(18 patients). The average follow up was 4 months. Most of the patients were treated with capecitabine-oxaliplatin, followed by those treated with capecitabine monotherapy and other minority schemes (cyclophosphamide or bevacizumab). The median starting dose of capecitabine was 3300 mg.

32% of patients required a dose adjustment (delay and/or dose reduction) during the follow-up period. The treatment of 26% of patients was delayed by an average of 16 days (2 of the patients had to delay 2 cycles). The initial dose was reduced in 24% of patients (twice in three of the patients).

Toxicity in any grade was reported by 30% of the patients. Severe toxicities (grade 3 of CTCAE) were sickness and neutropenia. Most frequent toxicities were gastrointestinal side effects (6 patients) and grade 2 hand-foot syndrome (4 patients), followed by mucositis, skin side effects, hyperbilirubinaemia and thrombopenia.

Toxicity and dose adjustment were not statistically related to the treatment regimen, ECOG, gender or age.

Conclusions The toxicity profile was consistent with the trials. 81% of patients who had a dose adjustment didn't need a further dose reduction.

No conflict of interest.

CPC-072 INCLUSION OF PHARMACOGENETICS STUDIES, PATIENT-REPORTED OUTCOMES AND COST MEASURES IN CLINICAL TRIALS; VARIABLES ADDED IN RECENT YEARS

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Background Pharmacogenetic studies analyse the variability of drug response; patient-reported outcome (PRO) measures complement traditional measures. Pharmacoeconomic studies tell us the efficiency of different therapeutic alternatives.

Purpose To evaluate the use of PRO measures, including health-related quality of life questionnaires (HRQoLQ), and the frequency of inclusion of pharmacogenetics studies and economic variables in the design of clinical trials (CT) and observational studies (ST). For CT, the quality of the study design was also measured.

Materials and Methods Observational study of CT and ST approved by a Clinical Research Ethics Committee (active between Jan/2008–May/2012). Information recorded: medical specialty, pathology, methodological quality (Jadad scale: 0–5), inclusion of PRO, HRQoLQ, pharmacogenetics studies (collection or not of human biological samples) and economic variables (use of health-care resources and/or indirect costs defined as the number of days lost due to sick leave of patients and caregivers). The information was systematically collected by 2 reviewers and checked by a third if discrepancies arose.

Results Ninety-four protocols (79CTs, 15ST) were analysed; 51 included PRO measures (54.3%), 44 CT (38 had HRQoLQ) and 7 ST (6 had HRQoLQ). Analysis by area showed PRO measures were most commonly studied in: endocrinology, neurology, digestive diseases and cardiology. The average quality score was 3.04. 31 studies incorporated pharmacogenetics studies, which were less frequent before 2010 than after (45.3% versus 65.4%). In 50% of the pharmacogenetics studies the storage of collected human biological material in biobanks was planned with the objective of conducting studies about drugs responses according to the genetic endowment. Twenty (25%) CTs and two (18.2%) STs included economic variables.

Conclusions The evaluation of economic variables in CTs and STs was low. More than half of the protocols included PRO measures, reflecting the importance of these parameters. Increasing knowledge of pharmacogenetics has resulted in a higher inclusion of these studies in more recent CTs. The average quality for the CT exceeded the value 3, indicating that studies analysed were of reasonable quality.

No conflict of interest.

CPC-073 INFLUENCE OF FIRST-LINE EGFR THERAPY ON SURVIVAL AND MORTALITY RATES IN NON-SMALL CELL LUNG CANCER

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Background The efficacy of chemotherapy has reached a plateau for advanced non-small cell lung cancer (NSCLC). Increasing evidence has demonstrated that patients with sensitising mutations in the epidermal growth factor receptor (EGFR) are associated with sensitivity to reversible EGFR tyrosine kinase inhibitors (TKIs). Numerous studies have demonstrated improvement of progression-free survival compared to conventional chemotherapy as first-line treatment for advanced NSCLC with EGFR mutations.

