peak level measurement and mean number of levels were significantly reduced (0.9 vs 17.2% resp. 0.8±1.0 vs 1.7±1.4, p<0.001). A significantly higher % of trough levels were ≤1 mg/l (68.5 vs 33.0%, p<0.001). Vancomycin: 38 versus 37 patients included (mean gestational age: 29.1±3.8 vs 30.8±4.1 weeks, p>0.05). After guidelines had been implemented, peak level measurements were significantly reduced (0 vs 25.2%, p<0.001) and a trend to more patients with <2 levels sampled was noted (52.6% vs 29.7%, p=0.061). No differences were observed in the mean number of levels or in the % of therapeutic levels (2.7±3.4 vs 2.6±2.2, resp. 45.7 vs 57.1%, p>0.05). Trough levels > 15 mg/l were significantly more frequent (21.0% vs 5.2%, p=0.004) possibly due to an error in the guidelines.
Conclusions Gentamicin dosing and TDM practices were improved after guidelines had been implemented. The effect of corrected guidelines on vancomycin TDM practice, the financial benefit of reduced blood sampling and clinical benefit should be evaluated in the future.

Competing interests None.

PHC015 THERAPEUTIC DRUG MONITORING OF CAFFEINE IN PRETERM NEONATES

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Background The methylxanthine caffeine reduces the frequency of apnoea in prematurity and the need for mechanical ventilation. The pharmacokinetics of caffeine in preterm infants shows inter- and intraindividual variability. Therefore therapeutic drug monitoring (TDM) of caffeine is used to optimise individual dosing to prevent toxicity and treatment failure. Because blood sampling in preterm neonates is an invasive procedure, the question arises whether routine drug monitoring is necessary.
Purpose To determine the value of TDM of caffeine in preterm neonates.
Materials and methods A retrospective study was conducted at Sint Franciscus Gasthuis, Rotterdam, The Netherlands. Preterm neonates treated with caffeine were identified in the period January 2008 to June 2010. Patients with at least one plasma caffeine level determination were included. The medical charts of preterm neonates with a caffeine level > 30 mg/ml were screened for adverse events.
Results A total of 601 caffeine plasma levels were measured in 149 patients. The average dose was an induction dose of 20 mg/kg caffeine citrate and a maintenance dosage of 10 mg/kg/day. Plasma caffeine levels were between 10 and 25 mg/l in 86.5%, < 5 mg/l in 6% and > 25 mg/l in 6.8%. 1.8% of the plasma levels were >30 mg/l (range 30.2–37.4 mg/ml). In one patient in the subgroup of 11 patients with a plasma level >30 mg/l tachycardia was recorded in the medical chart as an adverse event.
Conclusions The majority of preterm neonates attain plasma levels between 5 and 25 mg/l if a standard dose is used. In the subgroup of patients with levels > 30 mg/l only one adverse event was recorded. Based on these results routine TDM is not necessary in preterm neonates.

Competing interests None.

PHC016 THE IMPACT OF GASTROINTESTINAL TRACT RESECTION IN ORAL DRUG ABSORPTION

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Background Gastrointestinal tract resection (GIR) results in a range of physiological changes that affect the absorption of nutrients, water, and electrolytes. These changes may also affect the absorption of orally medication reducing its effect. The highly heterogeneous of GIR patients makes individual monitoring necessary to ensure an optimal clinical effect.
Purpose To determinate the incidence of patients with GIR and the proportion of patients with oral medication, which absorption may be affected after GIR.

Materials and methods Observational prospective study of patients undergoing gastrointestinal surgery in a third-level hospital. All patients undergoing general surgery during October 2010 were collected, selecting those with GIR. Demographics (age, sex), before and after admission pharmacological treatment (drug, dosage, drug formulation) and surgery information (site of resection) were collected. A bibliographic research was made to establish how GIR could affect the clinical efficacy of drugs.
Results Out of 249 patients undergoing surgery (106 women, 57,6 years (16-90)), 35 (14%) had GIR (mean age 58 years (24-84)). 15 (42,8%) had total/partial colectomy, 14 (40%) partial gastrectomy, 3 (8,6%) rectum resection, 2(5,7%) small bowel resection and 1 (2,9%) oesophagectomy. 7 (20%) patients were treated with oral medication which pharmacological effect may be reduced after GIR: 1(14.7%) had small bowel resection and received hydrochlorothiazide, 6(85.7%) had gastrectomy: one received Metformin which decreases B12 levels and 2 received enalapril and cotrimoxazole respectively which absorption may be decreased. Other 3 patients received drugs formulations which couldn't be absorbed because of the gastrectomy. To avoid a decrease in pharmacological effect patients medication was switched to a correct formulation or to an active substance with an appropriate absorption site.
Conclusions There were few patients treated with drugs affected by GIR, however, they should be closely monitored. There is limited and scarce updated literature regarding clinical outcome of drug efficacy in these patients. The authors should keep in mind those patients with GIR and poor pharmacological response.

Competing interests None.

PHC017 CLINICAL EVALUATION OF THE USE OF STATINS FOR DIABETIC DYSLIPIDAEMIA, ESPECIALLY IN THE SEOUL VETERANS HOSPITAL

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Background In diabetic patients, cardiovascular disease (CVD) is known to be the leading cause of mortality. Because dyslipidaemia can cause CVD, the management of dyslipidaemia is very important, for example by using statins to reduce low density lipoprotein cholesterol (LDL-C).
Purpose To evaluate the use of stains in the management of dyslipidaemia in diabetic patients, based on the updated National Cholesterol Education Program Adult Treatment Panel 3 (NCEP ATP3) guidelines and American Diabetes Association (ADA) guidelines.
Materials and methods The authors retrospectively evaluated the lipid profiles of diabetic outpatients (age >40), who started statins for the first time during the first half of 2010. The criteria of evaluation on starting statins were high LDL-C level (over 100 mg/dl) or 70 mg/dl with CVD: the goals of treatment were LDL-C <100 mg/dl or <70 mg/dl with CVD.
Results The patients totalled 69 (100% male), their mean age was 66±5. Among them, there were 56 patients with CVD (81%). 68(99%) had their cholesterol level measured before treating with statins. The cholesterol level was measured again on average 167 days after starting to take statins. The mean initial LDL-C level was 136±16 mg/dl. 99% (n=68) met the criteria for starting statins. After taking statins, their mean level fell to 90±29 mg/dl. So most patients missed the target and HDL-C levels showed an average reduction of 43±8 mg/dl. Only 26% (n=18) of patients reached the guideline goals. Atorvastatin was the most frequently used the statins (n=43, 43%). 13% (n=9) of patients changed to the other drugs, but no patients stopped taking their medicine because of complications.
Conclusions The authors found that 98% of our patients followed the guideline for initiation of statins. But only 26% of patients reached the NCEP ATP3's updated guidelines. So The authors recommend shortening the time to test to check LDL-C after starting the statins.

Competing interests None.

PHC018 USE OF ERYTHROPOIESIS-STIMULATING AGENTS IN PATIENTS WITH ANAEMIA OF CHRONIC KIDNEY DISEASE

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Background Anaemia is a common complication of chronic kidney disease (CKD), and its correction with erythropoiesis-stimulating agents (ESAs) is associated with improved patient outcomes and quality of life.
Purpose To evaluate the demographic and clinical characteristics of outpatients with CKD and anaemia, treated with epoetin alfa (EPO) or darbepoetin alfa (DARB). To compare the use of ESAs in predialysis patients.
Materials and methods Descriptive observational study, including patients with CKD and treated with ESAs, recorded in our pharmacy outpatient database and treated with ESAs, from March to July 2011. Data collected: age, gender, GRF, cause of CKD, ESA prescribed, dosage of ESA; during the period the latest data of haemoglobin (Hb), serum ferritin level and transferrin saturation were recorded. Use of ESAs was assessed in the group of predialysis patients (stage 3 and 4 of CKD) with Hb levels between 10 and 12 g/dl (the current FDA and EMA targets).
Results 476 patients were recorded (51.5% men, average age 69.4±15.6 years). 376 patients received EPO and 100 DARB. Hb levels: 10 to 12 g/dl (45.2%), < 10 g/dl (10.9%) and > 12 g/dl (43.9%). 18.4% of patients had Hb level >13 g/dl. CKD stages: stage 3 (30.6%), 4 (45.7%) and 5 (home dialysed patients) (19.2%). Subgroup of predialysis patients with Hb level between 10-12 g/dl: 155 patients (average age 70±16.4 years, 51% men), 77% with EPO and 23% DARB. Significant differences in EPO versus DARB patients were found in: average age (71.2 vs 65.0, p=0.04), men (55.5% vs 36.0%, p=0.04), the use of extended dosing (≥q 2 wk) (24.4% vs 66.7%, p<0.001). Mean weekly doses in each: 4986 IU (EPO) versus 25.88 mcg (DARB).
Conclusions A high number of patients were above the safe limit (12 g/dl); action must be taken to improve the quality of pharmacotherapy. The dose ratio within EPO and DARB was 192:1.

Competing interests None.

PHC019 DELAYED INTRODUCTION AT REDUCED DOSES OF PROLONGED-RELEASE TACROLIMUS IN KIDNEY TRANSPLANTS TREATED WITH QUADRUPLE IMMUNOSUPRESSIVE THERAPY

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Background The transplantation of organs from expanded criteria donors (ECDs) increases the risk of delayed graft function. In our hospital, when such kidneys are transplanted quadruple treatment is used: basiliximab, mycophenolate, corticosteroids and tacrolimus in deferred introduction at half dose (0.1 mg/kg/day).
Purpose To evaluate the progress of patients who have followed this immunosuppression regimen.
Materials and methods The authors assessed all kidney transplants from ECDs treated with quadruple immunosuppressive therapy from March 2009 to March 2010. The following data was obtained: donor and recipient age, incidence of delayed graft function and acute rejection, creatinine and glomerular filtration rate (GFR) at discharge and length of hospital stay. About the treatment with prolonged-release tacrolimus (PRT) The authors obtained: day of treatment initiation post-transplant, initial dose, dose at discharge and plasma levels. The PRT dose was adjusted to achieve target levels of 8 ng/ml.
Results The authors assessed 40 kidney transplants from ECD: mean age of donors was 60 +/- 13 years, recipients mean age was 58 +/- 11 years, 47% of recipients were male. PRT began on post-transplant day +4 +/- 1.5; the initial dose was 0.11 +/- 0.03 mg/kg/day and dose at discharge 0.15 +/- 0.08 mg/kg/day. Tacrolimus levels were: in the first determination 6.9 +/-4.5 ng/ml, at 14 days 7.7 +/- 2.3 ng/ml and at discharge 8.0 +/- 2.3 ng/ml. In 26 patients (65%) the initial dose of PRT was increased. 13 patients (32%) had delayed graft function, one episode of acute rejection presented and the average hospital stay was 22 +/- 9 days. Creatinine at discharge was 2.15 +/- 0.93 mg/dl, creatinine clearance (Cockroft-Gault 43.4 +/- 17 ml/min) and GFR (MDRD 33.9 ml/min/1.73m^2, 3 patients with GFR> 60).
Conclusions With the delayed introduction at half-dose of PRT it was possible to achieve the target plasma levels, although moderate increases of doses were frequent. The clinical results were favourable, so it could be a valid strategy to avoid the nephrotoxicity of calcineurin inhibitors. These are introduced later and at lower doses due to the coverage provided by the immunosuppression induced with basiliximab (approximate duration 4-6 weeks).

Competing interests None.

PHC020 ROLE OF BAYESIAN FORECASTING OF PHARMACOKINETIC PARAMETERS IN OLDER PATIENTS FOR GENTAMICIN

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Background Formulas for forecasting gentamicin concentrations have been proposed, such as the Sawchuk-Zaske method. These formulas use weight and creatinine clearance to determine the volume of distribution and clearance.
Purpose The aim of this study was to compare the power of this formula to a Bayesian method of forecasting pharmacokinetic parameters.
Materials and methods The files of 20 patients treated with gentamicin were used. The Sawchuk-Zaske formula was used to determine the volume of distribution and clearance in these patients. These parameters were introduced into a unicompartmental pharmacokinetic model to forecast the concentrations in each patient. Software for Bayesian forecasting of individual pharmacokinetic parameters (USC*Pack) was used to predict serum concentrations. Forecasts from the two methods were compared to concentrations actually measured in each patient.
Results There was a men/women ratio of 14/6, and patients included were a mean 84±5.9 years old, weighed 68.3 ±18.4 kg with a creatininemia of 95.2 ±3.2 µmol/l. A total of 102 serum concentrations were estimated or a mean 5.1±2.9 concentrations per patient. The Sawchuk-Zaske formula predicted concentrations with a bias of -1.31 mg/l, and a precision of 9.37 mg^2/l^2. Prediction after individual estimation of pharmacokinetic parameters included a bias of -0.27 mg/l ($p<4.10^{-6}$) and a precision of 2.28 mg^2/l^2 ($p<4.10^{-6}$). Considering only the first measured concentration (early treatment), the Sawchuk-Zaske formula presents a systematic error of -1.24 mg/l versus -0.08 mg/l for the Bayesian estimation method (p=0.001).The integration of additional data made during follow-up treatment can increase the precision of the method.
Conclusions The formula tested seems to forecast gentamicin concentrations less accurately than a Bayesian method of individual estimation of pharmacokinetic parameters, which was significantly more accurate. The formulas do not incorporate information obtained from patients after the first results. The limitations of the Sawchuk-Zaske formula may be due to an underestimation of non-renal gentamicin elimination. Bayesian approaches seem best suited to support older patients.

Competing interests None.

PHC021 COMPARISON OF MDRD, CKD-EPI AND OTHER FORMULA-BASED RENAL FUNCTION ESTIMATES FOR CHEMOTHERAPY DOSE ADJUSTMENT IN CANCER PATIENTS

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Background Clinicians frequently require an estimate of renal function when determining the dosage of drugs with a narrow therapeutic index, in particular, cytotoxic chemotherapeutic agents. In clinical practice indirect methods, such as formula-based equations, are used to approximate GFR. The MDRD and Cockcroft and Gault (CG) formulae are the most frequently used. A new equation, the CKD-EPI formula, has recently been published.
Purpose To assess the accuracy and impact of formula-based estimates of renal function on dosage selection of renally cleared chemotherapy agents in adult oncology patients.
Materials and methods GFR was determined using technetium-99m diethyl triamine penta-acetic acid (Tc99mDTPA) clearance, serum creatinine (Jaffe method) was measured and renal function estimates calculated using MDRD, Cockcroft and Gault (CG), Wright, Martin, and CKD-EPI formulae (MDRD and CKD-EPI adjusted for patients BSA). The Cancer Institute NSW, 'Cancer treatments online' was used to identify chemotherapy agents requiring dosage adjustment in renal impairment. The accuracy of the formulae were compared to measured GFR, concordance for dosage adjustment were compared and also stratified for gender, age and body mass index (BMI).
Results 311 patients were included (64% male, mean age 63 yrs). The mean measured GFR was 84 mL/min (SD 31, range 16-205 mL/min). Overall the least biased estimates of renal function were the MDRD, Wright and Martin formulae (<+/-5%); the bias of the CKD-EPI and CG formulae were -6.5% and -10.4% respectively. The overall concordance for

chemotherapy dosing, based on 'break points' of <30 ml/min and 30-50 ml/min, were 92% for MDRD, Wright, Martin, and CKD-EPI, and 88% for CG (p=0.06).
Conclusions All renal function estimates provide similarly accurate estimates for chemotherapy dosage adjustment in renally impaired patients. However, clinicians should be aware of the limitations of any bedside approximation.

Competing interests None.

PHC022 TDM AND STABILISATION OF PAEDIATRIC PATIENTS IN LIVER AND KIDNEY TRANSPLANTATION

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Background Immunosuppressants must be guided by therapeutic drug monitoring (TDM) to prevent rejection. Understanding and prevention of blood level variability is essential.
Purpose To evaluate TDM practice and factors associated with stabilisation.
Materials and methods Retrospective study of paediatric patients with liver (LT; since 2007) or kidney transplant (KT; since 2002) in two university hospitals. First-month % of tacrolimus (FK) and ciclosporin (CyA) therapeutic trough levels (FK: LT 10-15 ng/mL; KT 8-12 ng/mL / CyA KT 250-350 mcg/L). 30-day survival analysis (median survival in days (d) (CI 95%)) of stabilisation (discharge from intensive care or hospital / 3 consecutive therapeutic levels) and univariate analysis of associated factors in LT with stabilisation (log-rank test).
Results 46 patients included: 27 LT, 19 KT; mean age: 2.8 ±4.0 vs. 11.9 ±6.2 years. 100% of LT patients received FK; KT: 53% FK, 47% CyA. Only 32% (LT) and 41% (KT) of FK levels, and 22% (KT) of CyA levels were in the range. Discharge from intensive care and hospital occurred significantly later for LT (8d (6;12) versus 3 d (3;5) / 28 d (25; not available) versus 11.5 d (10;15) (p<0.001)), but stabilisation of levels earlier (18 d (15;27) vs not reached, p=0.04). Compared to FK levels, CyA levels were not stabilised in KT patients after one month (not reached vs 20.5 d (10; not available), p=0.02), but no difference was seen on discharge. Living donor transplant was significantly associated with an earlier discharge from intensive care (p=0.02), age <30 years and transplant weight ≥ 291 g with a trend to earlier discharge from hospital (p=0.048; p=0.06). Metabolic disease and weight-ratio transplant/patient ≥0.03 were associated with an earlier stabilisation of FK levels (p=0.01; p=0.05).
Conclusions Variability of immunosuppressant trough levels was high in the first month after liver transplantation and in kidney patients receiving ciclosporin. Factors associated with earlier stabilisation have to be confirmed in a larger study.

Competing interests None.

PHC023 ARE THE OFFICIAL RECOMMENDATIONS FOR AMIKACINE SERUM LEVELS SUITABLE FOR OLDER PATIENTS?

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Background The aminoglycosides represent the mainstay in the treatment of serious Gram-negative infections. Their use is difficult in older patients because of high potential toxicity and the large observed inter-individual variability. In recent years, higher peak serum concentrations have been suggested in official recommendations for amikacin treatment (peak level: 60 to 80 µg/ml, trough level: < 2.5 µg/ml). The applicability of these target concentrations is questionable in geriatric patients.
Purpose Our objective was to check the applicability of those target levels in older patients.
Materials and methods A retrospective study was undertaken with the medical files of all patients who were treated with amikacin during the last 3 years. Anthropometric data (age, weight, creatininemia) and history of amikacin administrations and serum levels were used to estimate individual pharmacokinetic parameters with a Bayesian software program (USC*Pack). The dosage regimen needed to reach a peak level of 60 µg/ml and a trough of 2.5 µg/ml was calculated. When a dose interval of more than 48 h was needed, a complementary calculation was done to estimate trough concentration after a week of treatment with infusions every two days.
Results Twenty-eight patients were considered, with a male/female ratio of 13/15, age 83±8 years, weight 64.2±3.7 kg and estimated creatinine clearance 55±21 ml/min. Mean estimated pharmacokinetic parameters were respectively: volume of distribution of 0.31±0.11 l/kg and amikacin clearance of 45.2±36.1 ml/min. Ideal dose interval was above 48 h for 12 patients (43%) with a mean dose interval of 62.5 h. For these patients, trough serum concentration level after a week of treatment, with infusions every two days, was 7.72±5.88 µg/ml.
Conclusions This study shows that for more than 40% of older patients, the target peak cannot be reached without potentially toxic trough levels even after 48 h, or without expanding the dose interval above. Such a wide dose interval can risk inefficacy for serious infections.
For a large number of older patients, actual amikacin target serum concentrations should be used with caution to avoid potential toxicity.

Competing interests None.

PHC024 ANALYSIS OF THE THERAPEUTIC POSITIONING OF BIOLOGICAL DRUGS IN THE TREATMENT ALGORITHM FOR RHEUMATIC DISEASES

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Background The current treatment for rheumatic diseases (RD) includes biological drugs such as infliximab (IFX), etanercept (ETT), adalimumab (ADM), golimumab (GLM) rituximab (RTX), abatacept (ABT) and tocilizumab (TCZ). The treatment algorithm (clinical guidelines) includes IFX, ADM, ETT and GLM as first line, RTX as second line and ABT and TCZ as third line of choice.
Purpose The aim of this study was to describe the pattern of RD and assess current and past biological drug treatments to evaluate how they match with the expected algorithm, in a reference third level hospital.
Materials and methods Cross sectional study (June 2011), that included a sample of 166 patients (30% of the complete

population), with 257 drug-patient records, treated with biological drugs and being monitored in our centre. The RDs included psoriatic arthritis (PA), rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic spondyloarthropathy (PS), Behçe syndrome (BS) and others.
Results The RD pattern was as follows: 52.4% of the population assessed had RA, 20.5% AS, 17.5% PA, 4.8% PS, 1.8% BS and 3% another RD. Currently, 30.1% of the population are being treated with IFX, 20.5% with ADM, 37.3% with ETT, 1.2% with GLM, 4.2% with RTX, 3% with ABT and 3.6% with TCZ. 4.3% of treatments were off-label indications. 98.2% of patients started treatment with a first-line biological drug. 99.7% of first-line biological drug treatments (IFX, ETT, ADM and GLM) complied with the treatment algorithm, 100% of treatments with RTX and 76.9% of third line treatments (ABT and TCZ) started before exhausting other therapeutic options. 9.3% of treatments did not comply with the treatment algorithm.
Conclusions The therapeutic positioning of biological drugs into the treatment algorithm is correct in 90.7% of the treatments and 95.7% of treatments were used in approved indications. 98.2% of patients started treatment with a first-line biological drug.

Competing interests None.

PHC025 REASONS FOR CHANGING TREATMENT IN MULTIPLE SCLEROSIS

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Background Multiple sclerosis (MS) is a disabling disease that affects the central nervous system.
Switching of first-line drugs (interferon β, glatiramer acetate) or initiation of a second-line treatment (natalizumab, mitoxantrone, cyclophosphamide, rituximab) should be considered if suboptimal response is observed with first-line drugs.
Purpose To analyse the treatment pattern and the main reasons for changing MS treatment.
Materials and methods Cross-sectional, retrospective descriptive study in MS patients, in a reference unit, in a tertiary hospital. A sample of 100 patients was analysed (10% of complete MS population) who picked up medicines from the outpatient pharmacy unit, following a database that included demographic and clinical information.
Results 30% of patients had switched treatment once and 7% at least twice (23.3% of the MS population that had changed previously). The main reasons for changing treatment, from initial to second and second to third treatment were: lack of efficacy: 65.4% and 20% respectively; drug withdrawal: 15.4% and 20%; pregnancy: 15.4% and 0%; drug intolerance: 3.8% and 0%; adverse reaction: 0% and 20%; maximum tolerated dose: 0% and 10%. By drugs, main reasons for changing MS treatment, from the initial to second treatment were: Avonex: lack of efficacy (75%) and pregnancy (25%); Betaferon: lack of efficacy (20%) and drug withdrawal (80%); Rebif 22 mcg lack of efficacy (75%) and pregnancy (25%); Rebif 44 mcg: lack of efficacy (100%); Copaxone: lack of efficacy (50%), intolerance (25%) and pregnancy (25%). The treatment mean time was 51±43 months prior to the first change, which decreased to 23.5±21.9 months for the second change of treatment. The mean Expanded Disability Status Scale (EDSS) score increased from 2.5±1.4 at the beginning to 3.9±1.9 in second-line treatment and 5.7±1.8 in third-line treatment.
Conclusions 30% of patients with MS had changed treatment. The main reason was progression of the disease.

Competing interests None.

PHC026 PATTERN OF ANTIBIOTIC USE IN A TERTIARY HOSPITAL IN NIGERIA

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Background Antibiotics are among the most commonly prescribed drugs in paediatrics. Due to an overall rise in healthcare costs, lack of uniformity in drug prescribing despite standard treatment guidelines and the emergence of antibiotic resistance, monitoring and control of antibiotic use is of growing concern and strict antibiotic policies are warranted.
Purpose To access the prescribing pattern of antibiotic use in the treatment of prevalent paediatric diseases at Federal Medical Centre Owerri, to compare this pattern to the standard treatment guidelines and to estimate the cost implications of this pattern on the hospital drug budget.
Materials and methods A retrospective study covering January 2002 to December 2006 was done. Medical records of paediatric inpatients of age 0-12 years were reviewed. Total number of cases was 5968.
Results The average number of medicines per patient ranged from 5.17 in 2002 to 7.9 in 2006 and percentage of antibiotics per prescription also ranged from 63.3 in 2002 to 86.6 in 2006 The most common disease in this hospital was malaria followed by bronchopneumonia. Out of the 5968 children clinically diagnosed with these diseases and treated with antibiotics, specimens were taken for culture in only 1648 cases (33%) to identify pathogenic organisms. Children 1-5 years received antibiotics more frequently than all the other groups. 80-86% of total antibiotics were administered parenterally and 80-85.5% of drugs were prescribed from the hospital formulary. Cephalosporins were the most frequently prescribed antibiotic followed by penicillin and then aminoglycosides. 21-26% of the hospital budget was spent on antibiotics. High-cost broad-spectrum antibiotics were commonly used.
Conclusions This study revealed significant flaws in the prescribing pattern of antibiotics in the paediatric department of this hospital. It is pertinent to note that because children are at greater risk of receiving multiple courses of antibiotics and in view of the risk of antibiotic resistance, strategies to control antibiotic resistance should focus on this patient population.

Competing interests None.

PHC027 EVALUATION OF THE REASONS FOR SWITCHING BIOLOGICAL DRUG TREATMENT IN RHEUMATIC DISEASES

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Background The current treatment for rheumatic disease (RD) includes biological drugs such as infliximab (IFX), etanercept (ETT), adalimumab (ADM), golimumab (GLM) rituximab (RTX), abatacept (ABT) and tocilizumab (TCZ). The

treatment algorithm (clinical guidelines) includes IFX, ADM, ETT and GLM as first line, RTX as second line and ABT and TCZ as third line of choice.

Purpose The aim of this study was to assess the incidence of, and evaluate the reasons for, switching biological drugs in a RD population, as well as to analyse the reasons for each biological drug separately.

Materials and methods Cross-sectional study (June 2011), which took a sample of 166 patients (30% of the complete population) with 257 drug-patient records, with RDs such as psoriatic arthritis (PA), rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic spondyloarthropathy (PS), Behçe syndrome (BS) and others, treated with biological drugs and who were being followed up in our centre. The indication (confirmed RD), clinical records of treatment with biological drugs and reasons for switching, were collected and analysed.

Results 35% (97/257) of biological drug treatments evaluated were switched for all reasons combined. 68.1% of switching of the biological drug was due to lack of efficacy, 29.7% was due to adverse effects, while a 1.1% was due to remission and 1.1% was due to unknown reasons. The table shows the reasons for switch in %, analysing biological drugs separately:

Conclusions The main reason for switching biological drugs was the lack of efficacy (68.1%) while the appearance of adverse effects represents 29.7%. The pattern for each biological drug shows than more than 50% of changes were due to lack of efficacy in treatments with IFX, ADM, ETT and RTX.

Competing interests None.

PHC028 INTRAINDIVIDUAL VARIABILITY IN TACROLIMUS PHARMACOKINETICS AND ITS RELATIONSHIP WITH CYP3A5*3 POLYMORPHISM IN RENAL TRANSPLANT RECIPIENTS: LOOKING FOR NEW MONITORING INTERVALS

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Background Tacrolimus, the basic component of immunosuppressive therapy to prevent allograft rejection after kidney transplantation, is characterised by great inter/intraindividual variability in its pharmacokinetics, partly explained by polymorphisms in metabolising enzymes.

Purpose To determine the relationship between CYP3A5*3 polymorphism and intraindividual variability in tacrolimus pharmacokinetics to assess monitoring trends.

Materials and methods Retrospective study in renal transplant recipients treated with tacrolimus, mycophenolate and methylprednisolone (May/2003-May/2011). Daily dose (DD), blood concentration (Cb, IMx and Architect immunoassay methods), monitoring date and CYP3A5*3 polymorphism (Real-Time PCR method) were recorded. To assess intraindividual variability, coefficient of variation of Cb/DD ratio ($CV_{Cp/DD}$) and % variation per day between consecutive Cb/DD ($V_{Cp/DD}$) were calculated. Stability was defined as the period in which the same DD was maintained for at least 3 months with Cb on target (5-10 ng/mL) and a $V_{Cp/DD}$<1%/day. Three post-transplant periods were studied (immediate (day 0-42), prestability and stability). Mean differences between groups were analysed by SPSS 18.0 (statistical significance if $p_{t\text{-}Student}$<0.05).

Results 38 patients were included, 95% (31 homozygous (HM), 5 heterozygous (HT)) achieved stability at follow-up (839±141 days). Times to stability were 40% higher in homozygous (HM: 367±65 vs HT: 258±117 days; p=0.067) and their variability was 25% greater in prestability time ($CV_{Cp/DD}$ (%): HM: 33.40±4.88 vs HT: 26.73±3.47; p<0.05). No differences were observed in $CV_{Cp/DD}$ in the immediate post-transplant period (HM: 30.28±3.51 vs HT: 32.52±8.92) or stability (HM: 19.88±3.42 vs HT: 19.28±10.3) or $V_{Cp/DD}$ in any period (global values (%/day): 19.28±10.3, 1.04±0.16, 0.36±0.09). Once stability was achieved, time with the same DD and Cb on target was similar in both groups (HM: 160±33 vs HT: 136±83 days) and 200-300% higher than between consecutive determinations (57±6 vs 64±17 days).

Conclusions CYP3A5*3 polymorphism increases, but does not fully explain, intraindividual variability in tacrolimus pharmacokinetics. Our data suggest that monitoring of patients can be extended to every 4-5 months from the 8th month (heterozygous) or the year post-transplant (homozygous) without compromising safety.

Competing interests None.

PHC029 SAFETY OF EXPANDED THERAPEUTIC RANGE OF VALPROIC ACID

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Background Therapeutic drug monitoring (TDM) of total valproic acid (TVPA) concentrations is challenging because of its variable pharmacokinetics. In our department The authors normalise the total VPA (NTVPA) according to serum albumin (Hermida *et al*). The accepted serum concentration range is 50-150 mg/L. Higher concentrations could be useful in complicated seizures such as status epilepticus (SE).

Purpose The aim of this study was to evaluate the safety of high NTVPA levels.

Materials and methods Retrospective observational study in patients treated with VPA included in TDM program with a minimum of two NTVPA levels over 150 mg/L separated by at least 7 days.

Parameters recorded: sex, age, ward admitted to, indication for VPA, dose administered, concomitant antiepileptic therapy, TVPA, albumin, efficacy variables (seizures, electroencephalogram (EEG)) and adverse effects.

Results 24 patients were included (13 men) with 140 TVPA analyses (5.8 analyses/patient (2-13)). Mean age was 61.9 years (29-86). 16 patients were admitted to intensive care units. Patients were followed for a mean of 31.4 days (7-156). Mean VPA dose was 27.6 mg/kg/day. 14 (58.3%) were treated for SE. 6 patients died. Mean TVPA and NTVPA (mg/L) were 65.6 (31.6-140) and 214.7 (151-377) respectively and a mean albuminaemia was 25 g/L. Median NTVPA was 203.5 mg/L and the 75th percentile was 245.2 mg/L.

Most of the patients (n=13) received combined treatment with one or more of the following antiepileptic drugs: phenytoin, levetiracetam, oxcarbazepine, carbamazepine, clonazepam, phenobarbital and lacosamide.

2 patients had clinical seizures despite high levels of NTVPA, both confirmed by EEG. Side effects due to VPA were: diarrhoea (n=1) and sedation (n=2). However, 15 patients were pharmacologically sedated. 7 patients had alanine-aminotransferase levels over twofold the normal range (>1.4 ukat/L) and 12 patients had platelet count <135x10E9/L.

Conclusions Expanded therapeutic range NTVPA levels may be a safe option to treat complicated seizures. In the light of our results, The authors suggest 245 mg/L as an upper level of the therapeutic range of NTVPA.

Competing interests None.

PHC030 ASSESSMENT OF PHARMACEUTICAL INTERVENTIONS IN A CLINICAL PHARMACOKINETICS UNIT

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Background Pharmaceutical interventions are a method of ensuring the efficacy and safety of treatments.
Purpose To classify pharmaceutical interventions made by a pharmacy resident in the pharmacokinetics unit of a tertiary hospital and evaluation of acceptance by the clinician.
Materials and methods For one month, The authors reviewed electronic prescriptions of drugs with a narrow therapeutic range in medical and intensive care wards. Pharmacokinetics studies were performed using the PKS software package and reports were issued to the patient's physician. Pharmaceutical interventions were classified according to the method described by Overhage *et al*, which measures the gravity of medication errors and the value of clinical interventions made by the pharmacist. Drug-related problems were classified according to the Granada Consensus.
Results Thirty-two patients (84% of those reviewed) were evaluated. The drugs prescribed were digoxin (55%), valproic acid (20%), vancomycin (11%), phenytoin (7%) and amikacin (7%). The authors made 29 pharmaceutical interventions (the remaining patients had drug levels within the therapeutic range), with a degree of acceptance of 93%. Interventions were classified as follows: 'dosing error (DE) consisting of a very low dose of a drug that is not potentially life-saving' (10/29); 'DE consisting of a very low dose of a potentially life-saving drug' (10/29); 'DE resulting in potentially toxic concentrations' (3/29); 'inappropriate dosing interval' (3/29); 'clinically significant interaction requiring follow-up' (2/29); 'adverse events related to precautions or contraindications' (1/29). The classification of interventions according to clinical importance were life-threatening (34%), serious (14%), and significant (52%). Drug-related problems were classified as quantitatively ineffective (20/29), qualitatively ineffective (2/29); quantitatively unsafe (4/29), qualitatively unsafe (3/29).
Conclusions Most of the patients required a pharmaceutical intervention to adjust their treatment. All interventions made had a relevant clinical impact, as they involved high-risk drugs with a narrow therapeutic range. The most common drug-related problem was quantitative inefficacy due to underdosing.

Competing interests None.

PHC031 A SURVEY OF DOSE TAILORING METHODS FOLLOWING THERAPEUTIC DRUG MONITORING OF AMINOGLYCOSIDE AND GLYCOPEPTIDES IN THE UNITED KINGDOM

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Background The use of aminoglycoside and glycopeptide antibiotics is increasing in the UK, while cephalosporin and fluoroquinolone use is decreasing. This is in response to *Clostridium difficile* infection rates, and the routine screening for methicillin-resistant *Staphylococcus aureus* (MRSA). Dose optimisation has been shown to decrease toxicity and improve outcome.
Purpose This survey aimed to quantify the methodology to adjust narrow therapeutic spectrum antibiotics where levels are routinely done.
Materials and methods A survey was design using SurveyMonkey software. Questions were asked if and how aminoglycoside and glycopeptide doses were tailored following serum levels monitoring in adults, children and neonates. This was circulated to the members of the UKCPA Infection Management Group with a link to the web-based survey. The software analyses the submitted data.
Results There were responses from 48 different hospitals: England =41 (25% of Acute Trusts), Scotland =4, Ireland =2, Wales =1. Written guidance (or nomogram) is most commonly used for gentamicin and vancomycin, whereas dose adjustment calculation by hand was most common for tobramycin, amikacin and teicoplanin. A software program was used rarely: gentamicin=6 hospitals, tobramycin =3, amikacin =1, vancomycin =3 and teicoplanin =1. 4 centres used a program developed inhouse and two used different commercial programmes: OPT or RxKinetics.
Conclusions Within the UK, most aminoglycoside and glycopeptide dose adjustment is done using nomograms or by hand. There is very little use of commercial or inhouse software.

Competing interests None.

PHC031 table 1

What do you use to tailor the dosing

Answer Options	No tailoring	Written guidance (or nomogram)	By hand	Software	Response Count (more than 1 allowed)
Gentamicin	1	30	17	6	48
Tobramycin	4	14	15	5	36
Amikacin	4	10	22	3	37
Vancomycin	0	30	20	3	47
Teicoplanin	10	9	15	1	34

PHC032 ANTI-INFLAMMATORY EFFECTS OF LONG-TERM LOW-DOSE CLARITHROMYCIN ADMINISTRATION IN PATIENTS WITH NASAL POLYPOSIS

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Background In the recently performed studies, various investigators have shown considerable interest in the immunomodulatory and anti-inflammatory action of the macrolide

antibiotics for long-term low-dose treatment of chronic rhinosinusitis and nasal polyposis. Previous investigations regarding the results of bacterial cultures (*Streptococcus pneumoniae, Haemophillus influenzae*) suggest that the risk of selecting resistant bacteria is low. In a small number of patients the cultures were positive, but this was not always linked with an increase in symptoms, which could be due to the fact that in addition to the direct bacteriostatic effects of macrolides, they may in some cases reduce the virulence of bacteria without eradicating them.

Purpose The present study was designed to investigate the anti-inflammatory and clinical effects of long-term low-dose clarithromycin (CAM) treatment of non-atopic and atopic patients with nasal polyposis.

Materials and methods Forty (n=40) nasal polyp patients, 22 non-allergic and 18 allergic were administered CAM 500 mg/day single oral dose for eight weeks. Nasal secretion samples were collected from nasal cavities of all 40 subjects before and after CAM treatment by absorption technique. The authors measured the levels of myeloperoxidase (MPO), a neutrophil activation marker, before and after therapy, using an enzyme-linked immunosolvent assay (ELISA) kit. Eosinophil cationic protein (ECP), an eosinophil activation marker, and tryptase (TRY), a mastocyte activation marker were measured in nasal secretions by fluoroenzyme assay. The authors also scored each of the forty patients before and after therapy according to nasal symptom score and endoscopic score.

Results Following treatment, The authors found significantly reduced levels of MPO in nasal secretions in both non-atopic and atopic patients ($p<0.05$). Treatment by CAM decreased the levels of ECP only in non-atopic nasal polyp patients ($p<0.05$). Macrolide therapy decreased the size of nasal polyps in 45.45% non-allergic and in 50% allergic patients. After CAM administration, The authors found 67.83% patients in non-atopic group and 55.55% patients in atopic group with improved nasal symptoms.

Conclusions Long-term low-dose treatment by CAM was effective in the management of nasal polyposis. Our results showed that macrolide administration have different anti-inflammatory and similar clinical effects in non-allergic and allergic subjects.

Competing interests None.

PHC033 MONITORING OF METHOTREXATE LEVELS FOLLOWING GLUCARPIDASE RESCUE TREATMENT REQUIRES DETECTION BY MASS SPECTROMETRY SINCE IMMUNOASSAY IS NOT APPLICABLE

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Background Patients treated with high-dose methotrexate may experience severe toxicity when excretion is delayed if acute renal dysfunction develops. Potentially lethal toxicity may be limited by hydration, alkalisation and administration of folinic acid as rescue treatment. In addition, the use of glucarpidase (Voraxaze) may be considered, which is an enzyme capable of degrading methotrexate into glutamate and the metabolite 2,4-diamino-N10-methylpteroic acid (DAMPA) with very low activity. Glucarpidase is unlicensed in the EU and US, partly due to concerns about pharmaceutical quality, and the interaction with folinic acid, but recent data support its efficacy in reducing methotrexate-induced toxicity. However, limited information is available to support the best dose of glucarpidase if combined with folinic acid.

Purpose In this study, The authors aimed to monitor the effect of glucarpidase administration on methotrexate levels and toxicity in two children with acute renal dysfunction following high-dose methotrexate treatment.

Materials and methods Plasma concentrations of methotrexate were analysed using fluorescence polarisation immunoassay (FPIA) and using two validated matrix-assisted laser desorption ionisation and liquid chromatography mass spectrometry (MALDI/LC-MS) assays.

Results Using FPIA to measure, methotrexate concentrations appeared to remain elevated after glucarpidase administration, and slowly declined thereafter, suggesting a second dose of glucarpidase and high doses of folinic acid. In contrast, MS measurements showed very rapid and nearly complete methotrexate clearance, followed by a minor increase in methotrexate levels, most likely resulting from redistribution. Furthermore, in both children renal function started to recover 24-48 h later, and additional toxicity was minimal.

Conclusions After glucarpidase has been administered, FPIA analysis cannot be used to monitor methotrexate levels, most likely due to cross-reactivity of the metabolite DAMPA. Instead, MS can detect the remaining methotrexate accurately, and confirms nearly complete methotrexate degradation. MS monitoring may result in the prevention of further glucarpidase administration or dialysis, limit the administration of folinic acid, and lead to more rapid discharge from hospital.

Competing interests None.

PHC034 ANALYSIS OF THE INCIDENCE OF POTENTIAL DRUG INTERACTIONS IN CARDIOLOGY AND INTERNAL HOSPITALISED PATIENTS

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Background Prescriptions with more than one drug increase the risk of drug-drug interactions, treatment failure, large pharmacological effect and adverse events.

Purpose The objectives of this study were to estimate the frequency of potential drug-drug interactions in prescriptions for hospitalised patients, and to identify the factors associated with these prescriptions.

Materials and methods The work was in part sited in the Specialty Hospital in Rybnik (Poland) with the pharmacotherapy team. One of the tasks of the Team was to assess on the basis of documentation, the frequency of random combinations of drugs prescribed and the risk of adverse interactions. Analyses of prescriptions for medicines were made on randomly selected days. The analysis included 276 patients on the two internal medicine wards and the cardiology ward of the hospital. Age, gender and administration of the drugs were noted. The potential D-DIs were identified and recorded.

Results Generally 73.5% of the patients received drugs identified as potentially causing D-DIs (50.3% of the patients were women, 49.7% were men). 66.5% of patients older than 65 years of age received a prescription including one potential D-DI. The average number of medicines taken by a cardiology patient was 8, the average number of medicines taken by an

internal patient was 5. The most frequently prescribed pairs of drugs that were potentially dangerous were: furosemide / ACE inhibitors, low-molecular weight heparin / non-steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs / clopidogrel, proton pump inhibitors / clopidogrel, spironolactone /potassium and theophylline / β blockers. Gender and the number of drugs received were associated factors to the potential D-DI.

Conclusions The high percentage of prescriptions with potential drug – drug interactions makes it necessary to adopt alerting strategies that include warning about any associated factors identified and to implement educational programs. This action may improve the quality of prescribing and reduce the risks for hospitalised patients.

Competing interests None.

PHC035

TREATMENT OF URINARY TRACT INFECTIONS IN PREGNANCY

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Background Urinary tract infections (UTIs) are one of the most common bacterial infections during pregnancy. UTIs are serious complications associated with risk to both the fetus and mother, including pyelonephritis, preterm birth and low birth weight.

Purpose To identify and treat pregnant women with asymptomatic and symptomatic bacteriuria.

Materials and methods 67 pregnant women at 12 – 16 weeks gestation were included. 24 of them were diagnosed with asymptomatic bacteriuria incidentally on routine urine analysis and 8 with symptomatic cystitis. The diagnosis of UTIs was based on the culture of a urine specimen collected in a manner that minimises contamination. Urine culture showed the presence of Escherichia coli in 24 women and Proteus in 8 women. The treatment was by administration of appropriate oral or parenteral antibiotics.

Results Antibiotic treatment for UTIs was initiated after all necessary cultures were obtained. 24 ambulatory women were treated with cefpodoxime 100 mg orally every 12 h for seven days. 8 pregnant women were admitted to hospital because of complications (nausea and pain) and were treated with ceftriaxone 2 g intravenous in 5% dextrose every 24 h for 5 days. Regarding cure rates and recurrent infections, the results in the ambulatory group were better than in the hospitalised group (23/5). Gestational age at birth was greater in women from the ambulatory group (21 vs 4).

Conclusion Treatment of UTIs is important. Although the study had a very small sample size The authors recommended cephalosporins for the treatment of UTIs. The administration schedule of these antibiotics is unobtrusive for the patients and complications are very rare, so they are promising antibiotics for maternal and neonatal outcomes.

Competing interests None.

