## **Clinical pharmacy and clinical trials**

Materials and Methods XAMOS was a phase IV, noninterventional, open-label cohort study in patients undergoing major orthopaedic surgery in daily clinical practise. The choice of rivaroxaban or standard of care (SOC) for VTE prophylaxis was at the discretion of the attending physicians. All adverse events, including symptomatic thromboembolic and bleeding events, and pre-trial and concomitant use of medicines were reported.

Results XAMOS enrolled 17,701 patients; the safety population included 17,413 patients, of whom 8778 received rivaroxaban and 8635 received SOC (81.7% low molecular weight heparin). Baseline patient demographics and use of cytochrome P450 (CYP) 3A4 inhibitors or inducers and platelet aggregation inhibitors (PAIs) before surgery were similar between groups; these drugs were used less frequently after surgery. There was a significant reduction in the incidence of symptomatic thromboembolic events in the rivaroxaban group compared with the SOC group, with numerically but not statistically higher incidence of major bleeding events. Concomitant use of PAIs was associated with higher incidences of symptomatic thromboembolic and any bleeding events compared with non-use in both the rivaroxaban and the SOC groups (Table).

Conclusions XAMOS confirmed the results of the RECORD studies. CYP3A4 inhibitors or inducers and PAIs were used less frequently after surgery compared with before surgery. The benefit-risk profile of rivaroxaban compared with SOC was maintained in routine clinical practise in patients undergoing major orthopaedic surgery, including patients with concomitant use of PAIs.

### Abstract CPC-124 Table 1

Pre-trial and concomitant use of drugs and clinical outcomes in the XAMOS study*		
	Rivaroxaban (%)	SOC (%)
Pretrial use (≤7 days before surgery)		
CYP3A4 inhibitors	2.3	3.0
CYP3A4 inducers	0.8	0.8
PAIs	6.8	8.2
Concomitant use during the study		
CYP3A4 inhibitors	0.5	1.0
CYP3A4 inducers	0.4	0.7
PAIs	2.8	3.7
Incidence of any symptomatic thromboembolic events		
Concomitant use of PAIs	2.4	4.0
No concomitant use of PAIs	0.6	0.9
Incidence of any treatment-emergent bleeding events		
Concomitant use of PAIs	8.4	8.1
No concomitant use of PAIs	4.6	3.0

<sup>\*</sup>Unadjusted data as crude estimates for comparison between groups (covariate-adjusted and propensity score-adjusted results will be presented elsewhere upon completion of the final data analyses)

No conflict of interest.

## CPC-125 SATISFACTION SURVEY WITH PHARMACEUTICAL **CARE IN AMBULATORY CANCER PATIENTS ON** TREATMENT WITH ORAL ANTINEOPLASTIC AGENTS

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Background In recent years, many oral antineoplastic agents (OAAs) have appeared providing patient convenience. According to law, in the Autonomous Community of Región de Murcia (Spain), these drugs are dispensed at hospital pharmacies in the outpatient setting.

Hospital pharmacists, because of their frequent contact with cancer patients on treatment with OAA, play a pivotal role in improving adherence and ensuring that medicines are taken correctly through oral and written information.

Purpose To know patient satisfaction with pharmaceutical care (PC) through a survey in ambulatory cancer patients who take OAA.

Materials and Methods A Likert-type scale on patient satisfaction with PC was designed and run on every other week for six weeks. The survey was completed by patients in an anonymous and voluntary manner. It included 17 questions in 5 groups: demographical data, PC request, opinion about the information provided to them, consultation with the pharmacist and global satisfaction degree with PC. Only these 2 latest question groups were considered for the analysis, including 5 items: pharmacist accessibility, courtesy, professional competence, patient opinion about pharmacist utility and global satisfaction degree with PC. Survey internal consistency was measured with Cronbach's alpha coefficient.

