year, pharmacy charges, sales tax, patient compliance, patient co-payments, hospital discount, hospital pharmacy costs, therapeutic drug monitoring (TDM), and wastage. A descriptive analysis of the frequency of reporting of the extracted data was performed. **RESULTS**: The dates and sources of drug costs were specified in the majority of cases (53 and 50 of 59 studies, respectively), but details of the routes of administration were absent from 39 studies. The source of drug costs was referenced in 48 studies. A minority of studies considered pharmacy charges(3), sales taxes(5), hospital discounts(3) or patient co-payments(1). The costs of TDM were reported in 2 out of 24 possible cases; and no evaluations accounted for costs associated with drug wastage. **CONCLUSIONS:** The costing of drugs in pharmacoeconomic studies is often poorly reported and sometimes poorly conducted. Estimates based on readily available list prices may not accurately reflect true costs to payers, and this may have a significant impact on estimates of cost-effectiveness. We propose recommendations for estimating drug costs for use in future studies.

CO4

COMPARISON OF INPATIENT COST ESTIMATION METHODS: USING DATA FROM A CYSTIC FIBROSIS TRIAL

Dinan M[1], Morgan Dewitt E[2], Grussemeyer C[1], Reed SD[1]
[1]Duke Clinical Research Institute, Durham, NC, USA, [2]Duke University, Durham, NC, USA

Inpatient costs are often assigned using reimbursement rates corresponding to diagnosis related groups (DRGs) or similar coding system. Other approaches to cost assignment may provide more valid estimates. **OBJECTIVE:** To evaluate different inpatient cost estimation methods utilizing data from the 2001–2005 National Inpatient Survey (NIS) applied to event-level data from a randomized trial of patients with cystic fibrosis and to compare these approaches within the NIS sample. **METHODS:** Hospitalizations in a Phase 3 clinical trial were matched (1:many) to NIS discharges representing cystic fibrosis patients based on ICD-9 diagnostic and surgical procedure codes. Costs for hospitalizations in the trial were estimated using these NIS discharges applying six different methods; mean cost, median cost, mean daily cost, median daily cost, DRG-based costs, and regression analysis. Cost estimation within the NIS sample was evaluated for each method by comparing root mean squared error (RMSE) and mean absolute percent error (MAPE) between predicted and actual discharge costs. **RESULTS:** All but two of the 98 hospital admissions from the trial could be matched with 10 or more NIS discharges. Mean estimates of inpatient costs in the trial ranged from $5,368 (SD = 2,071) with the standard DRG method to $16,635 (SD = 69,822) with the regression method. Of the six methods, median daily cost resulted in the smallest MAPE (51% ± 11% SE) with a RMSE of 12,597 within the NIS matched sample (N = 8,485), followed by the mean daily cost approach MAPE (60% ± 13% SE) with a RMSE of 12,248 and regression analysis (69% ± 12% SE). **CONCLUSION:** Different methods are available for estimating inpatient expenditures which may provide advantages over existing, more generalized cost estimation procedures such as DRGs. Further evaluation of such methods is warranted to improve the validity of costs assigned to hospitalizations in studies of patients with serious underlying conditions.

PODIUM SESSION II: CARDIOVASCULAR DISORDERS – Outcomes Research Studies

CV1

ASSOCIATION OF CARDIOMETABOLIC RISK FACTORS AND PREVALENT CARDIOVASCULAR EVENTS

Malone DC[1], Boudreau D[2], Nichols G[3], Raebel MA[4], Fishman P[5], Feldstein A[3], Ben-Joseph R[6], Okamoto LJ[7]
[1]University of Arizona College of Pharmacy, Tucson, AZ, USA, [2]United BioSource Corporation, Seattle, WA, USA, [3]Kaiser Permanente, Portland, OR, USA, [4]Kaiser Permanente Colorado, Denver, CO, USA, [5]Group Health, Seattle, WA, USA, [6]Sanofi-Aventis, Bridgewater, NJ, USA, [7]United BioSource Corporation, Bethesda, MD, USA