Other Hospital Pharmacy topics (including: medical devices)

OHP001 HOSPITAL PHARMACISTS' WILLINGNESS TO DEVELOP PHARMACY SERVICES IN OUTPATIENT DIALYSIS CENTRES: A QUALITATIVE STUDY

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Background Currently, no pharmacy services exist in outpatient dialysis centres in Australia, although the literature demonstrates the positive contribution of pharmacists to dialysis patients.
Purpose To explore hospital pharmacists' willingness to implement pharmacy services in outpatient dialysis centres.
Materials and methods Qualitative indepth, semistructured interviews were conducted with a convenience sample of hospital pharmacists recruited through the Society of Hospital Pharmacists of Australia Renal Special Interest Group. The interview guide was developed based on the Theory of Planned Behaviour, which explains human behaviour as the result of attitudes, subjective norm, and perceived behavioural control. These components determine behavioural intention which is the immediate antecedent of behaviour. The interviews were recorded, transcribed verbatim, and analysed for thematic content.
Results Thirteen renal hospital pharmacists were interviewed. All except one demonstrated high behavioural intention, as a consequence of positive attitudes towards the implementation of the service, favourable subjective norm, and high perceived behavioural control. The expected outcomes of the service perceived by pharmacists included benefits to patients, the renal team and the pharmacy profession, as well as financial savings due to dose optimisation and improvement of patients' adherence. Subjective norm was favourable meaning that nephrologists, nurses and patients were thought to be receptive towards a future service. Barriers pointed out for the implementation comprised: funding, hospital administrators' approval, time and staff shortages, academic training, relationship with physicians and attitudes of pharmacists, renal team, and patients. Facilitators included: having an interview room with access to information sources, consent from the team, access to patients' profiles, and a full-time pharmacist with a clearly-defined role.
Conclusions Pharmacists showed high willingness and perceived behavioural control to develop pharmacy services in outpatient dialysis centres. The potential barriers outlined should be taken into account, as well as the holistic approach for the successful implementation of cognitive pharmacy services.

Competing interests None.

OHP002 YOUNG POTENTIALS Ñ A TRAINEE PROGRAM QUALIFYING PHARMACISTS TO BECOME SUCCESSFUL EXECUTIVES

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Background German pharmacists receive a thorough training in how to analyse, to manufacture and how to dispense drugs.
Purpose At university pharmacists normally don't learn how to lead a pharmacy. Due to this fact there is a lack of knowledge for the successfully leading a hospital pharmacy. Because there are additional and possibly different skills, the German society of hospital pharmacists (ADKA) e.V. decided to offer a trainee-program to interested pharmacists which was subsequently coined 'Young Potentials'. Purpose of this trainee-programme is to qualify pharmacists to lead an hospital pharmacy.
Materials and methods The program, which is held during five weekends covers a number or different subjects such as rhetoric and presentation techniques, management and conflict resolution training and information on employment law. Additionally participants are encouraged to take an internship at a hospital pharmacy for two days to receive individual coaching by a pharmacy director. All hospital pharmacists who are members of the ADKA are eligible to apply for the program. The board members decide which applicant will get in the program. Decisions are made upon the degree of specialisation, the curriculum vitae, former activities in hospitals and a commitment to future posts within the ADKA. Applicants should be aiming for a leadership in a hospital pharmacy in the near future after finishing the program. The ADKA itself sponsors the program with € 5,000 while more than € 32,000 were raised from industrial sponsors.
Results From 2000 until today approximately fifty hospital pharmacists have completed the program, while twelve participate are enrolled in current program. Thirteen participants have been appointed as director of a hospital pharmacy; thirty-five are active in several boards of the ADKA. In addition they have presented posters on the program and attended scientific seminars about which reports were submitted our journal 'Hospital Pharmacy'.
Conclusions The programme 'Young potentials' is suited to qualify pharmacists to inherit a leading position in an hospital pharmacy. To this end all participants considered the program very useful since they were well trained in matters, they hardly had any experience in before. For the ADKA the YP program is an opportunity to recruit colleagues for positions within the society.

Competing interests None.

OHP003 IPERPTO: A NEW IDEA FOR THE ONLINE HOSPITAL DRUG FORMULARY

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Background In 2008, SIFO, the Italian Hospital Pharmacy Society, has decided to start a project about an on-line drug formulary based on guidelines as a tool of clinical governance. The name of the formulary is 'IPERPTO'. The introduction of the API in 'Iperpto' is only possible if connected to a qualified guideline which determines suitability for use.
Purpose To critically evaluate the quality of the guidelines already entered in' Iperpto'
using as assessment tool Agree instrument already available in Iperpto site.

Materials and methods IperPTO is available at www.laboratoriosifofarmacoeconomia.org/iperpto.htm and the new molecule can be added by logging in to www.laboratoriosifofarmacoeconomia.org/ptolg.htm .
The AGREE II consists of 23 key items organised within 6 domains followed by 2 global rating items ('Overall Assessment'). *Overall assessment* includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.
Results To date the database contains more than 400 active ingredients and 236 Guidelines. Of these, 34% concerns the 'field of oncology, 10% cardiovascular diseases, 9% musculoskeletal diseases; 6% metabolic and immune system disease, the other equally distributed in other classes ICD (International Classification of Disease). The sources are international, national and local.
Conclusions The 'iperpto' is a pilot experience than can be particularly interesting for both regional and local therapeutic committees as a tool for EBM-based evaluation in critical areas such oncology and cardiology. It is essential at this stage to asses the quality of guidelines included in the database and to select the most significant with the active participation by all colleagues.

Competing interests None.

OHP004 RETURN ON INVESTMENT FOR AUTOMATED DISPENSING CABINETS

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Background Automated Dispensing Cabinets (ADC) offer several benefits to the organisation and the user. They provide nurses with near total access of medications, ensure greater control of medications and reduce medication errors. It was necessary to evaluate in which way the ADC could potentially reduce the drug consumption on the ward.
Purpose To estimate the return on investment (ROI) of an ADC taking into accounts only the reduction in drug consumption.
Materials and methods The drug consumption in two wards of similar characteristics of internal medicine was compared in a tertiary hospital. The ward used as a control did not have an ADC and distribution of medicines was made from ward stock. The test ward made use of an ADC model OmniSupplier. An inventory of the medicines in both wards was made on January 10th, 2010. During a one year period 323 drugs were monitored in both wards, and the drug consumption data analysed and compared.
Results Two wards were selected with 29 patients each. The drug consumption during the one year period in the control ward came to 87.210 Euros, whereas the total cost of the test ward was 73.001 Euros. This represents a difference of 13.719 Euros (16,3% reduction) in drug consumption. The value of the stock in the control ward was 7.802 Euros, while the value of the test ward was 3.392 Euros, with a median stock reduction of 56,5%±21. Overall, when comparing the results obtained from the two wards, a consistent reduction is observed in almost all medicines. In some medications and dosage forms, the reduction of consumption was more significant for example oral analgesics, oral penicillins, simvastatin, antacids/gastric protectors and oral mucolitic drugs. At our hospital, the cost of the ADC, as configured, was approximately 55.000 Euros (costs of ADC's are dependent upon the number of drawers and hardware configuration and start at approximately 25.000 Euros) plus a maintenance contract of around of 3.000 Euros per year. Taking into account only the reduction in drug consumption, if The authors consider a 5 year maintenance contract, the cost of the ADC would be 70.000 Euros. If The authors divide this by the 13.719 Euros of the reduction in drug consumption, then an ADC could be payed off in about 5 years.
Conclusions The investment for the installation of the ADC can be justified on the reduction in drug consumption on the war.

Competing interests None.

OHP005 EVALUATION OF SOME QUALITY INDICATORS IN THE MANAGEMENT OF DRUG ACQUISITIONS

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Background According to the Standard Operating Procedure of our pharmacy service, several indicators are being calculated and compared to our historical standards in the absence of relevant literature.
Purpose To evaluate the results of some quality indicators in the management of medicines acquisition in the hospital pharmacy department in 2010.
Materials and methods Indicators and standards to achieve maximum quality in drug procurement have been established in the pharmacy's Standard Operating Procedure. In order to assess the quality of the actions performed in 2010, 4 indicators were calculated: 1. Drugs Rotation Index (RI): Annual procurement value / Stock average value. The standard set is > 12. 2. Efficiency in Procurement Management Index (EPMI): Procurement value / Consumption value. The standard set is ≤1. 3. Drugs Expiry Index (EI): Expired medicine value * 100 / value of acquisitions. Standard < 0.25%. 4. Savings rate (SR) for purchasing management: Value saved on purchases * 100 / Acquisitions value. The standard is to manage to meet or exceed the previous year's standard.
Results Total acquisitions in 2010 were € 50,801,425 and 75% were from sole suppliers. The RI for the year of study stands at 21.10. The EPMI was 1. The average annual EI was found to be 0.23%. The annual savings for the management of purchases is 22.19% of total purchases. For the year 2009 this indicator was 17.99%.
Conclusions

- 1- The high value obtained for the RI reduces the risk of obsolescence and expiry, and enables less capital to be tied up. However, The authors believe it would be advisable to reduce it to optimise the workload and increase efficiency.
- 2- The EPMI value indicates that the capital has remained fixed and the costs of which can be calculated and also allows better management of IR.
- 3- The EI reached reflects its relationship with RI. The better the RI indicator, the lower the EI.
- 4- Although nearly 75% of drugs were supplied by sole suppliers, the high savings situate procurement management as a strategic element in our department and help the hospital to have those vendors that provide good value for money.
- 5- The indicator values obtained suggest high quality management of the acquisitions made in 2010.

Competing interests None.

OHP006 ECONOMICS EVALUATION OF ERYTHROPOIESIS-STIMULATING AGENTS FOR THE TREATMENT OF CHEMOTHERAPY-INDUCED ANAEMIA IN ITALY

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Background Chemotherapeutic treatment of cancer patients is likely to cause anaemia (chemotherapy-induced anaemia, CIA), which is associated with high medical costs. Current guidelines recommend the use of erythropoiesis-stimulating agents (ESAs) for patients undergoing chemotherapy.
Purpose Following a cost-consequence approach, an economic evaluation was conducted of CIA treatment with ESAs in Italian clinical practice, from the perspective of the National Health Service.
Materials and methods Four pharmacological alternatives were considered: weekly epoetin alfa, epoetin β, darbepoetin α and darbepoetin alfa every three weeks. Clinical outcomes were obtained from the literature. Costs were estimated using a questionnaire addressed to clinicians employed in five hospitals. Data were collected regarding the six most common ESA administration settings (ranging from self-administration to hospitalisation). Resources used in each setting were accounted for. A decision-tree model was used based on these data and on the outcomes from the clinical trials of the drugs considered. The treatment period was set at 12 weeks.
Results The average treatment costs per responding patient (response based on haemoglobin level increment) were (2010, euros): € 4,291 (darbepoetin α every three weeks), € 5,051 (weekly darbepoetin α), € 5,111 (weekly epoetin β), € 5,810 (weekly epoetin α).
Conclusions Despite study limitations (costs estimates from survey data), in the treatment of CIA among cancer patients in Italy darbepoetin alfa weekly and every three weeks appear to provide more efficient use of healthcare resources compared to epoetin alfa and epoetin β.

Competing interests explained in presentation.

OHP007 THE RELATIONSHIP BETWEEN THE SAFETY OF PRESCRIBED CHEMOTHERAPY AND ADHERENCE TO BREAST CANCER GUIDELINES IN A LEVEL THREE HOSPITAL

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Background Some studies suggest that compliance with clinical practice guidelines (CPGs) for breast cancer is related to improved patient safety.
Purpose To analyse the compliance of chemotherapy prescriptions in a third level hospital with the breast cancer Integrated Care Process (ICP) and the protocol established by the Spanish Society of Gynaecology and Obstetrics (SEGO), and to analyse the relationship between safety and compliance with each protocol.
Materials and methods Retrospective observational study of patients diagnosed with breast cancer in 2006 and subsequently treated with chemotherapy; patients were followed up until December 2010. 'Compliance' was defined by the fulfilment of all recommended criteria: indication, regimen, dose, number and frequency of cycles. Toxicity was assessed as the number of admissions for this reason and as the number of chemotherapy-induced adverse reactions (ARs). Both the regional ICP and the national SEGO protocol were published in 2005.
Results The study included 131 patients, who received a total of 189 treatments. Compliance with the ICP was observed in 27% of cases and with the SEGO protocol in 21.7%. ARs were recorded in 61 patients and admittances for toxicity in 34. The mean no. of admissions for toxicity per patient was 1 for those receiving ICP-compliant treatment and 0.94 for those who were not (p=0.748); the mean no. of ARs was 4.6 in those receiving ICP-compliant treatment and 3.1 in those who were not (p=0.232). The mean no. of admissions was 3 for those receiving SEGO-compliant treatment and 0.81 for those who were not (p=0.010); the mean no. of ARs was 7.5 in those receiving SEGO-compliant treatment and 2.9 in those who were not (p=0.003).
Conclusions Compliance of prescriptions with ICP and SEGO guidelines is low and does not appear to be directly related to a reduction in chemotherapy-induced toxicity in breast cancer.

Competing interests None.

OHP008 VIGILANCE SYSTEM FOR MEDICAL DEVICES: THE EXPERIENCE OF AN ITALIAN HOSPITAL

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Background The pharmacovigilance on Medical Devices (MDs) and In Vitro Diagnostic Medical Devices (IVDs) represents a relevant system for improving the protection of patients and health workers. In our hospital, according to Italian law implementing European Directive 2007/47/CE and MEDDEV guidelines, the activity is performed by a multidisciplinary team (pharmacists, physicians, clinical engineers).
Purpose To evaluate the impact of the pharmacovigilance system on the correct use of MDs in our hospital.
Materials and methods In 2004 the Pharmacy set up a database to record every event (Incidents, Field Safety Notices – FSNs, reports from users) related to the use of MDs and IVDs. For each event, information about the device, warning procedures, subsequent actions from manufacturers or the Ministry and corrections put in place by the hospital team have been recorded.
Results Over the January 2009-September 2011 observation period 636 records were made: 33 incident reports (13 were near misses), 596 FSNs, 7 reports of non-conformity. In 12 cases, the reports involved non-specialist devices (extension cables, catheters, dampers, etc); in 20 cases specialist products (cardiac, obs/gynae, ophthalmic devices, etc.), in 1 case an IVD (test tube baby). Whenever possible, the device involved was retained and later returned to the manufacturer; if an incident occurred, stock of the same batch was collected and withdrawn from wards.
Conclusions Pharmacovigilance represents an important element in the management of MDs. In this context, Pharmacy plays a key role, as 1) it acts as first interlocutor for users, 2) withdraws the product involved 3) takes part in editing the reports to the Ministry and 4) cooperates in training activities for health workers. Data collected over the years represent an important support in all activities linked to the use of MDs: evaluation/selection, acquisition, troubleshooting, handling of incidents.

Competing interests None.

OHP009 ECONOMIC EVALUATION OF NEW ANTINEOPLASTICS DRUGS IN A TERTIARY HOSPITAL

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Background Because of its high cost, incorporation of new antineoplastic drugs to hospitals need to be evaluated.
Purpose Economic and clinical evaluation of the use of new parenteral anticancer drugs (PAD) authorised by the European Medicines Agency (EMA) between 2006 and 2011 in a Spanish tertiary hospital.
Materials and methods It is a descriptive study about new PAD. Purchase costs, number of treated patients and the incorporation rate to the Hospital Drug Therapy Guide (HDTG) were analysed using management database and electronic prescription program data.
Results The authors observed that three of the nine new PDA authorised by the EMA and marketed in Spain (bendamustine, clofarabine, ipilimumab, nelarabine, panitumumab, temsirolimus, trabectedine, azacitidine and vinflunine) were included on the HDTG as second line treatment. The rest of the new antineoplastic drugs were not incorporated to our HDTG but specific patient administration was accepted if there was a medical justification. 133 patients were treated with these medications between 2006 and 2011. Bendamustine Panitimumab and Clofarabine were used most frequently during the study period: Bendamustine was used in 24 patients, Clofarabine in 18 and Panitimumab in 40 patients. Leukaemia and lymphoma (28,7%) and colon and colorectal neoplasm (NCC) (33,3%) were the indication with the highest consumption of new antineoplastic drugs and with a higher cost. New PAD total cost purchased derived during the specified period of time was 1.658.792€, (0,37% of total drug expenses) with 3151 vials purchased. By the first half of 2011, new PAD supposed 0,93% of drug expenses, with an average consumption of 77,537€ per month.
Conclusions Despite the low incorporation rate of new PAD to the HDGT, they have an economic impact in our hospital. Economic repercussion and the number of patients in treatment show the importance of the drugs selection process in order to rationalise antineoplastic drugs use.

Competing interests None.

OHP010 NON-FORMULARY DRUGS: SITUATION ANALYSIS

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Background The analysis of Non-formulary drugs (NFD) most frequently prescribed is important in managing a hospital's formulary.
Purpose Determine the most frequently prescribed and dispensed NFD in a 376 bed community hospital.
Materials and methods The hospital's NFD policy demands physicians to submit a request form, which must be validated by a pharmacist prior to its dispensation. A retrospective descriptive study was conducted with information collected from NFD applications received between January and June 2009.
Results A total of 1504 applications were received, and 296 different NFD were dispensed. The 5 most frequently prescribed NFD accounted for 25% of applications. Many other medications were ordered only once or twice. The most dispensed drugs were levetirazetam (5.6%), trazodone (5.3%) and escitalopram (5.3%). Different strengths or dosage forms of formulary products represented 11.4% of applications. Eight percent of NFD had a formulary alternative through the hospital's Therapeutic Interchange Program (approved by the Pharmacy and Therapeutic Committee, PTC), but were not accepted by physicians. Drugs related to the nervous system were the most prescribed (56.4%), mainly psycoanaleptics (23.6%). Cardiovascular drugs supposed a 14,4%. The Internal Medicine Department held 31.7% of the applications, while the Psychiatry Department prescribed more number of NFD per patient. The most common cause of NFD prescription was 'no alternative available in the hospital's formulary' and 'outpatient's medication'. The majority of NFD requested were already in stock and accounted the acquisition cost of NFD for 0,95% of total drug spending in this period.
Conclusions More than half of the NFD prescribed were related to the nervous system, followed by cardiovascular ones. Most of medications were rarely needed, while a low number of drugs caused the majority of the prescriptions. A significant percentage of NFD were different forms of formulary products and drugs with a formulary therapeutic alternative.

Competing interests None.

OHP011 PHARMACEUTICAL CARE PROGRAM IN A SERVICE TO PEOPLE WITH DISABILITIES

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Background The Department of Health and The Department of Labour and Welfare signed an agreement to develop a Pharmaceutical Care Program in a centre that serves 122 people with severe intellectual disability.
Purpose To evaluate the clinical and economic impact of a Pharmaceutical Care Program, conducted by our Pharmacy Service, and to analyse the drug's usage profile in this centre.
Materials and methods One year retrospective observational study (January-December 2010) describing the implemented procedures and collecting the following information: a)cumulative drug consumption and the estimated savings generated by purchasing the drugs directly from the manufacturer, hence avoiding the cost of both the mark-up of the wholesaler (9.6%) and the community pharmacy (27,9%); b)classification of the consumption by therapeutic group; c)percentage of drugs not included in the pharmaceutical guide. Tools: computer applications Edu®, Silicon® and Sinfhos®.
Results The centre is located 34 kilometres away from the hospital, so The authors have designed an operating procedure that aims to optimise the human resources available while keeping an excellent quality of pharmaceutical care. The Pharmacy Service receives daily orders by fax from the centre. These are validated and transcribed by the pharmacist into Silicon® that same day. Any queries are resolved daily by phone. The Pharmacy service prepares a weekly unidosis and the pharmacist visits the centre once a week in order to facilitate communication between the Pharmacy Service and the centre's healthcare staff and to manage and date check the drug stock.
During the study period:

- a)The cumulative consumption of drugs was €98,106. Applying a margin of 37.5% (9.6%+27.9%) the direct savings amounted to €36,790.

- b)The analysis showed that therapeutic groups accounting for higher costs are those included in the nervous system (66%), followed by enteral nutrition (15%).
- c)From the 311 different drugs that the centre uses, 93% belong to the pharmaceutical guide of the hospital.

Conclusions Because the patients suffer from specific chronic conditions The authors were able to design and implement a procedure by means of which a part-time specialist pharmacist ensures the quality of care in terms of safety (daily validation of medical orders) and effectiveness (direct saving €3,066/month). The pharmaceutical care agreement ensures rational drug use and aids prescribing through the introduction of a pharmaceutical guide and a program of therapeutic equivalents.

Competing interests None.

OHP012 THE APPEARANCE OF DRUG-INDUCED DIARRHOEA

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Background Increased frequency of diarrhoea caused by medicines was noticed in the Emergency Centre of Clinical Centre of Serbia in 2010. Most of them were treated as pseudomembranous colitis.

Purpose The goal of our investigation was to determine if there was connection between the use of certain medicines and the appearance of diarrhoea.

Materials and methods The investigation was conducted from 1 August to 1 October 2011, in the Emergency Centre of the Serbian Clinical Centre. Patients with diarrhoea were recorded based on inspection of their medical records and notifications from nurses. The treatments that patients had been receiving before the diarrhoea appeared were analysed, and data were collected from case histories and lists of treatments.

Results There were 68 patients with diarrhoea. 35 from them were treated as pseudomembranous colitis. Diarrhoea appeared in 56 patients who were treated with antibiotics. 16 patients were treated with cephalosporins, 10 with carbapenems, 6 with ciprofloxacin, 9 with aminoglycosides, 12 with intravenous metronidazole, and 4 patients with vancomycin. 13 patients were treated with proton pump inhibitors and 30 with ranitidine. From other medicines, an increased incidence of diarrhoea was noticed during treatments with glucocorticoids (5), sertraline (6), metformin (2), amlodipine (5) aminophylline (7) and anticonvulsants (5). Candida was proven by stool specimens 9 times, while data for Clostridium difficile were not available.

Conclusions Increased numbers of people with diarrhoea could be in accordance with the use of certain medicines, but it is not possible to confirm that it was pseudomembranous colitis, due to poor organisation of collecting and sending samples for stool specimens.

Competing interests None.

OHP013 COMPLIANCE WITH SPANISH AND INTERNATIONAL GUIDELINES ON INTRADIALYTIC PARENTERAL NUTRITION IN CHRONIC RENAL DISEASE

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OHP013 table 1

Criteria	Patients
Albumin <3.5 g/dL and/or prealbumin <20 mg/dL	14 (57%)
Creatinine < 8 mg/dL	18 (86%)
BMI <18.5 (or SGA* score C)	1 (5%)
Weight loss (10-20%)	6 (29%)
Caloric intake control (<25-26 Kcal/Kg/day)	Not recorded
Protein intake control (<0.75 g/Kg/day)	Not recorded
*SGA was not recorded	
>3 criteria fulfilment	4 (19%)
> 2 criteria fulfilment	8 (43%)

Background The Spanish Nephrology Society and the Spanish Enteral and Parenteral Nutrition Society issued a consensus statement about indications, contraindications and the composition of intradialyticparenteral nutrition (IDPN) in 2010.

Purpose To find out whether these guidelines are being followed.

Materials and methods Patients who started IDPN during 2010 were included. Medical histories were revised retrospectively. The start and end date, subjective global assessment (SGA), intake of food, body mass index (BMI), age, creatinine, albumin and prealbumin were recorded.

Results 21 patients were included. Median age was 63. Start criteria: all had found supplementary oral intake impossible and had rejected a nasogastric tube according to the consensus. In addition, 3 criteria referred to in the table had to be present.

Composition criteria: All patients had Oliclinomel N7-1000 ml (Baxter). It complied with the recommendations except that:

- It had 40 grams of protein, which corresponded to 0.5-0.8 g/kg/day (consensus 0.8-1.2/kg/day)
- It had no vitamins, no added insulin and no phosphorus
- Carnitine was not added in dyslipidaemic patients

Discontinuation criteria: Only albumin was assayed. No patients were discontinued because of complications or intolerance. Four patients complied with the discontinuation criteria (albumin >3.8 g/dl).

Conclusions 19% of patients fulfilled the start criteria, 43% the discontinuation criteria and the composition did not fully fit the consensus. Initial screening should be improved by recording caloric and protein intake and SGA. It would be desirable to choose an IDPN better adapted to protein needs, and consider the addition of vitamins and carnitine in dyslipidaemic patients, as well as individualising phosphorus and insulin requirements.

Competing interests None.

OHP014 COST-EFFECTIVENESS ANALYSIS OF FEBRILE NEUTROPENIA (FN) PROPHYLAXIS WITH PEGFILGRASTIM IN NON-HODGKIN'S LYMPHOMA (NHL) PATIENTS TREATED WITH CHEMOTHERAPY IN SPAIN

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OHP014 Table 1 Costs and QALYs gained by strategy

	Pegfilgrastim		Filgrastim 6-day		Filgrastim 11-day		No prophylaxis	
	Cost	QALY	Cost	QALY	Cost	QALY	Cost	QALY
PP								
CHOP21	8,155	3.213	6,279	2.990	7,712	3.090	4,019	2.935
CHOP21-R	17,534	3.220	15,279	3.023	16,893	3.112	12,909	2.976
SP								
CHOP21	4,521	3.040	4,560	2.953	4,708	2.988	4,019	2.935
CHOP21-R	13,539	3.063	13,445	2.990	13,633	3.019	12,909	2.976

Cost= mean cost/patient (€)

Background Granulocyte-colony stimulating factor (G-CSF) prophylaxis reduces the risk of FN in NHL patients receiving myelosuppressive chemotherapy.
Purpose To estimate incremental cost-effectiveness ratios (ICERs) of pegfilgrastim prophylaxis versus other prophylaxis strategies in NHL patients from the perspective of the Spanish NHS.
Materials and methods A Markov model simulated lifetime effectiveness (quality adjusted life years-QALYs) and cost (€2011) in NHL patients receiving CHOP21±R. Pegfilgrastim was compared with 11-day filgrastim (Neupogen), 6-day filgrastim, and no prophylaxis (no use of G-CSF); these strategies were compared within primary (PP) and secondary (SP) prophylaxis. Model inputs were: risk of FN, mortality, probability of relative dose intensity RDI<85%, relative FN-risk of strategies, and utilities. The annual discount rate for cost and outcomes was 3%.
Results Effectiveness analyses (QALYs) demonstrated pegfilgrastim-PP was the most effective treatment. Assuming an accepted threshold of €30,000/QALY, PP with pegfilgrastim versus other PP strategies was cost-effective for CHOP21 (ICER of pegfilgrastim vs 11-day filgrastim, 6-day filgrastim or no prophylaxis of €3,606, €8,383 and €14,881 per QALY, respectively) and CHOP21-R (ICER of pegfilgrastim vs 11-day filgrastim, 6-day filgrastim or no prophylaxis of €5,895, €11,433 and €18,898 per QALY, respectively). Similarly, SP with pegfilgrastim versus other SP strategies was cost-effective, being the dominant SP strategy (more effective and less costly) versus 11- and 6-day filgrastim for CHOP21 and 11-day filgrastim for CHOP21-R. Compared to no prophylaxis, pegfilgrastim-SP had an ICER of €4,806/QALY for CHOP21 and €7,235/QALY for CHOP21-R.
Conclusions Pegfilgrastim prophylaxis is an effective and cost-effective treatment for NHL patients for the Spanish NHS.

Competing interests Advisory board: AD, AA and AL have been participated in advisory boards by Amgen. LG and GR are Amgen employees. IO and MAC are PORIB employees, a consultant paid by Amgen.

OHP015 COST ANALYSIS OF SELF-INJECTABLE ANTI-TNF IN ALMERIA (SPAIN)

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Background Etanercept (ETA) and adalimumab (ADA) are some of the biological agents available for treating severe psoriasis and a variety of inflammatory diseases in patients who have an inadequate response to standard treatment.
Purpose To analyse and evaluate current costs to the regional health system of the treatment of the following inflammatory diseases: Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA) with the main (self-injectable) anti-TNF drugs in Almería public hospitals (Spain).
Materials and methods Retrospective multicentre study including all patients treated with etanercept or adalimumab during the period January-December 2010 in all Almería public hospitals.
Results During the study period a total of 300 patients with AS, PsA or RA were treated; 112 (37.3%) received adalimumab and 188 (62.7%), etanercept; distribution of pathologies was: 51.6% RA, AS 29.7% and 18.7% PsA. The distribution per treatment indication was: RA (ADA 32.2%, 67.8% ETA), AS (39.3% ADA, ETA 60.7%) and PsA (48.2% ADA, ETA 51.8%). Average annual cost per patient for each therapeutic alternative was: RA (ADA 9931.6€, ETA 7363.5 €), AS (ADA 10162.5€, ETA 8146.2€) and PsA (ADA 6577.8€, ETA 8585.9€). In the light of these results and taking into account that the two drugs have similar efficacy, ETA appears to be the most favourable option in the treatment of RA and AS; PsA data with ETA could be influenced by double doses in dermatology-derived patients.
Conclusions For higher prevalence and incidence pathologies, etanercept is the most economical option, therefore it is proposed as first-line treatment, leaving adalimumab as a second line in case of lack of response. It is necessary to perform longer-term studies and include the rest of the anti-TNF drugs currently used to position each one in its maximum efficiency indication.

Competing interests None.

OHP016 PREVALENCE OF DYSPHAGIA IN THE OLDER USING 'EATING ASSESSMENT TOOL-10'

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Background Dysphagia is a symptom whose prevalence can be higher than 30% in the older. It is related to higher disability, longer hospital stay and more malnutrition and mortality. The Eating Assessment Tool (EAT-10) is a practical, analogical and easy dysphagia evaluation instrument.
Purpose Determine the prevalence of dysphagia in the older. Evaluate if it was previously detected by the physician and if he established corrective actions. Assess the nutritional status in patients with dysphagia.
Materials and methods 50 patients, 18 male and 32 female, were randomly selected in an older patient unit. Medium age was 78. Dysphagia was measured with EAT-10, a 10 question questionnaire (each scored from 0 to 4). If total score is ≥3, dysphagia may be present. The type of diet as well as gelatin and thickeners intake was registered. Nutritional status was assessed by CONUT (COntrol NUTritional) system. Unlike Nutritional Risk Screening (NRS-2002) which is a screening tool based on weight loss, Body Mass Index, food intake diminution and disease severity, CONUT is an automatic validated tool that classifies nutritional status in normal, mild, moderate or serious malnutrition, based on serum albumin, cholesterol and lymphocytes.
Results EAT-10 was ≥3 in 10 patients (20%) (mean =11,7; range 3-31). Average realisation time was 4 min. Four patients (40%) with EAT-10 ≥3 had corrective actions. All had crushed diet, and 3 had thickeners. None had gelatins. Eight patients out of ten with

dysphagia had malnutrition (5 mild, 3 moderate). All patients with moderate malnutrition had nutritional supplements.
Conclusions 20% of patients had dysphagia, but only 40% had corrective actions. Malnutrition prevalence was high (80%) in patients with dysphagia. EAT-10 is an easy and fast dysphagia detecting scale and could avoid malnutrition and other associated problems. So, it would be advisable its routine realisation in older so that corrective actions are established.
Competing interests None.

OHP017 COST OF ERYTHROPOIESIS-STIMULATING AGENTS IN THE TREATMENT OF CHEMOTHERAPY-INDUCED ANAEMIA IN GERMANY

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Background Spaepen *et al*. (The Oncologist 2008;13:596–607) reported lower costs to achieve similar outcomes with darbepoetin alfa (DARB) compared with epoetin alfa (EPO-A) and epoetin β (EPO-B) for similar patient profiles in the treatment of chemotherapy-induced anaemia. Data were derived from the IMS Hospital Disease Database, a longitudinal database in secondary care unique to Belgium.
Purpose The objectives of this study were to assess the applicability of the Spaepen *et al*. analysis in the German setting, and to evaluate differences in cost between ESAs in Germany.
Materials and methods To adapt the Belgian data to Germany, differences in epidemiology and treatment patterns were examined. Costs per patient in the Belgian dataset were replaced with German-specific unit costs (Euro 2011) for drugs, outpatient visits, hospitalisations and blood transfusions. Adjustments were made for tumour-specific incidence, chemotherapy use, setting of care (hospital vs retail) and frequency of DARB administration. Costs were analysed using a mixed-effects model stratifying for propensity score quintiles as in Spaepen 2008. Data sources included Eurostat, national cancer registries, IMS sales data, and reimbursement and treatment guidelines.
Results The German and Belgian populations were comparable in terms of age, gender, ESA use and blood transfusions. After adjusting for treatment-related factors, total (mean±SE) DARB costs (€7,237±516) were 17% lower compared with EPO-A (€8,720±408; p=0.0004) and 14% lower compared with EPO-B (€8,392±544; p=0.0385). Anaemia-related costs per patient were not statistically different between DARB (€2,893±140), EPO-A (€2,940±78; p=0.7628) or EPO-B (€2,529±153; p=0.0736). Mean duration of treatment was significantly shorter for DARB (43.22±2.37 days) compared with EPO-A (54.15±1.23 days; p<0.0001) and EPO-B (54.62±2.51 days; p=0.0010).
Conclusions Total costs were significantly lower in patients receiving DARB compared to EPO-A or EPO-B whereas anaemia-related costs were not significantly different. By using published epidemiologic and treatment pattern data, it was possible to adapt the Belgian Hospital database to the German setting.

Competing interests Ownership: Funding for this study was provided by Amgen GmbH

OHP018 ARE THE GUIDELINES CONCERNING THE PRESCRIPTION OF BIOTHERAPY RESPECTED? ENQUIRY IN AN INTERNAL MEDICINE DEPARTMENT AT BORDEAUX UNIVERSITY HOSPITAL

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Background Numerous biotherapies have been developed these previous years and have enhanced the prognosis of inflammatory diseases and cancers. Most of these molecules are onerous and clinicians must follow prescription guidelines.
Purpose The objective of this study is to evaluate the adequation of biotherapy prescriptions with edited guidelines and analyse off-label situations.
Materials and methods A prospective study was performed concerning patients treated by biotherapy from November 2010 to June 2011 in an internal medicine department. The following data were collected: indication, previous treatments, clinical and scientific relevance.
Results 76 patients were included receiving rituximab (37/76), infliximab (27/76), anakinra (4/76), adalimumab (3/76), eculizumab (1/76), tocilizumab (1/76), etanercept (1/76), alemtuzumab (1/76), bevacizumab (1/76). 62/76 indications were correctly specified; (a pharmacist corrected 14 errors). 57/76 prescriptions respected the guidelines. The 19 off label situations were: rituximab (9/37), anakinra (4/4), infliximab (2/27), adalimumab (2/3), tocilizumab (1/1), bevacizumab (1/1). These molecules were used as a third-line and over for 14 patients, second-line (3 patients), first-line (2 patients). These drugs were prescribed because classical therapies were ineffective, not well tolerated or contraindicated. Only 3 prescriptions were justified by scientific publications. One case was discussed in clinical pluridisciplinary comity of haematology. Biotherapy treatment was pursued with good efficacy for 13 patients: 11 had good tolerance and recurrent infections were recorded for 2 patients. The treatment was ceased for 1 patient because of it inefficacy. Efficacy evaluation was not possible for 5 patients: lack of experience (1), reserved prognosis when biotherapy started (3); 1 lost to follow-up patient.
Conclusions This study proved that most of off-label biotherapy prescriptions are used when classical therapies are not effective or contraindicated and have enhanced the prognosis for the great majority of patients. Nevertheless, physicians do not justify these prescriptions as recommended in France. Consequently a clinical pluridisciplinary comity of internal medicine was created to improve the therapeutic justification and decision and pharmacy elaborated documents to inform prescribers concerning the rules for off-label situations.

Competing interests None.

OHP019 COST EFFECTIVENESS OF TITANIUM NITRIDE-COATED BIOACTIVE CORONARY STENTS COMPARED TO BMS AND DES

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Background The Medical Devices Commission of United Hospitals of Ancona (UHA) was asked to authorise a coronary

stent made of steel, coated with bioactive titanium nitride (TITAN 2).

Purpose To consider whether Titan 2 is cost-effective compared to Bare Metal Stents (BMSs) and Drug Eluting Stents (DESs eluting paclitaxel, everolimus or sirolimus) in patients requiring Percutaneous Transluminal Coronary Angioplasty (PTCA).

Materials and methods The commission conducted a cost-effectiveness evaluation of the required stent with BMS and paclitaxel, everolimus and sirolimus-eluting stents. The direct healthcare costs were considered as overlapping, assuming that the only difference was the cost of the devices. Efficacy data were retrieved through a systematic review of the literature intended to provide conclusions with respect to relevant outcomes such as Composite Myocardial Infarction, target lesion revascularisation (TLR) and Major Adverse Cardiovascular Events (MACE).

Results The literature search showed that MACE was less frequent at six months in patients treated with Titan 2 compared to controls treated with BMSs of identical design (7% vs 17%). Based on the initial processed data, Titan 2 did not show a favourable cost-effectiveness ratio (C/E), 914 Euro compared to a BMS C/E of 890 Euro. The commission contacted the medical device distributor and obtained a discount on the price of 2.58%. A favourable C/E for Titan 2 was obtained comparing this stent to paclitaxel-eluting stents for MACE after 2 years of follow-up (11.2% vs 21.8%). This stent has proven cost-effective even with respect to everolimus and sirolimus-eluting stents showing non-inferiority in MACE end point.

Conclusions With the cost-effectiveness analysis conducted comparing with EBM methodology, it has been possible use Titan 2 stents with a discount of 24 Euro compared to the steel stents for patients with allergies to metals and their alloys and they require only a month of dual antiplatelet therapy.

Competing interests None.

OHP020 COST-EFFECTIVENESS ANALYSIS OF PATIENTS IN PERITONEAL DIALYSIS WITH METHOXY POLYETHYLENE GLYCOL-EPOETIN β VERSUS DARBEPOETIN A IN SANTIAGO DE COMPOSTELA UNIVERSITY HOSPITAL COMPLEX, SPAIN

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Background Costs related to anaemia treatment in chronic kidney disease (CKD) patients are still under discussion. Near 80% of CKD patients included in a peritoneal dialysis program receive erythropoietin stimulating agents for the anaemia treatment.

Purpose 80% of chronic kidney disease (CKD) patients included in a peritoneal dialysis program receive erythropoietin stimulating agents for the anaemia treatment. The purpose of this study is to evaluate the cost-effectiveness of methoxy polyethylene glycol-epoetin β (C.E.R.A.) compared with darbepoetin alfa (DA) in a population of CKD patients in a peritoneal dialysis program.

Materials and methods 37 CKD patients undergoing peritoneal dialysis were included in the study: 28 with C.E.R.A. and 9 with DA. A cost-effectiveness analysis was developed to estimate the incremental cost-effectiveness ratio (ICER) of C.E.R.A. and DA in Spain under the hospital perspective for the last 12 months. Effectiveness, in terms of percentage of patients within range 11-12 g/dl haemoglobin levels, was calculated from the last three analysis. Demographic variables such as sex and age, and nutritional variables BMI and albumin, as dialysis efficiency factor value KTV were used to compare both groups. Unitary costs (¤2010) were obtained from de Spanish Catalogue of Medicines.

Results Both groups are similar taking into a account the nutritional, demographic and KTV value. The mean dose of C.E.R.A. was 92.3 mcg/dl while the mean dose of DA was 136.8 mcg/dl. Treatment with C.E.R.A. provided better results in effectiveness than DA (64.29% vs 44.44%). The average yearly cost in the study was ¤2,179 with C.E.R.A. and ¤2,767 with DA. Savings per patient treated with C.E.R.A. were ¤588 per year. Sensitivity analysis confirmed the stability of the results.

Conclusions In Santiago de Compostela University Hospital Complex treatment of anaemia in CKD patients included in a peritoneal dialysis program with methoxy polyethylene glycol-epoetin β is a cost reducing strategy in comparison with darbepoetin alfa.

Competing interests None.

OHP021 GROUPING PATIENTS WITH THE SAME CANCER OR BIOLOGICAL TREATMENT ON THE SAME MEDICINES ADMINISTRATION DAY IS AN EFFICIENT TOOL

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Background Minimisation of total drug expenditure within the healthcare system has become a rational goal in today's economic environment. In our setting, a 400-bed community hospital, antineoplastic and biological agents that require aseptic preparation account for 20% (3,659,400 €/year) of the total drug expenditure. When the shelf-life of the drug allows it, the Pharmacy stores partially-used vials in appropriate conditions until the next working day. But some drugs are not stable for more than 24 h when handled.

Purpose To assess the financial effect of grouping patients with similar treatments on the same day for medicines administration.

Materials and methods In order to reduce medicines wastage and to minimise expenditure The authors scheduled patients with similar treatments on the same day. The pharmacist selected those drugs with poor stabilities (less than 24 h) after the manufacturer's original presentation had been handled. He also evaluated the prescribing patterns and the nurses' workflow, the possibility of grouping patients with the same treatment and doing it in several days during the week, but trying not to overload any professional. The pharmacy department recorded the number of vials reused after each working day.

Results During the period January to August 2011, 340 vials of 12 drugs with poor stabilities (less than 24 h) were reused. This has led to a total saving of 3.6% (106,311€) of the total costs of these drugs. Three drugs produced most of the cost savings: infliximab 52,270 € (49% of the total, 76 patients, 309 doses), azacitidine 25,036 € (24% of the total, 7 patients, 283 doses) and rituximab 11,216 € (11% of the total, 51 patients, 170 doses).

Conclusions The relatively simple task of coordinating the day of drug administration of different patients can produce a very significant reduction in wastage and consequent financial gain.

Competing interests None.

OHP022 THE EFFECT OF ACTIONS TO IMPROVE THE QUALITY AND EFFICIENCY OF PRESCRIBING IN SPECIALISED CARE

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Background One of the prescribing quality indicators (PQI) set by the program contract for specialised care (SC) in our sector is the prescription by active substance (AS) instead of prescribing by brand name.

Purpose To improve the quality and efficiency of the outpatient prescription in specialised care by reporting back and offering training sessions to prescribing physicians.

Materials and methods

- Throughout 2010 an analysis of the Clinical Services with higher rates of outpatient prescriptions was performed and a delivery calendar of individualised reports for each physician was planned. These reports contained information about the outpatient prescribing profile.
- The Pharmacy Service held informative sessions on the rational use of medicines (RUM) for the Clinical Services. The number of prescriptions written by AS was compared to 2009.

Results Three groups were established after analysing the number of outpatient prescriptions. Group A (71.0% of prescriptions) received 4 reports, group B 21.5% received 3 reports and group C 7.5% received one. During 2010, 1,410 reports were delivered and ten RUM sessions were held. During 2010 the prescriptions by AS for SC were 14.7% compared to 11.8% in 2009. The change in PQI by AS from 2009 to 2010 in Clinical Services with double intervention was: emergency (from 28.1% to 27.4%), cardiology (from 8.3% to 11.3%), gastroenterology (9.8% to 14.2%), endocrine (from 9.9% to 24.5%), internal medicine (from 14.0% to 20.3%), nephrology (from 5.9% to 9.3%), neurology (from 7.6% to 10.0%), pneumology (from 7.1% to 16.0%), obstetrics and gynaecology (from 7.9% to 9.1%) and traumatology (from 7.6% to 10.0%).

Conclusions

- 1. The regular presentation of prescription profile reports to physicians resulted in an improvement of 2.9 points of PQI by active substance during 2010 in our sector.
- 2. The regular presentation of prescription profile reports along with the RUM sessions produced an improvement on the PQI by active substance in the 9 hospital departments.

Competing interests None.

OHP023 ASSESMENT OF THE COMPLIANCE DEGREE IN NON-DEPENDANT RESIDENTS IN A NURSING-HOME AND REPERCUSIONS OF THE PHARMACEUTICAL INTERVENTIONS

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Background An important function of a Pharmacist in nursing homes is to assess residents compliance to self-administer their medication with the aim of improving their compliance. To interview the residents and to meet the doctors are the cornerstones to improve compliance in this group of population.

Purpose To assess the compliance degree in non-dependant residents as well as pharmaceutical interventions.

OHP023 Table 1 Compliance degree by drug

Number of residents	Drugs taken uncorrectly
29	0
4	1
1	2
3	3
1	12

OHP023 Table 2 Compliance degree by therapeutic group

Therapeutic group	Residents (number)	Compliance
Antihypertensive	25	96%
Antiacids	20	95%
Laxatives	13	78%
Benzodiazepines	13	82%
Diuretics	11	81%
Antivaricoses	9	100%
Antiplatelets	9	89%
Bronchodilators	7	71%
Hypolipidemics	6	83%
Ca+VitD	6	50%
Bifosfonates	5	100%
Antianginal	5	80%

Materials and methods 38 non-dependant resident treatments were reviewed (November 2009-April 2011), checking the compliance by therapeutic group. *Non-dependant residents*: self-administration of drugs; *partially non-dependant*: some drugs are administered by nursing staff. *Compliance*: personal interview, remaining units count. *Statistical analysis*: t Student, logistic regression.

Results Residents: 15 men, 23 women, mean age 84.7±7.3 (79,9±5,6 males, 88±6,8 females) Medications: drugs belonged to 27 therapeutic groups. Each resident received an average of 5.3±3.7 drugs. Relevant pharmaceutical interventions: 13. Loss of compliance: 4; recommend change to dependant status: 4; dose increase: 1; inefficacy: 1; analytical control: 1; wrong inhaler use: 1; wrong dose: 1. 13 residents (33%) became dependant, in 4, pharmaceutical intervention was determinant.