Purpose To evaluate mortality and overall survival (OS) in NSCLC patients treated with EGFR-TKIs or chemotherapy according to their EGFR status.

Materials and Methods Retrospective study. Sixty-one patients diagnosed with NSCLC and available EGFR status during 2008–2012 were included. Socio-demographic, clinical and pharmacological characteristics of patients were collected. Comparison of medians by Mann-Whitney-Wilcoxon Test for numerical variables and Chi-Square Test for categorical variables was performed.

Results Mean age was 62 ± 12years; 52.5% (32/61) male; 70.5% (43/61) smokers/ex-smokers; 60.7% (37/61) stage IV; 42.6% (23/54) mutant EGFR. Minimum follow-up of 6 months was accomplished in 54 patients.

An EGFR-TKI was prescribed as first-line treatment in 65.2% (15/23) EGFR-positive patients, 80.0% (12/15) stage IV, with an OS of 12.40[11.30–23.33] months and 53.3% (8/15) deaths. Two patients required second-line chemotherapy (2/15; 13.3%).

Chemotherapy as first-line treatment was prescribed in 75% patients (46/61), 17% EGFR-positive (8/46), 50.0% (4/8) stage IV, with 29% (2/7) deaths. EGFR-TKIs were used as second-line treatment in 87.5% (7/8) patients and third-line in 12.5% (1/8). OS was 17.97[8.83–60.84] months.

EGFR was native in 67.4% (31/46) patients, 58.1% (18/31) stage IV, and 61.3% (19/31) deaths. EGFR-TKIs as second-line treatment were prescribed in 61.3%. (19/31) patients, third-line in 35.5% (11/31) and fourth-line in 3.2% (1/31).

Seven patients had unknown EGFR status (7/61; 11.5%), 57.1% (4/7) stage IV, and 42.8% (3/7) deaths. EGFR-TKI as second-line treatment was prescribed in 85.7% (6/7) patients and fourth-line treatment in 14.3% (1/7).

OS and mortality were not statistically different between EGFR-positive patients treated with EGFR-TKIs/chemotherapy as first-line treatment (P = 0.836; p = 0.105). Mortality was not associated with stage or EGFR status (P = 0.086; p = 1.000).

Conclusions Mortality and OS are not associated with EGFR status or stage in this NSCLC population. EGFR-positive patients present similar OS and mortality rates regardless of first-line treatment.

No conflict of interest.

CPC-074 INTENSIVE MONITORING OF ADVERSE REACTIONS IN ONCOHEMATOLOGY: PROJECT FARMAREL

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Background The Pharmacy Department is involved in providing information and recording adverse drug reactions (ADRs) in the national system. The Oncology/Day Hospital provides clinical data. This study increases the culture of safety and security of processing through the collection of data, helping to give statistical and epidemiological value to otherwise casual observations.
Purpose To detect adverse drugs events in oncohaematology in a systematic and timely manner: the FARMAREL project.
Materials and Methods Following the training sessions at the regional level, meetings were held every three months, to monitor progress and analyse any problems found. All haematological patients treated from April 2009 to July 2012 were monitored and if ADRs occurred, a team of physicians and pharmacists analysed the event according to the World Health Organization definition.

The ADRs observed were posted to the network using special software, set up specifically to allow computerization and real-time monitoring progress of the project, as well as statistical analysis of epidemiological data.
Results We reported a total of 74 cases, categorised by the severity of adverse events (38 not severe, 3 deaths, 3 life-threatening, 30 hospitalizations or extended hospitalisation). Among the ADRs reported the most significant clinical cases in terms of severity were: Gram-negative septic shock (suspect drug: thalidomide), intestinal infarction (bortezomib), acute renal failure (amphotericin B); hypokinetic cardiomyopathy (doxorubicin); atrioventricular conduction block (lenalidomide). The most significant case studies were presented and discussed with other participating hospitals during a meeting of Lombardy Region, and in a national conference.
Conclusions The study has increased the culture of pharmacovigilance and awareness of the clinical data constituting ADRs. The present evaluation has revealed opportunities for intervention especially for the preventable ADRs which will help in promoting safer drug use.

