

## Abstracts

A3

FOLFIRI. CONCLUSIONS: FOLFIRI appears to have favorable cost effectiveness compared to other agents in the treatment of stage IV colorectal cancer, even after factoring in the impact of generic irinotecan.

## PODIUM SESSION I: DRUG UTILIZATION STUDIES

DU1

**PHYSICAL FUNCTION AND THE CONCOMITANT USE OF ANTICHOLINERGIC ANTIHISTAMINES AND CHOLINESTERASE INHIBITORS AMONG MEDICAID RECIPIENTS WITH DEMENTIA**

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**OBJECTIVES:** Antihistamines with anticholinergic properties (AA) are often used to treat comorbidities in patients with dementia. Use of AA with cholinesterase inhibitors (CHI) may counteract benefits of CHI in improving activities of daily living (ADL) or slowing ADL decline. Associations between use of AA with CHI and ADL function were assessed. **METHODS:** A retrospective cohort analysis of Indiana Medicaid claims and enrollment data from July 2001 through December 2005 merged with Minimum Data Set (MDS) identified persons ≥65 years, with dementia based on previously assessed criteria for identifying dementia and, receiving CHI. Persons taking anticholinergics other than AA during the study interval from first to last MDS assessment during CHI use were excluded. Piecewise repeated measures analysis used days taking AA and days not taking AA during each assessment interval as predictors to estimate influence of AA use on MDS ADL function scores (range 0–28, higher scores = more dependence). Presence of shifts in curves and changes in slopes defined changes in ADL. Age, gender, race, region, marital status and number of medications taken at the start of CHI use, Charlson comorbidity score and propensity score for receipt of AA were included as fixed covariates. **RESULTS:** A sample of 2,690 persons with mean age of 82 years, 75% female and, 90% white was identified. Of these, 691 (26%) used AA. Overall, a 0.45 ( $p = 0.02$ ) upward shift in ADL score indicated an immediate decrease in ADL function with AA use. Among persons with moderate ADL dependence (score 6–12), an increase in slope of 0.53 ( $p = 0.04$ ) per quarter also was observed indicating faster decline with AA use. **CONCLUSIONS:** Use of AA with CHI is associated with greater ADL decline in Medicaid recipients with dementia. Potential impact of AA use on physical function should be considered before prescribing AA with CHI.

not be administered within 14 days before or 24 hours after cytotoxic chemotherapy because of the potential for myeloid toxicity. This study examined use patterns of pegfilgrastim in real-life practice. **METHODS:** Analysis of health insurance claims data in 2000–2007 from >35 large health plans across the US was conducted. Patients who had a cancer diagnosis and chemotherapy within 120 days of their first pegfilgrastim injection were identified. The proportion of pegfilgrastim injections that were followed by administration of chemotherapy within 11 and 9 days was calculated. Analysis was also stratified by cancer type [Non-Hodgkin's lymphoma (NHL), lung, and breast]. **RESULTS:** A total of 13,526 cancer patients received 57,118 pegfilgrastim injections. NHL, lung, and breast cohorts comprised 2,722, 2,772, and 4,955 patients, respectively. Mean age (SD) was 55.0 (11.6) and women represented 65.9% of study population. Among all cancer types, 19.2% of pegfilgrastim injections had a chemotherapy claim within the following 11 and 9 days was the highest in NHL (18.9%), followed by lung (17.1%), and breast (16.2%). Similar results were observed in the 9-day sensitivity analysis (all cancer: 16.2%, NHL: 17.4%, lung: 16.0%, breast: 14.7%). **CONCLUSIONS:** Based on the retrospective analysis of this administrative claims database, the use of pegfilgrastim within 11 days of an administration of chemotherapy was observed in 15–20% of cases which is inconsistent with the recommended guidelines. Pegfilgrastim use in these situations may have the potential to increase sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy. Further research is being conducted to assess the related clinical and economic impact of this pattern of usage.

(For DU4 see page A185)

DU4

## PODIUM SESSION I: PERSONALIZED MEDICINE

PM1

**PERSONALIZED MEDICINE: FACTORS INFLUENCING REIMBURSEMENT**

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**OBJECTIVES:** Personalized medicine (PM) has attracted tremendous interest, but yielded few marketed products. We examined factors influencing the approval, coverage, and reimbursement of existing PM technologies. **METHODS:** We conducted six case studies of paired genetic tests and treatments in order to develop a framework to explain differences in adoption and reimbursement. We divided these case studies into three groups based on the purpose of the PM technology: Disease differentiation (HER2/neu with Herceptin (trastuzumab), hepatitis C genotyping with ribavirin/pegylated interferon, and Oncotype DX with chemotherapy); pharmacogenetics (UGT1A1 with irinotecan (Camptosar) and VKORC1/CYP2C9 with warfarin) and predisposition tests (BRCA 1/2 with prophylactic surgical measures and Oncotype DX with chemotherapy). **RESULTS:** The factors influencing approval, coverage and reimbursement appear based broadly on the purpose of, and evidence for, the PM technology, rather than the type of device regulation (i.e., PMA, CLIA or 510(k)). Disease differentiation test reimbursement is more widespread than other PM tests because of better evidence, guidelines, and clinician preferences. Predisposition tests may be reimbursed, despite the lack of randomized clinical trials, because people may value the information from testing, regardless of the clinical consequences. Pharmacogenetics (PGx) faces reimbursement hurdles because of the lack of evidence about clinical utility, though some companies bypass payers, and market PGx tests directly to consumers. An additional challenge for all PM is the cumbersome existing coding system for reimbursement and the lack of value-based arrangements. **CONCLUSIONS:** To date, the promise and hype of PM has outpaced its evidentiary support. In order to achieve favorable coverage and reimbursement and to support premium prices for PM, manufacturers will need to bring better clinical evidence to the marketplace and develop better support for the value of their products. More flexible reimbursement systems are needed to reward PM technologies that demonstrate evidence of value.