Conclusions Due to pharmaceutical interventions 10.5% of residents changed their status from non-dependant to dependant, and 27% had their treatments reviewed and modified. 76% were fully compliant, 13.5% were partially compliant and 10.5% were fully uncompliant. Antihypertensives (96%), antivaricoses and bifosfonates (100%) got the highest compliance. Tablet size, need to chew, and stomachache were related with the lowest compliance (50%) in calcium – vitamin D supplements.

Competing interests None.

OHP024 PROBLEMS AND SOLUTIONS RELATED TO THE STORAGE OF INVESTIGATIONAL DRUGS

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Background The pharmacist has to ensure the integrity and efficacy of drug products. Proper storage of experimental drugs is of great importance in the management of clinical trials. Temperature is one of the most important parameters to control. The authors are dealing with new substances and The authors have only a little information about their stability, therefore the temperature is strictly monitored.

Purpose Increasingly, drugs are required to be stored at a temperature below 25°C and the pharmacist has to certify it. Therefore, air conditioning systems are not sufficient and control systems are needed.
Materials and methods For continuous temperature monitoring inside the pharmacy, in addition to recording on paper, The authors are using ScanTEMP, an innovative series of data loggers. They are temperature monitoring devices with RFID interface; they can record up to 6400 samples in a temperature range from -25°C and +70°C.
Results The software automatically makes charts of temperature records and indicates any 'out of range' parameters with an alarm. Features: easy to use, cheap, small, mobile, accurate, long battery life, large memory, difficult to falsify; reading through specific device, connected to the USB port of a PC; working parameters customisable as needed (range of data acquisition, alarm); password protected data; 12 reports per year. Paper recording, on the other hand, requires: periodic replacement of the disks, periodic calibration of the probe; is easy to fake; provides 52 reports per year. Being able to see immediately when the temperature is outside limits, and for how long, is a great quality.
Conclusions Pharmaceutical companies increasingly ask for monitoring and recording even of the room temperature. It is necessary to implement temperature measuring systems, which also have to record data. In the event of temperature excursions, however, it is important to act promptly: it would be beneficial to use devices that allow recorded data to be seen immediately, with an alarm in case the temperature is out of the allowed range.

Competing interests None.

OHP025 CONFORMITY TO THE CHARTER FOR VISITS FROM PHARMACEUTICAL REPRESENTATIVES

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Background Visits from pharmaceutical representatives (PRs) are controlled in France by regulations, but also by a Charter of good practice, drafted by an organisation which represents 270 drug companies (LEEM). The goal is to control promotional visits from pharmaceutical laboratories to healthcare professionals.
Purpose The goal of this study was to measure compliance with the conditions of this charter by participating pharmaceutical companies.
Materials and methods An assessment grid was drafted to determine compliance to prohibitions and obligations concerning the information provided during visits from PR. Thus after each visit by a PR, The authors collected information identifying the PR and his company, the method of comparing a competitor's specialty, any donations (gifts, invitations, samples), promotion of proper use and documents provided.
Results The authors studied 20 visits from PRs. The PR's obligation to identify himself and his company was respected in 75% of cases. All of the documents and obligatory information were only provided in 5% of cases (notification from the French National Authority for Health (HAS) was absent in 90% of cases). During 80% of these meetings the PR made a comparison with competitor's drugs, which was associated with negative remarks in 44% of cases. The PR promoted cases of use outside those that had received marketing approval in 35% of conversations. Invitations to scientific meetings, promotional events and/or training were not offered to any of the participants of these meetings. On the other hand gifts or samples were offered at the end of these meetings in 20% of cases. Prohibited practices were observed in a total of 85% of cases.
Conclusions Our results suggest that at present hospital visits by PRs do not respect the commitments made by the pharmaceutical industry, and do not make it possible to ensure that honest information is provided or information that favours the proper use.

Competing interests None.

OHP026 CLINICAL AND FINANCIAL EFFECTS OF DISPENSING ANTINEOPLASTIC AND INFERTILITY TREATMENTS FROM A HOSPITAL PHARMACY

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Background In December of 2010 the Health System of Andalucía (Spain) approved new dispensing procedures for some drugs; this group included medicines used in infertility treatments and oral antineoplastic drugs. Prior to this reform these products were dispensed in Community Pharmacy, but now with the new arrangements they are dispensed in the Hospital Pharmacy.
Purpose The aim of this study was to describe the clinical and financial impact of this new activity in the Outpatients Unit in a Hospital Pharmacy.
Materials and methods The study period was from January to September of 2011. Using the computer program in the Outpatients Unit The authors assessed the increase in the number of patients, workload in the Outpatients Unit and the cost of these drugs.
Results The number of patients was 461 (14.2% of the total number of patients in this period). The cost of these treatments was 717,244.02 euros. (8.7% of the total cost of dispensed drugs in this period). Comparing with the same period in 2010 the increase in expenditure was 476,623.77 euros.
Conclusions The expenditure of the Pharmacy Hospital increased with the new drugs dispensed in the Outpatients Unit. On the other hand by dispensing these drugs The authors improved the quality of dispensing and passed on more information about the drugs to these patients.

Competing interests None.

OHP027 THE USE OF STABILITY CRITERIA FOR ÌALL IN ONEÎ PARENTERAL NUTRITION SOLUTIONS IN PAEDIATRICS

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Background The use of 'all in one' parenteral nutrition solutions (PNS) is supposed to reduce the problem of the instability of lipid emulsions, caused by the addition of different nutrients to the mixture. However, it is necessary to review the concentrations in the final mixture.
Purpose The objective was for the pharmacist to evaluate 'all in one' paediatric PNS prescriptions against stability criteria.
Materials and methods A prospective study was performed (January-June 2011). The prescriptions of PNS in children younger than 1 year were reviewed. Later, an evaluation was

made according to the 'all in one' PNS stability criteria developed by the Spanish Society of Hospital Pharmacy (SSHP). The requirements established for the maintenance of the stability are concentrations ≥5% glucose, ≥2.5% amino acids and ≥1.5% lipids. The pharmacist made the necessary adjustments according to the requirements of each patient and the SSHP criteria.

Results 50 paediatric patients received PNS. The average age of the patients was 1.76 months and an average weight of 3.97 kg. The average volume administered was 300 ml. The authors observed that 64.2% of the PNS prescribed achieved the requirements of stability. In 35.8% of the prescriptions The authors detected inadequate concentrations of nutrients, specifically, low concentrations of: glucose (0.2%), amino acids (1%), lipids (29.4%), glucose and lipids (0.2%), amino acids and lipids (3.8%) and glucose, amino acids and lipids (0.4%). The pharmacist made the necessary adjustments in the 30% of PNS prescriptions by changing the nutrient content and/or the volume.

Conclusions The 'all in one' PNS is the ideal form of administration in paediatrics. If the pharmacist evaluates and adjusts the composition of the nutrients according to the stability criteria, this will avoid mistakes in 35% of PNS prescriptions.

Competing interests None.

OHP028 PHARMACEUTICAL INTERVENTIONS IN PARENTERAL NUTRITION IN A TERTIARY HOSPITAL

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Background The clinical pharmacist's main functions in parenteral nutrition (PN) in the present clinical context are to ensure the quality and safety of the solutions prepared and to verify that the composition of the nutrition is the appropriate according to the type of patient and his/her clinical situation. Pharmaceutical interventions (PIs) are made to perform these checks.

Purpose The objective is to describe and to analyse the PIs made regarding the prescriptions for parenteral nutrition (PN) in a tertiary hospital.

Materials and methods A prospective study of the interventions in PN was conducted (January-June 2011). The PIs were classified into five categories: time of the intervention, type of patient (adult/paediatric, beginning/continuation), sufficiency of data on the application, accuracy in the reception/shipping of the request, problems of formulation and/or compatibility and departure from the clinical recommendations.

Results 1420 prescriptions for PN (780 adults and 640 children) were recorded for 250 patients (191 adults and 59 children). 99 interventions were recorded for 65 patients. 35.2% were made at the beginning of the prescription. 55.3% of the PIs were made about paediatric prescriptions corresponding to 33 patients. Regarding the kind of pharmaceutical intervention, 26.5% were made due to lack of information in the request for PN, 35% were about failures in the reception/shipping, 23.9% were to solve formulation problems and compatibility in the mixtures and in 15% departures from the clinical recommendations were detected, 11% corresponding to the detection of deviations in the composition of the formula with respect to the previous day without any justification and 4% to the detection of deviations in the maximum permitted levels of some nutrients.

Conclusions Pharmaceutical interventions detected a higher frequency of prescription errors in the use of paediatric PN (55.35%). A high percentage (23.9%) of the PIs were made to solve problems in the ordering and delivery of PN solutions to the wards.

Competing interests None.

OHP029 NUTRITIONAL ASSESSMENT OF INSTITUTIONALISED OLDER PATIENTS TAKING NUTRITIONAL SUPPLEMENTATION

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Background Pharmacist's role in a social-health centre is very wide. Control of nutritional supplementation is sometimes forgotten.

Purpose Nutritional status evaluation and follow-up of institutionalised older patients taking enteral nutrition.

Materials and methods Cross-sectional and longitudinal study in institutionalised older patients at a social-health centre. The authors selected patients who were receiving nutritional supplements in two wards of the centre. Patients were weighed and classified according to body mass index (BMI), and albumin values were requested. A protocol was prepared to evaluate them nutritionally. The classification according to BMI was: overweight, normal, potential risk of malnutrition, slight, moderate or severe malnutrition and according to albumin: mild, moderate, and severe malnutrition. Patients with moderate-severe malnutrition underwent a complete nutritional assessment (day intake record and fold measurement). The recommendations were: withdraw, replace, or continue with the supplement according to the needs of the older patients and their acceptance was recorded. Reevaluation was quarterly

Results Thirty-eight older patients were included with a mean age of 85 years. Six of them died. By BMI: 4 were overweight, 8 had normal BMI, 12 had possible malnutrition, 1 mild malnutrition, 2 moderate and 5 severe malnutrition. 37.5% had albumin levels indicative of mild malnutrition and 3% of moderate malnutrition. Three months later, 21 patient were reevaluated: 7 increased BMI (6 at risk of malnutrition), 8 decreased and 6 remained unchanged. 78% of patients had normal serum albumin levels and 22% had mild protein malnutrition. A total of 21 interventions were made, 18 were accepted and 3 rejected. Nine of them were proposals to discontinue

Conclusions Nutritional supplementation resulted in albumin levels normalisation, but was not such effective in terms of BMI changes. The authors noticed overutilisation of nutritional supplements and the need of a nutritional assessment protocol in the social-health setting

Competing interests None.

OHP030 DIFFERENT DOSE REGIMENS OF DARUNAVIR AND ITS ADHERENCE

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Background Darunavir was approved at a dose regimen of 600 mg twice daily, in combination with other antiretroviral agents, by the Hospital's Pharmacy and Therapeutic

Commission (CFT) in 2007 for treatment of HIV in adult patients that had been highly pretreated and had failed more than one prior therapy. In 2010, it was also approved for naïve patients in a dose regimen of 800 mg once daily. A patient is considered good compliant when adherence is above 90%, poorly compliant when it is between 80-90% and non-adherent when it is below 80%.

Purpose To evaluate the different posologies of darunavir/ritonavir used for the treatment of HIV infection in daily clinical practice.

Materials and methods A retrospective observational study of patients treated with darunavir since its inclusion in the Hospital's Pharmaceutical Guide (October 2007) until April 2011. Data were collected from AS-400 software which includes outpatient's dispensations. Adherence to treatment was estimated as the difference (as a percentage) between units of medication that should have been dispensed taking into account the dosage, and units that are registered in our software to have been dispensed in the last year.

Results 60 patients were treated with darunavir during this period, 42 men and 18 women. 32 of these 60 patients (53.3%) had 800 mg once daily dose regimen and 28 (46.7%) 600 mg twice daily. Only 14 of the 32 patients (43.8%) with the 800 mg dose regimen were naïve. All patients with the 600 mg dose regimen had been highly pretreated. With regard to adherence to antiretroviral treatment, The authors had data of 46 patients. 76.2% (16/21) of patients treated with 800 mg/day were good compliant, 9.5% (2/21) poorly compliant and 14.3% (3/21) non-compliant. In case of patients treated with 600 mg twice daily, 88.0% (22/25) were good adherent, 4.0% (1/25) bad adherent and 8.0% (2/25) non-adherent.

Conclusions In daily clinical practice, the indications approved by the CFT were not followed by clinicians. Although the dose regimen of a single daily dose aimed to simplify the antiretroviral therapy and improve adherence, The authors can not say that these patients were more adherent. Furthermore, The authors should take into account that adherence to treatment is influenced by more factors.

Competing interests None.

OHP031 DESIGNING AND IMPLEMENTING A STANDARD NUTRITIONAL STARTER SOLUTION FOR PRETERM INFANTS

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Background Administering parenteral nutrition to preterm infants in their first hours of life improves their survival. As it is not always possible for the pharmacy department to compound individual parenteral nutrition solutions, preparing a standard starter solution for preterm children to be administered within the first 24 h after birth was arranged with the Neonatology Department.

Purpose To design and implement a standard starter solution of suitable composition and stability for preterm infants, as a means of meeting their nutritional requirements during their first hours of life.

Materials and methods The authors performed a literature search to determine the nutritional requirements for neonates. In order to ensure a positive nitrogen balance and to avoid protein catabolism, adequate inputs of amino acids and glucose should be administered within the first hours of life in order to provide at least 4 g/kg/day of glucose and 1 g/kg/day of amino acids.

Results A standard nutritional starter solution was prepared in syringes. Each syringe contained 52.5 ml of solution (+3.5 ml of purge) comprising 1.5 g of amino acids (15 ml Primene 10%) and 3.75 g of glucose (37.5 ml of 10% glucose), with an osmolarity of 629 mOsm/l (allowing either peripheral or central intravenous administration) and a total calorie input of 21 kcal per syringe (15 kcal were non-protein). The stability of the solution was 7 days at 2-8°C, as recommended in the literature. From February 2010 (implementation) until August 2011, 840 starting syringes were prepared in the pharmacy department.

Conclusions This formulation makes it possible to meet the glucose and amino acid requirements for preterm neonates within their first 24 h of life, thus preventing excessive protein loss. Its long-term stability makes it possible to store it in the Neonatology Department, thus guaranteeing its availability at times when it is not possible to prepare a parenteral solution in the pharmacy department.

Competing interests None.

OHP032 EVALUATION OF THE COST SAVING ACHIEVED BY CENTRALISING TOTAL PARENTERAL NUTRITION COMPOUNDING

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Background Total parenteral nutrition (TPN) solutions are usually prepared by centralised compounding in the Pharmacy Department.

Purpose To evaluate the cost saving achieved with centralised compounding of TPN solutions (newborns and adults) and product use optimisation in our Pharmacy Department.

Materials and methods In order to calculate the number of TPN solutions and their cost, The authors studied preparation and dispensing on a single day. Data on the components of each TPN solution prepared were extracted from the software used for TPN compounding (MedicalOne® Parenteral). Given the differences in composition, solutions were classified as adult and newborn. For each solution, two different costs were calculated: first the theoretical cost if each TPN solution was prepared separately in another clinical department (considering the cost of whole vials of each component, though in some cases only fractions were needed) and, second, the real cost of TPN solutions prepared in the Pharmacy Department (calculating costs per mililitre and volumes used of each component). The cost saving was calculated as the difference between the theoretical and the real cost of each TPN solution. The mean saving per patient was calculated for adults and for newborns.

Results On the study day, 49 solutions were prepared: 33 for adults (oncology, 5; critical patients units, 13; surgery, 7; others, 8) and 16 for newborns (neonatology, 4; neonatal intensive care, 12). For adults, the mean cost was €39.53 per solution when prepared in clinical departments and €34.71 per solution when prepared in the Pharmacy department (mean cost saving, €4.82 (12.2%)). For newborns, the mean cost of TPN solutions was €24.71 per solution when prepared in clinical departments and €7.27 per solution when they were prepared in the Pharmacy Department (mean cost saving, €17.44 (70.6%)).

Conclusions When TPN solutions are compounded centrally, significant cost savings are achieved, especially in newborns. Therefore, Hospital management should implement centralised compounding.

Competing interests None.

OHP033 EVALUATION OF MALNUTRITION AND VITAMIN D LEVELS IN AN OLDER MEDICAL UNIT

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Background Malnutrition among hospital inpatients is very high (30-50%). It has important consequences in patients' clinical course and in hospitalisation costs so early detection and establishment of corrective action is crucial. Vitamin D deficiency is also common in the older, and leads to decreased bone mass and increased fractures and healthcare costs.
Purpose Evaluate the nutritional status and vitamin D levels in an older medical unit. Evaluate whether corrective actions such as nutritional supplements or vitamin D prescription were established.
Materials and methods Nutritional status was assessed in 50 randomly selected patients using CONUT (COntrol NUTritional) system, a validated tool that determines nutritional status according to serum albumin, cholesterol and lymphocytes. 25-OH vitamin D levels (deficiency <12 ng/mL; insufficiency 12-30 ng/mL; normal 30-80 ng/mL) were also measured. Prescription of nutritional or vitamin D supplements was registered.
Results Medium age was 78.8 years. 22 were male and 28 female. Prevalence of malnutrition was very high (68%): It was mild in 19 patients (38%), moderate in 13 (26%) and serious in 2 (4%). Nutritional supplements were prescribed to just 6 patients (17,6%) with malnutrition. Forty-six patients (92%) had vitamin D levels below recommendations: 15 (30%) had vitamin D insufficiency (mean= 17.8; range 12.1-25.8 ng/mL) and 31 (62%) had deficiency (mean= 7.5; range 3-11.4 ng/mL). Calcium + vitamin D supplements were prescribed in eight (17.4%) patients with insufficiency or deficiency, three (7%) prescribed before admission and five (10.9%) during admission.
Conclusions Due to the high prevalence of malnutrition and hypovitaminosis D in the older, it would be advisable to establish a nutritional screening system and to measure vitamin D levels at admission, so that corrective action such as prescription of vitamin D or nutritional supplements prescription can be established. In addition, general practitioners should continue monitoring malnutrition and vitamin D after patients are discharged.

Competing interests None.

OHP034 TRAINING ON PULMONARY HYPERTENSION DESIGNED BY A COLLABORATIVE PHARMACY PRACTICE†

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Background Since 2008, a clinical pharmacy program has been successfully implemented in the French referral centre for pulmonary hypertension (Pulmonary department, Clamart, France). However, the management of this rare and complex disease requires specialist knowledge from physicians and pharmacist residents. Physicians and pharmacist residents often have a limited knowledge of PH. Indeed, upon their arrival, this lack of specialist knowledge could affect PH patient care.
Purpose The aim of this study was to design, implement and assess the training of pharmaceutical and medical residents on PH for before their arrival, in order to optimise patient care.
Materials and methods From February to June 2011, an e-learning program was designed using the Dokeos Learning Management System (LMS). Web accesses were sent to the residents two weeks prior to their arrival. The e-learning course was evaluated for quality by interviewing new residents regarding its form and content. An evaluation of the type of training was also performed.
Results All the new residents appreciated the e-learning tool which was found 'user friendly' and suitable for their learning objectives. Four out of five new residents found that e-learning facilitated their integration into the pneumology department. Although individual knowledge of PH was erratic upon arrival, all the residents gained new knowledge demonstrating that e-learning could be a real 'à la carte' learning tool. E-learning was also appreciated as a tool of distance learning.
Conclusions The e-learning tool designed in this pilot study by a collaborative pharmacy practice approach improved the resident learning process on PH. Overall, this contributed to better management of patient care. Optimisation and final validation as a continuing medical education tool for PH are required prior to it being made available to other healthcare professionals.

Competing interests None.

OHP035 PROGRAM TO IMPROVE THE QUALITY OF PRESCRIPTIONS IN SPECIALISED HEALTHCARE: IMPLEMENTATION AND RESULTS

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Background Drug prescription is a complex activity that involves many factors. Improving the quality is very important due to the large health and economic impact of the use of drugs.
Purpose To assess the impact of a program that improves the quality of prescriptions in Specialised Healthcare.
Materials and methods Prospective and intervention study (2009-2011) that compares the outcomes of the main quality indicators of prescriptions one year before and one year after the development of the program. The results were obtained using MicroStrategy® software, an application where all prescriptions written by specialists for patients not staying at hospitals are registered. The program was implemented throughout 2010. The phases of the program were:

- 1.-Selection of prescription quality indicators (PQI):
- Indicator-1: Percentage of prescriptions with international non-proprietari names(INN) for pharmaceuticals substances.
- Indicator-2: Percentage of prescriptions with omeprazole versus all Proton Pump Inhibitors(PPI)
- Indicator-3: Percentage of prescriptions with Ibuprofen, Naproxen, Diclofenac versus non-steroidal anti-inflammatory drugs(NSAIDs)

OHP035 table 1

Prescription Quality Indicators: Results

	Before Pharmaceutical Intervention	After Pharmaceutical Intervention	Improvement
% of prescriptions with INN for pharmaceuticals substances	46,42%	67,15%	20,73%
% of prescriptions with omeprazole versus all PPI	76,85%	80,96%	4,11%
% of prescriptions with Ibuprofen, Naproxen, Diclofenac versus NSAIDs	48,07%	62,92%	14,85%
% of prescriptions with simvastatin versus all HMG-CoA reductase inhibitors.	35,78%	36,62%	0,84%

- Indicator-4: Percentage of prescriptions with simvastatin versus all HMG-CoA reductase inhibitors.
- 2.- Selection of the medical services with the greatest capacity for improvement.
- 3.-Training Sessions: The pharmacy department conducted two training sessions in selected medical services informing about the quality criteria in prescriptions(efficacy, safety, convenience and efficiency)and about which quality indicators should be improved.
- 4.-Design of a quarterly reporting system to inform doctors about the progression of their prescriptions.

Results

Conclusions The design and implementation of an active pharmaceutical intervention program to improve the quality of prescriptions in Specialised Healthcare has improved the outcome of PQI. However, The authors believe that it is necessary to go on following this line of work for further improvement.

Competing interests None.

OHP036 STUDY CONCERNING VULVOVAGINAL CANDIDIASIS IN WOMEN WITH DIABETES

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Background Changes in glucidic metabolism characteristic of diabetes are a contributing factor in causing vulvovaginal candidiasis.

Purpose The objective of this study was evaluating the prevalence of morbidity through vaginal candidiasis with Candida albicans in diabetic women and instituting of specific antifungal therapy.

Materials and methods The study was conducted on 140 women (aged between 22-40 years) with diabetes, admitted in the Diabetes and Nutrition diseases clinic from Clinical Emergency Hospital of Craiova, Romania, from who were harvested blood and vaginal secretions. Blood sugar levels were determined by biochemical methods. The vaginal secretions were subjected to mycological diagnosis (Gram stain, isolation on Sabouraud media, identification by using chromogenic differential media specific for Candida). The isolates strains were subjected to fungal sensitivity test, using commercial kits: ATB Fungus 3 (BioMerieux, Marcy l'Étoile, France) and Candifast (EliTech France SAS) (5-Fluorocytosine, Amphotericin B, Fluconazole Itraconazole, Voriconazole, Econazole, Miconazole, Ketoconazole and Nystatin). The data was analysed using the Student's t-test.

Results The authors isolated 98 strains of Candida albicans, thus the morbidity by candidiasis was 70%, most of the patients had blood sugar levels between 130–180 mg/dl. The condition was more common in patients aged between 51-60 years (39.80%) and 41-50 years (31.63%). The results of antifungigram showed susceptibility to: Ketoconazole (95.92%), Econazole (89.80%), Fluconazole (85.71%) and Itraconazole (85.71%).

Conclusions These results demonstrate the existence of a correlation between hyperglycaemia and vaginal candidiasis. Most of the vulvovaginal candidiases were treated successfully with new antifungal drugs. Although regarded as a banal infection by some, the increased incidence of vaginal candidiasis associated with diabetes raises additional issues regarding prevention and patient management.

Competing interests None.

OHP037 ASSESSMENT OF ADHERENCE TO ANTIRETROVIRAL THERAPY

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Background The effectiveness of antiretroviral treatment depends on several factors. Incorrect adherence is the main cause of treatment failure and it has been related to an increase in mortality.

Purpose To assess the compatibility of the recommendations for antiretroviral treatment administration with the recommendations in the product information. To discover the patients' adherence to the treatment.

Materials and methods Prospective observational study, conducted over two weeks, in an outpatient pharmacy department of a community hospital that serves a total of 415 HIV patients. All the HIV patients that came to collect their treatment in the pharmacy department and agreed to collaborate in the study were included. The exclusion criteria were: patients who started or changed their treatment, if it was a relative who collected the treatment or because of a language barrier. A data collection sheet was designed, which included demographic information (gender, age), data related to antiretroviral therapy (which drugs, how and when they were taken) and the SMAQ (Simplified Medication Adherence Questionnaire) adherence test.

Results 112 patients were interviewed. 76 of them were included in the study (78.95% (60) men, mean age 48). 40.80%

(31) of patients did not follow the product information recommendations. The drugs with which more discrepancies were found were ritonavir (14.47%; 11) and efavirenz (17.11%; 13). Ritonavir was mainly taken on an empty stomach instead of being taken with meals. Efavirenz was taken with meals instead of being taken on an empty stomach as recommended in the product information. 39.47% (30) of patients were considered non-adherent according to the SMAQ adherence test.
Conclusions These results confirm the need to include a pharmaceutical care programs for HIV patients. It would be advisable to inform them about their treatment prior to them starting it to achieve the maximum benefit and to improve the adherence to the treatment. Future studies with other adherence tests would be interesting in order to compare the results.

Competing interests None.

OHP038 EPIDEMIOLOGICAL AND SURVIVAL DATA OF PATIENTS WITH LUNG CANCER ASSOCIATED WITH SYMPTOMATIC BRAIN METASTASIS

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Background Brain metastasis are frequently associated with lung cancer. However, there are few epidemiological data on patients concerned.
Purpose The aim of this retrospective and descriptive epidemiological study was to compare diagnostical, therapeutical and survival data for symptomatic and asymptomatic patients.
Materials and methods This study reviews 55 records of patients hospitalised in 2008, previously diagnosed with lung cancer and brain metastasis. The studied parameters were sex ratio, proportion of death, mean time from primitive cancer diagnosis to brain metastasis diagnosis, from cancer and brain metastasis diagnosis to death, lung cancer type, histological type, TNM (tumour node metastasis) stage, number and anatomic situation of brain metastasis, treatment and neurological symptoms.
Results 48 out of 55 patients died. Median survival times for lung cancer and brain metastasis diagnosis were respectively 8 and 4 months. Mean times from lung cancer and brain metastasis diagnosis to death were statistically different (11 months vs 5.4 months, $p<0.003$). 33 patients (60.0%) were neurologically symptomatic and 22 (40.0%) were asymptomatic. For each of the studied parameters, no statistical difference was found between these 2 groups (t-test or χ^2 test $\alpha=0.05$). The 3 most frequent symptoms at metastasis diagnosis were motor deficiency (45.5%), confusion (18.2%) and headache (18.2%). The median survival time of asymptomatic patients was 4 months and 3.5 months for patients with symptoms (Kaplan-Meier method). The log-rank test of survival rates between symptomatic and asymptomatic patients had no significant outcome ($p=0.2$).
Conclusions These results are consistent with previous study on non-small cell lung cancer and brain metastasis (J. Sanchez de Cos – 2009) which shows the same order of magnitude for patient characteristics and median survival time for asymptomatic and patients with symptoms. However, it would be interesting to consolidate this study by including more patients in order to improve the statistical relevance and identify new prognostic factors.

Competing interests None.

OHP039 THE POSSIBILITIES FOR HOSPITAL PHARMACISTS IN REDUCING OF EXPIRED DRUGS EXPENDITURES

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Background In December 2010 withdrawal of drugs with expired date was done in Clinical Center of Serbia. It was noticed that value of these medicines presented significant part of money invested in medicines.
Purpose The aim of this research was to determine main reasons for large amount of drugs which had to be withdrawn due to expiration.
Materials and methods An inventory of all withdrawn medicines was done. It was noticed that change of protocols (including appearance of modern drugs for one indication on the market), cessation of financing by Republic Institute for Health Insurance (RIHI) and carelessness of healthcare professionals were main reasons that led to expiration date of drug usage. Therefore, all withdrawn medicines were classified in these three groups.
Results Total value of medicines that were withdrawn due to expiration date of usage in 2010 presented 0,045% of money which was spent for acquisition of all drugs in Clinical Center of Serbia. 53.14% of these expenditures were spent on anticancer group of drugs, 32.71% on antibiotics and 14.15% on other therapeutical groups. Medicines that were withdrawn as a result of protocol change or appearance of modern drugs took 51.88% of money invested in dated drugs. On the group of drugs withdrawn due to cessation of financing by RIHI was spent 24.18% of all the money spent on withdrawn drugs. Medicines withdrawn because of carelessness of healthcare professionals occupied 23.94% of money.
Conclusions Even though carelessness of healthcare professionals doesn't occupy the biggest part of expenditures spent on dated drugs, interventions of hospital pharmacists in this area could significantly contribute to money savings. Therefore, special precautions are taken in acquisition of anticancer drug, hospital pharmacists are more involved in drug prescription, communication between medical doctors and hospital pharmacists is improving from day to day, and FEFO principles are to be established through appropriate SOPs.

Competing interests None.

OHP040 ANALYSIS OF PRESCRIPTIONS OF DRUGS NOT INCLUDED IN THE FORMULARY

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Background A treatment exchange protocol (TEP) contains three ways of intervening: a) suspend the prescribed treatment (not very useful), b) keep the patient on his home medicines during the hospitalisation, c) exchange the treatment (TE) to another drug included in the hospital formulary.
The protocol used not to be applied to multidose drugs commonly used by patients.
Purpose To assess the prescription of drugs not included in the hospital formulary (NIDHF) and to know the acceptability of recommendations for a change of treatment.
Materials and methods Observational, prospective, two-month study in a General Hospital. Every day The authors recorded new NIDHF prescriptions, age, sex and diagnosis. TEP was applied to everyone. When the recommendation

wasn't accepted, The authors recorded the reason (eg, allergy). NIDHFs without a recommendation because of a lack of evaluation or agreement were quantified, knowing they were a therapeutic void in the hospital formulary (HF) and TEP.

Results The authors identified 251 NIDHFs from 209 patients (average age 66, 46% male). The authors obtained an average of six new prescriptions daily; half of them were replaced according to the TEP.

The analysis of the non-replaced NIDHF drugs was:

- 46% of NIDHF drugs were kept during hospitalisation. They were mainly oral antidiabetic and antidementia agents.
- In 12% the drug was acquired occasionally for a justified reason.
- In 7% they were multidose drugs.
- In 18% the TE was rejected.
- In 9% the TE wasn't available.
- In the remainder, the reason for rejection wasn't specified and patients provided treatment.

Clinical services with more NIDHF prescriptions were: Internal Medicine (40%) and Traumatology (10%). The lowest acceptance of recommendations was in Home Hospitalisation (45%) and Surgery (33%). The greatest number of prescriptions for drugs without agreed therapeutic exchange was in Pneumology (23%) and Otorhinolaryngology (28%).

Conclusions The adherence to the HF and acceptance of the TEP recommendations were high. Many of the requirements of NIDHF are solved with TEP. The study has enabled us to detect therapeutic areas in which the HF and TEP could be improved. Any changes must be reviewed and agreed with medical services to reduce the likelihood of adverse events and promote good-quality pharmacotherapy.

Competing interests None.

OHP041 CHANGES IN PHARMACOTHERAPY AND THEIR EFFECT ON SF-36 SCORES IN A PAIN MANAGEMENT UNIT

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Background SF-36 is a questionnaire used in clinical practice to measure subjective patient health. It includes 8 scales: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health.

Purpose To describe Pain Unit patients' pharmacotherapy and evaluate its influence on SF-36 responses.

Materials and methods Retrospective study that included patients attended in the **pain management unit** between October 2009 and May 2010. Patients completed at least two SF-36 questionnaires. The electronic history was used to collect demographic (sex, age) and treatment information (diagnosis, pain pharmacotherapy before and after the first clinical visit). Scores obtained in the two questionnaires were compared and The authors calculated the number of patients with improved SF-36 scores.

Results 173 patients were attended during the study period, but only 47 were included. Sex distribution: 61.7% female and 38.3% male. Mean age was 56.3 (22-82) years. Chronic lower back pain and postsurgical neuralgia were the main diagnoses. On the first clinical visit NSAIDs (36.2%) and analgesics (34%) were the most prescribed groups followed by weak opioids, antidepressants, anticonvulsants and strong opioids. On the second visit anticonvulsants, antidepressants and strong opioids were the most frequently-prescribed groups. There were no changes between the two questionnaires on role-physical and role-emotional scales and very little difference on bodily pain measures. More than half of patients reported improved results on physical functioning, general health, vitality and mental health scales. The combination of anticonvulsants and antidepressants was associated with an improvement on these scales. Better results were observed if opioids were added to treatment.

Conclusions Pharmacotherapy changes after the clinical visits improved physical functioning, general health, vitality and mental health. Antidepressants and anticonvulsants alone or in combination with opioids were the main groups involved. It is interesting to know the drugs used in a Pain Unit, their impact on SF-36, and to evaluate whether the goal of pain relief was really reached and whether patients received optimal pharmacotherapy.

Competing interests None.

OHP042 EVALUATION OF PHYSICAL COMPATABILITY AND DRUG PREPARATION TIMES OF THE VIALMATE ADAPTOR IN INTRAVENOUS DRUG PREPARATION

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Background The Baxter VialMate adaptor is a device used in the reconstitution of intravenously administered medicines. It is connected directly between the medicine phial and a small infusion bag resulting in a closed system with potential advantages associated with reducing errors, time required for drug preparation, consumable costs and contamination. Evaluation of the potential magnitude of these benefits is required to support routine adoption.

Purpose To investigate:

- 1. physical compatibility of parenteral medicine vials with the VialMate adaptor
- 2. the time difference between conventional methods and the VialMate adaptor when reconstituting medicines available in intravenous vials.

Materials and methods This research was conducted at an acute care government hospital.

- 1. All parenteral medicines available in vials and requiring reconstitution prior to administration were identified. The VialMate was attached to the selected phial and then to a sodium chloride 0.9% or glucose 5% 100 mL minibag, then reconstituted. Physical compatibility, defined as the adaptor fitting the phial, was documented.
- 2. A crossover simulation time and motion study was conducted. Ten specialist oncology nurses were randomised to prepare 10 infusions using conventional reconstitution methods or using the VialMate. The groups then crossed over to prepare 10 infusions using the alternate method. The time taken to complete each preparation was observed and recorded.

Results

- 1. 45 parenteral medicines were identified; 30 (66%) of these were suitable for reconstitution with the VialMate system. A reference guide was developed for VialMate compatibility, encompassing diluent and infusion suitability.
- 2. 100 1 g doses of cephazolin infusion were prepared using each method. Average time taken to prepare the infusions using the VialMate and conventional methods were 50.7 s

and 69.2 s, respectively (p<0.001). VialMate was 26% faster than the methods currently used.

Conclusions Approximately two thirds of intravenous medicines available in vials were compatible with the Baxter VialMate adaptor. There are significant time savings when using VialMate for preparation of intravenous infusions, compared to conventional preparation.

Competing interests Advisory board: An unrestricted research grant from Baxter HealthCare supported the conduct of this study

OHP043 ANALYSIS OF PAEDIATRIC PHARMACEUTICAL COMPOUNDING IN A HOSPITAL PHARMACY DEPARTMENT

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Background The paediatric population is a dynamic group, with major changes in pharmacokinetics and pharmacodynamics. Unfortunately, most medications commonly used in children do not have an approved labelling for use in these patients and are not available in appropriate formulations**.**

Purpose To analyse extemporaneous formulas compounded in a Pharmacy Department for pediatric patients during 2009.

Materials and methods Descriptive retrospective study of pediatric extemporaneous formulas made during 2009 in a 400-beds general hospital with 68 pediatric beds. Doctor's orders, compounding formula register book and standardised protocols were consulted in order to obtain the data. Each unit produced was considered as a formula.

Results 2158 pediatric extemporaneous formulas were made for 139 patients (50% girls), which corresponds to 8% of all compounded formulations developed. Patients' average age was 28 months. 29% of them were younger than 1 month, 25% between 1 and 5 months, 10% between 6 and 12 months, 20% between 1 and 5 years and 16% were older than 5 years. 76% of extemporaneous formulas were solid oral formulas, 18% liquid oral formulas, 5% were sterile parenteral preparations and only 1% were topical formulas. 36 different active ingredients were used. The most common formulas were redosed oral nutrition, followed by bosentan, omeprazole and methimazole capsules and liposomal amphotericin B preparations. 25% of the patients needed more than one different extemporaneous formula.

Conclusions Pharmaceutical compounding is essential to provide the appropriate doses or dosage forms that paediatric patients require. The compounding pharmacist is instrumental in assisting the medical staff with developing these new treatments and compounded formulations to treat these patients. It would be desirable that drug manufacturers could produce strengths and dosage forms appropriate for children.

Competing interests None.

OHP044 SYNERGIC ANTIFUNGAL AND ANTIBACTERIAL ACTIVITY OF ALCOHOLIC EXTRACT OF THE SPECIES ROBINIA PSEUDOACACIA L. (FABACEAE)

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Background Plant species Robinia pseudoacacia L. (Fabaceae) has been used as a medicinal plant since ancient times, as its infusions and extracts have antacid, antibacterial, purgative and emenagogic properties. The volatile oil of the flowers is also used in perfumery and cosmetics.

Purpose Due to its high content of volatile oil phenolic compounds, flavonoids and tannins with antimicrobial properties, the present study proposed to investigate the antibacterial and antifungal effect of the species Robinia pseudoacacia.

Materials and methods The dry powdered flowers, leaves, bark and seeds of Robinia pseudoacacia were subjected to extraction in a Soxhlet extractor with 90% ethanol. The alcoholic extract obtained in the concentration of 100 mg / ml, was tested using sterile discs of Whatman No. 1 filter paper, impregnated with 100 mg extract. Antibacterial and antifungal effects was evaluated by the Kirby-Bauer disc diffusion method, in accordance with the NCCLS / CLSI standard, using the following infectious agents isolated from patients and the corresponding reference strains: methicillin-resistant Staphylococcus aureus and methicillin-sensitive haemolytic S. epidermidis, Streptococcus pyogenes, Enterococcus, Enterobacter aerogenes, Escherichia coli, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus, Candida albicans.

Results Extracts from various different parts of the plant had different antibacterial activities. Extracts of flowers and seeds are efficient antibacterials for Gram positive cocci. Bark and leaf extracts were active against Escherichia coli, Pseudomonas, Proteus, Salmonella choleraesuis, Candida albicans.

Conclusions These results prove the antimicrobial or antifungal properties of certain extracts of Robinia pseudoacacia L., which offers an alternative treatment with a natural product with synergistic effects with conventional antibacterial treatment.

Competing interests None.

OHP045 ASSESSING THE IMPACT OF PHARMACEUTICAL INTERVENTIONS IN TRACKING NON-ADHERENT HIV PATIENTS

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Background Adherence in HIV patients is a basic factor in the effectiveness of the treatment. Pharmaceutical interventions may improve adherence.

Purpose To evaluate the effect of pharmaceutical interventions to enhance adherence (IEAs) on non-adherent HIV patients and to assess whether this improvement was maintained over time.

Materials and methods The authors retrospectively analysed the IEA carried out from January 2007 to September 2010, which were recorded in Farmatools software. IEAs (motivational interviews) were conducted when the patient didn't take the medication on time. The authors calculated the mean adherence 6 months before and 6 months after the date of IEA, using the repeat prescription records. The impact of the interventions was defined as the percentage of patients with adherence greater than 90 and 95% six months pre and postintervention. The variation of the percentage of adherence over time was also assessed (from 6 to 12 months post-intervention). SPSS 17.0 software was used.

Results 199 interventions were performed, 64 of which were excluded from analysis due to missing data (n=135). The mean adherences obtained 6 months pre and postintervention were 66.24% and 81.82% respectively (p<0.001).

The percentage of patients with adherence ≥95%:

- Preintervention: 5.19% (7/135)

- Postintervention: 20.74% (28/135).
- ARR (adjusted relative risk) =15.55. NNT=7 (95% CI 5-13).

The percentage of patients with adherence ≥90%:

- Preintervention: 6.67% (9/135)
- Postintervention: 38.52% (52/135).
- ARR=31.85 NNT=4 (95% CI 3-5).

Analysis of adherence modification (six and twelve months postintervention), showed that adherence decreased in 51.85% of cases, but the decrease was <5% in half of them.

Conclusions IEAs are an essential strategy to improve the adherence of HIV patients. The high increase of adherence postintervention and its persistence 12 months later shows the positive impact of this activity. Long-term studies are necessary to investigate the frequency of IEAs needed to maintain adequate adherence over time.

Competing interests None.

OHP046 IMPACT OF LIMITING PRESCRIPTION OF LOW THERAPEUTIC VALUE DRUGS

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Background During the last decade healthcare systems have developed different strategies for containing drug costs. Among others, in Spain the Ministry of Health together with regional Health Departments, have published guidelines for drugs considered to have low therapeutic value (LTVDs), through evidence-based studies and drug assessment data, and they encourage healthcare practitioners to avoid prescribing them.

Purpose Our aim was to estimate the cost saving obtained by limiting the use of LTVDs in our hospital.

Materials and methods The authors reviewed different guidelines published by Healthcare Authorities and compiled those drugs listed as LTVDs. Data was obtained from three sources: 'Therapeutic usefulness of medical drugs reimbursed by the National Health System' Spanish Ministry of Health 2001, 'List of medical drugs considered as Low Therapeutic Value' Canary Islands Health Department 2011, and 'Medical drugs with Non-High Intrinsic Value' Andalucia Health Department. The authors drew up a list of LTVDs and compared it with the formulary and non-formulary drugs purchased during the period August 2010–July 2011.

Results A total of 110 drugs were listed as LTVDs, 59 formulary drugs and 51 non-formulary drugs. The potential cost saving obtained by restricting the use of LTVDs during the reviewed period was estimated at €88,142. By ATC classification, the most significant groups were Sensory organs (€36,118), Nervous system (€15,347), Respiratory system (€11,917) and Dermatologicals (€11,440).

Conclusions Our drug formulary contains 59 LTVDs. Deleting them from the formulary as well as restricting the prescription of LTVDs through the Pharmacy and Therapeutic Committee would result in a potential saving of €88,142 per year. Furthermore, this approach encourages physicians to implement Healthcare Authorities recommendations and contributes to cost-effective and rational drug treatment.

Competing interests None.

OHP047 COCAINE AND HEROIN ADULTERANTS

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10.1136/ejhpharm-2012-000074.347

Background Health centres have many opportunities to improve community health. One of them is to give information among drug users about the adulterants of the substances that they will consume with the purpose of avoiding acute reactions to consumption

Purpose To know the main adulterants of intravenous samples and their effects among users of injected drugs.

Materials and methods Survey among active intravenous drugs users in Barcelona. Several drugs users were trained to interview other drugs users who did not use social and health services. The authors collected socioeconomic and consumption data and the users were asked to give a part of their samples to be analysed before their intravenous consumption.

Results Data from 63 men and 31 women were collected. 70 of them use cocaine, and 76 use heroin. Both substances alone or mixed. 69 were injecting drug users. 17 samples can be analysed. The additive substances found in cocaine samples were caffeine, lidocaine, procaine, phenacetine, tetracaine and levamisol; paracetamol and caffeine in heroin samples

Conclusions Studies of Hospital Services can be involved in real street research. In this study The authors reviewed proceedings of a high morbidity such as illicit drug consumption. The knowledge of main adulterants of intravenous samples enables us to study effects and interactions, to achieve the best healthcare and to develop educational programs among drug users.

Competing interests None.

OHP048 THE USE OF GLUTAMINE SUPPLEMENTATION IN THE PARENTERAL NUTRITION SUPPORT IN A THIRD LEVEL HOSPITAL

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Background Glutamine is the most abundant amino acid (AA) in the human body. It is classified as a non-essential AA, however in some situations may become essential and it is needed an exogenous supplementation. Glutamine plasma levels decrease in stress situations which is associated with alterations in protein turnover, intestinal barrier and immune function. Glutamine may be beneficial to critical ill patients due to it is associated with a decrease in infectious complications, decrease in hospital length of stay, and possibly a decrease in mortality. Dose recommended glutamine supplementation in PN is 0.35 g/Kg/d, no longer than nine consecutive days.

Purpose Assesment of the use of glutamine-supplemented parenteral nutrition (PN) according to last ESPEN and ASPEN recommendations.