OBJECTIVES: Although cardiovascular disease causes substantial morbidity and mortality, how individual and groups of risk factors contribute to cardiovascular outcomes is incompletely understood. This study evaluated cardiometabolic risk factors and their relationship to prevalent diagnosis of acute myocardial infarction (AMI) and stroke. **METHODS:** We used retrospective data from three integrated health care systems that systematically collect and store detailed patient-level data. Adult enrollees were eligible for inclusion if they had all of the following clinical measurements including weight, height, blood pressure, high density lipoproteins, triglycerides, and fasting blood glucose or evidence of diabetes from July 1, 2003 to June 30, 2005. We used National Cholesterol Education Program Adult Treatment Panel III guidelines to determine qualifying levels for cardiometabolic risk factors. **RESULTS:** A total of 170,648 persons met the inclusion/exclusion criteria; 11,757 had no qualifying risk factors, 25,684 had one, 38,176 had two, and 95,031 had three or more risk factors. Compared to those without risk factors, persons with any one risk factor were 2.21 (95% CI: 1.78–2.74) times more likely to have had a diagnosis of AMI or stroke. The risk increased to 2.79 (95% CI: 2.26–3.42) for persons with two, 3.45 (95% CI: 2.80–4.24) for persons with three, 4.35 (95% CI: 3.54–5.35) for persons with four, and 5.73 (95% CI: 4.65–7.07) for persons with five risk factors. The highest risk was conferred by having the combination of risk factors of diabetes, hypertension, and dyslipidemia, with or without weight risk. **CONCLUSIONS:** This study demonstrates a direct association between an increasing number of cardiometabolic risk factors and prevalent diagnosis of AMI and stroke. The combination of risk factors conferring highest risk was diabetes, hypertension, and dyslipidemia.

CV2

COMPARISON OF CARDIOVASCULAR EVENT RATES IN SUBJECTS WITH TYPE-2 DIABETES MELLITUS WHO AUGMENTED FROM STATIN MONOTHERAPY TO STATIN PLUS FIBRATE COMBINATION THERAPY WITH THOSE WHO REMAINED ON STATIN MONOTHERAPY

Suh HS, Doctor JN
University of Southern California, Los Angeles, CA, USA

OBJECTIVES: To compare cardiovascular-event (CV) rates in subjects with type II-diabetes who augmented from short-term statin-monotherapy to statin + fibrate combination-therapy with those who remained on statin-monotherapy in a managed care setting. **METHODS:** "Combo-group" (defined as subjects who used statin less than six-months and augmented to statin plus fibrate for more than six-months) and "mono-group" (defined as subjects who used statin less than six-months and remained on statin for more than six-months) were identified among subjects with type-2 diabetes with 2-years intake-period (July 1, 2002-June 30, 2004) and three-years follow-up using administrative claims from a Westcoast-based health plan in U.S. covering 4million lives. Outcomes measure was any occurrence of CV including ischemic heart disease, cerebrovascular disease, and peripheral vascular disease. A multivariate logistic model was developed to evaluate adjusted CV-risk. Multicollinearity test, model sensitivity, and specificity analyses were performed. **RESULTS:** Mean (+/–SD) age was 58(+/–11) years in combo-group(N = 322) and 61(+/–11) years in mono-group (N = 9955). In combo-group, mean(+/–SD) treatment-duration was 909(+/–409) days for statin plus fibrate following 118(+/–52) days for statin-monotherapy. In mono-group, mean(+/–SD) treatment-duration was 1339(+/–451) days for statin-monotherapy following 115(+/–51) days for statin-monotherapy. Unadjusted CV-rates between groups were not significantly different (odds ratio [OR] = 0.93, P = 0.496). Adjusting for age, gender, prior CV, CV related pharmacy-costs, Elixhauser-comorbidity, and diabetes with complication, combo-group experienced 23% risk reduction in CV compared with mono-group (OR = 0.67, P = 0.006). All covariates were significantly associated with CV-rates. The model did not suffer from multicollinearity and model sensitivity (71.8%) and specificity (76.6%) were satisfactory. **CONCLUSIONS:** In a managed care population with type-2 diabetes after adjusting for known baseline differences, CV-risk was significantly lower among subjects who augmented from short-term statin use to statin + fibrate combination-therapy compared with those remained on statin-monotherapy. We hope this result will be useful in health policy to reduce CV-risk in diabetics. Future research is in progress to address the causality behind this association.

