

unit. For each patient, we detected potentially inappropriate medication (overuse, misuse and underuse) depending on the chronic conditions and suggested drug modifications to the general practitioner (GP). Three months after discharge, we phoned the GPs to find out if the pharmaceutical interventions had been accepted or not, and if patients had fallen again.

**Results** 96 patients (65% of women; median age 85 years) were admitted for falls due to medicines. 86% of the patients were living at home. Medicines involved with the risk of falling were essentially diuretics, benzodiazepines, calcium inhibitors, antiarrhythmics, sartans, anticholinesterases. The modifications usually suggested related to diuretics, benzodiazepines, anticholinergics, vitamin-calcium supplements, osteoporosis treatment and the use of stockings. Among patients called three months later, 75% of the suggestions were still respected, but 29% of the patients had fallen again. There was no difference in the number of falls for patients for whom the modifications had been respected and those for whom they had not been.

**Conclusions** This study suggested that falls were more frequent among patients living at home; work needs to be done to secure elderly people's houses. The importance of inappropriate prescriptions on fall events was also underlined. Falls occurred because of multifactorial mechanisms: inappropriate home fittings, sarcopenia, neurodegenerative diseases and inappropriate medicines. One way of reducing the risk of falling in elderly people is to improve the medication.

No conflict of interest.

#### CPC-069 IMPLEMENTATION OF A CLINICAL PHARMACY AND MEDICINES DISPENSING SERVICE IN A CHEMOTHERAPY DAY TREATMENT UNIT

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**Background** Cancer patients at the Oxford University Hospitals NHS Trust receive the majority of their chemotherapy treatments as daycase patients. The clinical pharmacy service provision to patients receiving chemotherapy did not move with the patients from the inpatient to the daycase setting. The lack of clinical pharmacy provision to the day treatment unit (DTU) resulted in medicines wastage and an increase in nursing time to educate patients on their medication.

**Purpose** The pharmacy service to the DTU was reconfigured to provide a clinical pharmacy and medicines management service, and to dispense medicines as pre-packs at the patients' bedside.

**Materials and Methods** One pharmacist and half of a technician were funded from cost savings to implement the new service. Medication record cards were developed for each supportive regimen as a counselling aid to patients. A patient satisfaction survey was undertaken prior to initiating the new service, and two months after initiation. Drug expenditure and medicine wastage savings were recorded prior to and two months after implementation of the service. A satellite pharmacy was set up to dispense medicines next to the DTU. A trolley was used to dispense pre-packs at the bedside. Data was collected prior to and two months after initiation of the new service to assess patient satisfaction, impact on nursing time, medicines wastage and savings.

**Results** It was anticipated that approximately £25,000 [€31,000] per month would be saved on medicines wastage. Patients were very satisfied with the new service. The service resulted in a reduction in nursing time of 37.5 hours/week. The results of the service impact after two months will be presented.

**Conclusions** The DTU pharmacy service ensures medicines optimisation, reduces medicines expenditure, and improves the quality of patient care. Patients receiving chemotherapy as inpatients

always benefited from a clinical pharmacy service, so it is appropriate to provide this service in the day case setting.

No conflict of interest.

#### CPC-070 IMPORTANCE OF RESIDUAL INVESTIGATIONAL MEDICINAL PRODUCT COUNT

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**Background** Good Clinical Practice specifies the role of the pharmacist in clinical trials. For each prescription dispensed for a named patient, the pharmacist is responsible for educating the patient on the treatment, counting any residual Investigational Medicinal Product (IMP), and thus for evaluating the compliance.

**Purpose** To assess the importance of pharmaceutical vigilance about IMPs.

**Materials and Methods** This prospective study took three months. For each named-patient prescription dispensed, a count of returned treatment (RT) by the patient from the previously dispensed medicines was performed to assess compliance.

**Results** 117 RTs were analysed. 43 additional RTs from 1 clinical trial were not included in this study due to the impossibility of evaluating compliance (posology changes not notified to the pharmacy and unsuitable secondary packaging). The non-conformity rate was 20% (23 RT). 39% (n = 9) of the non conformities (NC) were due to allowing empty boxes not to be returned. In 61% (n = 14) of NC there was a discrepancy between the expected count of returned IMPs and the one actually made, showing poor compliance.

Average counting time was 12 minutes (5–30 min).

An exact count of returned IMP was operated during dispensing for 34% of returns and after dispensing for 66%. In all cases, a global analysis was performed before the prescription was dispensed.

**Conclusions** This study points out the major role of the pharmacist in the education of the patient enrolled in clinical trials, about the return of all experimental medicines and the therapeutic schedule. It appeared very important to evaluate compliance while the pharmacist was dispensing the next prescription, independently of the time consumed, in order to correct possible errors in taking the medicines at that time.

No conflict of interest.

#### CPC-071 INCIDENCE AND CAUSES OF CAPECITABINE DOSE ADJUSTMENT IN COLON CANCER PATIENTS

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**Background** Capecitabine is indicated in colon cancer alone or in combination. Recommended posology is calculated with reference to the body surface area (BSA) and pharmacotherapeutic regimen, although adjustments can be made if drug-related toxicity occurs.

**Purpose** To describe the incidence of capecitabine dose adjustment in colon cancer patients (CCPs). To analyse the reasons for this adjustment.

**Materials and Methods** Retrospective observational study of 49 CCPs treated with capecitabine with at least 3 cycles of 14 days from June 2011 to February 2012. Data were collected from the dispensary and medical history. The severity of the toxicity was classified according to the CTCAEv.4.

**Results** Forty-nine patients were enrolled: 25 male, average age of 61 (34–82), average BSA of 1.75 m<sup>2</sup>. Most of them presented ECOG0 (26 patients) at the beginning of the treatment, followed by ECOG1

(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 ± 12 years; 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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