peutic intervention and trial monitoring and outcome evaluation. Complicating this situation is inconsistencies in CFS case definition. The main objective is to provide a critical review of the similarities and differences between the varying approaches to CFS case definition. The conflicts and controversies that have emerged as a result of the differing methodological criteria for CFS are highlighted and the potential impact on future research is identified. A critical review of the most frequently used case definitions in CFS was conducted. There are currently five case definitions of CFS, however, the most prominent is the 1994 Centre for Disease Control and Prevention Case Definition. However, prima facie comparative advantages of this definition are elusive and indeed, it has been widely criticized for its lack of specificity. Counterintuitively, there is little compelling evidence to support the efficacy of any of the case definitions have produced evidence to demonstrate its accuracy or precision at defining cases of CFS. A summary description of the symptom profile for each of the case definitions is provided. The inconsistencies that have emerged in CFS research as a consequence of differing approaches to case definition are contrasted and discussed. Clinical and research implications are highlighted.

PHP13 IQWIG AND HIQA, WHAT ARE THEY GOOD FOR? THE EVOLUTION OF THE HTA AGENCY: TIME FROM CREATION TO FIRST ASSESSMENT AND IMPACTFUL APPRAISAL

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OBJECTIVES: To evaluate the time spent from the creation or charter of an HTA agency to endpoints indicating their effectiveness, such as publication of assessment or influence. Processors of HTA incorporation of assessment into meaningful decision making. RESULTS: This study looks at the creation of HTA agencies (e.g. AHRO, HIQA, IQWIG, PBAC, CADTH and NICE) and their evolution in terms of roles in assessment (advisory, coordinating, decision-making) and the impact they have with appraisal. CONCLUSIONS: It has been demonstrated that the time it takes for an agency to generate assessments impacting patient access varies widely. For example, in Ireland, HIQA was chartered in May 2007, and entrusted with performing HTA assessments. In 2008 and 2009, HIQA has published one health technology assessment per year, both of which were received and in turn implemented by the Minister for Health and Children. In comparison, NICE in the UK was founded in 1999, but its appraisals were not supported by mandate until 2005. Meanwhile, HTAs driven by DAHTA@DIMDI in Germany are known to rarely play a role in pricing and reimbursement. CONCLUSIONS: The evolution of HTA bodies has varied from country to country. However, evolution in scope and impact may provide useful lessons for countries where HTA is receiving renewed emphasis or where appraisal is under consideration for implementation, especially as new agencies are created and existing agencies evolve.

PHP114 OPTIMIZING THE ORGANIZATION; MIGRATING HEALTH SERVICES RESEARCH OPERATIONS INTO THE COLLABORATIVE SCIENCE CENTER OF EXCELLENCE

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The execution and management of Health Services Research projects can be an onerous task. Often there is no centralized body of knowledge within an organization around process and requirements. This leads to long execution timelines, difficulties with vendors and ultimately reduced productivity. The Collaborative Science Center of Excellence (CSCO) was established in 2006 at Bristol-Myers Squibb (BMS). This group manages the global operations of a wide variety of programs, a portion of which includes worldwide investigator sponsored research, non-clinical research, expanded access, and risk evaluation and mitigation programs. Beginning July 2009, operational management of the entire US Health Economics and Outcomes Research (HEOR) book of work was moved from the OR Scientists into the CSCO. This included administration, contract execution, master service agreement negotiation, financial management, protocol writing, AMCP dossier updates, and invoice tracking and payment. Within the first year over 90 projects were migrated into the CSCO. Benefits the Health Services Research group realized included: 1. A consolidated 2010 and planned 2011 book of work; 2. A reportable repository of project information, 3. HEOR protocol and AMCP dossier improvement through standardization of in-house scientific writing; 4. Expedited contract execution, 5. Innovative cost-sharing; 6. Tiered and batched review of contracts reduced corporate legal hours; 7. Rapid response to organizational queries. Centralized process management unlocked latent value by allowing OR Scientists to focus on value-added activities, increased organizational transparency and agility, and moved operations to a lower cost environment.

POSTER SESSION I:
DISEASE-SPECIFIC STUDIES
Cardiovascular Disorders – Clinical Outcome Studies

PCV1 DOES ROUTE OF ADMINISTRATION FOR ESTROGEN THERAPY IMPACT ON RISK OF VENOUS THROMBOEMBOLISM: A STRADIAL TRANSITIONAL SYSTEM VERSUS ORAL ESTROGEN-ONLY THERAPY