Materials and methods Retrospective, observational study of patients with PN support from January to March 2011. Data were collected from the PN software Multicomp 2006®: age, gender, ward, milligrams of glutamine and duration of PN support.

Results 192 patients received PN support (117 males, 75 females), 43 were prescribed glutamine-supplemented. The average age was 65 years. The allocation of patients by services was: ICU (34), surgery (7), Oncology (1), Gastroenterology (1). The prescription of the PN in this cases was: 23 postsurgical, 11 intestine diseases, 6 sepsis, 1 head injury, 1 posttraumatic and 1 pneumonia influenza A. Doses of glutamine were on average 13.2 total grams (range: 10-30g). Only 8 of the 43 patients received glutamine supplemented with an appropriate amount

to fulfil the guidelines recommendations. Glutamine supplementation was 9.8 days (range 2-42).

Conclusions The diagnoses included in our study 97% met the guidelines recommendations. Only 18% of patients received a correct dose of glutamine (0.35g/kg/day). Glutamine supplementation was longer than the recommendation in a 23% of patients. Glutamine supplementation to critically ill patients has been attempted to improve patient outcome, but data remain inconclusive.

Competing interests None.

OHP049 RE-ENGINEERING PROCESSES IN AN OUTPATIENTS PHARMACY AREA

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10.1136/ejhpharm-2012-000074.349

Background The Outpatient Pharmacy Area (OPA) has experienced an increase in patients and in the number and variety of medicines in recent years. Consequently new strategies are needed to ensure efficient OPA management that will bring benefits for both patients and hospital pharmacy.

Purpose To describe the OPA re-engineering process. Its aim was to improve the activity flow of pharmaceutical care services so as to match individual patient needs with the services provided.

Materials and methods A Standard Operating Procedure (SOP) was developed in 4 phases:

1) OPA infrastructure was restructured.
2) The Hospital Admissions Service set up an agenda for the OPA, to oversee appointments and collect data.
3) Pharmaceutical and nursing staffs were appropriately trained in using the relevant software to use the agenda. Patients were gradually informed about the new procedures.
4) Indicators were established to monitor the appointments system.

Results

1) OPA infrastructure comprises a pharmacists' office, a nurses' office and a waiting room.
2) The SOP defines three types of consultation: a first consultation, a follow-up consultation and continuing-treatment consultations.
3) First consultation: A hospital pharmacist interviews patients the first time they go to the outpatients area, initiates a drug treatment report and counsels on the treatment. Follow-up consultation: Patients are seen by a hospital pharmacist, who identifies and resolves medicines-related problems and monitors pharmacotherapy.
   - Continuing-treatment consultation: Nursing staff dispense medicine every two months, unless the drug treatment is modified. Follow-up and continuing-treatment consultations require an advance appointment. These appointments are made and data is captured at each consultation by a pharmacist or nurse.
   - 4) Indicators: no. of appointments made, no. of patients seen at an appointment, no. of patients seen without an appointment and no. of patients that don't turn up.

Conclusions The SOP has been able to minimise variation and promote quality during pharmacist counselling. The SOP has also improved patient flow, waiting times, medicines stock management. Further studies will be needed to evaluate the improvement of the pharmaceutical care services.

Competing interests None.

OHP050 OFF-LABEL DRUG USE IN DERMATOLOGY

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10.1136/ejhpharm-2012-000074.350

Background In 2010, 1% of our pharmaceutical expenditure corresponded to off-label use, except for cytostatics. The dermatology department has increased drug costs due to the off-label use.

Purpose To assess the applications and costs of off-label drug use in dermatology. To check the therapeutic results obtained and the number of available reports.

Materials and methods The authors reviewed off-label requests from Dermatology during 2009 and 2010. The authors reviewed the reports compiled in Medline from 1997 to 2010 and classified according to reported cases number in N < 10, N between 10 and 50, N between 51 and 100, and N>100. The results were classified as effective if dermatologists achieved the therapeutic objective, partially effective if they reached the initial objective at least in 50% and ineffective when they didn't achieved the therapeutic purpose.

Results In 2009, 95 drugs were requested for an off-label use representing 404,909 €; 7 were requests from Dermatology at a cost of 49,218 €. In 2010, 134 drugs were requested for off-label use representing 410,716 €; 5 were requests from Dermatology represented 117,565 €.

Conclusions During 2010 there was an increase in the cost of off-label use in dermatology due to lenalidomide. Half of the treatments were effective, 25% partially effective and 25% ineffective. One third of the requests were supported by fewer than 10 reported cases.

Competing interests None..

OHP050 table 1

Year	Drug – Indication	Results	Number of case reports
2009	8-methoxypsoralen – scleromyxedema	Effective	N < 10
	Ustekinumab – psoriasis (3 cases)	One case effective; one partially effective; one ineffective.	N > 100
	Propranolol – haemangioma	Effective	N > 100
	Etanercept – hidradenitis suppurativa (HI)	Ineffective	N between 51 – 100
	Etanercept – pyoderma gangrenosum (PG)	Ineffective	N between 10 – 50
2010	Infliximab – PG	Effective	N > 100
	Lenalidomide – lupus erythematosus (2 cases)	Effective	N < 10
	Alitretinoin – psoriasis	Partially effective	N < 10
	Infliximab – HI.	Partially effective	N between 51 – 100

Clinical pharmacy and clinical trials (including case series)

CPC001 EFFECT ON PARENTERAL NUTRITION OF AN IMPROVED RECOVERY ORAL NUTRITION PROTOCOL AFTER RADICAL UNCOMPLICATED CYSTECTOMY

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Background After radical cystectomy, postoperative ileus (POI) is a relatively common complication resulting in delayed oral nutritional intake with prolonged recovery and hospital stay. However, it is questionable whether nutritional support by routine use of parenteral nutrition (PN) is justifiable or cost effective.

Purpose To monitor the effect of an enhanced recovery oral nutrition protocol (ERONP).

Materials and methods Patients undergoing elective radical uncomplicated cystectomy were included in this before-after prospective interventional study. Exclusion criteria were preoperative contraindications for enteral nutrition (EN). Before implementation there were no restrictions on PN. After implementation patients were fed with progressively increasing amounts of fluids and easily digestible food. PN could only be initiated if oral intake was still insufficient after 5 days. Outcome measures were use of PN, time to removal of ureteral stents, institution of oral diet, interval from surgery to discharge and urgent readmission rate.

Results From 98 patients, two patients were excluded for preoperative contraindications. 48 patients suited the inclusion criteria for each group. Before implementation, early PN was initiated in 47/48 patients, while after implementation PN was initiated in only 1/48 patients (p=0.00). Considering the time to institution of oral diet 8.1±3.7 to 4.1±1.7 days (p=0.00), time to removal of ureteral stents 13.5 (IQR=5) to 11.0 (IQR=4) days (p=0.00), and time to discharge 19.3±5.6 to 15.1±4.3 days (p=0.00), there was an overall significant reduction with the new diet. There was no difference in urgent readmission rate (4/48 vs 3/48; p=0.70).

Conclusions The implementation of ERONP led to a reduction in PN and improved recovery after uncomplicated cystectomy.

Competing interests None.

CPC002 SUCCESSFUL CANNABIS DERIVATIVES OROMUCOSAL SPRAY THERAPY FOR A SERONEGATIVE STIFF-PERSON SYNDROME: A CASE REPORT.†

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Background Stiff-person syndrome (SPS) is an uncommon and disabling disorder characterised by progressive rigidity and episodic painful spasms involving axial and limb musculature. An autoimmune pathogenesis is suspected because of the high prevalence of particular autoantibodies. SPS treatment is mostly based on benzodiazepines, baclofen, immunosuppressants and intravenous immunoglobulin. Clinical experience with the cannabis derivatives tetrahydrocannabinol (THC) and cannabidiol (CBD) in patients with multiple sclerosis is accumulating steadily, but there is no current literature about its efficacy for SPS. The authors report a patient with seronegative SPS successfully treated with THC-CBD oromucosal spray.

Purpose The aim of this study was to check the effect on his quality of life (QoL), before off-label drug treatment with THC-CBC and after 14 months of treatment.

Materials and methods In 2003 electromyography revealed continuous activity in agonist and antagonist motor unit both axial musculature and abdominal region, without periods of relaxation. Laboratory analysis included required autoimmune profiles in order to exclude paraneoplastic syndromes, tumours and other autoimmune diseases. These were negative both in serum and CSF results. The patient was diagnosed with seronegative SPS. In 2009 the patient became wheelchair-bound and standing was only possible with support. Due to unsatisfactory treatment results a multidisciplinary group decided on off-label drug treatment with THC-CBD oromucosal spray (Sativex), with the patient's informed consent. Besides monitoring at the Neurology Department, compliance with the treatment and results of the treatment were also monitored at the Outpatient Pharmaceutical Care Unit (OPCU). The patient's target after titration was an average dose of two sprays, which achieves optimum symptom relief. Now this has been established, the patient can adjust his dose according to how he is feeling on a day-to-day basis, and is better able to perform his daily activities. In stressful situations the patient requires up to 6 sprays. QoL was evaluated with the Spanish version of the SF-36 health questionnaire, which is divided into 8 dimensions.

CPC002 Table 1. SF-36 questionnaire results

	Initial score	Final score	Percentage response
Physical Functioning	0	80	80%
Role-Physical	0	100	100%
Bodily Pain	0	100	100%
Social Functioning	0	100	100%
Role-Emotional	0	100	100%
Mental Health	28	96	68%
Vitality	10	50	40%
General Health	0	30	30%

The scores for each scale of SF-36 range between 0 and 100 (100 indicates perfect health and 0 reflects a very bad state of health)

Results Improvement was verified in the eight dimensions. Role-physical, bodily pain, social functioning and role-emotional were the dimensions in which the effect was more noticeable. After 14 months' treatment with THC-CBD oromucosal spray the patient has acceptable mobility and autonomy.

Conclusions In conclusion cannabinoids can be a therapeutic option to treat spasticity associated with neurological diseases such as stiff-person syndrome. Our patient's quality of life has improved remarkably although more information is needed about this particular use.

Competing interests None.

CPC003 PHARMACIST'S CONTRIBUTION ON THE WARDS†

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Background During the fourth year of training, pharmacy residents perform a rotation with the team doctor on various wards.

Purpose To describe and to classify the interventions made during the rotation through the wards and to assess the level of acceptance of the interventions by the doctor.
Materials and methods Prospective study of the interventions made during 8 months of rotation. Data were collected from each patient: name, age, sex, allergies, weight, date of admission and discharge, harmful habits, medical history, primary diagnosis, drug treatment, income and home diagnostic tests performed. Any contribution made to drug treatment was considered an intervention. These were classified as: change in dose / frequency, start / stop treatment, drug substitution, modified via and other (request for information, diagnostic tests and pharmacokinetics). Databases such as Micromedex 2.0, Antimicrobial Clinical Practice Guideline 2010, BOT Plus and the hospital's drug substitution program were used to record the interventions.
Results The wards were: Cardiology, Children's Oncology, Intensive Care, Gastroenterology, Internal Medicine HIV and Internal Medicine Infections. The average stay per unit was 1.3 months. The resident participated in the daily ward round and start and change of treatment. 98 interventions were performed in 85 patients treated (1.15 interventions / patient). Classification of interventions: change in dose (25.5%), request for information (23.5%), starting treatment (17.3%), discontinue treatment (9.2%), frequency change (8.2%), pharmacokinetic studies (6.1%), change in treatment (5.1%), modified via (3.1%), request additional tests (2%) and drug substitution (0%). 89% of the interventions were accepted. 11% of the interventions were not accepted, the initial stance was justified by the doctor.
Conclusions The integration of the pharmacy residents onto the wards has been widely accepted because it has helped adjust the treatment at the time of prescribing, improving safety in the care process.

Competing interests None.

CPC004 CARDIOVASCULAR RISK ASSOCIATED WITH USE OF BIOLOGICAL THERAPY WITH ETANERCEPT AND ADALIMUMAB

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Background Studies (Seriolo et al., 2007; Jamnitski et al., 2010) shows the influence of anti-TNF drugs on lipid profile, causing a variation on cardiovascular risk.
Purpose To study the influence of etanercept and adalimumab in parameters associated with cardiovascular risk (CVR) during the first year of treatment.
Materials and methods Retrospective observational study of 40 patients (15 men and 25 women) treated for 1 year with anti-TNF's. Mean age was 49.5 years (range 12-85). The pathologies treated were: rheumatoid arthritis (60%), ankylosing spondylitis (10%), psoriatic arthritis (7.5%), juvenile idiopathic arthritis (5%) and a final group of 7 patients with a heterogeneous group of rheumatic diseases (17.5%). Variables studied: total cholesterol (TC), triglycerides (TG) and renal function (RF), which analysed every 3 months. The RF was estimated by glomerular filtration rate (GFR) estimate by MDRD4 equation.
Results The mean TC at baseline was 190.5 mg/dL. Twelve months later, TC increased approximately 3% compared to baseline (194.8 mg/dL). Initial TG had a mean value of 93.8 mg/dL, six months later increased to 100.3 mg/dL and finally returned to initial values (91.9 mg/dL). No statistically significant differences between the TC and TG at baseline, 6 and 12 months ($p < 0.05$). The GFR show no significant difference between the baseline and those found at 6 and 12 months. The average GFR was at 91.8 mL/min/1.73 m^2. Statins were used by 25% of the patients throughout this study and only one patient was treated with fibrates.
Conclusions Significant differences in lipid profile for the first year of treatment were not found. It would be interesting to study the fractionated cholesterol. RF deterioration is also associated with an increased CVR but no significant changes were observed in this study. Although no significant differences in the parameters were found, clinical implications remain to be established by future investigations.

Competing interests None.

CPC005 SMOKING CESSATION PHARMACOTHERAPY IMPROVES PATIENTS ADHERENCE AND INCREASES THE ABILITY TO ACHIEVE ABSTINENCE FROM CIGARETTE SMOKING IN A BRAZILIAN TEACHING HOSPITAL

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Background The cessation smoking group (CSG) of University Hospital of University of São Paulo consists of a multidisciplinary team composed of pharmacists, a doctor, a psychologist, nurses, a system analyst, and dentists. Counselling and medicines, such as nicotine replacement therapy, bupropion, and varenicline, are available, free of charge, to treat nicotine dependence on the employees of University of São Paulo. CSG also offers smoking-cessation counselling to all other citizens from the community of São Paulo city who desire to participate in it, yet The authors do not delivery these medicines free of charge for this population.
Purpose The authors aimed to: a) verify patients adherence to CSG in those who received smoking cessation pharmacotherapy plus counselling (G1) compared to those who received only counselling (G2) and b) measure success in smoking cessation within these two groups.
Materials and methods A total of 303 smokers were followed at CSG from 2009 to 2010. The program included active follow-up during one year after quitting. 157 patients belonged to G1 and 146 to G2. Treatment adherence was defined as any subject who took >or=1 dose of any medicine prescribed for >or=80% days during the minimum 12-week treatment period for G1 and the frequency to the meetings >or=80% for G1 and G2. Smoking abstinence was assessed using breath carbon monoxide confirmed weekly and self-reported tobacco cessation.
Results There were no difference between G1 and G2 related to: gender (female 63%), age when enrolled at CSG (41-50 years old, 38%), years smoking (21 – 30 years, 38%), age at initiation of smoking (11-15 years old, 41%), current smoking intake (> 20 units/day, 50%) and Fagerström test (80%>5). On the other hand, there were statistically significant differences between G1 and G2 for: the outcome 'adheres to CSG': 68.8 versus 53.4%, respectively, p=0.006, RR=1.288, OR=1.92, CI 95% from 1.20 – 3.07 and the outcome 'quit smoking' (more

than one year): 44.6% versus 22.6%, respectively, p=0.001, RR=1.97, OR=2.75, CI 95% 1.67 – 4.54.

Conclusions It is of utmost importance to maintain the supply of medicines to achieve abstinence from cigarettes in programs such as CSG since it was found in the present study that patients who received anti-smoking medication free of charge not only dropped out less from CSG but also better able to quit smoking.

Competing interests None.

CPC006 STOPP (SCREENING TOOL OF OLDER PERSON'S PRESCRIPTIONS) AND START (SCREENING TOOL TO ALERT DOCTORS TO RIGHT TREATMENT) AS A PHARMACY SERVICE

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Background In 2009 National Quality Standards for Residential Care Settings for Older people in Ireland were written into Irish legislation by the Health Information and Quality Authority (HIQA). Standard 15 specifically states that each resident on long-term medication in the Residential Care Setting should be reviewed by his/her medical practitioner on a three monthly basis, in conjunction with nursing staff and the pharmacist.

Purpose Implementation of STOPP and START[1] as a clinical pharmacy service to facilitate three monthly medication reviews in an older residential care setting. Qualitative evaluation of the acceptability of the service to General Practitioners.

Materials and methods A total of 103 residents ≥65 years from two residential care units were eligible for inclusion (exclusion criteria included terminally ill or respite patients) in the study and six General Practitioners participated in the study. Each General Practitioner completed a qualitative post service evaluation interview to determine the acceptability of STOPP and START[1] as a clinical pharmacy service.

Results Of the residents reviewed (n=103), 75 (72.8%) were female; the median age was 86 years (IQR: 66-103). 884 regular medicines were prescribed (Median 9). 75.7% (78) residents had at least one potentially inappropriate medicine (PIM) or prescribing omission identified by STOPP and START criteria[1]. 65% of potentially inappropriate prescribing involved use of medicines that had unfavourable risk benefit ratio according to STOPP and 34.8% were instances of PIM through omission of potentially beneficial medicine according to START. 46.6% (95) of recommendations were accepted and implemented by General Practitioners. Of all recommendations declined a valid reason was provided in 93.5% (102) of cases. All General Practitioners interviewed found STOPP/START[1] to be acceptable as a clinical pharmacy service.

Conclusions Implementation of STOPP and START[1] as a clinical pharmacy service reduces inappropriate prescribing, facilitates the three monthly medication reviews required to meet HIQA's medication monitoring and review standard and is acceptable to General Practitioners.

Competing interests None.

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CPC007 THE USEFULNESS OF COMPUTER-ASSISTED PRESCRIBING OF RESTRICTED DRUGS

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Background The restricted use policy was established to assist the correct use of medicines. The Pharmacy and Infections Committee agreed to authorise indications for use that accorded with treatment protocols and clinical practice guidelines; once these prescribing rules were decided, the next step was pharmaceutical validation of the prescriptions. Computer-assisted prescribing provides information to prescribers and facilitates checking.

Purpose To assess the usefulness of computer-assisted prescribing in restricted-use drugs in our hospital.

Materials and methods The PRESEL application is used for electronic prescribing. Restricted drugs and the indications for their authorised use were defined in PRESEL. When prescribing these medicines it was necessary to type the clinical indication; at the same time authorised indications were shown on screen as advice. During the validation process the pharmacist could accept the prescription or not, and record the prescribing indication in PRESEL. At the time of this study, our hospital used computer-assisted prescribing for 49% of surgical beds. Prescriptions written between June 2010 and May 2011 were studied. Information about the restricted-use drugs prescribed, authorised indications, and clinical unit prescriptions were collected and analysed.

Results During the study period, there were 50,990 electronic prescriptions for 5,210 patients. 113 restricted-drug prescriptions for 10 different drugs were recorded. None of them was rejected. The antimycotics posaconazole and micafungin were the most prescribed (37%), followed by the antibiotics tigecycline and linezolid (28%). The most frequent indication for antimycotics was 'prophylaxis of fungal infections in immunocompromised haematopoietic stem cell transplantation recipients'; for antibiotics the most frequent was 'complicated intra-abdominal infection'. The majority of prescriptions were written on the Haematology (65.49%), Infectious Diseases (7.96%), Surgery (5.31%) and Neurology (5.31%) wards.

Conclusions In our hospital antifungals and antibiotics are most common restricted-use drugs. Haematology and Infectious clinical services are the main prescribers.

Computer-assisted prescription applications are useful to set restrictions and to check if prescriptions comply.

Competing interests None.

CPC008 OMEGA-3-POLYUNSATURATED FATTY ACID – ENRICHED PARENTERAL LIPID EMULSION AND PREVENTION OF CHOLESTASIS IN PRETERM INFANTS. COMPARISON WITH SOYBEAN-BASED LIPID EMULSION

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Background Total Parenteral nutrition (TPN) is crucial for the survival of premature and sick neonates. However, TPN

associated cholestasis (TPNAC) leading to cholestatic cirrhosis is a commonly occurring complication. Since recent findings suggest that fish oil-based LEs appear to be safe and efficacious for the treatment of TPNAC in children, data about its preventive effect on TPNAC in premature neonates could be important.

Purpose This study aimed to compare the effect of two LEs, MCTs/ω-3-PUFAs-enriched (MCTs/ω-3-LE) and soybean-based, on the incidence of TPNAC and lipid profile of preterm infants,

Materials and methods Neonates (GA 23-36 wks) without severe sepsis, congenital infections, or primary liver disease, needing parenteral LEs for at least 7 days, were included in a prospective double-blind controlled study. Infants were randomly assigned in intervention group (IG, n=127) receiving MCTs/ω-3-LE and control group (CG, n=122) receiving soybean-based LE. Biochemical measurements were performed on days of life (DOL) 15, 30, 45 and on discharge.

Results Cholestasis (direct bilirubin>2 mg/dL) was observed in 6.4% infants (3.9% and 9.0% in IG and CG, respectively, p=0.124, OR=0.41, CI=0.14-1.23). The duration of PN was the only factor independently associated with cholestasis (p<0.001, OR=0.934, 95% CI=0.911-0.959). The IG had lower alkaline phosphatase (ALP) at all time points, higher HDL and lower cholesterol-to-HDL ratio on DOL 30 and discharge. Additionally, IG had significantly lower incidence of bronchopulmonary dysplasia and shorter duration of hospitalisation and PN. The type of LE was significant independent predictor of ALP on DOL 15, 45, and discharge as well as of bronchopulmonary dysplasia development.

Conclusions Parenteral MCTs/ω-3-PUFAs-enriched LE is associated with a trend towards a lower incidence of cholestasis and a better lipoprotein profile in preterm infants compared to soybean-based LE. Future research should address the effect of MCTs/ω-3-PUFAs LE on bronchopulmonary dysplasia and osteopenia of prematurity.

Competing interests None.

CPC009 SIMPLIFICATION OF MEDICATION REGIMENS Ñ A NOVEL ASPECT OF PHARMACEUTICAL CARE IN HOSPITAL

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Background Complex medication regimens may cause non-adherence. It is not known to which extent regimens can be simplified by using combination and sustained release drugs and whether such simplifications 'survive' in the outpatient setting.

Purpose To investigate the development of medication complexity at the border between ambulatory and hospital care and the benefit of a pharmacist's intervention to minimise complexity.

Materials and methods In a prospective study complexity of medications of 240 hospital patients was analysed at times of admission, discharge and six weeks postdischarge using the Medication Regimen Complexity Index (MRCI-D). General practitioners (GPs) were questioned about the discharge medication and reasons to (dis-)continue it. In the intervention group, a pharmacist recommended simplifications for each individual regimen.

Results In the control group (n=109) complexity of the therapy regimens was comparable before, during and after hospital stay (MRCI-D= 13.27, 13.72, 13.73, respectively). In the intervention group (n=131) complexity of the discharge medication was reduced by the intervention to 85.2%, but increased again after discharge to 94.7% of the original value. For 48.6% of the patients medications were modified in hospital. The modifications were judged to improve therapy by 24.3% of the GPs and to impair it by 18.9%. Although around 80% of the GPs indicated willingness to accept drug-related recommendations from hospital and recognised the correlation between complexity and non-adherence, only 50% would accept a higher burden on their budgets for a more effective, but more expensive therapy.

Conclusions Medication regimens can be simplified by maximising the use of combination and sustained release drugs as recommended by a hospital pharmacist. However, this effect is partly reversed when patients return to the outpatient setting. One reason may be the higher costs of these drug formulations that GPs are not always willing to accept.

Competing interests None.

CPC010 AN EPIDEMIOLOGICAL ANALYSIS OF POISONINGS IN THE ITALIAN REGION OF EMILIA ROMAGNA FROM 2005 TO 2009

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Background The Department of Pharmacy of the University Hospital of Ferrara (AOUFE) activated a project called 'Monitoring and use of the Reference Centre for antidote stocks'. The project followed the correct allocation of available antidotes to the Reference Centre of the Emilia Romagna Region (ERR).

Purpose Epidemiological analysis to identify different types of intoxication and check that they have been treated successfully.

Materials and methods All 17 Hospitals of the ERR were asked to provide information about episodes of intoxication recorded from 1/1/2005 to 31/12/2009 as well as the antidote treatments administered. Required data were: year, type of intoxication and toxic substance, patient demographic data, type of antidote used and treatment period.

Results 16 hospitals took part in the analysis. 8151 intoxications were recorded and they are grouped as follows: 1704 intoxications in 2005 (21% of the 5-year total); 1523 in 2006 (19%); 1593 in 2007 (20%); 1560 in 2008 (19%); 1771 in 2009 (21%). Categorisation by toxic substance showed the following: 31% caused by drugs; 17% caused by ethanol; 4% by opioids; 3% by carbon monoxide; 3% by food; 1% by sodium hypochlorite and derivatives; 36% by non-classifiable intoxications; 5% by various intoxications. The authors only evaluated complete intoxication data (1223 cases) and The authors had calculated in 80% of these cases the following antidotes were used: 19% (232/1223) activated charcoal associated with gastric lavage; 11% (132/1223) activated charcoal; 9% (109/1223) activated charcoal associated with $MgSO_4$; 12% (144/1223) flumazenil; 6% (76/1223) hyperbaric oxygen; 12% (151/1223) naloxone; 7% (80/1223) metadoxine; 4% (53/1223) benzodiazepines.

Conclusions Drug and ethanol poisonings were the most frequent; non-specific treatments were the most frequently

performed, followed by the use of specific antidotes such as flumazenil and naloxone. Epidemiological analysis shows that the frequency of intoxications in ERR is 3.82 per 10000 inhabitants/year.

Competing interests None.

CPC011 LONG-TERM PROTEASE INHIBITORS-BASED MONOTHERAPY VERSUS REVERSE TRANSCRIPTASE INHIBITORS-BASED TRIPLE THERAPY: EXPERIENCE IN A SPANISH TERTIARY HOSPITAL

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Background Current guidelines and trials (OK04, KalMo) support the Highly-Active AntiRetroviral Therapy (HAART) simplification, but long-term experience with this treatment is still limited.
Purpose To assess the **E**fficacy, **S**afety, **A**dherence and **C**osts related to HAART based on Ritonavir-boosted protease inhibitors (r/PI) versus the standard combinations based on reverse-transcriptase inhibitors (RTI) in long-term stable patients.
Materials and methods The virological and immunological laboratory tests, the adverse events (AE) profile and the Karnofsky score, along with the pharmacy withdrawal registry and the calculated monthly costs per patient were monitored at 3, 6, 9 and 12 months after simplification and compared with the average for the previous period. Databases: Andalusian digital or paper medical records and the outpatient database (Farmatools).
Results 13 patients were enrolled: 2 female versus 11 male, mean age: 44 years (29-68), mean HIV+ diagnosis and HAART: 61 months (3-88) and 53 months (4-93). Previous RTIs: emtricitabine/tenofovir, abacavir/lamivudine, abacavir/tenofovir and didanosine/lamivudine in 8, 3, 1 and 1 cases, respectively. HAART in the previous period included r/PIs (atazanavir/ritonavir, saquinavir/r and lopinavir/r) in 84% of the cases, though 92% were not maintained after simplification. Patients were switched to DRV/r and LPV/r in 11 and 2 cases, respectively. Comparative outcomes: sustained Viral Load <50 copies/mL (100% both groups) and CD4+ >350 cells/µL: 10 versus 11 patients (up to 76.9% of patients experienced increased lymphocyte levels after simplification). **S** (in the previous period): neurotoxicity (1 case), mild-to-moderate lipodystrophy (2) and cotrimoxazole-related skin disease (1). No noticeable AEs after simplification. Karnofsky: 100% (both groups). **A**: 5(±2) versus 2(±1) missed intakes. **C**: 859 versus 492€ (57.2% reduction).
Conclusions In our cohort, monotherapy was an alternative at least as effective as traditional combinations. In addition, it showed better adherence and tolerance, plus remarkable reduction in costs. Therefore this study encourages us to trust the results of large trials intended to demonstrate favourable profiles in long-lasting treatments for selected patients.

Competing interests None.

CPC012 DEVELOPMENT AND EVALUATION OF A WARD-BASED CLINICAL PHARMACY SERVICE ON A NEONATAL INTENSIVE CARE UNIT (NICU)

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Background Several international documents highlight the benefits of ward-based clinical pharmacy services. The 2007 NPSA document 'Safety in doses – Medication incidents in the NHS' indicates that serious medication errors may be three times more common among children than in adults. Therefore a clinical pharmacy service was piloted on the 16-bedded NICU.
Purpose To evaluate the clinical significance of interventions made by a pharmacist on 'medicines management' and assess the perceptions of healthcare professionals.
Objectives
1. Literature review
2. Develop a clinical pharmacy Standard Operating Procedure for NICU.
3. Implement a clinical pharmacy service; evaluate clinical significance and level of risk of interventions.
4. Evaluate the perceptions of healthcare professionals on NICU to new service.
5. Recommend on future clinical pharmacy requirements in NICU.

Materials and methods The pharmacist attended the NICU to review prescriptions in accordance with a predefined SOP over a three month period. Activities were categorised into interventions* and other activities. All interventions were assessed by a clinical pharmacist for both clinical significance and level of risk. A random sample of these interventions was also assessed by a NICU/PICU pharmacist and a consultant neonatologist for validation. An anonymous questionnaire was circulated to healthcare professionals in the NICU to assess their perception of the new service. * An intervention was defined as any recommendation made by a pharmacist with the intent to change treatment or monitoring.
Results 110 patients were reviewed and 73 interventions made; the incidence rate for interventions was 5.4/100 patient care days and 9.1/100 reviewed prescriptions. Dosing errors accounted for 47.9% of all interventions. Over 69% of the interventions were considered significant and 11.1% very significant. The clinicians' acceptance rate of the interventions was 91.8%. The majority of responders to the questionnaire agreed that the presence of the ward pharmacist improved medication safety and the quality of care.
Conclusions The clinical significance of the interventions made demonstrates the requirement for a permanent specialist clinical pharmacist in the NICU.

Competing interests None.

CPC013 ASSESMENT OF A WRITTEN INFORMED CONSENT FORM IN CLINICAL TRIALS

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Background Informed consent is a requirement for clinical trials.
Purpose Assessing the quality of the written informed consent form (ICF) that a patient signs to participate in a clinical trial.
Materials and methods Retrospective observational study. 50 ICF of clinical trials initiated in the HUP La Fe were chosen between March 2010 and January 2011. To assess the quality of the ICF, the ' Good Clinical Practice Guideline' contained in the CPMP/ICH/135/95 the European Medicines Agency was used.

This guide contains 20 aspects. Data on the length and terminology were collected. In addition, the clarifications requested by the ethics committee (ECs) for these ICFs were reviewed.
Results Of the 50 ICFs analysed, 10% had all 20 aspects of the assessment correct. None of the ICFs were incorrect all sections. Four sections were correct in all ICFs: 'trial involves research,' 'trials goals', 'participation is voluntary and the subject may withdraw at any time without penalty' and 'documents that identify the patient are confidential'. The aspect least mentioned in the ICFs was 'the subject's responsibilities' (50%). Understandability of the objectives, risks and inconveniences of the trial, the conditions under which it is to be conducted being informed of the right to withdraw from the trial at any time were properly included in more than 90% of the ICFs. These aspects are contained as requirements of Directive 2001/CE/CE. Aspects of terminology and extension were weak (34 and 33%) All ICFs required clarification by the ET, with a mean of 4.46 changes per ICF (CI95%: 3,82-5,10).
Conclusions Compliance with different aspects that must appear in the ICF is high. Aspects to improve are the structure and terminology, as they are essential to a proper understanding of the study. The evaluation of the ICF by the EC is of great importance to preserve patients' safety and rights.

Competing interests None.

CPC014 THE LUND INTEGRATED MEDICINES MANAGEMENT MODEL, HEALTH OUTCOMES AND PROCESSES DEVELOPMENT.

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Background The effects from medication use in clinical trials are hard to achieve in standard care. Instead of health benefits for the patient there is risk of errors and negative consequences such as morbidity, mortality and costs. The risk is highest among older patients admitted and discharged to and from hospital care.
Purpose Develop a systematic model for improved medication use when a patient is admitted to hospital.
Materials and methods Systematic analysis of problems and limitations in the standard patient medication care process from admission, during stay, at, and after discharge was performed at Lund University hospital. A structured team based model with tools, checklists and responsibilities were developed and tested for each part and for the total model. The clinical pharmacist was introduced as the catalyst for improvement in the team and was responsible for performing medication reconciliation and medication review. Each part of the model was researched stepwise and compared to standard care in studies powered to detect significant differences in processes and outcomes. Three of the outcomes studies were used as input in a probabilistic decision tree model for cost-utility analyses.
Results 18 scientific publications and manuscripts have been produced from the development and is the base for four PhD- and more than 30 MSc-theses. The model improves the process of care, that is identifies and solves drug related problem, reduces medication reconciliation errors, and improves medication appropriateness. It also improves healthcare outcomes. Healthcare contacts and hospital readmissions due to medication errors were reduced by 50 percent. For each hour spent by a pharmacist 2-3 h were saved among physicians and nurses. The total model generated savings of €390 and gained utility of 0.005 for each patient. The model is cost saving at a 98% chance. Finally all involved professionals are very satisfied with the process and the pharmacist professional contribution.
Conclusions The model has successfully been implemented, researched and also rewarded as best innovation in Swedish healthcare. In Scania (the south of Sweden) there is a political consensus on the benefit and there are concrete plans to employ 40 additional clinical pharmacists

Competing interests None.

CPC015 ROMIPLOSTIM FOR CHILDREN WITH CHRONIC IDIOPATHIC THROMBOCYTOPENIC PURPURA: EVALUATION OF ITS EFFECTIVENESS AND SAFETY

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Background Idiopathic Thrombocytopenic Purpura (ITP) is a haemorrhagic disorder well known about its condition of having an abnormally low platelet count in blood. Romiplostim is a new thrombopoietin agent that stimulates the thrombopoietin receptors increasing the production of platelet.
Purpose The objective is to assess the effectiveness and safety of romiplostism in two paediatric patients with ITP and bad response to previous treatments, through off-label use. Some previous studies seem to support this indication, despite the limited experience of use.
Materials and methods Two patients of 8 and 12 years old are studied. They are diagnosed with chronic ITP and they didn't respond favourably to previous treatments (glucocorticoids in high doses and INTRAVENOUS immunoglobulins). The first of them was also splenectomised since 2009. Off-label use is applied in both cases before treatment starting, because technical specifications don't include the paediatric population. The evaluation of its effectiveness has been done by monitoring the patients through electronic medical history (patient platelet re-count, clinical situation and bleeding) for a period of 16 and 10 months respectively. The objective was to obtain a platelet count between 50-200 10^9 / litre. The safety is measured through the study of the adverse side effects and the tolerance.
Results Before the treatment with romiplostism, patient 1 had the thrombocytopaenia for 7 years and the average platelet count was less than 50 10^9 / litre. In patient 2 the previous values were 13 months and less than 40 10^9 / litre, respectively. The initial dose, in both cases, was of 1 mcg/kg q1w and it was increased depending on the platelet count, being 4,5 mcg/kg q1w and 6,5 mcg/kg q1w the actual maintenance dose. The average platelet count achieved with these doses were 161 10^9 / litre and 96 10^9 / litre, respectively. Both patients have suffered some isolated decreases in their platelet counts, below the wanted values, this occurred until the ideal dose was found to achieve the desired levels though. Nevertheless, the clinical situation was favourable, with an improvement of the quality of life, such as psychological and physical conditions (neither hematomas nor epistaxis were present), during the studied period. The drug was well tolerated and without evidence of any adverse side effects.
Conclusions Romiplostism has shown as an effective option for the maintenance of the platelet count in comparison to previous treatments. Although a longer monitoring period is required to establish the optimal doses, it seems a well tolerated

medication. Additional studies and long term monitoring of the possible side effects (reticulin formation in the bone marrow and malignant risks) are required, especially in specially in paediatrics. The authors shouldn't forget that this medicament has an elevated economic impact and a careful selection of the patient candidates should be done to be treated with it.

Competing interests None.

CPC016 RITUXIMAB IN THE TREATMENT OF ACQUIRED HAEMOPHILIA A: A CASE REPORT

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Background Acquired haemophilia A is a very rare disease caused by the development of clotting factor VIII (FVIII) inhibitors, resulting in haemorrhage and bleeding episodes. This situation has been reported during interferon therapy for chronic hepatitis C virus (HCV) infection. To eliminate FVIII inhibitors, immunosuppressive therapy with corticosteroids and cytotoxic drugs is regarded as the mainstay of therapy.
Purpose To describe a case of acquired haemophilia A refractory to conventional immunomodulatory therapy that has responded to rituximab.
Materials and methods Patient clinical history was reviewed and the following laboratory investigations were collected: haemoglobin, platelets count, coagulation tests (prothrombin time (PT) and activated partial thromboplastin time (APTT)) and FVIII and inhibitor levels.
Results A non-haemophilic 63 years old male patient with chronic HCV infection was receiving antiviral therapy with pegylated-interferon at 180 mcg weekly plus ribavirin at 400 mg twice daily. After 21 weeks of antiviral therapy, patient was admitted to hospital for a large haematoma in right lateral abdominal muscles, coagulopathy and acquired haemophilia. Haemoglobin and platelets count were decreased, PT was normal, APTT was increased, FVIII level was 0% and FVIII inhibitor level was 345 Bethesda units (BU). Immunosuppressive therapy with intravenous metilprednisolone and oral cyclophosphamide was started. After 4 weeks, a slight improvement in FVIII level and a decrease in inhibitors were obtained; for this reason, oral cyclophosphamide was replaced by intravenous rituximab. Patient received rituximab at 375 mg/m^2 four once-weekly doses and oral prednisone at 30 mg twice daily. Before the second dose of rituximab, FVIII level was 25% and FVIII inhibitors level, 3 BU; coagulation tests were normalised and haemoglobin and platelets count remained diminished.
Conclusions After failure of standard therapy, the use of rituximab in off label condition appears to be an effective option to eliminate FVIII inhibitors in patients with acquired haemophilia.

Competing interests None.

CPC017 PHARMACOTHERAPEUTIC FOLLOW-UP IN ONCOLOGY

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Background Morbidity and mortality associated with the use of medicines is a great problem of public health. The pharmacist has a key role in detection, preventing and resolving drug-related problems (DRP). This is even more important in the case of cancer patients, where the high number of treatment protocols and the extensive supportive therapy increases the number of drugs used. This particular setting is a challenge to the clinical pharmacist.
Purpose Analysis and characterisation of pharmacotherapeutic follow-up and pharmacist interventions in oncology patients.
Materials and methods Retrospective study of pharmacotherapeutic follow-up from January to September of 2011, in a central hospital.
Results Between January to September of 2011 the team of oncology pharmacists monitored 56 patients (29 males and 26 females) with mean age of 69 years (min.: 33; max.: 93). Colorectal cancer was the most prevalent cancer in the study population, followed by breast and pulmonary cancers. The team monitored 316 drugs (a mean of 5.64 drugs per patient). The follow-up detected 43 DRPs, resulted in 43 pharmaceutical interventions (0.77/patient). The majority of interventions were related to the need to adjust dosages (53.5%), followed by the need to substitute one or more medicines (11.6%) and those related to adverse effects (11.6%), such as emesis protocol optimisation and other supportive treatment. The physicians accepted approximately 79% of pharmacist interventions.
Conclusions The results show that cancer patients are one of the groups most at risk of DRPs. The analysis, characterisation and quantification of pharmaceutical interventions performed on the oncology unit are an important step in documenting the activities of hospital pharmacists in this area, enabling them to be measured. The pharmacist interventions stand out as individual contributions throughout the patient's cancer treatment, highlighting the role of the pharmacist as part of the multidisciplinary team.

Competing interests None.

CPC018 A PROSPECTIVE OBSERVATIONAL STUDY ON PREVALENCE OF POISONING CASES – FOCUS ON VASMOL POISONING (PARA-PHENYLENEDIAMINE(PPD) POISONING)

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Background The intentional and accidental poisoning by various modes are common in India. Nearly 1 million people die each year globally due to poisoning. Vasmol is an external preparation that contains para-phenylenediamine as major ingredient, used as hair dye. There were no much studies on Vasmol(PPD) poisoning. Our study mainly focused on Vasmol(PPD) poisoning, as its incidence is more in our region.
Purpose To detect and evaluate the prevalence of different poisoning cases and to analyse the clinical symptoms, causes, their outcome and finally to assess the effectiveness of supportive therapy for Vasmol(PPD) poisoning.
Materials and methods A prospective observational study was conducted on different poisoning cases over 5-months period(March-2011 to July-2011) in general medicine and ICU departments of a tertiary care teaching hospital. A specially designed patient data collection proforma was used to collect the information and various parameters were analysed.
Results Out of 680 poisoning cases, Vasmol(PPD)-419, Organophosphorous-90, Tablets-62, Others-109 were observed. In Vasmol(PPD) poisoning 126(30%)-male and

293(69%)-female with most cases between the age-group of 12-25. The clinical features were Cervicofacial oedema-163(40%), Stridor-102(24%), Myalgia-79(19%), Gastrointestinal disturbances-37(9%), Seizures-5(1%), Vertigo-56(13%) and Rhabdomyolysis-135(32%). Tracheostomy is the most commonly used supportive therapy which was done for 71(17%) cases where 52 recovered and 19 died. Deaths were mainly due to Cardiorespiratory failure-11(58%), Myocarditis-5(26%), Cardiac-arrest-2(11%) and Acute renal failure-1(5%). Rest of the results were categorised based on socio-demographic status, volume consumed, reasons for poisoning and laboratory findings.

Conclusions Vasmol(PPD) hair dye intoxication is a life threatening condition. Clinical outcomes rely on early recognition, prompt referral and supportive therapy. This study has shown that Vasmol(PPD) poisoning mortality was 5%, due to Cardiorespiratory failure, Cardiac-arrest, Myocarditis and Acute renal failure. Tracheostomy is the life-saving measure in reducing mortality. Community should be educated about handling of poisonous substances which endanger their life and there should also be a proper control over sale of Vasmol.

Competing interests None.

CPC019 THE USE OF DABIGATRAN ETEXILATE IN HOSPITALISED PATIENTS

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Background Dabigatran etexilate (DE) is a new oral anticoagulant. It was included in the hospital's formulary as a restricted-use drug in December 2009.

Purpose To analyse DE use, compliance with the authorised indications and use restrictions, and to quantify the incidence of adverse events.

Materials and methods An observational, prospective, utilisation study was carried out over four months in a general tertiary care hospital. The Pharmacy and Therapeutics Committee approved DE, with prescriptions restricted to the Traumatology and Geriatrics Departments for the primary prevention of thromboembolic events in adults who have undergone elective total hip or knee replacement surgery.

Patient treatments were reviewed through the CPOE program as were their lab test results and clinical records. DE indications and posology were examined comparing to the summary of product characteristics and the hospital's use protocol. The standard recommended dose in adults is 220 mg/day for 10 or 28-35 days after total knee or hip replacement respectively. The only difference between the drug specifications and the hospital's protocol is that the latter allows the treatment to be extended to 4-6 weeks after total knee replacement. The incidence of adverse events related to DE was recorded.

Results During the study, 138 patients started DE; 78.99% were women, 6.52% had taken it previously and 97.10% were admitted to the Traumatology Unit. In most patients (89.13%), of whom 73.98% had undergone elective total knee replacement surgery and the remaining 26.02% total hip replacement, DE was prescribed for the licensed indications. Treatment duration accorded with the indications in 82.42% and 78.13% of patients respectively. DE was also used 'off-label' (10.87%), mainly for thromboembolic prophylaxis after hip fracture. Overall, 57.24% of prescriptions stuck to the recommendations. Most commonly reported adverse events were: bleeding in the surgical wound (7.97%) followed by gastrointestinal side effects (4.35%). 15.94% of patients needed transfusion of red blood cell concentrates.

Conclusions The use of dabigatran etexilate was appropriate in most patients, but more studies and close monitoring by the pharmacy are needed to confirm the safety of this drug in common practice.

Competing interests None.

CPC020 CLINICAL PHARMACIST CONTRIBUTION TO PROFILE AND MANAGE POTENTIAL DRUG INTERACTION IN INTENSIVE CARE UNIT

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Background The chances of Adverse Drug Reactions (ADR) occurrence can be correlated to the presence of Potential Drug Interactions (PDI) in medical prescriptions, which makes PDIs one of the main concerns for a Clinical Pharmacist in the Intensive Care Unit (ICU).