CV3

THE IMPACT OF PROTON PUMP INHIBITORS ON CARDIOVASCULAR-RELATED EVENT COSTS IN PATIENTS INITIATING CLOPIDOGREL

Aubert RE, Stanek EJ, Yao J, Frueh FW, Teagarden JR, Epstein RS
Medco Health Solutions, Inc, Franklin Lakes, NJ, USA

OBJECTIVES: Proton pump inhibitors (PPI) have been associated with inhibiting the impact of clopidogrel on cardiovascular risk. This study explores the costs associated with cardiovascular events among patients taking clopidogrel and PPIs compared to patients on clopidogrel alone. **METHODS:** We retrospectively analyzed 16,690 patients who had undergone percutaneous coronary intervention (PCI) with stenting between October 2005 to September 2006, and who received clopidogrel alone (N = 9862) or with a PPI (N = 6828). The primary endpoint was the incidence of major cardiovascular event defined as hospitalization for myocardial infarction/unstable angina (MI/ACS), stroke/transient ischemic attack (TIA), percutaneous coronary intervention/coronary artery bypass graft (PCI/CABG), or cardiovascular death over a 12-month period. For each primary end-point, event costs per patient-year of follow-up (US$2009) were calculated using Healthcare Cost and Utilization Project (HCUP) data for 2006 hospitalization events inflated by 5%/year. Costs were derived from HCUP charges applying an actual cost: charge ratio of 0.4 for hospitalization. **RESULTS:** The rate of primary end-point was 25.1% in patients on combined clopidogrel and PPI therapy and 17.9% in patients not receiving a PPI (hazard ratio 1.51, 95% confidence interval 1.39–1.64, $p < 0.001$). Hospitalization event costs per pt-year related to the composite primary end point were $6061 in patients on combined clopidogrel-PPI therapy and $4400 in patients taking clopidogrel alone (diff = $1662 per pt-yr; 37.8%). Costs differences between combined clopidogrel-PPI therapy and clopidogrel alone were driven by MI/ACS ($3903 vs. $2367; 65%) and PCI/CABG ($4283 vs. $3508; 22%). **CONCLUSIONS:** Combined clopidogrel and PPI therapy significantly increased the risk of major cardiovascular events and associated costs over 12-months following PCI/stent placement.

CV4

ASPIRIN VERSUS CLOPIDOGREL IN COMBINATION WITH PROTON-PUMP INHIBITORS FOR PREVENTION OF RECURRENT PEPTIC ULCER COMPLICATIONS IN PATIENTS WITH PREVIOUS GASTROINTESTINAL BLEEDING

Hsiao FY[1], Tsai YW[2], Huang WF[3], Wen YW[4], Chen PF[4], Chang PY[3], Kuo KN[4]
[1]University of Maryland School of Pharmacy, Baltimore, MD, USA, [2]National Health Research Institutes, Zhunan Town, Taiwan, [3]National Yang-Ming University, Taipei, Taiwan, [4]National Health Research Institutes, Miaoli County, Taiwan

OBJECTIVES: To compare the risk of recurrent peptic ulcer in patients who have experienced gastrointestinal bleeding and who require ongoing anti-platelet therapy (aspirin or clopidogrel) whether using proton-pump inhibitor (PPI) in combination. **METHODS:** In this population-based, retrospective cohort study, we used Taiwan's 2000–2006 National Health Insurance Database to explore the risk of hospitalization