PM2

**IMPACT OF PHARMACOGENETICS ON THE COSTS OF MANAGING ADVERSE EVENTS WITH WARFARIN: A PROSPECTIVE ANALYSIS**

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**OBJECTIVES:** The anticoagulant effect of warfarin is subject to wide dose variability that may lead to hemorrhagic and thrombotic events. Variations in the CYP2C9 and VKORC1 genes together with clinical factors explain approximately 50% of this variability. The aim was to estimate the health care resource use, and overall costs associated with therapy from the perspective of the UK NHS. **METHODS:** As part of a 6-month prospective cohort study evaluating pharmacogenetic and clinical factors associated with warfarin therapy, patients' use of resources were recorded and costs valued (UK £ for 2006/7). Resource use was compared among patient sub-groups (defined by age; gender; CYP2C9 genotype; VKORC1 genotype; adverse events; co-medication; co-morbidities; and smoking status). Mean costs were calculated with 95%CI estimated using non-parametric bootstrap sampling. **RESULTS:** Complete data were available for 254 patients. During the study period a total of 930 anticoagulation visits (median 3 per patient, IQR 1, 5) and 4059 INR measurements (median 15, IQR 10, 20) were recorded. Of the 70 patients who had experienced an adverse event, 16 (6.3%) required hospitalisation. Controlling for age, gender, and co-morbidities in patients who experienced an adverse event, the OR for hospitalization was 8.35

**RACIAL DIAPARITIES AND BARRIER TO DRUG UTILIZATION IN PATIENTS WITH DIABETES IN THE UNITED STATES**

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**OBJECTIVES:** We sought to assess barriers to the appropriate statin usage measured through out-of-pocket payment by insurance status and racial disparities in patients with diabetes. **METHODS:** We analyzed 1,708 civilian, non-institutionalized patients with diabetes aged between 20 and 85 in the 2003 Medical Expenditure Panel survey (MEPS), a nationally representative survey in the United States which was linked to drug utilization files. We categorized patients with diabetes into six mutually exclusive insurance groups. We performed bivariate chi-square tests to assess the association between race and statin use, and insurance status and statin use during the year. We further performed multivariate logistic regression analysis to assess the effect of race/ethnicity on statin usage for patients of different races/ethnicity, controlling for socioeconomic variables, and co-morbid conditions. **RESULTS:** Among the population, 369 (21.6%) were African American, 66 (3.9%) Asian and 396 (23.2%) were Hispanic; the mean out-of-pocket payment per prescription of statins was \$61.4 (SD \$62.5) for Medicare patients, \$24.0 (SD \$43.7) for Medicaid patients, \$ 25.4 (SD \$49.0) for patients with dual eligibility, \$35.2 (SD \$33.5) for those with private insurance, \$76.7 (SD \$47.8) for those without insurance, and \$83.9 (SD \$90.5) for others. In bivariate analysis, statin usage was found to be significantly different across races and insurance status ( $p = 0.020$  and  $p < 0.0001$ , respectively). In multivariate regression analysis, compared to White patients, African American patients were less likely to use statin (adjusted OR 0.57, 95% CI 0.43–0.76,  $p < 0.0001$ ). Asian and Hispanic patients were marginally less likely to use statin (adjusted OR 0.60, 95% CI 0.34–1.05,  $p = 0.078$ ; and adjusted OR 0.75, 95% CI 0.56–1.00,  $p = 0.055$ , respectively). **CONCLUSIONS:** Drug utilization is associated with insurance coverage. Racial/ethnicity disparity is observed in drug utilization of patients with diabetes after adjusting for insurance status.

DU3

**PATTERN OF UTILIZATION OF PEGFILGRASTIM IN PATIENTS WITH CHEMOTHERAPY-INDUCED NEUTROPENIA: A RETROSPECTIVE ANALYSIS OF ADMINISTRATIVE CLAIMS DATA**

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**OBJECTIVES:** Pegfilgrastim is a long-acting granulocyte colony-stimulating factor (G-CSF) used to prevent or treat febrile neutropenia associated with myelosuppressive anticancer therapies. According to the prescribing information, pegfilgrastim should