Purpose The aim of this study was to evaluate the existence of Theoretical Potential Drug Interactions (TPDI) in prescriptions made at the ICU of a Public Hospital (Hospital de Clinicas-UNICAMP), and also quantify and classify them based on level of severity, thus providing a profile of the prescriptions of this sector.

Materials and methods Between the months of January to June of 2011, a total of 195 prescriptions to patients aged 18 years or older who had been hospitalised for more than 24 h in adult ICU were evaluated.

Results During the study period, 172 different types of medications were prescribed, with an average of 12.9±4.3 by prescription. Among the prescriptions evaluated, 88.2% had theoretical potential drug interactions that resulted in an average of 4.7±4.9 by prescription. The 915 TPDI observed in that prescriptions were classified as contraindicated (20), major (257), moderate (516) and minor (122), using information from the database Micromedex. These TPDI were reported to the medical team according to their severity and the need for clinical management. The pharmaceutical interventions were immediately carried out, based on the classification of severity and the patient's condition.

Conclusions This research collaborates to the delimitation of the pharmacotherapy procedures used in intensive care, demonstrating that there is a high incidence of TPDI in them, and providing immediate and future interventions based on the classification of severity for the prevention of avoidable adverse events in this sector. It also highlights the Clinical Pharmacist's contribution in this area, helping the multidisciplinary team to reduce the risks in drug therapy.

Competing interests None.

CPC021 ANTIMICROBIAL STEWARDSHIP PROGRAMME IN A MEDICAL INTENSIVE CARE UNIT AT A TERTIARY CARE HOSPITAL IN SAUDI ARABIA

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Background The inappropriate use of antimicrobials is currently observed in intensive care units (ICUs). Published data has shown that implementation of an antimicrobial stewardship program (ASP) will prevent emergence of antimicrobial resistance. KFSHRC, ICUs in particular, is one setting where monitoring the use of antimicrobials is essential.
Purpose To compare the appropriateness of empirical antibiotic treatment before and after implementation of 'proactive' ASP in the medical intensive care unit (MICU).
Materials and methods This was a comparative, non-randomised, historical-controlled study. Adult medical ICU patients were prospectively enrolled in the active ASP arm if they were on five targeted antibiotics and compared with historical patients who were admitted to the same unit before the ASP was used. The primary outcome was the appropriateness of empirical antibiotic treatment before and after implementation of ASP. Secondary outcomes included the rate of clostridium difficile-associated diarrhoea (CDAD), frequency of multi-drug resistant organisms (MDR) and rate of acceptance of recommendation by physicians. It was determined that 73 participants would yield 90% power to detect a difference of 0.20% between groups for the primary outcome.
Results A total of 73 subjects were recruited, 49 as historical controls and 24 in the active arm. ASP implementation resulted in improving the appropriate use of empirical antibiotics from 30.6% (15/49) in the historical control arm to 100% (24/24) in the active ASP arm ($P < 0.0001$). For the active group, initially 19/24 (79.1%) of the antibiotic use was inappropriate, and this improved with the ASP to 24/24 (100%). A total of 27 interventions were made, with an acceptance rate of 96.3%. A positive effect was noted in the emergence of MDR organisms 15/49 (30.6%) in the historical control arm compared to 2/24 (8.3%) in the active arm ($P = .034$). The rate of CDAD did not differ between the groups.
Conclusions Implementation of ASP in the ICU can ensure appropriate empirical antibiotic treatment and reduce the emergence of MDR.

Competing interests None.

CPC022 ANTIBIOTIC PROPHYLAXIS AND INCIDENCE OF ENDOCARDITIS AND MEDIASTINITIS IN PATIENTS UNDERGOING CARDIAC SURGERY

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Background Mediastinitis and endocarditis after cardiac surgery are serious complications that increase short and long term morbidity and mortality and also costs. Antibiotic prophylaxis aims to reduce the risk of surgical wound infection; however these infections occur in 0.4 to 4% of cardiac surgery procedures.
Purpose To evaluate compliance with prophylactic antibiotic guidelines at Hospital Santa Cruz (HSC) Portugal in cardiac surgery. To assess the incidence of mediastinitis and endocarditis after cardiac surgery.
Materials and methods A retrospective study was performed in 456 patients undergoing cardiac surgery (replacement/valve repair, coronary bypass graft (CABG) or both) by sternotomy, between January and December 2010. Data were collected from medical and pharmaceutical databases and other records available in the hospital.
Results 456 patients were evaluated in this study, 74% male, with an average age of 68±12 years (range 22-90 years). Of these patients 45.6% underwent valve surgery (VS), 44.3% coronary artery bypass surgery (CABG) and 10.1% underwent both procedures. The prophylactic regimens used were cefazolin in monotherapy (45.8%), cefazolin + vancomycin (2.0%), vancomycin + gentamicin (52.2%), with an average duration of 1.5±0.8 days. The cefazolin monotherapy was used more frequently in CABG (42.8%) and vancomycin + gentamicin in VS (42.2%). The incidence of endocarditis and mediastinitis was 3.55%.
Conclusions The prophylactic regimens used in cardiac surgery at HSC are in agreement with international and local guidelines. Given the high prevalence of MRSA in HSC, vancomycin and gentamicin were often used, as referred to in the literature. The incidence of postoperative endocarditis and mediastinitis is similar to that reported in several studies.

Competing interests None.

CPC023 HOSPITALISED ESTONIAN NEWBORNS ARE EXPOSED TO A SIGNIFICANT AMOUNT OF POTENTIALLY TOXIC EXCIPIENTS

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Background The information on neonatal exposure to excipients is limited. Previous studies have focused on the excipients known to be toxic, but have not evaluated the general extent of excipient use or assessed the potential neonatal toxicity of excipients.
Purpose To classify the excipients administered into categories according to the possible toxicity to neonates; to record the extent of inpatient neonatal exposure to potentially harmful excipients; and to assess the quantities of toxic excipients in used medicines.
Materials and methods A prospective cohort study recorded all drugs prescribed to neonates hospitalised in Tartu University Hospital from 01.02-01.08 2008 and in Tallinn Children's Hospital from 01.02- 01.08 2009. Excipients were recorded from the Summaries of Product Characteristics and divided into categories by literature review – potentially harmful (likely to be toxic, known toxicity as a substance / as an excipient); unlikely to be toxic; non-toxic; no safety data found; description too unspecific.
Results 348 neonates received 1961 prescriptions for 107 drugs of which 1620 (83%) contained 123 excipients, 41 of them potentially harmful to neonates. Most neonates (89%) received at least one drug with potentially harmful excipients; exposure was similar in preterm and term neonates – median 2 (range 1 to 15) and 1 (range 1 to 11), respectively. Parabens and sodium metabisulfite were the most commonly used potentially harmful excipients, received by 343 and 297 neonates, respectively. Of all medicines 67% contained at least one potentially harmful excipient, average 1.45 (max 5) per drug. The most common medicines with potentially harmful excipients were parenteral gentamicin and oral simethicone, 200 and 108 prescriptions, respectively.
Conclusions Hospitalised neonates are exposed to significant amounts of potentially harmful excipients. Information about excipients should be made more available to pharmacists and treating physicians to help to evaluate neonatal drug safety.

Competing interests None.

CPC024 CAN A YEAR OF PHARMACOTHERAPEUTIC FOLLOW-UP REDUCE THE INCIDENCE OF DRUG-RELATED PROBLEMS AND INCREASE CD4 COUNTS IN HIV-POSITIVE OUTPATIENTS?

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Background Surrogate markers for HIV infection are important and should be used simultaneously with definitive indicators of health and well-being such as drug-related problems (DRPs) within a patient population. Few studies demonstrate the results of pharmacist interventions with statistically significant differences with a comparison group.
Purpose To show that one year of pharmaceutical interventions (PIs) in a group of HIV-positive patients receiving pharmacotherapeutic follow-up (PFU) can significantly reduce the incidence of DRPs and improve clinical outcomes, when compared to a control group.
Materials and methods A prospective controlled study, with a systematic sample by quota controls paired according to random characteristics among cases in 64 HIV-positive outpatients. Patients were divided into a Control Group (CG) and an Intervention Group (PFU). Clinical outcomes were assessed by CD4+ lymphocyte (CD4) and viral load (VL) counts. Lab results, the occurrence of DRPs and types of PI performed were compared.
Results Forty six (71.8%) patients were included in this study and were allocated to the CG (n=23) or the IG (n=23); 28.1% patients discontinued. Ninety-nine PIs were performed (4.3 PIs/patient): 24.2% to prevent DRPs regarding compliance with treatment and 20.2% to guide patients on how to take the medicines. After one year, the DRP count presented a statistically and clinic significant reduction in the IG: 6.1 to 3.1 DRPs/patient ($p<0.001$; ANOVA TWO-WAY). The CD4 count was statistically ($p<0.01$; ANOVA TWO-WAY) and clinically significantly higher in the IG: 233.6±69.8 ($\alpha=0.05$) to 318.4±73.0 ($\alpha=0.05$); whereas no difference was observed in the CG. Although the difference in VL between the IG or CG was not statistically significant, a significant clinical difference was observed: initially 56% of both groups had an undetectable VL, one year later, 74% of the IG reached CV<50 while the percentage in the CG remained the same.
Conclusions The data indicate with statistical power that one year of PI improves patient clinical outcomes and quality of life by reducing DRPs and increasing the CD4 count compared to a control group.

Competing interests None.

CPC025 LIPID-LOWERING EFFECT OF TENOFOVIR IN PATIENTS WITH CHRONIC HEPATITIS B

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Background Some studies have suggested a lipid-lowering effect of tenofovir (TDF) in HIV infected patients who take antiretroviral therapy. Whether this effect appears in other kinds of patients remains unknown.
Purpose To assess the lipid-lowering effects of TDF in patients with chronic hepatitis B.
Materials and methods Retrospective single-institution study. Inclusion criteria: adults with chronic hepatitis B, not HIV-co-infected, treated with tenofovir since 2009. The authors included patients treated with TDF for at least one month and a baseline value for total cholesterol levels (TC) and triglycerides.
Demographics (age, sex) and treatment data (prior antiviral treatment, lipid-lowering treatment) were collected. TC and baseline triglycerides values were compared with those obtained 3-6 months after the start of treatment. Mean values were compared using Student's two-tailed test for paired samples.
Results Eighteen patients were included. Ten patients (56%) were male. Mean (±SD) age was 47.7±10.8 years. None of the patients took lipid-lowering agents at baseline or during the study. Seven patients (38.9%) received other hepatitis B treatment before tenofovir. Only one patient took another anti-hepatitis drug combined with TDF. At baseline, the mean±SD lipids (mg/dl) were 202.4±38.9 for TC and 96.2±45.2 for triglycerides. After 3-6 months of tenofovir treatment mean values were 174.6±30.9 for total cholesterol and 97.2±49,2 mg/dl for triglycerides. The TC levels of 16 patients (89%) improved with a mean reduction of 27.6 mg/dl (CI 95% 12.8-42,3) which is a statistically significant difference ($p=0.001$). Triglycerides did not improve significantly (difference-1.0 mg/dl CI 95% -20.9 to 18.9; $p=0.917$). These results are consistent with those found in HIV-infected patients.
Conclusions TC decreased significantly over the study period for most patients. TDF did not seem to have a positive effect on triglycerides. These data give the first evidence of a lipid-lowering effect of TDF in chronic hepatitis B patients although it must be confirmed in a prospective study.

Competing interests None.

CPC026 IMPLEMENTATION OF FRONT-LINE CLINICAL PHARMACY IN AN EMERGENCY DEPARTMENT

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Background There is strong evidence supporting that pharmacist involvement strengthens quality of the medication process. There is also evidence indicating that many emergency admissions among the older are medicine related. Hillerød Hospital is chosen to perform an implementation study of front-line-clinical pharmacy in an Emergency Department. Hillerød Hospital is a mid-size teaching hospital in the capitol region of Denmark.
Purpose The purpose of the study is to investigate how front-line clinical pharmacy can be implemented in a Danish Emergency Department.
Materials and methods The implementation study is designed as an action-research project using 'Model for Improvement' as the driver methodology. The task is to implement pharmacist driven medication reconciliation and medication review at admission of patients over 50 years of age receiving more than five prescribed drugs. The pharmacists produce an updated medication status before physicians see the patient. The pharmacists document problem-oriented findings and recommendations in the patient record and inform clinicians directly in urgent cases. The evaluation of implementation will be based on; audits of 10 patient records every fortnight to monitor the implementation of pharmacists' recommendations, sequential

analysis of recommendations (sample; recommendations made in 14 days recorded every 3 months), qualitative analysis of pharmacist records and finally merging of all PlanDoStudyAct supporting the implementation process.
Results The pharmacists have adjusted known models for medication reconciliation and medication review to the acute care setting. Up to 90% of pharmacists' recommendations are included in clinicians' management plan for their patients. On average the pharmacists find 1.3 drug related problems per medication review. The implementation process is continuously supported by PlanDoStudyAct's and input from the ongoing qualitative analysis.
Conclusions A close collaboration between pharmacy managers and clinicians has formed a successful basis for coordinating and evaluating the task.

Competing interests None.

CPC027 EVOLUTION OF INDICATORS OF ACTIVITY RELATED TO THE MANAGEMENT OF INVESTIGATIONAL DRUGS IN A PHARMACY SERVICE OVER A PERIOD OF 10 YEARS

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Background In the last years there has been an increase in clinical trials (CT) developed in the hospital as well as in their complexity.
Purpose Describe the evolution of the indicators of activity related to the management of investigational drugs (ID) in a pharmacy service (PS).
Materials and methods Retrospective, 2001-2010, tertiary hospital. Data source: memories of PS, hospital scorecard management and applications of CT. Variables studied: number of CT, medical specialty, patients enrolled who have dispensations of CT (outpatients/inpatients), dispensations performed, phase of the CT, visits by monitors and audits. Receipts and PS-prepared dosages recorded began in PS in January/2009.
Results 496 CT have been developed. CT/years: 94 (63% phase III) in 2001, 95 (60% phase III) in 2002, 104 (59% phase III) in 2003, 97 (65% phase III) in 2004, 87 (61% phase III) in 2005, 102 (58% phase III) in 2006, 129 (53% phase III) in 2007, 163 (53% phase III) in 2008, 147 (59% phase III) in 2009 and 175 (55% phase III) in 2010. CT/medical specialty: oncology-298, rheumatology-111, urology-61, nephrology-57, pneumology-49, HIV infection-39, endocrinology-39, haematology-38, cardiology-29, dermatology-28, hepatitis-21, liver transplantation-20, laboratory haematology-17, ICU-16, others-65. 4168 patients were included (370 inpatients/3798 outpatients). 19998 dispensations were made to patients/investigator. There were 984 medication receipts (2009-530 and 2010-454). Dosages of ID in the PS: 1408 (2009) and 1599 (2010). There have been 1876 monitor's visits and 9 quality audits (without any non-compliance). Limitations: Number of dosage and medication receipts available only from 2009. Not recorded returns and type of monitor's visits.
Conclusions There has been a significant increase in the number of CT in recent years and the resulting activity. The high number of CT and their increasing complexity requires greater dedication of PS as regards the management of ID.

Competing interests None.

CPC028 SHORT FORM 36 AND HOSPITAL ANXIETY AND DEPRESSION SCALE AND ITS PREDICTORS IN SAUDI DIALYSIS PATIENTS AND HEALTHY CONTROLS

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Background Decreased health-related quality of life (HRQOL) and increased anxiety and depression are documented in dialysis patients. Stable HRQOL, lower anxiety and depression are important goals for treatment; however little is known about the specific case of Saudi dialysis patients.
Purpose To study HRQOL, anxiety and depression in stable Saudi dialysis patients and to explore predictors of poor HRQOL, anxiety and depression.
Materials and methods Fifty-three dialysis patients from two dialysis centres in Riyadh and age and education-matched healthy volunteers (36 subjects) from the same hospitals were recruited. HRQOL, anxiety and depression were assessed using the 36-item Short-Form Health Survey, hospital anxiety and depression scales (HADS) respectively (Arabic versions). Age, education, gender, duration of dialysis, DM and smoking were explored as independent predictors.
Results Patients and controls had similar ages (33.7±9.9 vs 36.6±10.9 years), and education level (12.1±3.0 vs 11.5±3.3 years). 55.6% of controls and 64.2% of patients were male. Patients had significantly lower total HRQOL scores (p =.001), specifically in the physical component summary (PCS) (p =.001) although not in the mental component summary (MCS); one item in MCS (social functioning) was significantly higher in controls (p =.03). There were no differences in anxiety and depression. Longer dialysis duration predicted poor HRQOL (R^2 =.08, p=.04), PCS (R^2 =.09, p=.03) and MCS (R^2 =.09, p=.02), and higher anxiety (R^2 =.07, p=.04). Female gender (R^2 =.11, p=.045) and lower education level (R^2 =.06, p=.048) also predicted higher anxiety.
Conclusions Low QOL in Saudi dialysis patients was identified with the score worsening the longer they were on dialysis. Anxiety and depression test scores were unaffected which contradicts previous reports. The effect of female gender, low education level and longer dialysis duration on anxiety was expected and documented previously.

Competing interests None.

CPC029 HOSPITAL PHARMACY RESIDENT COLLABORATION IN A CLINICAL INFECTIOUS DISEASES UNIT (CIDU))

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Background There are some hospitals in Spain where a pharmacist already belongs to a Antimicrobial Management Team (AMT), thus it is important and necessary that the Pharmacy Residency Program includes a rotation by the clinical infectious diseases unit.
Purpose To describe the experience and contribution of a third-year hospital pharmacy resident in the first rotation planned by an CIDU in an University Hospital.

Materials and methods During a month, a third-year resident accompanied the members of an CIDU in their daily workday, full time (from 8 am to 3 pm). The pharmacist resolved queries during the round up with physicians related to the patients admitted in their unit, the ones admitted in other units and those who attended to External consultations. Then, the pharmacist registered and assessed his pharmaceutical interventions (PI). The information collected was processed in an Access® database and classified according to these variables. The types of PI were: A: Sequential Therapy; B: Dosage adjustment in renal failure; C: Pharmacokinetics monitoring; D: Antibiotic switching according to best cost / effectiveness; E: Antibiotic switching according to better coverage; F: Medication administration; G: Drugs interaction. It was also estimated the PI by service, the acceptation and the savings with antibiotic switching according to best cost / efectiveness ratio.

Results During our study, 43 interventions were proposed, accepting 79% (34). Divided by our variables, the acceptance ratio was: A: 66.7% (6) B: 100% (4), C: 59% (8), E: 100% (9), F: 100% (2) and G: 100% (1).

According to clinical services, the distribution was: Postsurgical cardiovascular unit 25.6%, resuscitation 23.3%, cardiology 9.3%. general surgery 7%, pulmonology 4.7%, oncology 4.7%, neurology 2.3% and neurosurgery 2.3%. With D intervention (antibiotic interchange according to best cost / effectiveness ratio), 55.6% acceptation resulted in savings of 5285€ approximately.

Conclusions This rotation development experience has been positive, and it has been included in the Pharmacy Residency Program (PRP) in our hospital. This program could be a significant impact on patient care by becoming an integral part of the medical team by working directly on the hospital floors. Also, the pharmacist was provided more information about the patients, improving the PI's. Regarding the assessment of our interventions, we should highlight those related with antibiotic interchange according to best cost / effectiveness ratio and better efficacy, used to optimise antimicrobial therapy achieving both clinical and economical positive outcomes.

Competing interests None.

CPC030 KALAEMIA DISORDERS: A WARNING FOR CLINICAL PHARMACISTS?

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Background Reviewing prescriptions for high-risk patients must be a priority. Because of their cardiac consequences, disorders of potassium blood levels represent a frequently-occurring preventable iatrogenic event.

Purpose The authors decided to analyse the effect of pharmacists' alerts on patients with dyskalaemia, and thus show that their prescriptions must be reviewed with priority.

Materials and methods A prospective study was conducted in 2 medical units (neurology and pneumology) and a surgery department. Prescriptions were daily reviewed for four months with a computerised physician order entry (CPOE) system (Cristal Net). Dyskalaemic patients were identified (hypo/hyperkalaemia defined on biological laboratory limits). Therapeutic problems and pharmacists' alerts were codified according to the French Clinical Pharmacy Society's coding tables (SFPC). Physicians' acceptance rate was evaluated.

Results 873 patients were hospitalised during the study. A total of 3016 prescriptions were reviewed by pharmacists. 159 patients (18%) showed a blood potassium level disorder during their stay and 337 prescriptions were evaluated for these patients. Of these, 103 (31%) required pharmaceutical intervention (PI). 74% of PIs were directly related to kalaemia disorders. The numbers were higher in general surgery with 49% of PIs in dyskalaemic patients. The main causes of PI were: a contraindication (22%), an adverse drug effect (23%) or an overdose (17%). 12 patients left the ward before physicians responded to the PI. For the remaining patients, practitioners accepted 79% of PIs and modified their prescriptions.

Conclusions The results show a higher percentage of PIs in dyskalaemic patients (31%) compared with the results in non-dyskalaemic patients (11%) and literature reviews (<10%). Therefore, it is more likely that prescriptions in dyskalaemic patients will have a problem. The high acceptance of PIs by prescribers shows how important and relevant they are. The consequences of kalaemia disorders can be fatal, particularly among older and/or multi-medicated patients. Dyskalaemic patients' prescriptions should be reviewed by pharmacists with the highest priority.

Competing interests None.

CPC031 ASSESSMENT OF THE INFORMATION ON INVESTIGATIONAL ORAL TREATMENT PROVIDED TO PATIENTS IN CLINICAL TRIALS

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Background Sponsors of clinical trials (CTs) provide information for patients about the objective of the trial, describe the treatment and alternatives and answer other related questions.

Purpose To evaluate the information provided to patients by the CT sponsors and to assess the need to develop a complementary information form.

Materials and methods A cross-sectional, descriptive study was conducted during August 2011. The informed consent, patient information forms (PIFs) and patient diaries were reviewed. In these documents the quality of the following items was checked: a) Posology: high (description of the dose, allowed delays and route of administration), medium (only refers to the dose) and low (no references or details about drug information). b) Adverse events (AE): information present or not. c) Interactions with the study drug. Documents were divided in those that were detailed and those that did not give any information.

Results At the time of analysis there were 104 active trials. In 35 (33.7%) the pharmacist dispensed the investigational oral drug to patients. In all trials a PIF was provided, in 15 (42.9%) patients had an identity card and in 13 (37.1%) a diary. Regarding to the type and quality of the information contained in these documents it was found that the dose schedule and route of administration were described in all the CTs. However only in 24 (68.6%) of trials was the quality of information about the posology high, in 6 medium (17.1%) and in 5 low (14.3%). AEs were described in all the documents reviewed but the interacting drugs were specified only in 19 (54.3%) of them.

Conclusions The information provided by the sponsors is in some cases deficient or confusing. For this reason the clinical trials department of the pharmacy department decided

to make a complementary information form which will contain: simplified information about the dose schedule, route of administration, storage and how to contact the pharmacy.

Competing interests None.

CPC032 COST EFFECTIVENESS OF PHARMACOTHERAPEUTIC FOLLOW-UP IN HIV-POSITIVE PATIENTS TO IMPROVE IMMUNE RESPONSE

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Background Health costs are a global concern as the financial resources are limited. Identifying new practices that lead to economies in resources is a great challenge. Some studies have already indicated that pharmacotherapeutic follow-up (PFU) can decrease the costs, but more studies must be performed in this area to obtain more precise data.

Purpose To evaluate the cost effectiveness of PFU in HIV-positive outpatients, considering their immune response and costs generated by these patients to the health system.

Materials and methods A 1–year prospective controlled study with 68 HIV outpatients was performed in Brazil, with a systematic sample by quota controls paired according to random characteristics. Patients were allocated to the Control Group (CG) or Intervention Group (IG; receiving PFU). The authors counselled the patients based on the Pharmacist Workup of Drug Therapy (PWDT). The demographic characteristics and the costs generated by each patient (appointments, laboratory tests, procedures and hospitalisations) were obtained from the medical charts. The clinical outcomes of immune response measured were lymphocyte CD4+ higher than 200 cells/mm^3 and absence of new infections during the study. The authors performed a cost effectiveness analysis using a decision tree analytical approach.

Results The patients were allocated to CG (n=30) and IG (n=30) and eighteen patients were discontinued. The intervention group improved in clinical immune response outcomes compared with the control group: lymphocyte CD4+ higher than 200 cells/mm3 (68.2 vs 63.7%) and absence of new infections (77.0 vs 50.0%), respectively. Mean total patient costs (range) were US$ 429.81 (22.45-1312.12) for the control group and US$ 418.13 for the intervention group (125.86-1589.33). Intervention was less costly and more effective than non-intervention.

Conclusions The pharmacoeconomic analysis suggests the study intervention may be effective, with a reduced overall cost to the health system.

Competing interests None.

CPC033 PHARMACEUTICAL INTERVENTIONS IN HOSPITAL PRACTICE- CARE OF THE POLYPHARMACY-PATIENT UPON HOSPITALISATION

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Background Safety and quality of patient medication upon hospitalisation has been in focus at Amager Hospital, Denmark during 2009 and 2010. Pharmacists working at the hospital were engaged to perform systematic medication reconciliation and medication review upon hospitalisation.

Purpose Increase the focus of the medication process at Amager Hospital and hereby ensure the quality of the medical treatment of patients. Pharmacists help reduce discrepancies in medical records and ensure quality of medical treatment by obtaining and reviewing information about the medication from medical records, Electronic Patient Medication list (EPM), the general practitioner, inhome care provider and the patient.

Materials and methods Most patients are admitted to the hospital via the emergency room. The ward experiences a great patient flow, therefore pharmaceutical resources were allocated here. Hence, pharmaceutical interventions were more likely to benefit the majority of hospital patients.
Pharmaceutical interventions were communicated in the medical record and included discrepancies between the medical records upon hospitalisation, rational pharmacotherapy and optimising the use of EPM. Furthermore, pharmacists were delegated limited prescribing rights, hence implementing specific interventions independently.

Results The pharmacists reviewed medical records from 616 patients during 2009 and 2010. Comparing medical records and EPM the pharmacists found 557 discrepancies, equivalent to 0.9 discrepancies per patient. By medication reconciliation 929 pharmaceutical interventions were recommended, equivalent to 1,5 interventions per patient. The interventions lead to 624 (67%) changes in the medical records, implemented by the pharmacists or the physicians.

Conclusions Safety and quality of the hospital medication was increased by pharmaceutical expertise and interventions, by revealing discrepancies within patient medication upon hospitalisation.

Competing interests None.

CPC034 PRESCRIPTION AND ADMINISTRATION OF MEDICINE IN A SURGICAL DEPARTMENT. CLINICAL PHARMACISTS INCREASE THE SAFETY OF MEDICAL TREATMENT OF SURGICAL PATIENTS

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Background General surgeons do not focus on the medical treatment of their patients. This conclusion can be drawn following an internal survey on the way prescription and administrations of medicine were handled on Department of Surgery, Randers Regional Hospital. The surgeons faced a big challenge in order to pass the standards set by the Danish Healthcare quality Programme (DDKM). The requisites for medication set by DDKM, involved requirements for preparation and registration of the medical history, medication reconciliation and allergy-registration. Therefore, a collaboration between the clinical pharmacists and the surgical department was initiated.

Purpose To ensure accreditation by the DDKM by performing medication related interventions. -To gather information and experience from the concept of having a clinical pharmacist at the ward.

Materials and methods The clinical pharmacist worked at the surgical ward 2 h a day (mon-fri) for a 5 months period. Using the patients´ electronic health records, the clinical pharmacist reviewed the prescribed medicine of the admitted patients and made comments about the results of the medication review. The interventions were implemented by: -Teaching the staff about the elements of the accreditation

process. -Weekly presentation of interim results from the individual accreditations elements. -Presentation of the final results at staff-meetings.

Results In the intervention period 672 patients (82%) had their medication evaluated. This resulted in 1297 interventions in 413 patients (3,2/patient). The Department of Surgery passed the standards set by the DDKM. Safe medication of the patients was observed during the period, and the pharmacists gave several recommendations for future collaboration and for further increasing safety.

Conclusions The clinical pharmacist can, through education of the staff, various tools, intense focus and dialogue, guide surgeons to better focus on medicine prescription and thereby ensure accreditation according to DDKM. By a proactive attitude the clinical pharmacist can contribute to increased patient safety.

Competing interests None.

CPC035 THE USE OF MITOMYCIN C IN OPHTHALMIC PATHOLOGIES

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Background Mitomycin C (MMC) is a drug used in some ophthalmic conditions due to its efficacy, which is supported by the literature. However this is an off-label use, not approved by the European Medicines Agency (EMA).

Purpose To assess the use of MMC in ophthalmic pathologies, describing the pharmacist's involvement in the treatment process.

Materials and methods Retrospective observational study of patients with ophthalmic pathologies treated with MMC during 2009 and 2010 in a regional hospital. Data was gathered by reviewing clinical histories and the validation of the treatments by the pharmacist.

Results Thirty-one patients were treated, 6 were excluded due to lack of information. Of the 25 patients included, 14 (56%) were women. The mean age was 65. Eighty-eight percent (n=22) of the patients presented dacryocystitis and 12% (n=3) neovascular glaucoma. The pharmacist would process the authorisation for the off-label treatment, and MMC would then be reconstituted in vertical flow cabins at a concentration of 0.2 mg/ml; this optimised the use of vials of MMC while providing a sterile preparation. The treatment consisted of a single intraocular dose of 0.2 mg MMC. Treatment was effective in 13 patients (52%), partially effective in 6 (24%) and not effective in 6 (24%). Twelve patients (48%) suffered recurrence, 58% of them during the first six months after treatment.

Conclusions Treatment with MMC in the off-label indication studied was total or partially effective in the majority of the patients, confirming the data in the existing literature. More than half the recurrences took place during the six first months after administration. Collaboration between the ophthalmology and the pharmacy departments in devising a system to speed up patient access to MMC treatment has been a success.

Competing interests None.

CPC036 THE ACTIVITY OF PHARMACOVIGILANCE AT SPEDALI CIVILI OF BRESCIA: THE FIRST DATA OF 'FARMAMICO' PROJECT

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Background Oral anticoagulant therapy is at high risk of interactions, potentially serious, because of the nature of the drugs and the older patients, with chronic diseases and treated with multiple medications.

Purpose to evaluate the adverse events, the outcome, the suspected and concomitant medical products; to analyse the interactions, already known or not yet reported in literature, with drugs, phytotherapies, homeopathic.

Materials and methods The project involves 7 hospitals for an amount of 11,000 patients treated. The authors analysed the reports collected by Spedali Civili of Brescia, the coordinator centre, for the period 01/11/2009 – 30/09/2011. Patients with a suspected ADR (Adverse Drug Reaction) answered to a questionnaire during the visit or by phone; the collected data were put into a provided database, and also into the National Network.

Results 266 reports were recorded. The 86% concerned patients between 60 and 89 years, male for 59.8%. The most frequent ADRs are changes of INR, increased in 21.8% (INR > 6 in 1.5 %) decreased in 15%. 71 patients (26.7%) developed major haemorrhage. 56% of the reported cases are not serious, while 40.2% required hospitalisation and / or lengthening of hospitalisation, 194 patients (72.9%) resolved completely the ADR, 45 (16.9%) improved, for 16 the reaction was unchanged or worsened and 6 died. The most frequent indication for which anticoagulant was prescribed was atrial fibrillation. 16 patients took 10 concomitant medications; in 9 cases supplements, or herbal products could be correlated to adverse reaction. The medium hospitalisation length after an ADR was 7.5 days.

Conclusions despite warfarin and acenocoumarol are used for a long time, they are still responsible for serious adverse reactions. It's important to report the ADRs, especially those with new drugs and non-conventional drugs in order to identify the fatal interactions to avoid.

Competing interests None.

CPC037 PHARMACEUTICAL INTERVENTIONS AT A DANISH EMERGENCY DEPARTMENT: INCIDENCE, IMPORTANCE AND SPECIAL TARGET GROUPS FOR PHARMACEUTICAL INTERVENTION

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Background A common reason for emergency admissions is medication related adverse events.

Purpose To evaluate whether the addition of a specialist in clinical pharmacy in the Emergency Department (ED) would be beneficial for the quality of care, and identify which patients should be focused on.

Materials and methods The pharmacist reviewed the patient files in the ED. A tentative diagnosis and a plan for treatment should be established. In case of a pharmacist suggesting any kind of medical intervention, a notice in the file was made describing the problem and a suggestion for a solution. After the study period 2 specialists in internal medicine, clinical pharmacology and geriatric disease reviewed a sample of the patient's files. An evaluation of the importance of the pharmacist notice was put into 4 categories: 1. Minimal (4%) 2. Moderate, risk of increased examination or treatment intensity (49%) 3. Significant, risk of significant increased examination or treatment intensity (44%) 4. Disastrous, risk of death

or permanent damage (3%) Statistics included univariate and multivariate analysis of all variables registered. A p-value of <0,05 was chosen as significant.
Results During the study period (130 working days) a total of 1696 patient files were reviewed. The number of pharmacists' notices amounted to 420. Among these a random sample of 324 notices were studied. In the multivariate analysis only age above 70 years remained of significant importance for identifying patients with a serious intervention. Furthermore there was a higher risk of serious interventions for patients with one drug as opposed to 2-9 drugs.
Conclusions The authors found that there is a high incidence of serious pharmaceutical intervention in the ED not discovered by the physicians. These are especially prevalent among the older patients, regardless of the number of prescriptions. It is remarkable that risk situations occur even with one drug prescription.

Competing interests None.

CPC038 USE OF ELTROMBOPAG IN PRIMARY IMMUNE THROMBOCYTOPENIA: REPORT OF FOUR CASES

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Background Primary immune thrombocytopenia (ITP) is a disorder that is characterised by immune-mediated platelet destruction and impaired platelet production.
Purpose To evaluate the effectiveness of eltrombopag, the first oral thrombopoietin receptor agonist in the treatment of ITP.
Materials and methods The authors report the cases of four patients (patients 1-4) with ITP refractory to first-line treatment (glucocorticoids and immunoglobulin) who were treated with eltrombopag to achieve platelet counts of at least $50x10^9$/l (threshold count, TC). Data were obtained from clinical histories and laboratory tests. Parameters evaluated: previous treatments, platelet counts before eltrombopag, platelet response (achievement of TC), length of treatment to achieve TC and period of study.
Results The four patients (2 men and 2 women, mean age 67±19) had been refractory to first-line treatment. Patient 4 had also been refractory to splenectomy, rituximab, dapsone and azathioprine, and had been treated with romiplostim, which was not well tolerated. Patient 1 started treatment with $11x10^9$/l platelets, patient 2 with 34 $x10^9$/l, patient 3 with 19 $x10^9$/l and patient 4 with 9 $x10^9$/l. After a period of 6 weeks (patient 1), 3 weeks (patients 2 and 3) and 1 day (patient 4) of treatment with 50 mg of eltrombopag once daily (combined with 2 doses of 40 g of immunoglobulin at the beginning of the treatment in patient 4) they all achieved platelet counts above the TC and have maintained them. The total period of study was 28 weeks (patient 1), 15 weeks (patients 2 and 3) and 10 weeks (patient 4). No adverse effects were reported. All the patients are still receiving eltrombopag.
Conclusions Our results agree with those of clinical studies that show that eltrombopag could be an effective and safe treatment for ITP patients who are refractory to other treatments. Nevertheless, further studies should be carried out to evaluate long term safety and efficacy.

Competing interests None.

CPC039 LOCAL INJECTION OF INFLIXIMAB FOR THE TREATMENT OF PERIANAL FISTULAS IN CROHN¥S DISEASE

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Background The formation of perianal fistulas is a serious complication that affects up to 30% of patients with Cohn's disease (CD). It has been suggested that intrafistula injection of infliximab could have some potential healing benefit becoming an adjuvant therapy or an alternative when intravenous infusion is contraindicated.
Purpose The authors describe the preparation, posology, effectiveness and tolerance of infliximab syringes.
Materials and methods Our patients were a 27-year-old woman and a 30-year-old man diagnosed with CD with luminal disease control with certolizumab and adalimumab respectively but multiple perianal draining fistulas without abscesses. Both had been previously treated with infliximab but one of them had experienced an infusion reaction and the another one had relapsed. The gastroenterology physician asked our department to prepare infliximab syringes to inject into each fistula.
Results The syringes were prepared in the pharmacy service under aseptic conditions. To prepare several syringes The authors diluted a 100 mg infliximab phial with 10 mL of water for injection; 12 mL dextrose 5% were added to 2 mL of this dilution so each syringe contained 20 mg of infliximab. The contents of one syringe were injected per fistula (at the internal and external orifices and along the fistula tract). Patients were treated under general anaesthesia and signed an informed consent. The local injections were scheduled at weeks 0, 4, 8, 12, 16 and 20. Efficacy was assessed before the injection of the next dose in terms of remission (complete cessation of fistula drainage) and response (more than 50% reduction of the draining orifices). After the third dose (week 8) both patients had achieved a response, one without remission. No adverse effects were reported.
Conclusions Although few cases have been reported, local infliximab injections may help in fistula healing and be well tolerated even by patients for whom intravenous infusion is not suitable.

Competing interests None.

CPC040 THE USE OF SUNITINIB IN METASTATIC THYROID CARCINOMA: CASE REPORT OF AN OFF-LABEL TREATMENT

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Background Thyroid cancer typically has a good outcome following standard treatments, which include surgery or radioactive iodine or systemic chemotherapy. During the last two years many randomised trials have demonstrated that multikinase inhibitors, such as sunitinib, are active in metastatic thyroid carcinoma.
In Italy, sunitinib is only approved for the treatment of metastatic renal carcinoma, GIST (gastrointestinal stromal tumour)

or HCC (hepatocellular carcinoma), but if there are no other valid therapeutic options a Sicilian regional law allows clinicians to prescribe an off-label treatment and hospital pharmacies to dispense it.
Purpose To evaluate the treatment of a multikinase inhibitor, sunitinib, for an off-label indication and to assess the safety and efficacy of the treatment for an older patient, female, 80 years old, with metastatic thyroid cancer not responsive to cisplatin/epirubicin and gemcitabine.
Materials and methods The oncologist prepared a formal request, with the patient's informed consent and all the phase II and III trials available in literature. These documents were also evaluated by the hospital pharmacist and then finally approved by the hospital's medical director. After this procedure the pharmacy supplied and distributed the drug to the patient who was being treated at home.
Results Since April 2011, the patient took sunitinib at the standard dose of 50 mg/day for 8 weeks and the volume of the lesion reduced. The clinician monitored vigilantly for hypertension. Fatigue was the side effect that led to a reduction of dose to 25 mg/day for another 8 weeks. At present, six months later, the disease has regressed further.
Conclusions Our data support the use of sunitinib in metastatic thyroid cancer, demonstrating also a low incidence of adverse reactions. This case report can also demonstrate the advantages of using off-label treatments if they are supported by valid clinical evidence rather than updating the regulatory approval of some drugs.

Competing interests None.

CPC041 PHARMACOLOGICAL VITRECTOMY WITH UROKINASE: DESCRIPTION OF THE METHOD AND REVIEW OF A CASE SERIES.

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Background Pharmacological vitrectomy (PV) with autologous plasmin is used to detach the vitreous, with or without subsequent surgical vitrectomy, in several pathologies such as proliferative diabetic retinopathy, proliferative vitreoretinopathy, macular hole, posterior hyaloid contracture syndrome and vitreomacular traction syndrome. Autologous plasmin is obtained by an expensive and complicated method. An alternative method is the use of urokinase as an enzymatic activator of the plasmin; it is cheap and simple to make.
Purpose To describe the technique and our experience with it during the first year of use in our hospital.
Materials and methods The steps are as follows: 1- Take 7 ml of blood from the patient, place in the centrifuge tube and centrifuge at 4,000 rpm for 15 min. Simultaneously, a phial of urokinase is heated for 15 min at 37°C. 2- Mix 1.8 ml of plasmin with 0.2 ml of urokinase, shaking the mixture vigorously for another 2-3 min, keeping the mixture in incubation at 37°C until use. 3- Sterilise the solution by filtration through a 0.22 mm filter, immediately preceding the injection of 0.2 ml into the eye.
Results Over this year using this technique in our hospital 17 patients have been treated with it, in 3 of them the procedure had to be repeated. An improvement in visual acuity was observed in 62.5% of these patients one month after the intervention but was not associated with an improvement in retinal anatomy.
Conclusions PV is a cheaper, faster and easier technique than the operation used prior to PV. PV is an interesting technique to perform in hospitals that do not have retinal surgery or in patients with comorbidities that contraindicate vitrectomy under anaesthesia.

Competing interests None.

CPC042 CUTANEOUS TOXICITY ASSOCIATED WITH PANITUMUMAB

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Background Epidermal growth factor receptor (EGFR) inhibitors, such as panitumumab, are used for the treatment of colorectal carcinoma. These treatments have fewer systemic side effects than traditional chemotherapy, but dermatological adverse effects are significantly more common.
Purpose To investigate the cutaneous toxicity of panitumumab in patients who received this treatment during the period from May 2010 to September 2011.
Materials and methods Patients were identified using an oncology pharmacy informatics tool (Farmis). Dosage, number of cycles, concomitant treatments and dermatological side effects were listed from the electronic medical records. Treatments for the dermatological reactions, such as topical and systemic antibiotics, antihistamines or steroids, were also recorded.
Results 12 patients were given panitumumab from May 2010 to September 2011 (The authors have excluded two patients who only received one dose). 8 patients (83.3%) were in monotherapy with panitumumab. 66.7% were male and average age was 66 years old. Side effects on the skin were described in 10 patients (83.3%). 8 patients (66.7%) presented an acneiform rash and 6 (50%) patients presented pruritus. One patient presented a severe eruption which led to dosage reduction and finally stopping the treatment. The other patients presented mild forms of eruption and pruritus. All the dermatological events appeared after first cycle of panitumumab, except in one patient (after the second cycle). 50% of patients were receiving systemic antihistamines and topical antibiotics, and 3 patients (25%) required systemic antibiotics.
Conclusions Our results are similar to the findings in current literature (cutaneous eruptions occur in 30-90% of patients treated with EGFR). These side effects of EGFR inhibitors stigmatise the patient in daily life and is necessary to recognise and treat them.

Competing interests None.

CPC043 STOPP AND START SCREENING TOOLS AS SUPPLEMENTS TO THE PHARMACEUTICAL MEDICINES REVIEW

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Background Inappropriate prescribing is a well-documented problem in older people. The screening tools STOPP (Screening Tool of Older Peoples' Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment) have been formulated to identify potentially inappropriate medications (PIMs) and potential errors of omission (PEO) in older patients. Literature

has shown that pharmacists can use STOPP and START reliably during their everyday practice to identify PIMs and PEOs in older patients.
Purpose To ensure high quality of the prescriptions for patients admitted to geriatric wards.
Materials and methods A clinical pharmacist used the STOPP and START criteria for each patient record of patients admitted to the geriatric ward. The screening tools were also presented to the physicians on the ward by the senior physician and all were given a pocket card with the criteria. The PIMs and PEOs were recorded as if identified by the pharmacist or by the physician. PIMs and PEOs identified by the pharmacist were presented to the physician for further action. The action taken on the PIMs and PEOs identified by the physician were also recorded.
Results In the period May to August 2011 151 patients were reviewed. PIMs were identified in 19% of the patients and most were due to overuse of proton pump inhibitors and long-term use of benzodiazepines. Seventeen percent had PEOs that were mostly related to the cardiovascular system; four identified by the pharmacist and accepted by the physician were due to lack of aspirin in the presence of chronic atrial fibrillation, where warfarin was contraindicated or due to lack of aspirin or clopidogrel in patients with coronary or cerebral disease.
Conclusions Using STOPP and START criteria as supplements to the medicines review the clinical pharmacist ensures high quality in the medicines prescribed for geriatric patients, a population for whom it is important to take precautions when prescribing.

Competing interests None.