No conflict of interest.

CPC-075 INTERDISCIPLINARY TASKFORCE BRINGS DOWN PRICE OF HIV DRUGS!

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Background The board in the Danish Regions decided on a new specialist consultancy structure called 'The Council for Use of Expensive Hospital Medicine' (RADS). The aim of RADS is to help standardise the rational use of medicine throughout Denmark, to be achieved primarily by setting guidelines for the use of expensive hospital medicine at the clinical level. The intention is to obtain the best healthcare in relation to expenditure whilst ensuring a high quality of treatment.
Purpose The purpose of this study was to identify an effective way of implementing the RADS guidelines in a multi-centred clinical practise and optimise the pressure on the pricing of the drugs concerned. This was exemplified using data on HIV treatment.
Materials and Methods The task was to change the HIV-treatment from a triple compound to three single compounds. To implement the RADS guidelines, the Capital Regional Pharmacy formed a taskforce consisting of the pharmacy director, top leaders from logistics and clinical pharmaceutical services, IT-department and a data-expert on medication use analysis. The implementation of the HIV-guideline was followed in each clinic during which time the leadership was in close dialogue with the clinicians. Feedback on actual prescribing behaviour was supplied every month to the responsible clinician.
Results The national goal for guidelines implementation was 95%. At 98% the Capital Region has the highest rate for guidelines implementation in Denmark. Following the next tender and one year after guidelines implementation, the price of the triple compound had dropped by 16%. Result – the price of the clinicians' first choice medicine was acceptable to the Region.
Conclusions The interdisciplinary taskforce achieved its goals. Intensive monitoring and feedback to the clinician in charge, followed by direct management involvement and support at all centres, is an effective implementation strategy.

No conflict of interest.

CPC-076 INTERNAL AUDIT ON THE LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS

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Background The purpose of labelling is to protect persons who take part to biomedical research. It must enable the product and study to be identified and the drugs to be used safely. The decree of 24 May 2006 [1] sets out the information to be included on the labelling of investigational medical product (IMPs).
Purpose To evaluate the regulatory conformity of the labelling of IMPs.
Materials and Methods An assessment grid was established from the decree of 24 May 2006. This audit investigated the labelling of the primary or secondary packaging, according to the presentation, of 135 IMPs corresponding to 75 clinical trials.
Results Of 135 labels analysed, only 11 (8.1%) bore all the information required by the legislation. On 3 labels, information didn't appear in French. In more than 5% of the cases, information allowing identification of the product and the study and the good use of the drugs was absent from label. In other cases the following was missing: pharmaceutical form (15.4%), route of administration (15.3%), content of the active substance (11.6%), product identification (6.88%), clinical trial reference (6.88%), patient visit number (71.9%) and storage conditions (14.4%). 57.8% of the labels came in layers. Basic information was not present on the first layer in 26.1% of the cases for the pharmaceutical form, route of administration (55.9%), dosage (13.8%), product identification (11.7%) or storage conditions (45.8%).
Conclusions In spite of important and rigorous regulation, we noted non-conformities in labelling with sometimes important omissions. The significant number of statements required to appear on the label leads sponsors to reduce font size and to present the labels in layers. This audit highlights that the significant amount of information on the label makes it difficult to read and can lead to medicines errors, especially in elderly patients.

Reference

1. Order of 24 May 2006 establishing the content for the labelling of investigational medicinal products published in France's official journal on 30 May 2006.

No conflict of interest.

CPC-077 INVOLVING PHARMACY TECHNICIANS IN MEDICINES RECONCILIATION IN THE EMERGENCY DEPARTMENT: WHAT CAN WE EXPECT?

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Background In 2011, the Centre Hospitalier de Valenciennes Emergency Department (ED) treated an average of 140 patients per day, and 38.8% of these patients were hospitalised. Thus, 54 patients a day were eligible for medicines reconciliation at admission.

A previous study showed that the medicines reconciliation of 46.4% of the patients admitted at the Centre Hospitalier de