**Results** This survey was completed by 57 patients (71.25% of the total; 53% men; 47% women). Answers to questions were graded with 5 points. For the items pharmacist accessibility, courtesy, professional competence, patient opinion about pharmacist utility and global satisfaction degree with PC, the mean plus/minus standard deviation values achieved were  $4.53 \pm 0.49$ ,  $4.53 \pm 0.49$ ,  $4.29 \pm 0.53$ ,  $4.29 \pm 0.53$  and  $4.46 \pm 0.53$ , respectively. Overall satisfaction extent was 88.33%. In this survey, Cronbach's alpha coefficient was 0.85, so we can say that this scale is trustworthy.

Conclusions In this patient group, the degree of overall satisfaction with pharmaceutical care was satisfactory. Future surveys will be needed to cheque and improve our service.

No conflict of interest.

### CPC-126 SECOND-LINE CHEMOTHERAPY WITH NAB-PACLITAXEL IN PATIENTS WITH PANCREAS CANCER

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**Background** Pancreatic cancer is one of the most deadly forms of cancer. Standard treatment in metastatic disease is the quemotherapy with gemcitabine, but there is not a standard therapy for gemcitabine-refractory patients.

**Purpose** Assess the off-label efficacy of nab-paclitaxel, in patients who progressed on gemcitabine-based therapy, in our hospital.

Materials and Methods Observational retrospective study of pancreatic cancer patients treated with nab-paclitaxel who progressed on gemcitabine-based therapy from June 2011 to April 2012. Data were collected from clinical history, Oncofarm® and Omega-3MIL® programmes. We determined: Progression free survival (PFS) and Overall Survival (OS). 12 patients (100% male) were treated with nab-paclitaxel. Eleven of them presented metastatic desease. The patients were treated with two therapies:

- nab-paclitaxel 100 mg/m<sup>2</sup> (1.8,15/28d). 5 patients received this treatment. Median age was 79.4 years (sd = 4.2 years)
- Gemcitabine  $1000 \text{ mg/m}^2$  plus nab-paclitaxel  $100 \text{ mg/m}^2$ (1.8,15/28d): 7 patients received this treatment; Median age was 65.5 years (sd = 6.9 years).

Results Median PFS was 2,8 months (95% CI, 1.5 to 4.1 months) with single agent, and 5.3 months (95% CI, 4.0 to 6.5 months) with gemcitabine plus nab-paclitaxel. The PFS in the study was 20% and 83% respectively. The OS couldn't be determine in the nab-paclitaxel group, because there wasn't any event during the study period. The OS with gemcitabine plus nab-paclitaxel was 66.7%.

### **Conclusions**

- It showed better clinical outcomes in the gemcitabine plus nab-paclitaxel group in PFS.
- The nab-paclitaxel can be an effective second-line chemotherapy in gemcitabine resistant patients.

No conflict of interest.

### CPC-127 SEVERAL TYPES OF PROTEINURIA AND ASSOCIATED **FACTORS AMONG HIV-INFECTED ADULTS IN THE HAART ERA**

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Background HIV-infected individuals have an increased risk of chronic kidney disease.

**Purpose** To evaluate the prevalence of different types of proteinuria and associated factors in a HIV-infected population with a high percentage (92%) of Caucasian origin.

Materials and Methods Cross-sectional study of all HIV-infected adults seen at the Montpellier University Hospital HIV outpatients unit over 6 months. Demographics, treatment history, comorbidities and laboratory data were collected from an electronic database and manual review chart. Spot urine protein to creatinine (uPCR) and albumin to creatinine (uACR) ratios, estimated glomerular filtration rate using the MDRD equation (eGFR) were assessed. Three types of proteinuria were defined: tubular proteinuria (uPCR > 200 mg/g and albuminuria/proteinuria < 0.5), glomerular proteinuria (uPCR > 200 mg/g and albuminuria/ proteinuria > 0.5), microalbuminuria (uPCR < 200 mg/g and uACR 30-300 mg/g). Multivariate logistic regression was used to identify independent factors of proteinuria for patients with eGFR> 60 mL/min/1.73 m<sup>2</sup>.