CPC044 SHARING INFORMATION ABOUT MEDICINES AMONG CLINICAL PHARMACISTS

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Background The Hospital Pharmacy of Zealand Region receives requests about medicines from physicians, nurses and top-up pharmaconomists (pharmacy assistants). The clinical pharmacist is responsible for providing answers. In 2009 the three former Hospital Pharmacies in Zealand Region became one Hospital Pharmacy. A regional electronic tool with the possibility of sharing knowledge among all the clinical pharmacists and documenting the requests was required.
Purpose To create a regional electronic tool to:
- share knowledge easily
- document the number, type of requests and the pharmacist's answers
- search in previous requests and answers

Materials and methods Microsoft Outlook has a tool called 'Journal'. The clinical pharmacists record and categorise the requests and answers in a journal. Date, profession and working place of the questioner is recorded in the journal as well as the background references used for the answers.
Results The Microsoft Outlook 'Journal' is a useful regional tool that makes it easier to share knowledge and to document the number of requests received and answers provided to the questioner. In the first six months of 2010 a total of 973 requests were recorded. In the first six months of 2011 a total of 1213 requests were recorded. Most of the requests dealt with drug storage, stability, administration of drugs, mixing drugs and questions regarding prescriptions for drugs not recommended by the Regional Drug and Therapeutics Committee.
Conclusions The use of this electronic tool to record the requests has relieved the daily work for the pharmacists in Zealand Region. The Journal has shown to be an effective and easy regional electronic tool for the clinical pharmacists in Zealand Region, to document information about the medicine, share knowledge about medicines and to provide answers in a more uniform way.

Competing interests None.

CPC045 LENALIDOMIDE: SAFETY AND CLINICAL BENEFIT†

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Background With the adoption of electronic medical records in our hospital, it became easier to conduct medicines use studies.
Purpose Aim of the study: To describe the safety and clinical benefit that lenalidomide treatment yielded in our patients.
Materials and methods An observational and retrospective study was conducted including patients who received lenalidomide for multiple myeloma (MM) (authorised indication) or myelodysplastic syndrome with 5q deletion (MDS5q-) (off-label use). Patients were identified from the pharmacy's electronic register.
The variables were: demographics, diagnosis, duration of response, reason for stopping treatment, transfusion requirements (MDS), and incidence of adverse drug events.
Results A total of 20 patients entered the study (11 men and 9 women): 16 affected with MM and 4 with MDS. MM patients began at the standard dose of 25 mg/day and MDS at 10 mg/day. Of all, 6 (30%) required dose reduction during treatment (4 MM and 2 SMD), and the main reason for it was toxicity.
Among patients with MM, 4 (25%) stopped treatment because of progression, another 4 (25%) died and 1 (6%) underwent transplantation. Among patients with MDS, 2 patients discontinued: one died and another evolved to acute myeloid leukaemia. 13 out of 20 (65%) experienced toxicity, 5 (25%) haematological, 4 (20%) respiratory infection, 2 (10%) diarrhoea and 2 (10%) renal failure. None of the patients with MDS 5q- required blood transfusions during treatment. The mean duration of response of patients who completed treatment was 13 months (range: 1-41). For patients who are still on treatment the mean duration is 15 months (range: 3-29).
Conclusions Lenalidomide offers good clinical results due to the average duration of response. Our case series has showed frequent and severe toxicity that has led to dose reductions or even patient death. Therefore, the limiting factor for lenalidomide therapy is its toxicity and consequently close safety monitoring is mandatory.

Competing interests None.

CPC046 ECHINOCANDINS FOR INVASIVE FUNGAL INFECTIONS†

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Background During recent years, an increase in the incidence of Invasive Fungal Infections (IFI) has been observed, in parallel to a progressive shift of invasive species from Candida albicans to fungi resistant to previously-effective treatments.

The use of echinocandins in this context is spreading as an alternative to azoles.
Purpose To determine the distribution of invasive fungal species in the population of patients treated with echinocandins in our hospital and the outcomes in this context over a year.
Materials and methods All patients treated with echinocandins during 2010 were evaluated. Data such as sex, age and length of hospital stay were taken from the electronic chart. Information regarding treatment with caspofungin and anidulafungin was taken from electronic prescription programs.
Results The authors identified 136 patients: 97 were men, the median of age was 65 years (17 months to 84 years) and median duration of hospital stay 37 days (2-137 days). There were 160 prescriptions: 127 for caspofungin, 33 for anidulafungin. The median duration of treatment was 7 days (1-37 days).
In 52 prescriptions a positive isolate for fungi was detected. Of them, 26.9% (14) cultures were positive for C. albicans, 14 positive for species less susceptible to echinocandins (C. parapsilosis and A. fumigatus) and 29 positive for non-albicans susceptible species. In 5 cultures, two different species were found. 28.6% of patients exposed to species less susceptible to echinocandins died during the treatment (4 patients). Among the population whose positive cultures were sensitive to echinocandins, there were 6 deaths (15.8%).
Conclusions The population studied confirms the tendency pointed out on the literature, a shift towards species different from C. albicans in IFI. Though the use of echinocandins seems to be effective and safe, attention should be paid to local sensitivities since less susceptible species such as C. parapsilosis and A. fumigatus are spreading

Competing interests None.

CPC047

EVALUATION OF THE PROTHROMBIN TIME FOR MEASURING RIVAROXABAN PLASMA CONCENTRATIONS USING CALIBRATORS AND CONTROLS

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Background Rivaroxaban is widely used in clinical practice. Although routine coagulation monitoring is not required, quantitative determination of rivaroxaban might be valuable in certain clinical circumstances. Variation in response sensitivity of prothrombin time (PT) reagents to rivaroxaban is well described in the literature, and the conventional international normalised ratio cannot be used for rivaroxaban.
Purpose This multicentre study assessed the intra and inter-laboratory precision of measurements of rivaroxaban plasma concentrations using the PT assay together with rivaroxaban calibrators and controls.
Materials and methods Participating laboratories (Europe and North America) were provided with rivaroxaban calibrators (0, 41, 219 and 430 ng/ml), rivaroxaban pooled human plasma controls (19, 160 and 643 ng/ml) and PT reagent. Evaluation was performed over 10 consecutive days by each laboratory using local PT reagents as well as the centrally provided PT reagent (STA Neoplastine CI Plus; Diagnostica Stago). A calibration curve was produced each day, and day-to-day precision was evaluated by testing three control plasma samples. The control was diluted and re-tested if the level was above the highest concentration of the calibration curve.
Results Intralaboratory variations in PT were dependent on the sensitivity of the local PT reagents, regardless of the type of instrument used. A large inter-laboratory variation (in seconds) was observed with local PT reagents; the coefficient of variation (CV) was 13.6–29.7%. When the results were expressed as rivaroxaban concentration (ng/ml), the inter-reagent variations were reduced; less variation was found with both local reagents (CV: 5.1–15.5%) and the central reagent (CV: 2.2–7.5%). However, over-estimation was observed with both local and central reagents. The CV for the calibrator containing 41 ng/ml rivaroxaban was 5.8% when the central reagent was used.
Conclusions The PT assay may be useful for measuring rivaroxaban peak plasma concentrations (2–3 h after drug intake) using rivaroxaban calibrators and controls.

Competing interests None.

CPC048

EVALUATION OF GEFITINIB USE IN A GENERAL HOSPITAL

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Background Gefitinib, an oral tyrosine kinase inhibitor, is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of the epidermal growth factor receptor (EGFR).
Purpose To review gefitinib clinical use in patients with NSCLC in a general hospital.
Materials and methods Observational retrospective study of patients who started treatment with gefitinib from May 2010 (inclusion of gefitinib in our hospital formulary) to July 2011. Data source: clinical history and pharmacy department records. Data collected: age, sex, smoker, histologic classification of the tumour, EGFR mutation, line of treatment of gefitinib and treatment duration of gefitinib.
Results 19 patients started treatment with gefitinib (11 female and 8 male), median age was 71 years (46-83). 2 patients were smokers, 4 ex-smokers, 1 passive smoker and 10 non-smokers (2 unknown). 17 patients were classified as adenocarcinoma and 2 as squamous cell NSCLC, 79% of patients had grade IIIB or IV NSCLC. EGFR mutation was positive in 63% of patients (12), negative in 1 patient (off-label use) and 6 patients unknown. Gefitinib was first-line treatment in 42% of patients. Median duration of treatment was 3 months (1-14). At the end of the study period: 9 patients continued treatment with gefitinib, 7 died and 3 were lost to follow-up (probably died). Treatment was well tolerated in all patients.
Conclusions Gefitinib was well tolerated. Mutation EGFR test is needed to achieve treatment efficacy. In our study most patients being treated with gefitinib had advanced NSCLC and, despite treatment with gefitinib, a high percentage of patients died during treatment. This is a short study, so that it is necessary to continue reviewing its clinical use.

Competing interests None.

CPC049

EVALUATION OF THE ANTIFACTOR XA CHROMOGENIC ASSAY FOR MEASURING RIVAROXABAN PLASMA CONCENTRATIONS USING CALIBRATORS AND CONTROLS

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Background Rivaroxaban is an oral, direct Factor Xa inhibitor approved for clinical use for the prevention and treatment of thromboembolic disorders across several indications. Routine coagulation monitoring is not required, but a quantitative determination of rivaroxaban concentrations might be useful in some clinical circumstances.
Purpose This multicentre study evaluated the suitability of a modified antifactor Xa chromogenic assay for the measurement of plasma rivaroxaban concentrations (ng/ml) using rivaroxaban calibrators and controls, and to assess the inter-laboratory precision of the measurement.
Materials and methods Twenty-four centres in Europe and North America were provided with sets of rivaroxaban calibrators (0, 41, 209 and 422 ng/ml) and rivaroxaban pooled human plasma controls (20, 199 and 662 ng/ml; the concentrations were unknown to the participating laboratories). The evaluation was carried out over 10 days by each laboratory using local antifactor Xa reagents as well as a centrally provided, modified STA Rotachrom assay (Diagnostica Stago, Asnières-sur-Seine, France). A calibration curve was produced each day, and day-to-day precision was evaluated by testing three human plasma controls.
Results When using the local antifactor Xa reagents, the measured rivaroxaban concentrations (mean±SD/actual value) were 17±6.4/20, 205±28.2/199 and 668±94.4 (in diluted samples)/662 ng/ml, and the coefficients of variance (CV) were 37.0%, 13.7% and 14.1%, respectively. When the modified STA Rotachrom method was used, the measured±SD/actual values were 18±3.4/20, 199±21.7/199 and 656±65.8 (in diluted samples)/662 ng/ml and the CV were 19.1%, 10.9% and 10.0%, respectively. Satisfactory inter-laboratory precision was achieved using rivaroxaban calibrators regardless of the type of antifactor Xa reagent and instrument used, except for the lowest concentration tested (20 ng/ml) when using the different local reagent/instrument combinations.
Conclusions The results indicate that the antifactor Xa chromogenic method is suitable for measuring a wide range of plasma rivaroxaban concentrations (20–660 ng/ml), covering the expected concentrations after therapeutic doses, by using rivaroxaban calibrators and controls.

Competing interests None.

CPC050 COST BENEFITS OF UK HOSPITAL PHARMACY INTERVENTIONS: UNLICENSED MEDICINES DISPENSED IN THE COMMUNITY

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Background Birmingham Children's Hospital (BCH) issues over 36,000 prescriptions each year that are dispensed by community pharmacists at a cost exceeding £2.2 million. Costs are incurred by the NHS and are rising. Some of these prescriptions include unlicensed medicines (ULMs). At present pricing of ULMs is unregulated in the UK.
Purpose To identify drug-related cost benefits of hospital pharmacy interventions for ULMs prescribed by hospital physicians but dispensed in the community.
Materials and methods Clinical pharmacists reviewed and, if necessary, modified hospital physician-prescribed outpatient prescriptions prior to being dispensed by community pharmacists (the intervention). Preintervention drug costs (net ingredient costs and dispensing fees) were estimated using historical data held on ePACT database and were compared with intervention drug costs identified through payment systems.
Results During the period 8 April to 30 September 2011, 442 prescriptions (638 items) were reviewed. These included 81 items (13%) for ULMs. Interventions on ULMs included: 17 (21%) drug or dose changes; 50 (62%) quantity changes and 51 (63%) where the prescription was re-directed to be dispensed under hospital control (either by a community pharmacy partner hired by BCH, or by the BCH Pharmacy itself). Drug-related cost benefits of the interventions are estimated to exceed £70,000.
Conclusions This study identifies drug-related financial benefits of hospital pharmacist interventions when ULMs are prescribed by hospital physicians for children at home and dispensed by community pharmacists. This finding supports proposed innovations in NHS processes, that providing long-term medicines for children at home should be led by secondary care.

Competing interests None.

CPC051 PHARMACEUTICAL RESEARCH NURSE: EXPERIENCE OF THE NATIONAL TUMOUR INSTITUTE OF MILAN

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Background Often, due to a heavy workload, nurses are unable to analyse clinical protocols and administer experimental drugs without prior, detailed information regarding characteristics, dilution and side effects. Precise, reliable administration can only be guaranteed when resulting from complete familiarity with the clinical protocol. Sometimes, pharmaceutical handling is governed by mechanical, non-universal regulations encouraging administration errors. The clinical research activity taking place in the Pharmacy of the IRCCS Tumour Institute Foundation is complex due to the vast numbers of experimental protocols it handles. The pool of professionals comprises a research nurse who manages the practical, organisational aspects of the clinical trials conducted on patients.
Purpose To assess the nurse's knowledge regarding clinical studies through internal, investigatory procedures and instruments that monitor the quality of personnel training facilitating comprehension of the research protocols.
Materials and methods Literature research: study published in 1994 in Cancer Nursing of the EORTC Nursing Group lists the nurses involved in Clinical Trials, documenting participation and specific needs.
Internal research directed at hospital nurses who use experimental drugs more often.
Results Duration of the investigation was one month. 144 questionnaires were issued of which: 48% were completed and subsequently returned. Results show a disturbing lack of postbase training when one considers the role of the nurse and her influence on patient care and study results.
Conclusions It is imperative that nurses administering experimental drugs fully understand the therapeutic effects of such substances as well as administration guidelines in order to protect patient safety, hence guaranteeing

optimum execution of the study. Appointing an experienced and reliable nurse for the pharmaceutical, clinical studies encourages colleague participation and guarantees quality control of performance. Such nurses constitute key figures for ensuring efficiency and correct conduct in clinical experimentation.

Competing interests None.

CPC052 EVALUATION OF PHARMACIST CLINICAL INTERVENTIONS PROFILE IN A UNIVERSITY HOSPITAL

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Background The pharmacist is incorporated step by step to daily clinical activities at hospital. However, there is still a lack of uniformity both among the tasks assumed and also the way of performing these tasks.
Purpose The aim of this paper is to evaluate the profile for clinical pharmacy interventions at University Hospital environment.
Materials and methods The authors performed a prospective, open and descriptive study for twelve months (January-December 2010) of the interventions made by pharmacists in a centralised model, after establishing a classification of tasks, and their codification, that the pharmacist could assume in relation to the clinical patient management. This relation was made after reviewing the methodology proposed by Dader Group (Granada's pharmaceutical group), and introducing some important modifications. As a previous result The authors proposed an encoding system of pharmacist's clinical tasks grouped into seven categories: proposing to withdraw a drug, propose to incorporate a drug, exchange, dosage recommendation, confirmation personal treatment, information and monitoring.
Results The authors have evaluated a total of 35.642 inpatients, distributed into 12 surgical units (17.437 inpatients), 16 medical units (14.545 inpatients), and 14 units without individualised dose distribution system (3.660 patients). There have been a total of 7.219 pharmacist interventions: 3.836 (medical), 3.200 (surgical) and 183 (no unit dose). The rate interventions / patient is equal in medical and surgical units (0.22) and both four times higher than in units without unit dose (0.05). Profile evaluated interventions shows that the main intervention in any area is the therapeutic exchange (73%), followed by dosage recommendation (14.2%), withdrawal proposal (4.7%), monitoring (2.7%), information (2.2%), proposed incorporation (1.8%) and confirmation of treatment (1.2%). There is no difference between the profile of interventions in medical, surgical or wards without unit doses. There is an important difference between the medical profile and haematology profile for pharmaceutical interventions, because this is a unit that has a pharmacist assigned in a decentralised model.
Conclusions The pharmaceutical intervention profile does not change between surgical and medical units in our centralised model. The intervention rate for wards with unit dose is five times higher. The average intervention rate is 0.22. The higher average intervention rate for medical units is 0.46 , and for surgical units is 0.65.

Competing interests None.

CPC053 ANTIBIOTIC PRESCRIPTION TRENDS IN UTIS AT A HOSPITAL EMERGENCY DEPARTMENT

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Background Many patients visit the emergency department because of urinary tract infections (UTIs). Appropriate antibiotic prescriptions are necessary due to high resistance patterns and both the clinical and financial impact on the health system.
Purpose To describe characteristics of population diagnosed with UTIs attended at a tertiary hospital emergency department as well as the antibiotic prescription at discharge.
Materials and methods Retrospective study of adult patients attended at a hospital emergency department with a diagnosis at discharge of urinary tract infectious disease from January to June 2011. A random sample was selected. The authors analysed discharge reports to find: sex, age, main diagnosis, pregnancy, recent history of UTI and antibiotic prescription at discharge.
Results A total of 201 patients were included. (70.1% women, mean age 49.7 years). UTI was the most frequent diagnosis (188 patients, 93.5%) and 13 had an added urological disease. Antibiotics were prescribed to 91.54% of patients. Most often antibiotics prescribed were third generation cephalosporins cefixime and ceftriaxone (27.9%), followed by fosfomycin (26.4%) and fluoroquinolones (14.9%). Oral cefuroxime was prescribed in 10.9% patients and amoxicillin- clavulanic acid in 7%. The authors found out that 39 patients (19.4%) had a recent history of UTI. In those patients, the most frequently prescribed antibiotics were cephalosporins (46.1%) followed by fosfomycin (25.6%). Seven of the 141 women included in the study were pregnant. Four of them received cephalosporin, 2 fosfomycin and one of them amoxicillyn-clavulanic acid.
Conclusions Most patients attended at the emergency department due to UTI received an antibiotic prescription at discharge. The authors found a high rate of cephalosporin prescriptions. The authors should conduct a more extensive study including laboratory results and resistance rates in the region in order to assess the appropriate or inappropriate choice of the antibiotic therapy.

Competing interests None.

CPC054 TOXICITY AND RELATIVE DOSE INTENSITY (RDI) OF FOLFOX 6 CHEMOTHERAPY IN PATIENTS OF DIFFERING BODY MASS INDEX TREATED FOR COLORECTAL CANCER

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Background Colorectal cancer is the third leading cause of death from cancer worldwide. It has been suggested that obesity may be a promoting factor in the growth of colorectal carcinoma. Although adiposity has been a recognised risk factor its effect on treatment success and prevalence of treatment-associated toxicities remains unclear.
Purpose To investigate the difference in relative dose intensity and treatment-induced toxicity in patients of normal BMI compared to overweight patients.

Materials and methods A retrospective study of patients receiving FOLFOX 6 for colorectal cancer between January 2006 and March 2010 at St. James's hospital, Dublin.
Results Patients of normal BMI (18.5 kg/m^2 to 25 kg/m^2) had higher dose intensity at treatment initiation but received a lower dose intensity for the remaining cycles compared to overweight patients (BMI >25 kg/m^2). The average relative dose intensity of FOLFOX was 64.78% (normal BMI group) and 67.05% (overweight group). The incidence of fatigue was significantly higher in patients with a normal BMI, (p=0.016) but there was no significant difference in the rate of hospital admission due to FOLFOX toxicity.
Patients with a 'National Cancer Institute's Common Terminology Criteria for Adverse Events' (CTCAE) grade 3/4 toxicity had their dose reduced to prevent such severe toxicity reoccurring. CTCAE grade 3/4 was prevalent in 41% of overweight, and in 65% of normal weight patients. Subsequent dose reductions occurred in 53% of overweight and 65% of the normal weight patients.
Conclusions The overweight group experienced less severe toxicities than the normal BMI group indicating that they may be capable of tolerating doses based on actual body weight rather than capping the BSA which is common practice. The low % RDI (relative dose intensity) received by both study groups may highlight a need to gain better control of toxicities. Future studies should investigate the impact of pharmacist counselling on supportive medication on % RDI-related toxicities.

Competing interests None.

CPC055 NEUTROPENIC COMPLICATIONS ASSOCIATED WITH CHEMOTHERAPY IN PATIENTS WITH BREAST CANCER

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Background Chemotherapy-induced neutropenia is the main dose-limiting toxicity, with high morbidity, mortality and associated costs. Febrile neutropenia (FN) rates vary considerably between studies.
Purpose To know neutropenic complications (NC) incidence in our breast cancer patients treated with Doxorubicin-Cyclophosphamide (AC) and Doxorubicin-Cyclophosphamide-sequential Docetaxel (AC-T) schemes; determine their consequences; analyse sample's characteristics and myeloid growth factors use.
Materials and methods Patients with breast cancer treated over 20 months were selected retrospectively. 107 patients treated with AC or AC-T comprised the sample. Descriptive variables were obtained.
Results 97% of patients were in stage I, II or III; 95.8% received chemotherapy for the first time; 98% started treatment at full dose. 35.5% (95CI 27 to 45) of patients developed NC and 24.3% (95CI 17 to 33.2) suffered FN. 36% of NC were due to first AC cycle. No patient received primary prophylaxis with myeloid growth factors even when docetaxel was started. Secondary prophylaxis was administered in subsequent cycles after patient developed the first NC (it was administered to 91,3% of patients who developed FN and 78% of patients with NC without fever). Apart from two cases, no patient on secondary prophylaxis developed a NC again. Filgrastim and/or Peg-filgrastim were used. 77% of patients with FN were hospitalised (mean= 5±3 days) and 7% had to be attended in the emergency department (ED). 25% of patients with NC without fever were treated in the ED. Next cycle was delayed in 31.5% of NC (mean= 6.6±2.8 days); dose was reduced to 79.5%±4.4% of the scheduled dose in 39.4%; chemotherapy was finished in 7.9%. 5% of the sample received a relative dose intensity (RDI) <85% due to NC.
Conclusions The risk of NC in our patients is higher than reported in literature. According to current recommendations, primary prophylaxis with myeloid growth factors would be indicated in our patients.

Competing interests None.

CPC056 ANTIRETROVIRAL NAÔVE PATIENTS HAVE BETTER FIRST YEAR AND FOLLOW-UP ADHERENCE DATA IN OUR COHORT

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10.1136/ejhpharm-2012-000074.405

Background Adherence to antiretroviral treatment is critical to the success of the therapy.
Purpose The authors conducted a study to assess adherence in patients included into a cohort from 2001 until 2008.
Materials and methods The authors performed a retrospective cohort analysis of adherence data from each new patient enrolled between 2001 and 2008. Pharmacy refill records from all medication in the therapy were used to measure mean annual adherence. The primary outcome was optimal adherence (considered as ≥ 95%). Multivariate logistic regression and survival analysis for repeated measurement was applied. Gender, age at the moment of the recruitment and being immigrant were also collected.
Results There were 241 HIV-positive adults eligible for analysis (68.5% male; mean age: 39.1±8.3). In our cohort, 137 (56.9%) were antiretroviral- naïve and 104 (43.1%) antiretroviral- experienced patients. 8.3% were immigrants and the median of follow-up was 4 years (1- 6). Naïve patients showed statistically better mean adherence in the first year and also higher rate of patients with optimal adherence ($p < 0.001$ in both cases). In the immigrant population the rate of non-adherence was higher ($p = 0.07$). Regarding the multivariate analysis, non-immigrant patients (OR 5.4; 95% CI 1.9 to 15.4) and starting treatment after 2005 (OR 2.93; 95% CI 1.4 to 6.1) showed to be predictors of optimal adherence. For every five- year increase in age, being non-immigrant had 14% higher probability to be adherent (OR 1.14; 95% CI 1.05 to 1.23). During the follow-up, being naïve was the unique variable to maintain optimal adherence.
Conclusions In our cohort, antiretroviral naïve and non-immigrant patients who started treatment after 2005 had higher probability to achieve optimal adherence during the first year. But the only predictor of maintain good adherence levels was being naive.

Competing interests None.

CPC057 SELF-ADMINISTERED HOME PARENTERAL ANTIBIOTIC TREATMENT USING ELASTOMERIC INFUSION PUMPS IN ORTHOPAEDIC PATIENTS

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Background Aarhus Hospital Pharmacy offers portable elastomeric infusion pumps containing dicloxacillin and piperacillin/tazobactam to selected patients. During 2009, The authors documented stability data for both antibiotics in elastomeric infusions pumps. The expiry date for dicloxacillin 10 mg/ml in normal saline (NS) is 4 days at 2-8 °C, and 7 days at 2-8°C followed by 1 day below 32°C for piperacillin/tazobactam 12 g and 16 g in 270 ml NS.
Purpose Infections in bone and joints are treated with intravenous antibiotics for weeks and they need hospitalisation. In order to maintain the patients' physical and social skills and to minimise the need for hospitalisation, a number of selected orthopaedic patients were offered self administration of their parenteral antibiotics at home.
Materials and methods All patients were fitted with a central venous catheter (CVC) and the patient or parent was trained to administer intravenous antibiotics during the period of waiting for the organism identification report. The patients were discharged with all equipment needed and written instructions. Due to the expiry date of the antibiotics, the patients returned to the hospital for new pumps.
Results From August 2009 to April 2011 twelve patients with median age of 37 (1-59) years self-administered their intravenous antibiotics, required due to osteomyelitis (n=10) and septic arthritis (n=3). Two patients received piperacillin/tazobactam and the rest dicloxacillin. Totally intravenous antibiotics were administered for 193 days. The period of self-administration was 133 days, thus decreasing hospital stay by 69 %. One patient developed allergic erythema due to dicloxacillin and was hospitalised and received cefuroxime. All other patients fulfilled their treatment without complications. The patients/parents felt secure and were satisfied with the treatment and preferred the treatment offered over hospitalisation.
Conclusions Self-administration of parenteral antibiotics at home for selected patients can reduce hospital stays significantly. The patients/parents preferred the treatment offered to hospitalisation.

Competing interests None.

CPC058 ADHERENCE TO DISEASE-MODIFYING TREATMENTS IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background The current treatment of multiple sclerosis is based on disease-modifying treatments, including intramuscular and subcutaneous interferon (IFN) or subcutaneous glatiramer acetate.
Observational studies have shown that patient adherence to treatment is suboptimal and adherence is a key issue in chronic diseases to maximise treatment benefits.
Purpose The goal of this study was to evaluate the level of adherence to disease- modifying treatment in multiple sclerosis in our patients during 2011.
Materials and methods The study cohort consisted of patients with multiple sclerosis attended at Galdakao- Usansolo Hospital Outpatient Pharmacy. The authors conducted a retrospective analysis of pharmacy claim data from January to September of 2011, and The authors calculated the medicines possession rate to assess adherence to treatment. Percentage of patients with optimal adherence (more than 95%) was the primary outcome measured. Patients included were older than 18 years and had been on treatment for at least 6 months at the moment of analysis.
Results At the beginning of the study The authors selected for analysis 41 patients on treatment, 6 of whom started treatment during 2011 (61% female; mean age: 40.5±10.2 years). Regarding the drug, 14 patients received intramuscular IFN β-1a, 10 subcutaneous IFN β-1a, 10 subcutaneous IFN β-1b and seven glatiramer acetate. 85.4% of the patients had an adherence level greater than 95%, however 4.9% had suboptimal adherence and 9.8% discontinued the treatment during the monitoring period. They abandoned the treatment voluntarily and in one case the drug was withdrawn because the illness progressed. The mean adherence level in our cohort was 89.5%±29.9.
Conclusions Although the level of adherence in our multiple sclerosis patients during 2011 was high, The authors had almost ten percent of treatment discontinuation.

Competing interests None.

CPC059 USE AND EFFECTIVENESS OF ELTROMBOPAG IN A TERTIARY HOSPITAL

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Background Eltrombopag is authorised by the EMA for adult chronic immune thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments and as second-line treatment for non-splenectomised patients for whom surgery is contraindicated. Eltrombopag was effective in 59% of patients in a randomised controlled trial (Bussel, 2009).
Purpose
1) To determine whether eltrombopag is prescribed according to the approved indications.
2) To observe the effect on platelet levels.

Materials and methods Observational study. The authors included patients treated with eltrombopag from 01/01/2011 to 31/08/2011. Variables analysed: demographics, diagnosis, previous treatments, duration, rescue medication, changes in platelet levels, and reason for suspension (where applicable).
Results Seven patients were treated with eltrombopag. Median age: 65 years, 4 males. Six had ITP and 1 had multifactorial essential thrombocytopenia. All patients with ITP had received first-line treatment with corticosteroids and immunoglobulins and were refractory to at least 2 second-line treatments, as follows: immunosuppressants (3 patients), rituximab (3), Vinca alkaloids (2), tranexamic acid (3), and romiplostim (2). One patient with ITP was splenectomised, while 5 were not (old age (3), multiple comorbidities, refusal (1 each)). Four of the 7 patients discontinued treatment before the end of the study (median duration, 87 days), while 3 continued with treatment (median interval from initiation, 46 days). The 3 patients who continued with treatment maintained increased platelet levels from baseline (>50 x 10^3/μL). Of the 4 who stopped treatment, 3 did not have increased platelet levels at any time during the study, while 1, despite reaching and maintaining platelet levels, discontinued treatment due to uncontrolled bleeding events. All non-responders required rescue with immunoglobulins.
Conclusions Eltrombopag was prescribed according to the approved indication in 6 out of 7 patients and was effective in

half of the patients with ITP. Despite our small study population, the percentage of responders was similar to that found by Bussel *et al*.

Competing interests None.

CPC060 OBSERVING GOOD PRACTICE GUIDELINES FOR PROTON PUMP INHIBITORS IN GERIATRICS UNITS

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Background Proton pump inhibitors (PPIs) are a therapeutic class of drugs that are effective for the reduction of gastric acids. Misuse has already been reported in this class of drugs.
Purpose Within the framework of the evaluation of professional practice, The authors performed an audit of the prescription of PPIs in university hospitals.
Materials and methods This multicentre study included three geriatric hospital centres, or approximately 1000 beds, and was performed according to 'one day study' methodology. A sample of 20% of all patients taking PPIs was randomly tested. All data on the patient, his/her treatment and disease were recovered from the patient's file. The conformity of the treatment to official guidelines, published by the French National Health Authority (HAS), and its traceability, were verified.
Results 95 medical records were audited. Only 6% of the patients included an appropriate indication and posology. Indications that were not approved in reference documents such as gastrointestinal haemorrhage (10), hiatus hernia (4) or anaemia (2) were described in 21 patients (22%). No indication was found in 59 patients, or 62%. Finally in the 15 patients in which the indication was appropriate, there were errors in length of treatment, posology and the choice of specialities, resulting in non-conforming treatment.
The traceability in the medical record showed that information was insufficient in 100% of the cases. Missing information included the indication (62%) as well as prescription details (length of treatment 95%, posology 50%, and name of the speciality 47%).
Conclusions This audit shows that the main problem is traceability. Because PPI treatment has a satisfactory tolerance profile, it is not the subject of attention by doctors or subject to re-evaluation.
As a result of this study, a computer protocol will be used which is linked to prescription software including all indications validated by official guidelines.

Competing interests None.

CPC061 INVESTIGATOR PERCEPTION OF TRIAL PRESENTATION TO THE CLINICAL RESEARCH ETHICS COMMITTEE

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Background There has been a Clinical Research Ethics Committee (CREC) in the hospital since 1993. A characteristic of the committee is that the main investigators (MIs) are called to present the project at the CREC evaluation meeting.
Purpose To analyse the MIs' perceptions about face-to-face project presentation and the CREC's handling of administrative and advisory matters.
Materials and methods Descriptive study performed over nine months (January to September 2011) through a voluntary questionnaire given to MIs who attended the CREC meetings. Each MI was only give on questionnaire regardless of the number of projects presented during the study period.
The questionnaire contained a numeric range (1-10) with which to evaluate presenting the study and the satisfaction with the CREC considering bureaucratic, ethical, scientific-methodological aspects, its legal recommendations and overall functioning.
Results The questionnaire was answered by 36 MIs (94.7%). Projects presented to the CREC meetings comprised 55.3% observational studies and the rest (44.7%) clinical trials. 77.8% of the MIs polled did not have previous experience in presenting studies to other CRECs. Average score obtained in the evaluation of face-to-face study presentation was 9.2 (SD 0.9) and the subjective benefit of balancing time spent and result obtained was rated 8.4 (SD 1.3). Average scores for selected administrative points such as meeting organisation, document formalities and contract procedures were 8.3 (SD 1.2), 8.7 (SD 1.0) and 8.1 (SD 1.3) respectively. The average scores obtained for CREC recommendations relating to ethical aspects of the trial treatment, the patient information sheet and informed consent were 8.0 (SD 1.2) and 8.3 (SD 1.2). An average of 7.9 (SD 1.4) was recorded for the proposed changes related to scientific/methodological aspects and 8.4 (SD 1.2) for other suggestions made by CREC members. Evaluations of legal issues such as the insurance policy and procedures with various agencies and institutions were 7.4 (SD 1.9) and 6.8 (SD 2.2) respectively. Overall average evaluation of CREC tasks was 8.6 (SD 1.0). The main comments made by 61% of the MIs were positive about presenting the project because they were closely involved in the subject presented. 8.3% emphasised the difficulty of juggling clinical services and the CREC meeting timetable. 22.2% did not have any comments.
Conclusions The study showed a high opinion of defending projects face-to-face and expressed the effort made by MIs to contribute for the smooth running of CREC meetings. MIs evaluated the administrative and advisory performance of the CREC as very satisfactory.

Competing interests None.

CPC062 REGISTRATION RATES OF CLINICAL TRIAL RESULTS ON WEBSITE REGISTRIES

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Background Creation of free website registries of clinical trial databases answers the absolute necessity of transparency in human research. Sponsors make a moral commitment to put results on the website not later than one year after the study's primary completion date. Voluntary participants, the public and investigators now have access to the results. Up to now, a lot of scientific teams have worked on publication bias of clinical trial results. A few have estimated registration of results on trial registries available for free consultation by the public.
Purpose Our objective was to quantify the rate of result registration for clinical trials on an international registry attested by the FDA.

Materials and methods The authors consulted the United States registry Clinicaltrial.gov, which listed 111,427 trials for 174 different countries, on 3 August 2011.
Only Phase III and IV studies were selected. The recruitment completion date had passed and the primary completion date had passed by more than one year for the clinical trials. Data were extracted from the registry: sponsor name, sponsor category (institutional or industrial) and whether the results had been put on the website or not.
Results After selection, 12,895 trials were studied. Of them, 42% had an institutional sponsor and 58% had an industrial sponsor. Only 779 trials had posted results (6.04%). Result registration rates of institutional sponsors were 1.48% and 9.32% for industrial sponsors ($p < 0.001$).
Conclusions Protocols of clinical trials are easily available for public consultation on website registries. However, our study shows poor result registration. It is a moral responsibility for sponsors to post the results of clinical trials. This commitment, set out in 1964 in the declaration of Helsinki, has been confirmed by the FDA. The low rate of result registration and negative publication bias does not improve the transparency of clinical trial results.

Competing interests None.

CPC063 THE DEGREE OF PATIENT SATISFACTION WITH DILTIAZEM GEL IN THE TREATMENT OF ANAL FISSURES

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Background Anal fissure is a common and painful condition that often affects young adults of both sexes. Topical 2% diltiazem gel is described as an effective first-line treatment for chronic fissure with an optimised toxicity profile. When it became unavailable on the Portuguese market, our hospital and the Faculty of Pharmacy from Lisbon University developed a formulation and are producing and dispensing it.
Purpose To assess the degree of patient satisfaction with the use of diltiazem gel in anal fissure.
Materials and methods Cross-sectional descriptive study with information collected at a single moment in time through a telephone interview.
Results All patients to whom the Pharmacy Department dispensed diltiazem gel between January and July 2011 were included. Number of patients was 137 (68 females, 69 males); mean age: 50.3 years. 70 patients answered the questionnaire (52 were excluded). The majority had higher education (baccalaureate or a degree). Regarding health status evolution, pain improved or improved considerably in 77% of patients. With regard to bleeding, it improved a lot or completely in 63% patients. As for itching and/or perianal irritation, it improved or improved considerably in 41% patients (33% didn't know). As for passing faeces, in 14% patients it greatly improved or improved completely (77% didn't know). Concerning side effects, only 2 patients had headaches and 1 mentioned dizziness. In terms of degree of satisfaction with the gel, 17% were completely satisfied, 57% very satisfied, 17% at least somewhat satisfied, 4% somewhat satisfied, 1% completely unsatisfied and 3% didn't know. Of the 70 patients, 56% considered themselves cured, not cured 39% and 6% didn't know.
Conclusions Diltiazem gel seems to be a good alternative for treating anal fissure. The production of medicines by pharmacy departments is very important for meeting patients' needs not met by the pharmaceutical industry.

Competing interests None.

CPC064 THE IMPROVEMENT OF ADHERENCE TO ANTIRETROVIRAL TREATMENT THROUGH THE PHARMACEUTICAL CARE AND THE ANALYSIS OF FACTORS AFFECTING IT

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Background The lack of adherence to antiretroviral therapy(ART) is the leading cause of treatment failure. The ART has all the factors to make difficult the adherence. The authors have applied a pharmaceutical care program with the purpose of evaluating patients adherence to ART by means of questioners and interviews, as well as improving it providing information and education about their illness and treatment.
Purpose To evaluate the impact of pharmaceutical care program on adherence to ART and analyse the factors that affect it in a negative way.
Materials and methods Ambispective experimental study, with a prospective phase of 12 months, comparing ART adherence in patients in a pharmaceutical care program(n=28) versus adherence in patients not included(n=24).Adherence was measured in the experimental group, using the SMAQ validated questionnaire(Simplified Medication Adherence Questionnaire) and by means of the dispensary data management system, and it was only measured retrospectively for this last method in the control group. The socio-economic factors together with the disease characteristics were obtained from medical records and through a validated questionnaire made by Gemma's group (Grupo Español para el Estudio Multifactorial de la Adherencia). After that, The authors evaluated their influence on adherence by using a multivariate model estimated on a binary logistic regression.
Results The proportion of adherent patients was higher in the group who received pharmaceutical care (81.8%) than in the control group (68.4%)($p=0.058$). It was also higher in the subgroup Q24 h for both groups, experimental (94.4%) and control (75%)($p=0.09$).Considering the socio-economic variables dichotomous and binary, adhesion ratio was lower in patients who had children ($p=0.045$),with low education leve l ($p=0.001$), injecting-drug ($p=0.000$), smoking ($p=0.000$), alcohol ($p=0.002$) and methadone users ($p=0.000$),those who live with another HIV positive person ($p=0.003$) or who had HIV positive friends ($p=0.024$).
Conclusions Our pharmaceutical care program was able to increase the number of adherent patients. Given the negative influence of the social economic factors on adherence here described, it would be desirable to implement new strategies to improve adherence based on psycho-educational programs for these patients.

Competing interests None.

CPC065 PREVALENCE OF POLYPHARMACY IN OLDER HOSPITALISED PATIENTS

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Background The use of multiple medications and/or the administration of more medications that are clinically indicated, representing unnecessary drug use (polypharmacy) increases the risk of non-adherence, adverse drug reaction and drug interaction. These problems are specially common and relevant in older hospitalised patients.
Purpose Analyse the prevalence of polypharmacy at hospital admission and at hospital discharge in a group of older patients, and how the hospital stay modifies this prevalence.
Materials and methods Patients enrolled in our retrospective study were hospitalised at the Internal Medicine Department during October 2010. Only Patients ³ 75 years old were enrolled. Polypharmacy was defined as the concomitant use of five or more medications and high-level polypharmacy was defined as concomitant use of ten or more medications. The following data were recorded for each patient: sociodemographic details, functional status, Charlson co-morbidity index (predicts the ten-year mortality for a patient who may have a range of co-morbid conditions), diagnoses at discharge, and treatments at hospital admission and discharge.
Results Of the 109 patients enrolled, 61 were women. The average age was 82,69±5,15 years. At admission, 29,4% of patients were independents. The average of Charlson index was 4,62±2,3. On average, the patients studied were taking 9,01±4,01 drugs at the time of hospital admission and 9,84±3,83 drugs at discharge. Hospitalisation led to a significant increase in the number medications (p=0,001). Polypharmacy on admission and at discharge was observed in 87,2% and 91,8% of patients, respectively; and 42,2% were taking ten or more different drugs at admission and 53,2% at discharge, existing statistically significant difference between high-level polypharmacy at admission and discharge (p=0,036).
Conclusions Our study confirmed a relatively high prevalence of polypharmacy in older hospitalised patients at the Internal Medicine Department. Hospitalisation led to a significant increase in the number of medications and in the prevalence of the high-level polypharmacy. The high prevalence of polypharmacy in elderly patients shows the need to reevaluate the pharmacotherapy during hospital stay.

Competing interests None.

CPC066 COMPASSIONATE DRUG USE: THE EXPERIENCE OF THE LECCE-ASL ETHICS COMMITTEE

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Background Compassionate drug use allows treatment with investigational drugs when there are no therapeutic alternatives. In Italy this is regulated by Ministerial Decree 08/5/2003. The reason for, and conditions of, use must be submitted by the physician for the approval of the competent Ethics Committee. Compassionate use is authorised for individual patients.
Purpose The increasing number of requests for compassionate drug use made it desirable for the ASL Lecce Ethics Committee to set up a database to record the epidemiology.
Materials and methods The Scientific Secretariat of the Ethics Committee receives the request for compassionate drug use, verifies the completeness and examines the information supplied, and prepares documents for submission to the Ethics Committee. Once approved, it is recorded in an Excel database which shows the clinic, hospital ward, physician, the proposed drug use, name of the patient and date of approval.
Results The analysis included all data recorded from 01/01/2009 to 01/09/2011, from which it emerged that during this period 34 requests for compassionate drug use were submitted to the Ethics Committee, 10 of which were in 2009, 7 in 2010, and 16 in the first 9 months of 2011. Seventy-three percent of the requests came from the Oncology ward, 15% from Haematology, 9% from Rheumatology and 3% from Endocrinology.
Conclusions Growing numbers of requests for compassionate drug use underline the need for doctors and patients to have access to innovative drugs when there are no therapeutic alternatives and no possibility of inclusion in clinical trials. The monitoring system has made it possible to find out whether the drugs for which compassionate use was requested were then licensed for that purpose by AIFA; and it will enable the Ethics Committee to suggest that doctors set up non-profit clinical trials when the requests for compassionate drug use become sufficient.

Competing interests None.

CPC067 PHARMACEUTICAL INTERVENTIONS IN ANTIBIOTIC DOSAGE ADJUSTMENT IN RENAL IMPAIRMENT. CLINICAL IMPLICATIONS.

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Background Drug dose adjustment in renal impairment is basic in pharmaceutical validation.
Purpose To evaluate the acceptance of pharmaceutical interventions during the validation of antibiotic treatments in patients with impaired renal function.
Materials and methods Retrospective observational study of pharmaceutical interventions (PIs) for dose adjustment in renal impairment, in patients treated with levofloxacin, ciprofloxacin, meropenem, ertapenem, amoxicillin/clavulanic acid or piperacillin/tazobactam, in the period January 2010-September 2011.
The data collected were: number of clinical history, age, sex, weight, serum creatinine and clinical department. The creatinine clearance was calculated using the Crockcroft-Gault formula. Patients were classified according to renal clearance in 3 groups: A (CrCl 50-30 ml/min), B (CrCl 29-10 ml/min), C (CrCl < 10 ml/min). The dosage adjustments recommended were based on the summary of product characteristics and the antimicrobial treatment guide published by J. Mensa et al. in 2011.
Results The total number of patients whose antibiotic dose had to be adjusted because of the creatinine clearance was 139 (58 men and 81 women), with an average age of 82. Of the patients, 67% were prescribed levofloxacin, 8.6% ciprofloxacin, 14% meropenem, 9% ertapenem, 29% amoxicillin/clavulanic acid and 8% piperacillin/tazobactam. 27.3% of patients were in group A, 70.5% in group B and 2.2% in C. The overall percentage of acceptance of the PI was 79.1%. For antibiotic treatment, the acceptance rate for levofloxacin was 85%, ciprofloxacin 41.6%, ertapenem 77.7%, meropenem 92.8%, amoxicillin/clavulanic acid 82.7% and 50% for piperacillin/tazobactam. 55.4% of interventions were made in the Internal Medicine ward.

Conclusions The high degree of acceptance of pharmaceutical interventions among prescribers promotes the integration of the pharmacist in multidisciplinary teams.

Competing interests None.

CPC068 IMPROVING THE QUALITY OF DATA IN THE ONCO-AIFA REGISTER AS A PREREQUISITE FOR OUTCOME RESEARCH STUDIES

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Background The Ministry of Health promoted in 2010 a project to improve the management of cancer drug treatments in five Italian oncology hospitals. A pharmacist was assigned to assist physicians in prescribing, one of the main aims being improving the quality of the data recorded in the Italian web-based Register on oncology drugs. The register onco AIFA was set up in 2006 to evaluate new and costly drugs introduced in the market. For each drug, it ensures both patient eligibility and periodic evaluation of treatment toxicity and patient follow-up.
Purpose One of the outstanding critical issues in the management of the onco-AIFA register was the delay in the data entry of toxicity/patient revaluation. The objective of this project was to verify how the pharmacist's activity could improve the data quality in the tumour registry, which represents a potentially powerful tool in outcome research.
Materials and methods A daily monitoring of the recorded data allowed to identify the pending requests. A reminder e-mail was daily sent to each physician to highlight the incomplete records. Number of patients entry data / overall patients treated, number of treatment completed forms / overall treatments, risk sharing reimbursement obtained / overall treatment cost were evaluated as indicators of the process efficiency.
Results Owing the centralised drug distribution in the IOV Pharmacy department, all the treated patients were eligible and inserted in onco-AIFA. Improving margins have been focused, rather than as of 'number of entries', as number of closed and reimbursed treatments. Both doubled compared to the period before the project. In addition, data suggest the investigation and the evaluation of others indicators, which could better demonstrate the efficiency of pharmacist's role in the department. Although daily data entry was not achieved, a significant improvement (81, 42% vs 51.80%) in records within a week was obtained. A predefined report has been developed and suggested as standard format for monitoring oncological data.
Conclusions Results obtained confirm the value of the pharmacist in a multidisciplinary team as part of the process of patient care as warranty of prescriptive appropriateness and as an 'added value' in different areas of health intervention, including administrative implications.

Competing interests None.

CPC069 COMPARING ORAL RIVAROXABAN VERSUS STANDARD TREATMENT IN THE TREATMENT OF SYMPTOMATIC DEEP VEIN THROMBOSIS: A PATIENT-REPORTED TREATMENT SATISFACTION STUDY

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Background The EINSTEIN DVT study was a large, open-label, randomised trial comparing rivaroxaban with the standard care (enoxaparin/vitamin K antagonist (VKA)) in patients with acute deep vein thrombosis (DVT) and without symptomatic pulmonary embolism. Rivaroxaban was evaluated for the treatment of DVT in a single-drug approach with a fixed-dose regimen without the need for initial heparinisation, routine laboratory monitoring or dose adjustment.
Purpose To investigate patient-reported treatment satisfaction in a subset of patients from the EINSTEIN DVT study.
Materials and methods More than 1400 patients from seven countries (Canada, France, Germany, Italy, The Netherlands, UK and USA) were requested to complete a new, validated measure of treatment satisfaction: the AntiClot Treatment Scale (ACTS). At scheduled visits throughout treatment (day 15, months 1, 2, 3, 6 and 12) patients completed the ACTS, which consists of two scales: ACTS Burdens (12 items) and ACTS Benefits (3 items). For each scale, higher total scores indicate higher satisfaction. A prespecified repeated-measures regression analysis was used to compare ACTS scores in the intention-to-treat population.
Results Patients reported higher treatment satisfaction in the rivaroxaban group compared with the enoxaparin/VKA group, with higher mean ACTS scores across visits. Mean ACTS Burdens scores were 55.2 versus 52.6 ($p<0.0001$) in favour of rivaroxaban; a consistent treatment effect over time was observed, with the difference in mean scores ranging from 2.2 at month 2 to 3.2 at month 12. Mean ACTS Benefits scores were 11.7 versus 11.5 ($p=0.006$), showing an improvement in satisfaction for the rivaroxaban group. There was no difference in mean ACTS Benefits scores at day 15, with the treatment effect for rivaroxaban becoming apparent at month 2 and later.
Conclusions These data show that rivaroxaban provided improved treatment satisfaction for patients with DVT compared with enoxaparin/VKA, particularly in reducing patient-reported anticoagulation burden.

Competing interests • Luke Bamber and Anthonie WA. Lensing are employees of Bayer HealthCare, Wuppertal, Germany • Maria Y. Wang is an employee of Bayer HealthCare Pharmaceuticals Inc., Montville, NJ, USA • Rupert Bauersachs has received honoraria for lectures or consultancies from Bayer HealthCare • Martin H. Prins has received consultancy fees from Bayer HealthCare • Stefan J Cano has received consultancy fees from Bayer HealthCare

CPC070 VIROLOGICAL RESPONSE AT 24 WEEKS AND SAFETY OF DARUNAVIR/RITONAVIR IN HIV INFECTED PATIENTS

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Background Use evaluation in clinical practice of darunavir boosted with ritonavir(DRV/r) in HIV patients. **Purpose** Study the effectiveness and safety of DRV/r at 24 weeks (24Ws).
Materials and methods Retrospective observational study of series of HIV patients treated with DRV/r between January-2008 and September-2011. The changes in viral load (VL) and CD4 cell counts were evaluated in patients at baseline and

CPC070 table 1 At time of analysis 28/30 patients completed 24Ws of therapy.

			HIV stage(%)				Reasons starting(%)			
	Age(year)	Sex (%) (Female)	A	B	C	Median CD4(cell/ mm3)<> <><>	VF	AEs	Simplification Therapy	(%)Resistance Testing(Pis) <> <><>
VL<50 copies/ml (n=11)	41.7(95% CI: 37.1-46.3)	54.5	54.5	9.1	36.4	527(IQR:441-792)	0	72.7	27.3	18(negative)
VF(n=17)	50.5(95% CI: 45.6-55.4)	29.4	11.8	23.5	64.7	205(IQR:137-475)	100	0	0	88.2(13.3% positive, none DRV mutation) <> <> <>

at 24Ws. Also, safety and tolerability. End points: i)Primary effectiveness: % patients with VL<50 copies/ml at 24Ws, in patients with virologic failure(VF) or VL<50 initially; ii) Security: discontinuation rate due to intolerance or toxicity. Secondary effectiveness end points: i)Increased CD4 at 24w; ii) Security: hepatotoxicity(criteria: ALT/AST concentrations(U/L)>5N(55/41) in HCV/HBV non-coinfected and >3.5 baseline in coinfected). Data analysis using descriptive statistics

Results Most common DRV/r-based regimens: 27.3% PI/r, 54.5% PI/r+2NRTIs in VL<50 group and 35.3% PI/r+RAL+NNRTIs, 29.4% PI/r in VF group. 39.3% HCV/HBV coinfected(Child-Pugh A 90.9% and B 9.1%), none antihepatitis treatment, median ALT=125(IQR: 48-170)/AST=113(IQR: 55-136). Non-coinfected, median ALT=20(IQR: 12-24)/AST=20(IQR: 17.5-24.5). Two patients 18.2%(95% CI:2.3-51.7) with VL>50(94/113 copies/ml respectively) in VL<50 group, while 47%(95% CI:23-72.2) in VF group achieved undetectable VL. Median CD4 variation in VL<50 group was -16cell/mm^3(95% CI: -88-102) and in VF group was 50 cell/mm^3(95% CI: 33-179). 6.6%(n=30) patients discontinued treatment (abdominal pain/constipation and hypersensitivity). No episodes of hepatotoxicity.

Conclusions This study, performed in a small group of patients in routine clinical care, showed that, at 24Ws, the regimens of rescue which contain DRV/r, achieve similar rates of virological suppression than those observed in the clinical trials. During the study, DRV/r was well tolerated and safe in HIV non-coinfected and coinfected patients with mild and moderate hepatic impairment.

Competing interests None.

CPC071 DISCREPANCIES IN DRUG ALLERGIES RECORD IN THE COMPUTERISED PRESCRIPTION ORDER ENTRY SYSTEM

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Background Modules detection and warning of drug allergies is one of the brackets for the prescription offered by prescription order entry systems (CPOE). This tool is an important aid in order to prevent potentially medication errors. However, there aren't studies that analyse the proper use of these modules by the physicians.

Purpose To quantify and analyse the discrepancies drug allergy registered in CPOE and in admission and discharge patients records.

Materials and methods On day cross-sectional study in a hospital with 1000 beds. The CPOE provides register patient allergies and which will be saved in the pharmacotherapeutic profile for future admission. Allergies can be inserted and updated in the system by physicians. The pharmacist compared the allergy registered in the discharge and admission records of all hospitalised patients with the information included in CPOE. The number and type of discrepancies in the drug allergy record was analysed.

Results A total of 803 hospital admissions were reviewed. 11.98% (67) of patients records hadn't any information regarding to history of drug allergies. 13.7% (101) from the 736 remaining patients had allergies to some medication. 127 discrepancies were found that affected to 85% (86) of patients with drug allergies. 81.9% (104) of discrepancies were due to allergies collected in medical record but not registered in the CPOE, 10.2% (13) was included in the CPOE but not in the medical record and 7.9% (10) were incorrectly registered in the CPOE. The main drug groups involved in the discrepancies were: allergy to betalactams (25.2%), Non-steroidal antiinflammatory drug (7.8%) and sulfonamides (7.1%).

Conclusions Discrepancies were found in 85% of patients with drug allergies, mainly affecting the betalactam group.

Competing interests None.

CPC072 COMPLIANCE WITH ANTIRETROVIRAL TREATMENT IN HIV PATIENTS

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Background Adherence to HIV treatment is crucial to avoid the illness progressing or drug resistance appearing.

Purpose The aim of this study is to assess the compliance with triple highly-active antiretroviral therapy (HAART) in HIV outpatients depending on the daily number of tablets prescribed.

Materials and methods The authors performed a retrospective study in patients who started HAART treatment in 2010. To carry out this study, The authors examined the data recorded in the computerised dispensing record. The compliance was evaluated by the relationship of the no. of doses prescribed/dispensed for each patient. The ARV regimen of each patient was also classified into four groups, depending on the daily number of tablets prescribed: group A: single-tablet regimen; group B: two-tablet regimen; group C: three-tablet regimen; group D: four-tablet regimen.

Results During the period studied, 86 patients started treatment; 13 of them were discarded for various reasons (death, change of treatment, etc.), so finally The authors assessed the compliance in 69 patients whose results are shown in Table 1.

Conclusions The overall percentage adherence to the treatment was really high in the population studied. It exceeded 95% in 86.4% of the cases. Furthermore, this adherence increased when the therapeutic regime was less complex, possibly due to the fact that is easier for the patient to take the medicine as intended. The compliance was measured by only one method, which was to assume that patients who collected drugs took them properly. So The authors consider that further studies must be done using different methods.

Competing interests None.

CPC072 Table 1. Adherence results

% Adherence	A	B	C	D	Overall
> 95%	86.4 (32)	57.1 (4)	71.4 (15)	75 (3)	78.3 (54)
95-90%	5.4 (2)	–	4.8 (1)	–	4.3 (3)
< 90%	8.1 (3)	42.9 (3)	23.8 (5)	25 (1)	17.4 (12)
Overall	78.3 (37)	2.9 (7)	30.4 (21)	5.8 (4)	100 (61)

CPC073 EVALUATION OF TOCILIZUMAB IN TWO OFF-LABEL INFLAMMATORY PROCESSES REFRACTORY TO OTHER APPROVED TREATMENTS

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Background Tocilizumab is a monoclonal antibody for human use, capable of neutralising the biological effect of IL-6 by blocking its specific receptor IL-6R; it has proven effective in the treatment of rheumatoid arthritis (RA). There are a few published cases in off-label amyloidosis and SLE (systemic lupus erythematosus).
Purpose To find out whether tocilizumab got good results in two individuals with off-label inflammatory processes refractory to other approved treatment.
Materials and methods A Senegalese patient aged 27 was diagnosed with nephrotic syndrome secondary to renal amyloidosis. No possible cause except a history of having had tuberculosis (Mantoux +, negative Lowenstein). Prophylactic treatment was started with rifampicin/isoniazid but given the poor prognosis treatment with tocilizumab 8 mg /kg was initiated monthly and the response assessed. A patient 28 years of age was diagnosed with systemic lupus erythematosus 2 years ago. At the onset of the disease several treatments were used with corticosteroids, mycophenolate and cyclophosphamide. Since the disease was progressing it was decided to introduce rituximab treatment with little response, the patient even had an allergic reaction and the treatment was stopped. The patient suffered clinical and laboratory deterioration with recurrence of systemic symptoms (fever, rash, polyarthritis and increased acute phase reactions). It was decided to initiate treatment with tocilizumab (off label) (8 mg / kg=160 mg) every 2 weeks.
Results After the first dose, the amyloidosis patient showed a good response with decreased proteinuria and improved creatinine clearance, but the proteinuria deteriorated again after the second dose. Tocilizumab was stopped. In the SLE patient, after the third dose an insufficient respond was obtained and the dose was increased to 240 mg. At the time of writing the patient had received 7 doses of tocilizumab in combination with corticosteroids and the symptoms of the disease were controlled.
Conclusions Tocilizumab was not able to control the effects of amyloidosis but it was able to control those of SLE in another patient.

Competing interests None.

CPC074 THE EFFECT OF INTRAVITREAL BEVACIZUMAB INJECTION IN NEOVASCULAR MACULAR DEGENERATION

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CPC074 table 1

Number of legible letters	% of patients
82	33.7
68	31.8
67	38.9
53	42.6
52	19.8
38	19.2
37	7.6
23	6.4

Background Bevacizumab is a monoclonal antibody that binds vascular endothelial growth factor. It reduces angiogenesis and vascular permeability. In Italy it is approved for colorectal, lung, breast and renal cancer. In 2007, law 648/96 allowed bevacizumab to be used in exudative macular degeneration (MD) and neovascular glaucoma. In 2009 AIFA authorised its use in patients aged under 65 and in non-treatment naive patients aged over 65. Since 2010 bevacizumab can be used only in patients aged under 65.
Purpose To assess the effectiveness of intravitreal bevacizumab injection on visual acuity (VA) in patients with neovascular MD.
Materials and methods Between January 1, 2008 and September 30, 2011 The authors assessed 356 patients (179 females and 177 males) who were 69.7±1.22 years of age. 81 patients received a dose of 1.25 mg of bevacizumab three times a year, prepared by pharmacists from Avastin 100 mg in the Antineoplastic Drug Preparation Room. The other 275 patients received bevacizumab as needed. Patient changes in VA were evaluated monthly with a Snellen-equivalent method.
Results There were 245 age-related MD patients, of whom 77.4% showed stability of vision, 2.8% showed an improvement in VA and 19.8% had slightly worse acuity. There were 111 non-age-related MD patients, of whom 81.8% showed stability of vision, 9.5% showed an improvement in VA and 8.7% had slightly worse acuity. The VA scores of patients who were given bevacizumab quarterly or as needed were:
Conclusions Macular degeneration is the leading cause of irreversible vision loss in the industrialised world. Bevacizumab optimises vision-related quality of life because it immediately reduces the amount of fluid in or under the retina. In fact, in this analysis, it showed a beneficial effect in stabilising loss of visual acuity and in a few patients even led to an improvement.

Competing interests None.

CPC075 EVALUATION OF NUTRITIONAL STATUS AND ITS FINANCIAL EFFECTS IN A TERTIARY HOSPITAL

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10.1136/ejhpharm-2012-000074.424

Background Disease-related malnutrition affects 20-50% of hospital inpatients. Nevertheless, only 5-50% of malnourished patients receive nutritional support. It has several consequences for hospitals. One of the most important is the increase in health costs, estimated at 20-60%. However, detailed data on the financial outcomes of malnourished patients are usually less available than results from malnutrition screening tools.

Purpose This study's main objective was to estimate the increased costs due to malnutrition in hospitals. Secondary goals were to calculate the prevalence of malnutrition in a tertiary care hospital and to study the relationship between malnutrition, disease, the age of the patient and the length of hospital stay.
Materials and methods A retrospective observational study was performed between March and May 2011. Inpatients from two medical wards were selected at the moment of discharge. The following variables were collected: demographic and anthropometric data, length of stay, number of medical tests performed, number of drugs administered, nutritional treatment and costs of the stay. Nutritional screening was performed using the Short Nutritional Assessment Questionnaire (SNAQ) and Nutritional Risk Screening 2002 (NRS-2002). Statistics were analysed using SPSS.
Results 58 patients were recruited: 67.2% men, 69% with chronic diseases with acute deterioration, average age 70.3 and length of stay 15.7 days. Prevalence of malnutrition was 46.6% (32.8% with frank malnutrition and 13.8% at risk of malnutrition). Only 1.7% of inpatients received nutritional support. The relation between nutritional status and length of hospital stay, kind of pathology, number of medical tests performed, number of drugs administered and stay costs were statistically significant.
Conclusions The prevalence of malnutrition is high in hospital inpatients. Malnourished patients have a longer stay in hospital than well-nourished patients. Nutritional status is influenced by several factors such as gender and disease severity. Inadequate nutritional status is associated with increased resource utilisation, leading to a significant increase in stay costs.

Competing interests None.

CPC076 SITUATION OF INFECTION BY M. TUBERCULOSIS IN A SPANISH TERTIARY CARE HOSPITAL

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Background Nowadays tuberculosis continues to be a global public health problem. In 2009, 6,131 cases of respiratory tuberculosis were notified in Spain, making it the 8th European country with the highest number of cases notified.
Purpose To analyse the use of tuberculostatic drugs on patients admitted and diagnosed with tuberculosis in a Spanish tertiary care hospital.
Materials and methods A retrospective observational study was carried out for which The authors located patients admitted in the period from September 2010 to September 2011 diagnosed with infection by M. tuberculosis, undergoing treatment with any of the drugs in the following therapeutic groups: J04AB, J04AC, J04AK and J04AM. The authors created a data gathering sheet which included demographic data (sex, age, country of origin) as well as information regarding the treatment received, taking into consideration resistances, intolerances and adherence to the treatment.
Results The authors located 33 patients (68% men) admitted and diagnosed with tuberculosis, of which 14 (42%) were not of Spanish nationality (8 Rumanians, 2 Moroccans, 1 Congolese, 1 Colombian, 1 Bolivian and 1 Peruvian). All the Spanish patients received the first-choice treatment indicated: rifampicin, isoniazid, pyrazinamide and ethambutol, while out of the patients of other nationalities, 12 were found to have first-choice treatment, of which 2 also received amikacin and/or levofloxacin as second-choice drugs used on patients with high suspicion of multi-resistant infection. Another 2 patients showed confirmed multi-resistant infection after various failed treatments carried out over the last few years, and therefore, second-choice drugs had to be used, including ethionamide, cycloserine, p-aminosalycilic acid and ofloxacin.
Conclusions The results obtained confirm the trend observed in the last few years in the most industrialised countries, with a notable increase in the number of cases of tuberculosis among immigrants. Furthermore, in these cases a greater rate of resistances of mycobacterium to traditional drugs has been observed, which complicates therapeutic handling and makes the use of 2nd-choice drugs essential.

Competing interests None.

CPC077 SALMETEROL & OTHER DRUGS AND FORMOTEROL & OTHER DRUGS PRESCRIBING PATTERNS IN THE LOCAL HEALTH AUTHORITY OF MESSINA (ITALY) DURING 2010

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Background Asthma and COPD are chronic diseases of the airways characterised by variable and recurring symptoms, airflow obstruction and bronchospasm. The progressive increase in incidence and prevalence has increased significally care related costs, with a specific contribution of R03AK drugs especially for the Local Health Authority (LHA) of Messina, Italy.
Purpose This study was carried out to evaluate the incidence and cost of use of drugs with ATC R03AK06-R03AK07 in order to assess prescribing patterns in the LHA between January 1, 2010 – December 31, 2010 comparing them with those recorded in the same LHA in 2009 and in Sicily and Italy in 2010.
Materials and methods Data were collected from the database 'Farmanalisi.it' that includes all prescriptions reimbursed by the LHA of Messina and compared to Sicilian and Italian one. All consumption data have been expressed as units/1000 inhabitants and costs as euro/1000 inhabitants.
Results Local data are higher than Sicilian and National ones. The annual use of association salmeterol & other drugs (R03AK06) decreased from 91.05 units/1000 inhabitants in 2009 to 88.5/1000 inhabitants in 2010 but still remains the most frequently prescribed association followed by salbutamol & other drugs (R03AK07) with 55.46 units/1000 inhabitants (vs 51.91 units/inhabitants in 2009). In the evaluated period treated patients were mostly males (52,56%) mainly over 75 years. For LHA, in 2010, direct cost for evaluated drugs were 8309€/1000 inhabitants (vs 8351€/1000 inhabitants in 2009) about 20% higher than the value reported in Sicily and Italy.
Conclusions Data obtained confirm that pharmacological treatments for asthma and COPD diseases do represent one of the areas where a closer monitoring of direct cost, as well of the appropriateness of prescription is needed because both values are higher than Sicilian and Italian values. Presentation of drugs consumption is one of the activities of Pharmaceutical Department and, also, the basis for communication among healthcare providers, such as General Practitioners, in order to improve appropriate prescribing policies.

Competing interests None.

CPC078 CLINICAL USE OF TIGECYCLINE IN A UNIVERSITY HOSPITAL

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Background Tigecycline, a glycylcycline antibiotic, is indicated in adults for the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections. FDA and EMA have reviewed their indications.
Purpose The aim of this study is to describe the use of tigecycline in our hospital.
Materials and methods The patient's clinical histories were reviewed to verify the correct use of tigecycline. A descriptive observational study was performed to evaluate the use of tigecycline over a 3 months period. Several variables were studied, including patient information, diagnosis, evaluation of empirical treatment, duration of treatment or change of antibiotic and clinical resolution.
Results 39 patients, 22 men and 17 women, with mean age 61 years old (range 49-72) were investigated. 29 (74,4%) were sent to the Urgency Service. Co-morbilities were: diabetes mellitus (25,6%), renal failure (23,1%), cancer (18%), congestive cardiac failure (15,8%), chronic obstructive pulmonary disease (10%) and peripheral arteriopathy (10%). The majority of the treatments were prescribed in medical intensive care units. Of the 39 patients: 15 were assessed in Anaesthesia and Reanimation Unit and 13 in the Intensive Care. An internal medicine physician specialising in infectious diseases prescribed tigecycline to 5 patients (12,8%). And the rest were from surgical units. The most common infections were: intra-abdominal infection (35,8%), skin and soft tissue (17,9%), bacteraemia (15,4%), pneumonia (10,3%), fever syndrome (7,7%), central catheter infections (5,1%), central nervous system infection (2,6%), respiratory infections (2,6%), and not identified (12,8%). In 18 patients (46,2%) treatment was suspended due to clinical resolution, 2 of them were de-escalated. 15 patients (38%) died during the study period. In 6 patients were not collected.
Conclusions Tigecycline was prescribed to many infections, most of them were not indicated. It was necessary to insist on dissemination of the protocols of empirical treatment to ensure the proper use of antibiotics.

Competing interests None.

CPC079 COURSE OF A PATIENT DURING IMIGLUCERASE SHORTAGE. APROPOS OF A CASE

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Background Gaucher disease is a hereditary metabolic disorder characterised by deficiency of the lysosomal enzyme β-glucocerebrosidase which catalyses the hydrolysis of glucosylceramide to glucose and ceramide. This causes accumulation of glucosylceramide within the lysosomes with systemic manifestations consisting of bone and haematological abnormalities and visceromegaly.
Purpose To describe the course of a patient diagnosed with Gaucher disease in whom the treatment she was receiving with imiglucerase was replaced by miglustat, an oral drug also indicated for Gaucher disease.
Materials and methods Review of patient history and recording of biomarkers of the disease: Chitotriosidase activity (nM/mL.h) and CCL-18 PARC concentration (ng/mL). Blood count data were collected: platelets, haemoglobin, and white blood cells.
Results Miglustat treatment was between November 2009 and March 2010, reintroducing imiglucerase in April 2010. Before starting miglustat the patient had the following values: chitotriosidase 1432 nM/mL.h and CCL-18 PARC of 367 ng/mL, 127000 platelets/μL, haemoglobin 13.4 g/dl and 4200 WBC/μl with good general condition. In March 2010, laboratory tests were: chitotriosidase 2546 nM/ml.h and CCL-18 PARC of 561 ng/mL, 113000 platelets/μL, haemoglobin 12.4 g/dl and 4400 WBCs/μL. During this period, the patient did not worsen clinically but showed tremor, flatulence, and mild diarrhoea during treatment with miglustat.
Conclusions The increase in markers after switching shows disease worsening. Switching to the oral route may seem an improvement in quality of life.

Competing interests None.

CPC080 SUGAMMADEX FOR NEUROMUSCULAR BLOCKADE REVERSAL: A REVIEW OF ITS USE IN A GENERAL HOSPITAL†

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Background Sugammadex is a newly-developed agent indicated to reverse the neuromuscular blockade (NMB) induced by rocuronium or vecuronium during general anaesthesia in surgical procedures. It can improve patient safety in particular cases in which commonly-used reversal agents should not be employed.
Purpose To evaluate the use of sugammadex for reversal of NMB in surgical patients. To assess their effect on the consumption of neuromuscular blocking agents.
Materials and methods The authors performed a retrospective study from February 2010 to April 2011, which included all patients treated with sugammadex. The variables studied were age, sex, indication, dosage, neuromuscular blocking agent used and surgical department by which the patient was treated. The authors also collected rocuronium and vecuronium consumption data from 2009 and 2010.
Results The authors included 137 patients (51% women) with a mean age of 58.3 years (19-92). The most common reason for use was the need to maintain NMB until the end of the intervention (39.43%), followed by premature termination of surgery (34.5%), history of cardiovascular and/or lung disease (21.8%), rapid sequence intubation (1.4%), neuromuscular disorder (1.4%), change of procedure (0.7%) and inoperable process (0.7%). The most common dose was 4 mg/kg (52.55%), followed by 2 mg/kg (43.79%). Rocuronium was the most frequently used muscle relaxant (68.61%). Vecuronium was used only once. In the remaining patients (29.92%) no blocker was identified. Clinical departments involved were general surgery (51.09%), otolaryngology (27.73%), gynaecology (8.75%), traumatology (5.10%), urology (5.10%) and pneumology (0.72%). Consumption of rocuronium and vecuronium increased (by 230% and 390%) between 2009 and 2010.
Conclusions The availability of sugammadex has generated an increased use of more expensive drugs such as rocuronium and vecuronium. These results suggest incorporation of the drug into the surgical routine replacing physiological reversal.

Competing interests None.

CPC081 ASSESSMENT OF HEALTH LITERACY IN PATIENTS RECEIVING WARFARIN ANTICOAGULATION THERAPY AND CORRELATION OF RESULTS WITH ANTICOAGULANT CONTROL

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Background By identifying a patient's level of health literacy (HL) one can help to ensure that any health information is tailored to the correct level and by doing so empower the patient to take responsibility for his/her own health and consequently help improve medicines adherence and healthcare outcomes. The efficacy of oral anticoagulation treatment depends on maximising the length of time within the therapeutic range (TTR).
Purpose To assess the HL of patients attending a pharmacist-led warfarin anticoagulation clinic using the Rapid Estimate of Adult Literacy in Medicine (REALM) screening tool. To obtain data on the TTR of each patient who has completed the REALM. To analyse the results of the above and establish whether there is a link between adequate HL and anticoagulation control as measured by TTR.
Materials and methods Patients were asked to participate and included if they met the following criteria: aged over 18 years, not visually impaired, no hearing impairment, English as a first language and on warfarin for at least 3 months. Patients were asked a series of questions linked to HL and the REALM screening tool was administered. The level of statistical probability used to determine significance was set at $p < 0.05$.
Results 129 patients completed the study with a mean age of 72 years (SD 9.5). The most common indication for warfarin was atrial fibrillation (74.4%). Adequate HL was usual among the patients who completed the study (82.2%). A statistically significant positive correlation was found between TTR and level of education and between REALM and level of education. A statistically significant correlation was also found between REALM and how often the patient read a book.
Conclusions This study showed an association between a likely predictor of HL (namely level of education) and TTR. Pharmacists are well positioned to identify at-risk patients and tailor education to their needs.

Competing interests None.

CPC082 PROFILE OF ALBUMIN PRESCRIPTION ON A SURGERY DEPARTMENT OF A UNIVERSITY HOSPITAL

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Background Although the wide use of human albumin(HA), the risks and benefits of its use in clinical practice remains not conclusive. Since Surgery is the specialty that most uses HA in our hospital, it is relevant to analyse how it is used and what are the outcomes.
Purpose Evaluation of concordance of HA prescription on a surgery department(SD) with hospital general recommendations.
Materials and methods Retrospective study of six month prescription of HA from January-June 2010. Review of patient's medical record to collect prescription data from the SD. Evaluated data: number of vials (10g) prescribed and administered; plasma albumin value before treatment (ABT) and after; prescribed daily dose; treatment duration prescribed and administered; daily cost/patient and global costs; percentage of prescriptions with ABT<2.5 g/dl and percentage of prescriptions with ABT≥2.5 g/dl; justification for use. Descriptive statistics (mean±SD).
Results During six months 329 prescriptions were made to 226 patients:

- Number of vials prescribed: 3121 and administered: 2705 with global cost 68.950,45€;
- Plasma albumin before treatment: 2.4±0.5 g/dl(1.2-5.4) and after: 3.0±0.5 g/dl(1.9-5.2);
- Prescribed daily dose: 27.7±6.3 g (10-60);
- Treatment duration- prescribed: 4.0±1.0 days (1-10) and administered: 3.0±1.2 days (1-10);
- Daily cost/patient: 70.6±16.1€(25.5€-152.9€);
- Percentage of prescriptions with ABT<2.5g/dl: 56.8%;
- Percentage of prescriptions with ABT≥2.5 g/dl: 41.3% – 1135 administered vials with a cost of 28.931,15€;
- Justification for use: hypoalbuminaemia: 57.3%, postoperative hypoalbuminaemia: 12.4%, pathology of gastrointestinal tract: 7.0% and others: 23.3%. A percentage of 13.3 HA are not administered and return to pharmacy department.

Conclusions The authors found 41.3% of prescription profile not in accordance with hospital general recommendations – HA administration only if the ABT<2.5g/dl. The results of this pilot study, lead us to conclude that, to better support prescription, plasma albumin ought to be measured before and after treatment, and that, systematic drug utilisation review programs, should be started to assure a better cost/effectiveness ratio.

Competing interests None.

CPC083 RESULTS OF THE USE OF TOLVAPTAN

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Background Tolvaptan is indicated to treat syndrome of inappropriate antidiuretic hormone secretion (SIADH).
Purpose To describe and assess the use of tolvaptan in a tertiary hospital.
Materials and methods An observational and retrospective study was conducted on patients treated with tolvaptan. Data was collected from the review of medical histories, lab tests and dispensing records. These data included age, sex, diagnosis, cause of prescription, clinical department that prescribed it and sodium blood concentration at start of the treatment.
Results The study was conducted with 4 patients. The average age was 70 years and all the patients were men. Depending on the condition, the clinical department that wrote the prescription was cardiology in three of the cases and digestive in the other one. The background pathology was heart failure in three cases and liver carcinoma in the fourth. The cause of prescription was that all the patients had serious oedema, anasarca and no response to diuretics. Only three of the subjects had hyponatraemia at the beginning of the treatment and none of them had syndrome of inappropriate antidiuretic hormone secretion (SIADH). Two subjects started the treatment with an initial dosage of 15 mg/day and the other two started directly with 30 mg/day. The maintenance dosage was 30 mg/day for all of them. The cost-day average per patient was 88.32 €. The average length of treatment was 55.75 days, SD 39.89. The reason for stopping the treatment was death for the first three patients and the fourth is still on treatment.

Conclusions In our hospital, tolvaptan was not used for the approved indication in any of the patients and for all them it was processed as compassionate use. The authors do not have enough data to evaluate the efficacy of this treatment in these patients. The high cost of the treatment and the limited experience in its use require strict control in its administration.

Competing interests None.

CPC084 PHARMACIST'S ROLE IN THE TREATMENT OF PATIENTS WITH TUBERCULOSIS Ñ OUR POSITIVE EXPERIENCE

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Background Tuberculosis as a disease which demands long-term multidrug treatment, which can cause serious adverse drug reactions that can affect the course of therapy. Moreover, antituberculotic drugs interact with a variety of drugs, OTC preparations and food, all of which can significantly alter the effectiveness of patient's therapy. Patient's compliance and patient-tailored therapy are thus crucial for achieving effective treatment. In the University Clinic Golnik, clinical pharmacists are included in the treatment of patients with tuberculosis. They perform patient counselling on correct drug use, management of possible adverse drug events and drug therapy reviews. These most frequently include counselling on clinically important drug-drug interactions.
Purpose Improving the quality of care for patients with tuberculosis with focus on drug-drug interactions.
Materials and methods Data was collected from clinical pharmacist reports and other relevant clinical data. Drug interactions were checked by at least two distinct drug interactions databases and interpreted by clinical pharmacist for each patient individually. Clinical importance was defined as possible drug effect change that required either detailed drug effectiveness monitoring, dose adjustment, dosing regime adjustment or additional laboratory tests performed.
Results From June to September 2011 clinical pharmacists performed 44 drug therapy reviews in 32 patients on the tuberculosis department. In 46,9% cases (15/32) at least one clinical important drug-drug interaction was observed, mostly with warfarin, calcium, levothyroxine and methadone.
The detected interactions and adjusted therapy were documented in the hospital electronic clinical files as well as in the patients' discharge documentation. This allowed the patient's GP and local pulmonologist to be informed about the therapy adjustments and the need for readjustments at the end of antituberculotic treatment.
Conclusions The collaboration of different healthcare professional in the healthcare team at the University Clinic Golnik aims at ensuring high quality patient care. At the tuberculosis department, clinical pharmacists counsel to patients and advise on the management of clinically important interactions on a daily basis and thus constantly improve the high quality of patient care.

Competing interests Ownership: In 2011, the collaboration of clinical pharmacists in the treatment of tuberculosis in University Clinic Golnik was supported by the Health Insurance Institute of Slovenia.

CPC085 DEVELOPMENT OF A PRACTICAL GUIDE TO DRUG THERAPY OF REFRACTORY PAIN IN ADVANCED PALLIATIVE SITUATION

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Background Complex situations of medical management of refractory pain in patients in advanced or terminal phase of a serious and incurable disease and development of home care have led the French Agency for Sanitary Safety of Health Products to develop recommendations on how to use eight classes of drugs outside their Marketing Authorisation.
Purpose Our work is to provide a guide to regulate off-label use of these drugs often reserved for hospital use or restricted prescription and unknown by the non-hospital health professionals or non-specialist who often called for assistance.
Materials and methods A multidisciplinary working group (specialists in palliative care, pharmacists, paramedics) was established to develop practical guide for using these drugs. This booklet is a tool for the prescribing, dispensing and administration of these products. After validation by the Committee against Pain and the Committee of Drug, this guide will be disseminated to doctors and nurses at the Hospital of Pau, but also to non-hospital doctors, paramedics and pharmacists through the local network of palliative care and various continuing education sessions.
Results The guide was written on A4 size, foldable three. It includes a table summarising, for each class of medications, the following informations: context of use, methods of administration, specialties available (in hospital or city pharmacy), dosages, rules of prescription, adverse effects and monitoring. Various practical informations are associated with it. After approval by committees, the guide was tested by hospital professionals. Much appreciated by users because it provides quickly essential information (especially dosages, procedures for administering and monitoring), The authors decided to distribute it to non-hospital professionals during continuing medical education organised by the network.
Conclusions The authors hope this tool will provide assistance to every professional affected by palliative situations in hospital and at patient's home. The authors will conduct a satisfaction survey of the different users in order to make improvements if necessary.

Competing interests None.

CPC086 ANTIMICROBIAL RESISTANCE OF URINARY ESCHERICHIA COLI ISOLATES

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Background Escherichia coli is the most common bacteria involved in the aetiology of the urinary tract infections (UTI).
Purpose The aim of the study is to compare the susceptibility to antibacterial agents of Escherichia coli strains isolated from adults and children.
Materials and methods The study was conducted between 1.01.2009-31.12.2010 on 192 patients divided in two groups. Group A-72 hospitalised children under 15 years with clinical

signs of UTI. Group B – 120 adult outpatients who had presented various conditions of the reno-urinary tract.
Urine samples were investigated using biochemical and microbiological (urine culture) methods. The authors used culture media to isolate specific bacterial species, whose identification was performed with API 20 E galleries. The antibiotic susceptibility test was performed on Mueller Hinton agar plates using the Kirby-Bauer disc diffusion method, according to NCCLS / CLSI – 2009 guidelines.
Results The morbidity by UTIs in children was 40.90%, mostly in girls (54.4%), in the age group of 1-3 years (43.91%) and infants (37.16%). The isolated E. coli strains (65.2%) were resistant to Ampicillin (65.14%), Ciprofloxacin (30.12%), Cefuroxime (26.18%) and Nalidixic acid (14.92%).
In adults the prevalence of UTIs was 43.33%, the infections were more common in women and in patients over 60 years. The isolated E. coli strains (55.77%) were resistant to Ampicillin (74.25%), Cefuroxime (39.29%), Ciprofloxacin (27.59%) and Nalidixic acid (24.14%). There was a significant difference in antibiotic resistance of the strains isolated from the two patient categories (Student's T test, p=0.0168).
Conclusions The tested strains of Escherichia coli involved in UTIs in adults had a higher resistance to antibiotics, compared with those isolated from children. It is recommended that the neonatologists, paediatricians and family physicians initiate therapy for these infections only after antibiotic susceptibility tests, in order to prevent selection of multidrug-resistant strains.

Competing interests None.

CPC087 AETIOLOGY AND THERAPY OF FUNGAL INFECTIONS IN PREGNANT WOMEN

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Background Vulvovaginal candidiasis in pregnant women may affect the physiological development of pregnancy representing a risk factor for premature labour onset. Premature infants can develop respiratory, neurological, cardiovascular and digestive complications which can disturb the normal development of these newborns.
Purpose The purpose of this study is to assess the prevalence of vulvovaginal candidiasis in pregnant women, to identify the isolated Candida species and to determine their behaviour towards antifungal agents. **Materials and methods** The study was conducted between 01.02.2010 – 31.01.2011 on 50 vaginal secretions from women who came to the ambulatory of the Clinical Emergency Hospital of Craiova, Romania, which have been subjected to mycological diagnosis: Giemsa stained smears, isolation on Sabouraud media and chromogenic media (ChromID Candida) in order to identify the Candida species. Antifungal susceptibility test was performed using the standardised systems ATB Fungus 3 (bioMérieux, Marcy l'Etoile, France) and Candifast (EliTech France SAS). It was assessed the susceptibility to: 5-Fluorocytosine, Amphotericin B, Fluconazole, Itraconazole, Voriconazole, Econazole, Miconazole, Ketoconazole and Nystatin.
Results Vulvovaginal candidiasis was detected in 30 pregnant women. The isolated Candida species were C. albicans (53.33%), C. glabrata (20.00%), C. tropicalis (13.33%), C. parapsilosis (6.67%) and C. krusei (6.67%). The isolated Candida strains had a high susceptibility to Amphotericin B (96.67%), Voriconazole (96.67%), 5-Fluorocytosine (86.67%), Clotrimazole (80%), Econazole (80%), and Ketoconazole (80%).
Conclusions The detection of the vaginal mycosis in pregnant women requires the establishment of an appropriate therapy, according to the antifungigram, that can concur to reduce the risk of premature birth and associated complications.

Competing interests None.

CPC088 INITIATING THROMBOPROPHYLAXIS WITH LOW MOLECULAR WEIGHT HEPARIN AND TRANSITIONING TO ORAL RIVAROXABAN

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Background The first dose of rivaroxaban for venous thromboembolism (VTE) prophylaxis is recommended 6–10 h after major orthopaedic surgery; some patients may experience early postoperative nausea and vomiting, which may restrict the use of oral medications after surgery. Initiating thromboprophylaxis with subcutaneous low molecular weight heparin (LMWH) after surgery and transitioning to oral rivaroxaban may be an attractive option in this clinical situation.
Purpose To determine the pharmacodynamic effects of rivaroxaban after serial administration compared with responses on the first day of rivaroxaban after transitioning from postoperative LMWH.
Materials and methods An open-label, single-arm, multicentre study was conducted in the US, involving patients aged ≥18 years who had undergone elective unilateral total hip or total knee replacement and initially received LMWH thromboprophylaxis postoperatively. Thromboprophylaxis was planned for a minimum of 3 days and patients received the first dose of oral rivaroxaban (10 mg once daily) within 2 days of admission. The initial dose was given 22–28 h after the last dose of LMWH od, or 12–18 h after the last dose of LMWH twice daily. Blood samples were taken at baseline and at regular intervals on study days 1 and 3 for the measurement of antiFactor Xa activity and prothrombin time.
Results The safety population included 53 patients. Mean antiFactor Xa activity was not increased on day 1 versus day 3 but was slightly increased on day 3 compared with day 1 ($p<0.01$). There were no significant differences between the area under the concentration–time curves of antiFactor Xa activity on days 1 and 3. Mean prothrombin time was slightly, but not significantly, higher on day 1 than day 3 ($p=0.11$).
Conclusions These data support initiating oral rivaroxaban after a final dose of LMWH (od or twice daily) in patients who have undergone surgery and initially received LMWH prophylaxis.

Competing interests Ownership: RM Mills, CV Damaraju and P Wildgoose are employees of Johnson and Johnson Pharmaceuticals LLC.

CPC089 A SURVEY OF NHS CONSULTANT PHARMACISTS IN ENGLAND

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Background Consultant pharmacist is a restricted title in the National Health Service (NHS). They were introduced in 2005 to provide best care for patients and to retain experienced pharmacists in clinical practice. The posts have four key functions: expert practice (max. 50%); research, evaluation and service development; education, mentoring and overview of practice; professional leadership.
Purpose The aim of the survey was to quantify for the first time the quantity and range of activities being undertaken by the NHS consultant pharmacists in England.
Materials and methods The survey built on a North West England survey of non-medical consultants in 2010 with additional information required added to the existing survey. All were e-mailed the link to the SurveyMonkey in March 2011. This software collected and assimilated the responses.
Results There are 41 consultant pharmacists (23 female). Average age at appointment was 40. 17 were appointed under transition arrangements and 25 new posts. There are currently no posts in Scotland, Northern Ireland or Wales. 68% work in acute teaching hospitals, 12% acute non-teaching, 5% in mental health, 7% in primary care and 5% in specialist trusts. The most common specialties are: 8 in critical care, 7 in antimicrobials / infectious disease / HIV, 5 in haemato-oncology, 4 paediatrics, 3 cardiology and 3 in medication safety. 73% work full time. On average 50% of time was in direct or indirect patient care, 15% leadership, 10% education, 10% research and 10% practice development. 36% run a clinic and 28% have their own caseload. 69% are prescribers. Two-thirds provide advice at a national level. Only 36% are formally linked to a university, but most are research active and published. 68% intended remaining in post.
Conclusions Consultant Pharmacists deliver the four key functions required by the post, and retain experienced pharmacists in clinical practice.

Competing interests None.

CPC090 DEVELOPMENT AND IMPLEMENTATION OF A PHARMACEUTICAL CONSULTATION IN A PAEDIATRIC HAEMATOLOGY UNIT: A PILOT STUDY

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Background Paediatric haemato-oncology is a highly specialised medical field. Prior studies suggested that children who received more therapeutic education were better prepared to manage their disease.
Purpose The purpose of our study was to develop and implement a pharmaceutical consultation (PC) for children and parents in the haematology unit of a French teaching paediatric hospital.
Materials and methods The authors performed PCs during 5 months, for patients≤ 18 years, admitted with ≥1 medication. These were conducted by pharmacists, at admission or discharge. They performed a medication history (MH) and an interview for each patient, addressing the following points: prescriptions, adverse events, medication omission and adherence. Duration of interview was about 40 min. Pharmacist MH necessity, medication knowledge (name/role), drugs related problems (DRP) and pharmaceutical interventions (PI) were analysed. The actual need for each PI was rated by 2 pharmacists dedicated to haematology unit.
Results The authors performed 15 interviews, 6 patients (≥6y), 15 care givers, patient mean age: 6y, 11 girls, 8 at discharge. The authors did not find any MH mistake. The medications knowledge was good (1/3), intermediate (1/3) or inadequate (1/3). The authors identified 36 DRP: improper drug selection (n=17), failure to administer drug properly (14), failure to manipulate oral chemotherapy properly (5). The authors performed 47 PI: drug switch (n=14), drug information (12), method of administration optimisation (12), adherence optimisation (9). 34 PIs were considered to have moderate to major usefulness.
Conclusions The frequency, nature and impact of PIs and the low medication knowledge justify to implement PC. This pilot study enabled us to perform a PC form, incorporating the key points to address during interviews. Next steps are to determine indicators to assess the Medication Use Review process with patients at discharge and to develop tools contributing to improve patient safety. Finally, a therapeutic patient education programme should be put in place.

Competing interests None.

CPC091 LIPIDS IN TOTAL PARENTERAL NUTRITION FOR PREMATURE INFANTS.