Results Characteristics for 1210 patients were: median age 48 years, 26% women, 7.1% black, 93% on HAART, 54% on tenofovir, median CD4 cell count 488 cell/ $\mu$ l, 73% with HIV viral load <20 copies/ml, 7.8% hypertensive, 3.4% diabetic, 18.2% HCV positive, 2.1% with history of kidney disease.eGFR was >90 for 59.5%, 60 to 90 for 36% and <60 for 4.5%. Of 1156 patients with eGFR>60 mL/ min/1.73 m<sup>2</sup>, proteinuria was observed in 159 patients (13.7%) [tubular: 124 (10.7%), glomerular: 35 (3%)] and microalbuminuria for 51 patients (4.4%)]. Factors associated with tubular proteinuria were: current regimen with tenofovir (OR 2.70), diabetes (OR 2.54), HCV+ (OR 1.62), AIDS stage (OR 1.54), older age (OR 1.46/10year increment). Diabetes (OR 5.15) and hypertension (OR 3.74) were associated with glomerular proteinuria.

**Conclusions** The prevalence of proteinuria or microalbuminuria was 18.1% in this predominantly white, cART (current antiretroviral therapy)-experienced cohort. Measuring uPCR and albuminuria may assist in the diagnosis of early renal disease.

### Abstract CPC-127 Table 1

1210 patients DFG < 60 DFG > 60

54 patients 1156 patients

No Proteinuria uPCR < 200 mg/g Proteinuria = uPCR > 200 mg/g 13.7% (159/1156) 86.3% (997/1156)

Tubular proteinuria alb/ Glomerular proteinuria Microalbuminuria uACR 30 to 300 mg/g prot < 0.5alb/prot > 0.5 10.7% (124/1156) 4.4% (51/1156) 3% (35/1156)

No conflict of interest.

## CPC-128 START SMART THEN FOCUS – A SURVEY OF **ANTIMICROBIAL STEWARDSHIP GUIDELINES IMPLEMENTATION IN ENGLAND**

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Background Start Smart then Focus Antimicrobial Stewardship (AMS) guidance for England was launched in November 2011 on European Antimicrobial Awareness Day.

Purpose To identify the extent of guideline implementation, whether the guidelines had improved AMS, and to collect examples of good practise.

Materials and Methods A web-based survey was developed using SurveyMonkey software, piloted, and then distributed through the microbiology, infectious diseases and pharmacy networks in July

Results There were 74 responses (44%) to the Start Smart then Focus (SSTF) guidance by September. SSTF was rated excellent or good by 65% for making AMS a Trust priority; by 57% for improving their AMS infrastructure; by 51% for improving prescribing practise; by 57% for improving audit and by 31% for improved usage reporting. Only 12% to 22% thought it was poor or less than satisfactory for the same criteria.

A formal review of SSTF has been done by 41%, with 17% planning to do so. 86% had done an informal review. 52% had developed an action plan.

The main barriers to implementation were a lack of microbiology/ infectious diseases time, then pharmacist time. An established AMS group, an enthusiastic pharmacist or microbiologist, or adequate time, were the main facilitators.

Putting the indication and duration or a review date on inpatient antimicrobial prescriptions were in place prior to SSTF in 67% and 73% of centres respectively. Since SSTF a further 9% have started and another 13% and 10% plan to implement these suggestions by April 2013.

Additional antimicrobial ward rounds have started or are planned since SSTF in medical wards by 20%, surgical wards by 19% and paediatrics by 10% of centres.

Conclusions The Start Smart then Focus Antimicrobial Stewardship guidance has helped to further implement AMS in England.

No conflict of interest.

# CPC-129 STUDY OF A PHARMACISTS CONTRIBUTION TO **MEDICINES RECONCILIATION IN CRITICALLY ILL PATIENTS**

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**Background** Medicines reconciliation in intensive care units (ICU) is essential in preventing medicines errors. Medicines reconciliation errors have been found to occur mainly in the transition of care.

Purpose To develop and evaluate a medicines reconciliation programme in critically ill patients.

Materials and Methods Prospective study. Discrepancies between chronic treatment and treatment prescribed by the hospital physician in patients admitted to the ICU were analysed. Medicines histories were obtained from the medical history and patient interview. If discrepancies were found, the ICU physician was contacted.