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Background Lipids of TPN can cause liver toxicity in premature infants, so it is important to evaluate the introduction of new emulsions
Purpose To describe the safety of two lipid emulsions used in the compounding of total parenteral nutrition (TPN) for premature infants.
Materials and methods A retrospective study of two time periods, 2009 and 2010, of preterm infants population whit TPN. The analysis excluded those cases of death, sepsis and those who had a liver disease. 20 children received parenteral nutrition with lipid emulsion derived from soybean oil (Intralipid ®), from August to December 2009. In the second group were evaluated 19 children, whose lipid emulsion was derived from olive oil (ClinOleic ®) in the period from August to December 2010. The authors evaluated the following criteria: levels of bilirubin and liver enzymes (ALT/AST) and maximum insulin requirements (IU/kg/h).
Results 39 infants within 72 h of life completed the study. The group that received parenteral nutrition with soybean oil derived (n=20) showed a mean gestational age of 31.4 weeks (27-34) and an average weight of 1.64 kg (0.76-2.8), the second group with lipids olive oil derived (n=19) 30.4 weeks (28-32) of age and weighing 1.82 kg (0.6-.2.28). Bilirubin levels were similar in both groups: soybean 8.4 mg / dl (2.4-20.02) and olive 9.1 mg / dl (2,52-16.9). There were no significant differences in levels of liver enzymes AST of 43.6 U/L (17-235.3) and ALT of 5.21 U/L (4.1-9.2) and oil olive group AST 43.1 U/L (19.2-170.3) and 13.7 U/L (5.2-37.3) ALT. In the study population also did not show higher insulin requirements in any of the two groups referred to maximum needs, 0.034 UI/kg/h (0.02-0.03) versus 0.036 IU/kg/day (0.02-0.035). **Conclusions** Both lipid emulsions were well tolerated, showing no difference in hepatic damage. The results suggest that both lipid preparations have similar safety profile in preterm parenteral nutrition.

Competing interests None.

CPC092 A SURVEY OF NATIONAL, REGIONAL AND HOSPITAL CHIEF PHARMACISTS ON CONSULTANT PHARMACIST APPOINTMENT STRATEGY AND PERFORMANCE IN THE UNITED KINGDOM

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Background Consultant pharmacists were introduced in hospitals in 2005 to provide the best care for patients and retain experienced pharmacists in practice. The framework stated that posts had to be approved at regional level, but local organisations should determine where they were required, and posts could be shared. Posts should provide expert practice, research and service development, education and professional leadership.
Purpose This survey aimed to identify the strategic approaches to planning new posts at all levels, barriers to appointment, assessment of current performance and improvements to current roles.
Materials and methods A SurveyMonkey was e-mailed to all the national, regional and Chief Pharmacists in the UK.
Results Responses were received from 70% of regional pharmacists and 73 Chief Pharmacists. Scotland, Northern Ireland and Wales were planning Consultant Pharmacists but currently had none in place. 44% of regions had a strategy for the appointment of new posts. Only 23% of Trust Chief Pharmacists had an agreed strategy for future appointments at regional level, 2% at local health economy level and 7% at Trust level. Both regional and Trust Chief Pharmacists identified a need for a strategy at local level (85% and 58% respectively), regional level: 65% and 50%, and national level 85% and 51%. The main barriers that prevented future appointments were finance, lack of transitional arrangements, insufficient funding for time at University, no need, and lack of quality applicants. 58% would part fund a post. Posts in planning were haemato-oncology, antimicrobials, critical care, renal, medicines safety and nutrition. Review of performance was good. Only 18% thought leadership was below expectation, 11% for education but 31% wanted more research. Trusts would like to bring more research funding in, whereas regions would like more research published.
Conclusions Consultant Pharmacists are generally delivering what their employers want. There needs to be a strategy for new posts at all levels.

Competing interests None.

CPC093 PHARMACIST-DETECTED INAPPROPRIATE MEDICINES AND RECOMMENDATIONS MADE REGARDING A CHANGE OF MEDICINES IN THE EMERGENCY WARD

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Background Emergency departments have serious concerns about drug safety. Inappropriate medicines are common. Medicines charts may often remain incomplete. Physicians and nurses may not have enough time to review medicines charts regularly.
Purpose To evaluate the inappropriate medicines in the emergency ward based on the pharmacist's medicines chart review. To review the physicians' acceptance rate of pharmacist recommendations regarding a change in the medicines regimen on the emergency ward.
Materials and methods Medicines charts of all emergency ward patients were reviewed by a pharmacist prospectively for five months from April to August 2011. The pharmacist made oral or written recommendations to physicians regarding a change in medicines regimen. Recommendations were made on drug interactions, inappropriate drug dosages, inappropriate duration of drug treatments, wrong medicines, missing medicines and duplications.
Results 855 admissions were reviewed. 94 recommendations regarding 67 admissions were made for 38 drug interactions (40.4%), 26 inappropriate drug dosages (27.7%), 10 inappropriate duration of drug treatments (10,6%), 8 wrong medicines (8.5%), 6 missing medicines (6.4%) and 6 duplications (6.4%). The overall physicians' acceptance rate for all pharmacist recommendations was 62% (n:58). Of the accepted recommendations 20 of 38 (52.6%) drug interactions, 14 of 26 (54%) inappropriate drug dosages, 8 of 10 (80%) inappropriate duration of drug treatments, 6 of 8 (75%) wrong medicines, 4 of 6 (66.7%) missing medicines and all duplications were accepted by physicians. The most common inappropriate medicines detected by the pharmacist were NSAIDs, SSRIs, benzodiazepines and warfarin.
Conclusions A pharmacist was able to detect important inappropriate medicines by reviewing medicines charts of emergency ward patients. Many pharmacist recommendations leading to a change in medicines regimen were accepted by the physicians.

Competing interests None.

CPC094 A FIVE-YEARS SURVEILLANCE OF DRUG COMPASSIONATE USE IN A UNIVERSITY HOSPITAL IN ROME

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Background Italian Ministerial Decree 8 May 2003, amended in 2008, on the therapeutic use of an investigational medicinal product, represents the legislative frame defining a Compassionate Use Program (CUP). Accordingly, an investigational drug can be requested to the manufacturing Company for use outside clinical trials, for a single patient or a group, if alternative treatments are not available. Safety and efficacy data from completed or ongoing phase III trials – in life threatening condition, data from completed phase II – must be available and comparable, and a positive opinion be adopted by the local Ethics Committee (EC).
Purpose The aim of this surveillance was to achieve a picture of the CUPs at Hospital level. The outcome as subsequent Marketing Authorisation (MA) of the involved products was also considered.
Materials and methods The authors analysed data on the CUPs reported in our local Clinical Trial database, managed by a Pharmacist of the EC scientific Secretariat, in the timeframe between July 2006 and July 2011. The following main parameters were considered: active substance, ATC, patients' number, therapeutic indication, MA.
Results More than 66 patients were involved in 27 CUPs that received a positive opinion by EC. Sixteen programs were approved in oncology (59%), 11 in autoimmune/neurological diseases (41%); the higher number of patients (17) in neuroendocrine tumours. CUPs accounted for 18 different active substances, the most representatives being Everolimus

(18 patients), Riluzole (14), Rituximab (7), Panitumumab (5), Abiraterone (4), Nilotinib (3). Eleven active substance out of 16 in oncology CUPs obtained a subsequent centralised MA. The cost for patients' monthly treatment with the a.m. products (except abiraterone) can be calculated as 143352 €.

Conclusions CUPs may be therapeutic options for patients in settings where there still are unmet medical needs and can also represent a cost-saving opportunity for the Hospital.

Competing interests None.

CPC095 PAEDIATRIC CLINICAL TRIALS FROM 2002 TO 2011 IN THE PHARMACY DEPARTMENT OF LAPEYRONIE AND ARNAUD DE VILLENEUVE HOSPITALS

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Background The lack of drugs specifically designed and developed for paediatric population is a problem at European scale. Nowadays, over 50% of drugs prescribed to children have not been studied and, therefore, approved for this purpose. In 2006, the European Parliament promulgated a new regulation (No. 1901/2006)(1) to facilitate the development and availability of medicines for children.

Purpose The authors compiled an inventory of biomedical research in paediatrics (except oncologic trials) to describe paediatric clinical trials characteristics in a French hospital and measure the impact of this regulation on clinical trials number and quality.

Materials and methods This study was conducted between November 2010 and May 2011 and the data collected from November 2002 to May 2011. On each trial file The authors collect: 1. The start date, design and sponsor of the study; 2. The population (number of inclusion, age and pathology); 3. Treatment (drugs and route of administration).

Results The authors reviewed 31 trials, which 11 are in progress (about 5% of all our studies). The industry sponsorised 25 of them and practically all were in phase 3. 18 (58%) started between 2002 and 2006 and 13 (42%) between 2007 and 2011. Only 5 (16%) studies were double-blind randomised (all started after 2006) and 14 (45%) failed to include patients. 144 children were included (84 in studies on milk and probiotics). The patients were aged between 1 day and 15 years (101 patients were old less than 30 days). Most of the trials concerned hormonal and endocrine pathologies (51%). No studies concerned new molecules or pharmaceutical forms adapted to the paediatric population.

Conclusions The regulations of 2006 had no impact on the number of clinical trials in our hospital. However, The authors observe an improvement of the quality of the studies. In addition to the small number of studies, The authors observe that many studies have difficulty to recruit. This difficulty could be connected to the exclusion and inclusion criteria, the rarity of the patients but also to the refusals of the parents.

Competing interests None.

REFERENCE

1. Regulation (EC) No 1901/2006 of the European parliament and of the council of 12 December 2006.

CPC096 UPDATE ON COMBINED ORAL CONTRACEPTIVES: RISK OF VENOUS THROMBOEMBOLISM. DROSPIRENONE VERSUS OTHER PROGESTINS

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Background The risk of venous thromboembolism (VTE) associated with combined oral contraceptives (COCs) is well known, but the relation with the progestin type is controversial.

Purpose To describe a suspected deep vein thrombosis (DVT) associated with drospirenone (DRSP)-containing COCs. Literature review about the VTE risk of versus DRSP and other progestins.

Materials and methods Medical record review. Search of PubMed (hormonal oral contraceptives, COCs, DRSP, combined DRSP and ethinyl oestradiol (EE), progestins, thromboembolism, VTE, drug toxicity.)

Results Woman, 36 years old, G_4 A_2 V_2, dysmenorrhea, ovarian cysts and fibroadenoma, non-smoker, no allergies, user of NSAIDs and COCs (2007 – March 2010: 35 mcg EE/250 mcg norgestimate, March-November 2010: 20 mcg EE/75 mcg gestodene, November 2010-August 2011: 20 mcg EE/3 mg DRSP). On August 2011, was attended in an Internal Medicine Outpatient Consultation after a previous admission in which a radiological test ruled out DVT, although D-dimers (DDs)=1220 ng/mL. She was readmitted to hospital due to persistent induration and pain in right calf (DD= 571 ng/mL). DVT was suspected again and a Doppler ultrasound was confirmatory. Low molecular weight heparin was initiated, followed by acenocoumarol. She was discharged (medium compression stockings, acenocoumarol and analgesics). The COC was stopped and she was referred to the Gynaecology Outpatient Consultation. Suspected adverse drug reaction (ADR) was reported to the regional pharmacovigilance centre.

Conclusions Spontaneously reporting ADRs can improve the safety profile of drugs. Our case adds further information to the recently published epidemiological studies that suggest an increased risk of VTE associated with DRSP.

Competing interests None.

CPC096 table 1 Literature review

Author (year)	Study design	Adjusted rate ratio (95% CI) DRSP versus levonorgestrel	Adjusted odds ratio (95% CI) DRSP vsersus levonorgestrel
Seeger (2007)	Cohort	0.9 (0.5-1.6)	X
Dinger (2007)	Cohort	1 (0.6-1.8)*	X
Lidegaard (2009)	Cohort	1.64 (1.27-2.10)	X
Van Hylckama (2009)	Case control	X	1.7 (0.7- 3.9)
Jick (2011)	Nested case control	2.8 (2.1-3.8)	2.4 (1.7-3.4)
Parkin (2011)	Nested case control	2.7 (1.5-4.7)	3.3 (1.4-7.6)

* vs. others progestins.

CPC097 THE EFFICACY OF 20 % AUTOLOGOUS SERUM EYE DROPS IN THE TREATMENT OF CORNEAL ULCERS

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Background Nowadays, autologous serum eye drops are used in a lot of corneal epithelium pathologies. Their action is based on the high concentration of vitamins, nutrients, and other substances that improve regeneration of the corneal epithelium.
Purpose To evaluate the effectiveness of 20% autologous serum eye drops, prepared by the Farmacotecnia Unit of the Pharmacy Department, in the treatment of corneal ulcers.
Materials and methods Retrospective study of all forms of 20% autologous serum eye drops, included in Magistra MICOF 2.0.1. software, used from 2008 to 2010. The population being researched were patients with corneal ulcers of different aetiologies who came as outpatients to our hospital Ophthalmology Department, and who received as contributing treatment 20% autologous serum eye drops. The clinical histories of these patients were checked and the effectiveness of the treatment was evaluated; it was considered effective when the corneal ulcer healed completely.
Results 14 patients were included in the study (57% female), with an average age of 69.2±14.7 years. The number bottles of 20% autologous serum eye drops produced was 11 in 2008, 43 during 2009, and 59 in 2010. Patients suffered from corneal ulcers of different aetiology: 8 had trophic corneal ulcers (57%), 3 infectious corneal ulcers (21%), 2 herpetic corneal ulcers (14%) and 1 corneal ulcer caused by a caustic substance (7%). Treatment with 20% autologous serum eye drops was effective in 11 of the study patients (79%).
Conclusions Our results prove that treatment with 20% autologous serum eye drops improved the clinical evolution for most patients studied (79%).

Competing interests None.

CPC098 OBSERVATIONAL STUDY OF CHEMOTHERAPY FOR NON-SMALL CELL LUNG CANCER

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Background Since pemetrexed was marketed for the treatment of non-squamous non-small cell lung cancer (NSCLC), several patients have been treated with the combination of platinum-pemetrexed instead of other cytotoxic regimens, which is much more expensive, although its efficacy is unknown.
Purpose To describe the treatment of patients diagnosed with non-squamous NSCLC over time and to explore the differences in efficacy.
Materials and methods Observational study of all the patients treated in a university hospital for metastatic non-squamous NSCLC during the period 1 July 2008 to 30 June 2010. Clinical and anthropometric data were collected from medical history records, treatment data were collected from pharmacy records. Efficacy was measured as overall survival, measured as the difference between the date of diagnosis and date of death.
Results 59 patients were treated during the study period for metastatic non-squamous NSCLC. The most frequent regimens were platinum-paclitaxel (22), platinum-pemetrexed (19) and platinum-vinorelbine (11). 7 patients received other different chemotherapy regimens. Anthropometric characteristics were similar between the two first groups (table 1). In the second six months of 2008 the most frequently-prescribed regimen was the combination of platinum-paclitaxel. During the first six months of 2009, the combination platinum-pemetrexed became the most frequently prescribed regimen, at the expense of the previous. During the second six months of 2009 and the first six months of 2010 these combinations were used approximately equally often. During these periods overall survival was similar, between 9.5 and 11.7 months, with a total of 10 censored data (Fig 1). Median overall survival times for each regimen were: platinum-paclitaxel 9 months, platinum-pemetrexed 10.1 months, platinum-vinorelbine 16.8 months, other regimens 9 months.
Conclusions Most patients with non-squamous NSCLC were treated over these 2.5 years with two different regimens: platinum-paclitaxel and platinum-pemetrexed, with similar results in overall survival. Studies should be performed to demonstrate if the quality of life is worth the price difference.

Competing interests None.

CPC099 COST/EFFECTIVENESS STUDY OF RANIBIZUMAB VERSUS BEVACIZUMAB IN GARCIA DE ORTA HOSPITAL

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Background Age-related macular degeneration (AMD) is one of the main causes of blindness over the age of 50 in developed Western countries. Angiogenic growth factors, particularly vascular endothelial growth factor (VEGF), have a key role in macular degeneration. Therapies that inhibit active forms of VEGF have been shown to be effective in the treatment of wet AMD. Both ranibizumab and bevacizumab inhibit active forms of VEGF although the latter has an off-label use.

CPC098 table 1

Table 1. Anthropometric characteristics

	Sex			Performance status (%)		
Chemotherapy	**Male (%)**	**Female (%)**	**Age (mean)**	**0-1**	**2-3**	**Total**
Pt-Paclitaxel	68.2	31.8	61	75	25	22
Pt-Pemetrexed	63.2	36.8	62	75	25	19
Pt-Vinorelbine	45.5	54.5	55	90	10	11
Other	57.1	42.9	66	43	57	7

Purpose The aim of this study was to compare the use of ranibizumab versus bevacizumab in the treatment of wet AMD in two groups of patients in Garcia de Orta hospital.
Materials and methods This retrospective study, which included 29 patients treated with a 0.05 mg intravitreal injection of ranibizumab and 9 patients treated with 1.25 mg of bevacizumab, was performed from January 2009 to August 2011. Patients were first treated monthly, during the three first months, and then whenever necessary. The number of treatments, visual acuity (Snellen scale), retina thickness and associated costs were compared.
Results Patient ages were 78.2±6.9 and 76±7.5 years, the number of administrations was 3.2±1.7 and 2.9±1.2, the improvement of visual acuity was 0.05±0.11 and 0.06±0.4, the decrease of retina thickness was 80.6±118.4 mm and 133.6±214.4 mm, the cost of administration was 525.5€ and 9.6€ and the cost per patient was 1681.6 € ±893.4 and 27.8€ ±11.5, for the ranibizumab and bevacizumab groups, respectively. Adverse reactions were not reported.
Conclusions Despite the different sizes of the two groups the study has shown no relevant differences between them, in accordance with the CATT group findings, in all the assessed parameters, except the cost with bevacizumab was 60 times lower.

Competing interests None.

CPC100 SMALL CELL LUNG CANCER: PATIENTS REPORT

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Background Platinum based chemotherapy is the backbone of small-cell lung cancer (SCLC) therapy. However, how it works in our population has not been evaluated.
Purpose The aim of this study is to evaluate the progression-free interval (PFI) on SCLC patients receiving first line platinum based chemotherapy.
Materials and methods Retrospective observational study focused on patients diagnosed during two years (2009-2010). Data were collected from medical records (treatment orders, Oncofarm® program and medical history). These data were: age, sex, history of smoking, stage of the disease, treatments received, and PFI.
Results Forty patients were diagnosed with SCLC, 4(10%) were women and 36(90%) were men. Average age was 65,3 years (±9,9; 44-84). All the patients have history of smoking, but 30(75%) were active smokers. Fifteen (37.5%) were diagnosed at the limited stage disease (LD) and 25(62.5%) at extended stage disease (ED). Average first line platinum chemotherapy cycles received were 3(1-6), and only one patient did not receive any chemotherapic treatment. First line treatment results on LD patients:
*73,3%(11) patients had a PFI longer than six months. 54,5%(6) of them remain stable at the end of the study, 36,4%(4) received second line chemotherapy and one received palliative treatment.
*20,0%(3) patients had a PFI shorter than six months and received second line chemotherapy.
First line treatment results on ED patients:
*28,0%(7) patients had a PFI longer than six months. 57,0%(4) remain stable at the end of the study, one received second line chemotherapy and 28,6%(2) received palliative treatment.
*68,0%(17) patients had a PFI shorter than 6 months, 47,1%(8) received second line chemotherapy and 52,9%(9) received palliative treatment.
*One patient refused chemotherapy.
Conclusions Platinum based chemotherapy has been shown to be more effective in SCLC patients when they start the treatment at the LD stage. The 73.3% of the patients diagnosed and treated at the LD stage had a PFI longer than 6 months. However, only 28% of the patients who started the treatment at the ED stage reached a PFI longer than 6 months.

Competing interests None.

CPC101 PATIENT WITH REFRACTORY NEURO-BEHÁET DISEASE. TREATMENT WITH RITUXIMAB.

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Background Behçet's disease is a multisystem vasculitis of unknown origin in which neurologic involvement has been reported in the range of 5% to 10%.
Purpose To assess the efficacy and safety of rituximab in a patient with Neuro-Behçet disease.
Materials and methods The authors used the report carried out by our pharmacotherapeutic information section, following the request for the off-label use of rituximab in a Neuro-Behçet disease patient.
The authors obtained effectiveness and safety data using the electronic medical record and the doses used in this patient from our program for intravenous mixtures.
Results The patient was 31 years old. He presented recurrent aphthae, erythema nodosum in the lower limbs, frequent skin folliculitis in the arms and head, and involvement of the central nervous system with multiple seizures, sequels in the form of ataxia and loss of strength in half his body. The symptoms were refractory to treatment with α-2a interferon, azathioprine, methotrexate, infliximab and steroids. The authors used rituximab at two 1000 mg doses, administered 15 days apart. This was the same dose as was used with the few cases reported for the treatment of ocular manifestations of Behçet's disease. The treatment was well tolerated. After the first dose, administered when The authors admitted the patient to hospital, The authors observed improvement in both the loss of strength in the lower limbs and the patient's frame of mind. Consequently, the second dose was given as an outpatient. 8 months after completion of the treatment, the patient is stable from the clinical and radiological points of view, and has evolved favourably with regard to gaining strength and balance.
Conclusions Despite the low number of cases in the literature, in which rituximab has been used mainly for the ocular manifestations of Behçet's disease, it appears to be a valid alternative in cases similar to ours. It produces an improvement in the disease, which is not only objective, but also highly valued subjectively by the patient.

Competing interests None.

CPC102 APPROPRIATE USE OF BISPHOSPHONATES IN OSTEOPOROSIS IN COSENZA HEALTH DISTRICT (ITALY).

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Background Osteoporosis is a disease characterised by underdiagnosis and undertreatment. Persistence and adherence are an important problem in patients treated for osteoporosis.
Purpose To evaluate and monitor the use of bisphosphonates considering the appropriateness either with regard to the indication/limitation or to the persistence to the treatment.
Materials and methods The authors investigated the patients in Cosenza health district (Italy) in the years 2009 and 2010. The whole population is 291,086 (51.3% women and 48.7% men). 9694 patients were treated with raloxifene, alendronic acid – alone or in association with cholecalciferol -, ibandronic acid, risedronic acid, strontium ranelate: 92.34% women and only 284 patients above 50 years old.
Results 56.2% of patients took raloxifene for less than 25% of the investigational period (six months); 11.9% took it for 25% – 50% of the investigational period (6-12 months); 18.9% took it between 50% and 75% of the time (12-18 months) and 13% took it for more than 75% of the time. Of the patients treated with alendronic acid, alone or in combination with cholecalciferol, 53.3% took the drug less than 25% of the investigational period, 13.3% for between 25% and 50%, 20.7% for between 50% and 75% and 12.7% took it for more than 75% of the time. 49.8% of the patients treated by ibandronic acid took the drug less than 25% of the investigational period, 13.4% took it between 25% and 50% of the time, 21.2% had it between 50% and 75% and 15.6% had it for more than 75% of the time. 52.2% of the patients treated by risedronic acid had the drug less than 25% of the investigational period, 12.6% had it between 25% and 50% of the time, 21.9% had it between 50% and 75% of the time and 13.3% had it more than 75% of the time. 75.8% of the patients treated by strontium ranelate took the drug less than 25% of the period studied, 9.6% took it between 25% and 50% of the time, 11.7% took it between 50% and 75% of the period studied and only 2.9% lasted for more than 75% of the time.
Conclusions Our observations confirm the underdiagnosis and the undertreatment of osteoporosis. Appropriate prescribing is the first step to adherence, the real target in chronic treatment.

Competing interests None.

CPC103 TRANSFERABILITY OF CLINICAL TRIALS RESULTS TO CLINICAL PRACTICE: THE EXAMPLE OF NEW DRUGS FOR RENAL CELL CARCINOMA

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Background In recent years, due to scarcity of evidence at the time of registration, approved indications/patient characteristics for anticancer drugs closely resemble those of the pivotal RCTs. At the same time, many authors complain it is hard to transfer the results of clinical trials to clinical practice, due to the high selectivity of patient eligibility criteria. In Italy, at the time of marketing, the majority of new anticancer drugs are subject to a compulsory electronic outcome registry called 'oncoAIFA'. In order to prescribe these drugs and have them dispensed, clinicians need to enter the patient's clinical profile, to prove they correspond to approved indications, and each prescription. Subsequently, hospital pharmacists record every prescription they dispense. At the end of the treatment, physicians need to report the patient's outcome.
Purpose To compare baseline characteristics and outcomes of clinical trial patients with the one of a cohort of patients treated with new drugs for renal cell carcinoma, sorafenib and sunitinib, in the Veneto Region (North East of Italy, 4.9 million inhabitants).
Materials and methods Pivotal clinical trials for sorafenib and sunitinib for the indication 'renal cell carcinoma' were selected. Data of the Veneto Region patients treated with sorafenib and sunitinib were extracted from the oncoAIFA register for the period January 2007-March 2011. Baseline characteristics were compared between clinical trials and clinical practice: gender, age, ECOG performance status, number of metastatic organs. The outcome compared was the proportion of patients with disease progression or death.
Results In the Veneto Region, 209 patients were treated with sorafenib and 570 with sunitinib. For sorafenib, baseline characteristics were similar for gender (% male: 70% RCT, 70% register), ECOG performance status (% ECOG zero: 49% RCT, 49% register). Relevant differences were found for age (median 58 years RCT, 67 years register), number of metastatic sites (% > 2: 57% RCT, 27% register), and previous cytokines use (% yes: 83% RCT, 57% register). For sunitinib, gender (% male: 71% RCT, 69% register), median age (62 years RCT, 66 years register), and ECOG performance status (% ECOG zero: 62% RCT, 56% register) were similar, while the two populations differed greatly for number of metastatic sites (% >= 3: 57% for RCT, 18% for register). Regarding outcome, 38.1% of patients experienced disease progression or death in the sorafenib trial versus 58% in real life; this proportion was 21% in the sunitinib trial versus 46% in the register.
Conclusions Although approved indications for new drugs often resemble RCT patient characteristics, patients treated in clinical practice differ from the study populations. This difference is also described in patient outcomes.

Competing interests None.

CPC104 OFF-LABEL USE OF OMALIZUMAB IN CASES REFRACTORY TO APPROVED TREATMENTS

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Background Omalizumab is an antibody used for the treatment of asthma with high blood levels of IgE (>76 IU/ml), as it is not expected to show much efficacy when levels are lower. In the first case The authors present, use of omalizumab was requested for a severe case of asthma with normal levels of IgE. It was also used in a case of persistent atopic dermatitis with high levels of IgE (800-900 IU/mL).
Purpose To evaluate the use of omalizumab beyond its approved indications and to discuss the results of the treatment in two off-label uses resistant to approved treatments.
Materials and methods Medical charts were reviewed and literature research was carried out for both cases in order to process the off-label approval. Clinical evolution was followed from the first administration of the antibody to present.
Results The first case was uncontrolled asthma secondary to Churg-Strauss vasculitis, with normal IgE levels and no allergic component (negative standard prick-test results and normal fraction of nitric oxide in exhalation). Omalizumab was prescribed at a dose of 150 mg every 4 weeks. After 4 doses, the vasculitis no longer caused symptoms; recurrent asthma flares continued, although not causing emergency episodes. In the second case, after adverse effects to all therapeutic options tried, off-label use of omalizumab was considered. After 450

mg every 15 days over a year, the patient had made satisfactory clinical progress with remission of the symptoms and normal serum levels of IgE.
Conclusions At present, the first patient is continuing treatment with omalizumab in order to need less emergency care, reduce oral corticosteroids and achieve a better quality of life. It was effective against the dermatitis and did not produce adverse effects. Neither of them developed anaphylaxis, the main adverse effect of the use of omalizumab.

Competing interests None.

CPC105 PHARMACEUTICAL INTERVENTION FOR VITAMIN D LEVEL

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Background Vitamin D is essential for strong bones because it helps the body use calcium from the diet. Because most people have low levels of vitamin D, correcting to the recommended ranges will bring added value to patient healthcare in hospital.
Purpose To detect patients with low vitamin D levels in an Orthopedic ward. To evaluate the degree of acceptance of the pharmacist's recommendations to correct vitamin D levels by the physicians. To devise an educational session for patients and evaluate the efficacy of the intervention.
Materials and methods From 7/03/2011 to 9/03/2011, total serum 25-hydroxycholecalciferol ($(25OH)D_3$) was measured in patients on the Orthopedic ward. A lack of vitamin D was defined as ($(25OH)D_3$) ≤30 ng/mL. The individual recommendation for vitamin D supplementation was written in each patient's medical record by the pharmacist. Patients presenting low vitamin D levels were randomised to enrol in the educational programme, consisting of a 15-min session about vitamin D, nutritional habits, and supplementation with vitamin D. All patients were given an appointment 2 months later for a vitamin D test to evaluate the efficacy of the intervention.
Conclusions There was a significant vitamin D deficiency in the population studied. Pharmaceutical intervention has been proved useful when adjusting vitamin D levels.

Competing interests None.

CPC105 table 1

Total patients included	46
Patients with low vit D blood levels	46 (100%)
Patients in Educational Programme	37 (9 dropouts)
-Experimental Group	19
Patients checked 2 months later	12/19 (63 %)
Patients achieving ($(25OH)D_3$) ≥ 30 ng/mL	9/12 (75%)
-Control Group	18
Patients checked 2 months later	9/18 (50%)
Patients achieving ($(25OH)D_3$) ≥ 30 ng/mL	6/9 (67%)
-Total serum levels ($(25OH)D_3$) ≥ 30 ng/mL, 2 months later	15/21 (71%)
Recommendations to the Physicians	37
-Accepted	31 (84%)
-Refused	6 (16%)

CPC106 PATIENT EDUCATION FOR HIV-INFECTED PATIENTS: A TOOL FOR SUCCESS

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10.1136/ejhpharm-2012-000074.455

Background Patient education (PE) is a discipline supported by the current legislation in France. A PE programme has been set up at Tenon Hospital (Paris, France) by pharmacists and nurses for patients infected with HIV.
Purpose The aim of this study was to assess the programme in terms of virological efficacy among patients referred to PE between 2009 and 2010 for treatment initiation or failure.
Materials and methods The last available plasma viral load (VL) dating from at least 6 months after starting treatment or last change of treatment was recorded for each patient followed in PE. The proportion of patients with virological suppression, that is having an undetectable VL at the threshold of 50 copies per mL, was then compared to that observed under the same conditions on all patients treated by the Infectious and Tropical Diseases Department (ITD) in 2010 and who were not referred for PE.
Results 63 patients were followed between 2009 and 2010 in the PE program. 86.0% of them (43/50) were in virological success after at least 6 months of therapy. This rate is comparable to the 86.1% (1979/2297) of patients with virological suppression from the active list of patients followed at ITD and who have not benefited from PE. At the beginning of PE, 38% (8/21) of pretreated patients were undetectable; to date, they are 81% (17/21) with virological suppression ($p < 0.01$). These preliminary results suggest that among patients in therapeutic failure or having adherence difficulties, the PE program provides outcomes comparable to those observed in the active list.
Conclusions These encouraging results enable us to prepare a prospective, comparative, randomised study to confirm them and to consider new end points such as patient satisfaction, quality of life and the expected benefits in terms of reduced costs thanks to the PE program.

Competing interests None.

CPC107 DOSE MODIFICATION OF MFOLFOX6 REGIMEN FOR COLORECTAL CANCER

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Background Colorectal cancer (CRC) is the third most common cancer in Korea. The FOLFOX regimen is widely used chemotherapy in CRC, and the modified (mFOLFOX6) regimen is frequently used in the National Cancer Center in view of adverse events, patient convenience and the time for nursing. The mFOLFOX6 regimen consisted of oxaliplatin 85 mg/m^2 and folinic acid 200 mg/m^2 intravenous on day 1, followed by 5-FU 400 mg/m^2 INTRAVENOUS and then 5-FU 2,400 mg/m^2 INTRAVENOUS over 46 h, administered every 2 weeks. Although a modified regimen is used, adverse events have occurred frequently and dose modifications may be needed.
Purpose The objective of this study was to analyse the cause and pattern of dose modifications of mFOLFOX6 regimen, to determine the factors that affect dose modification in CRC patients.
Materials and methods A retrospective study was conducted on 70 patients who were diagnosed with CRC and received mFOLFOX6 between January 2009 and March 2010. Dose modification was needed in 68 patients (97.2%) and the average incidence (including delay of administration and dose reduction) was 2.90±1.58. The most frequently used way of modifying the dose was to delay the chemotherapy schedule for a week, and the primary cause of dose modification was neutropenia.

Factors that affect dose requirements include gender, age, body surface area (BSA), blood level, underlying disease, stage, metastasis, performance status (PS), previous disease and the history of drinking and smoking.

Results Dose modification and reduction occurred more frequently in patients in their 70's than in their 50's or 60's (P=0.015, 0.027, respectively). From blood level tests, patients with high alkaline phosphatase levels had more dose modification and delay of chemotherapy (P=0.035, 0.033, respectively). The dose was also modified and reduced more frequently in patients who had a case history of hypertension (P=0.046, 0.027, respectively). In the relation to the stage, patients in advanced stages had more dose modification and delayed administration than those in the first stage of CRC. The dose was modified and administration was delayed more frequently in metastatic cancer patients than non-metastatic cancer patients (P=0.021, 0.015, respectively). The incidence of dose modification and reduction increased with poorer PS (P=0.019, 0.025, respectively). In patients who had previously undergone radiotherapy, the dose was modified and reduced more frequently (P=0.259, 0.005 respectively). In those with a history of drinking, the dose was reduced more frequently (P=0.004). The dose was modified and administration was delayed more frequently in patients who had a history of smoking (P=0.001, 0.002, 0.002, respectively).

Conclusions From this study, the cause of dose modification depended on individual differences and could be predicted in advance. Further study is needed to confirm predictive factors that could affect dose modification and to apply them effectively to individual treatment.

Competing interests explained in presentation

CPC108 THE EFFECT OF DAILY VERSUS WEEKLY FOLIC ACID SUPPLEMENTATION ON THE INCIDENCE OF TRANSAMINASE ELEVATIONS IN METHOTREXATE-TREATED PATIENTS

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10.1136/ejhpharm-2012-000074.457

Background Methotrexate (MTX) treatment in rheumatoid arthritis (RA) can be hindered by side effects, including transaminase elevations. These might be a surrogate marker for liver disease. Folic acid (FA) supplementation reduces the incidence of toxicity while not compromising efficacy, thereby allowing more patients to continue treatment. Dutch rheumatologists prescribed 1 mg daily, and since 2004 5 mg (twice) weekly, due to changing reimbursement. No evidence is available that directly compares these doses with regards to liver enzyme elevations.

Purpose This non-inferiority comparative study compared the occurrence of transaminase elevations in RA patients on MTX, supplementing folic acid on either a (twice) weekly or daily basis.

Materials and methods All patients participating in the Nijmegen early RA inception cohort, initiating MTX and FA from January 1, 2000 with available charts and follow-up transaminase values were included in this study. Patients were split into two cohorts based on folic acid administration (daily vs (twice) weekly). The primary end point was the proportion of patients with abnormal liver enzyme findings in each group, measured in time to event. 'Persistent abnormal liver enzyme values' were defined as serum values of AST and/or ALT of either >3x more than the upper limit (UL), or >2x but <3x more than the UL, occurring on at least 2 of 4 consecutive evaluations Secondary outcome parameters included gastrointestinal (GI) intolerance, MTX dose and DAS28. Data were analysed using Cox proportional hazard analysis for the specified end points. Sensitivity analysis was performed for alternate event definitions.

Results 133 (38%) patients had twice-weekly folic acid supplementation, 61 (18%) weekly and 153 (44%) daily folic acid supplementation. When corrected for location and ESR, an HR of 1.20 (0.46-3.10) was found for the association between folic acid dose and liver enzyme events. This remained non-significant in sensitivity analysis. For GI complaints, an HR of 4.22 (1.19-14.98) was found corrected for location, DMARD use, and disease duration.

Conclusions Changing to a weekly regimen makes no difference to the occurrence of liver enzyme elevations, but abolishes the preventive effect of folic acid with regards to GI intolerance. Combining this information with a comparatively low cost difference, daily folic acid supplementation should be preferred above weekly supplementation.

Competing interests None.

CPC109 THE IMPACT OF PHARMACIST PARTICIPATION IN A MULTIDISCIPLINARY TEAM ON AN ONCOLOGY WARD COMPARED WITH A WARD CLINICAL PHARMACY SERVICE

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Background Integration of pharmacists into multidisciplinary teams has been shown to have a positive effect in several clinical, pharmaceutical and financial indicators. Literature on the oncology setting and in non-teaching facilities is sparse and no literature is available on fully private healthcare facilities or

CPC108 table 1

	Hazard ratio (95%-CI)		
	Crude:	**Adjusted:**	**Adjusted for:**
Persistent abnormal transaminase elevations - > 3x above UL or - > 2x above UL on at least 2 of 4 consecutive evaluations	1.47 (0.57-3.79)	1.20 (0.46-3.10)	Location, ESR
Single transaminase elevations (>1x above UL)	1.59 (0.93-2.64)	1.67 (0.97-2.88)	Location, baseline AST
GI events	4.20 (1.25-14.13)	4.22 (1.19-14.98)	Location, RA duration, DMARD use

on Irish hospitals. Differences in methods, outcome measures and working frameworks make the available evidence difficult to generalise.

Purpose To compare 2 models of pharmaceutical care delivery, with and without pharmacist participation in multidisciplinary teams, and identify the more effective.

Materials and methods This was a prospective study over two periods of 26 consecutive working days. The pharmacist provided a clinical pharmacy service to the oncology ward in both groups. In the intervention group (IG) the pharmacist participated in daily multidisciplinary meetings. Number and nature of Drug Related Problems (DRPs), time needed to provided clinical service and physician acceptance rates were the outcome measures. Numerical variables were analysed with the Student t-test and χ^2 test for categorical variables.

Results 124 patients in the control group (CG) and 130 in the IG were included in this study. 86 DRPs in 37 patients were identified in the CG and 129 in 57 patients in the IG (p=0.024; RR=1.47 95% CI 1.05 to 2.05). The time needed to provide the clinical service increased from 177 min. (CG) to 231 min. (IG) (p<0.01). The acceptance rate of the pharmacist's interventions was 88.6%. The type, causes and outcomes of the DRPs did not differ between groups. Central nervous system drugs (23.3%) were the class most involved in DRPs. Over 83% of patients with DRPs were prescribed 6 or more regular drugs.

Conclusion When integrated into a multidisciplinary team, the pharmacist's work resulted in higher number of DRPs prevented and resolved with a higher percentage of patients having DRPs detected. This contributes to drug rationalisation and safety with potential clinical benefits for patients, potential cost savings for the hospital and pharmacy department.

Competing interests None.

International Posters

The International poster session includes the 1st poster prize winners of EAHP member associations' national congresses. You can view the complete International poster session (INT001 – INT011) in the poster area located on Level 0 at the Milan Convention Center.

INT003 A WEB PAGE FOR COMMUNITY PHARMACISTS TO IMPROVE CONTINUITY OF CARE BETWEEN HOSPITAL AND AMBULATORY CARE

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Background In Switzerland, in the absence of a pharmaceutical service ensuring seamless care, treatment plans prescribed at hospital discharge may be difficult to understand and to validate for community pharmacists. Information sources on products and drug doses used in the hospital are often lacking. Continuity of care may be therefore disrupted.
Purpose To determine which information could be useful for community pharmacists to ensure seamless care and provided through a dedicated web page.
Material and method 1. Internet search (July 2009) of web sites from 43 hospitals (Switzerland 28, France 5, Canada 10) and evaluation of the available pharmaceutical information. 2. Survey of problems at hospital discharge observed by 9 students during their assistantship in community pharmacies (May 2009). 3. Creation of a web page on the internet site of the hospital pharmacy.
Results Of the 43 hospital web sites, 22 (51%) had a web page dedicated to their hospital pharmacy but only 9 (21%) (Switzerland 6, France 0, Canada 3) did contain pharmaceutical information like preparation and administration of drugs, or pharmacology data. No web page was specifically intended for community pharmacists. Problems observed by students at discharge were mainly related to manufactured or imported products and to knowledge of paediatric doses used in the hospital setting. A web page was created with information about the hospital pharmacy (i.e out-of-hours pharmaceutical services), protocols of manufactured products with stability data, information on imported drugs and useful pharmacological and medical information for the validation of prescriptions (i.e usual hospital paediatric drug doses).
Conclusion No web page specifically intended for community pharmacists has been found on the internet. A model has been created and published on the web site of the HUG pharmacy (http://pharmacie.hug-ge.ch/infos_prat/infos_officine.html). Satisfaction of community pharmacists regarding the content of this web page and impact on seamless care should be evaluated in the future.

Competing interests None.

INT009 ANTIBIOTIC USAGE IN HOSPITALISED CHILDREN TREATMENT: RETROSPECTIVE OBSERVATIONAL STUDY IN THE INFECTIOUS DISEASES UNIT AT THE CHILDREN UNIVERSITY HOSPITAL

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Background Antibiotics are among the most frequently prescribed drugs in children. Although antibiotics are mainly used in the primary care, hospitals are considered to be the centre of antimicrobial resistance due to high density of broad-spectrum antibiotic use both in children and adult population.
Purpose To analyse antibiotic prescribing tendencies and their usage in hospitalised children treatment as a first step to improve antibiotic usage at the hospital.
Materials and methods A retrospective, analytic observational study. Evaluated patients were aged 0-18 years and were consecutively admitted to the Infectious diseases unit from January 1st to February 28th, 2011. Antibiotic usage was analysed within the following age groups: <1 year, 1-2 years, 2-5 years, 5-12 years, and 12-18 years. For each child, information was obtained from full-text medical charts. The following data were collected: age, gender, weight, diagnosis, used systemic antibiotics (ATC J01), dose per administration, number of doses per day, route of administration, the day of hospitalisation (when antibiotic treatment started), duration of the treatment, number of days spent at hospital, and microbiology data.
Results In total, 609 (307 females and 302 males) of hospitalised children were evaluated. Antibiotics were prescribed for 294 (48%) of patients (134 females and 160 males). The majority of children treated with antibiotics (130; 44%) fell in the group of age between 2 and 5 years. The average duration of the hospital stay was 5.7 days. Respiratory tract infections (pneumonia, bronchitis) were the most common indications for prescribing antibiotic usage. The second most common indication was gastroenteritis (mostly rotavirus aetiology). Ampicillin and cefotaxime were used to treat at least 90% of patients. The parenteral route was used in 97% of indications. In total, there were 5% 'off-label' prescriptions (mainly Sulfamethoxazole/Trimethoprim). 97% of prescriptions had a correct dose, but 3% had a lower dose than recommended. During the study period there was no antibiotic prescription that had a higher dose than recommended. Sulfamethoxazole/Trimethoprim was prescribed more often under the recommended minimum dose than other drugs. There was no 'unlicensed' or 'unregistered' use of antibiotics. 179 (61%) of 294 children received antibiotics based on clinical signs of possible infection, but without any microbiological confirmation.
Conclusions Further analysis of antibiotic prescribing tendencies in hospitalised children treatment and the development of local guidelines for antibiotic use in children treatment should be developed as soon as possible. In addition, physicians and parents should receive additional education.

Competing interests None.

INT011 EXAMINATION OF COMPOUND INJECTIONS AND INFUSIONS

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Background In Hungary preparation of mixed infusions is regulated by a national guideline which contains the role of the hospital pharmacists in the process. The permission of preparation of mixed infusions is given by the hospital pharmacist.
Purpose Compounding parenteral solutions may cause several problems. Mixed infusions should be prepared according to the application prescription and the national guideline. Incorrect preparation may result in physical, chemical,

physical-chemical incompatibilities, therapeutic interactions and the decomposition products may be toxic.

Materials and methods At Bajcsy-Zsilinszky Hospital a mixed infusion list was compiled containing 159 mixed infusions from several wards. Immediate use mixed infusions prepared insitu on clinical departments were reviewed from pharmaceutical aspect. Where the application prescription and literature data do not contain any information about the compounding, the compatibility and stability of mixed infusions were analysed. The inspections were based on organoleptic observations and instrumental analysis. UV spectrophotometric and colorimetric measurements were carried out. UV absorption spectra of starting materials and the mixtures were taken between wavelengths 200 and 400 nm. The samples were divided into two groups; one stored for one week at room temperature, the other for three days at 50°C, then the absorption spectra were taken again.

Results The UV absorbance values changed to some extent in samples stored for a week at room temperature. More significant changes were recorded for samples stored for three days at 50°C. Discolouration and change of pH were also detected for some samples but no precipitation occurred.

Conclusions Based on the results the compounding certain infusions were permitted or prohibited in the hospital. The results were shared with other healthcare institutions which indicated their need for detailed information.

Competing interests None.

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