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OBJECTIVES: To evaluate the risk of developing venous thromboembolism (VTE) events associated with the use of estradiol transdermal system (ETS; Vivelle-Dot®) relative to oral estrogen-only hormone therapy (HT) agents. METHODS: A health insurance claims analysis was conducted using the Thomson Reuters MarketScan database from January 2002 through October 2009. Patients ≥35 years old newly initiated on an ETS or oral estrogen-only HT with ≥2 dispensions were analyzed. VTE was defined as ≥1 diagnosis code for deep vein thrombosis or pulmonary embolism. As a secondary endpoint, we assessed incident VTE resulting in hospitalization. Cohorts of ETS and oral estrogen-only HT were matched 1:1 based on both exact factor and propensity score matching. Incidence rate (IRR) was used to compare the rates of VTE between the matched cohorts. Remaining baseline demographics were included as covariates in the appropriate models. RESULTS: Among the matched ETS and oral estrogen-only HT users (27,018 subjects in each group), the mean (SD) ages of the cohorts were 48.9 (7.1) years; in each cohort 6,044 (22.4%) and 1,788 (6.6%) patients had a hysterectomy and an oophorectomy at baseline, respectively. The mean (median) drug exposure for the ETS and from estrogen-only HT users was 391 (264) and 401 (272) days, respectively. A total of 115 ETS users developed VTE compared to 164 subjects in the estrogen-only HT cohort (unadjusted IRR: 0.72; 95% CI: 0.57-0.91, P = 0.006). After adjustments, ETS remained statistically significantly associated with a lower incidence (85% reduction, P = 0.0134) of VTE. The incidence reduction for hospitalization-related VTE events among the ETS users was even more pronounced with the adjusted incidence being 62% lower for ETS users relative to oral estrogen-only HT users. CONCLUSIONS: Results of this large population-based study showed that patients receiving ETS had a significantly lower incidence of VTE compared to patients receiving oral estrogen-only HT.

PCV2 THE RISK OF CARDIOVASCULAR EVENTS ASSOCIATED WITH DIETARY CALCIUM AND VITAMIN D SUPPLEMENTS IN PATIENTS WITH OSTEOPOROSIS

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OBJECTIVES: Calcium and vitamin D supplements have been widely used and recommended for women to prevent or delay the onset of osteoporosis and the risk of osteoporotic fractures. Other benefits include the improvement of bone mineral density and lipid levels and a lowering of body weight. In theory, the beneficial effects of calcium and vitamin D suggest improvements in cardiovascular health. Recent publications suggest the contrary and add to increase serum calcium as a risk factor for adverse cardiovascular events. This study examines whether the exposure to these supplements is associated with cardiovascular events. METHODS: The study was based on California Medicaid (Medi-Cal) fee-for-service administrative claims data from January 1995 to December 2002. The study population consisted of patients >50 years with records of diagnoses of osteoporosis followed from diagnoses to the end of eligibility. Patients were excluded for pre-index use of the supplement or diagnosis of cardiovascular events or drug induced osteoporosis. Propensity score matching based on age, gender, elixhauser comorbidities and eligibility criteria created case (n = 1,594) and control groups (n = 4,782). Chi-square analysis was conducted for comparison of the cardiovascular events defined as ICD9 codes for myocardial infarction and searchable terms of “cerebral hemorrhage, ischemia” for stroke. RESULTS: No statistically significant relationship was found between the study groups for stroke (p = 0.56) and myocardial infarction (p = 0.54). Components of stroke included cerebral artery occlusion (p = 0.94), preclinical artery occlusion (p = 0.27), intracranial hemorrhage (p = 0.005) and subarachnoid hemorrhage (p = 0.05). The clinical benefits of the supplements were evident with subarachnoid hemorrhage with 0 recorded diagnoses in the case group compared to 12 recorded diagnoses in the control group, however statistical significance was not established. CONCLUSIONS: The use of calcium and vitamin D supplementation did not change the relationship to adverse cardiovascular events. Moreover, no broad cardio-protective effects can be concluded from the study.

PCV3 RISK OF HOSPITALIZATIONS FOR VENOUS THROMBOEMBOLISM IN ATYPICAL VERSUS TRADITIONAL ANTIPSYCHOTIC USERS IN A NATIONAL SAMPLE OF MEDICARE BENEFICIARIES: A CLAIMS DATA ANALYSIS

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OBJECTIVES: To examine the difference between typical and atypical antipsychotic drug use in the risk of hospitalization for venous thromboembolism (VTE) in an elderly medicare population. METHODS: This is a retrospective, using ≥5% national sample of 2006-2007 Medicare claims data. Medicare beneficiaries with continuous Part A, B, and D enrollment in 2006-2007 who initiated atypical or typical antipsychotic drug therapy in July 2006-June 2007 were included. All study subjects were followed for a period of 180 days from the date of index prescription. Atypical and typical users were matched on propensity score, calculated using pre-index demographics, clinical comorbidities, and medication use. A conditional logistic regression model stratified on the propensity score-matched pair using the greedy matching algorithm was used to compare the risk of hospitalization for VTE in new users of atypical and traditional antipsychotic drugs. Sensitivity analysis in the unmatched cohort was performed using propensity score as a continuous, linear term in logistic regression. RESULTS: A total of 15,637 new users of atypical and 2,337 new users of typical antipsychotic drugs were identified. There were 472 (2.6%) hospitalizations with a diagnosis code for VTE diagnosed in atypical and 55 (2.4%) were typical antipsychotic users. A 1:1 propensity score match yielded 2,337 matched pairs (4,666 individuals). In the matched cohort, 55 typical and 64 atypical drug users were hospitalized for VTE in the follow up period. Compared to typical antipsychotic users, users of atypical antipsychotics were less likely to have
VTE-related hospitalizations but the results were not statistically significant (odds ratio: 0.857; 95% CI: 0.596-1.233). Sensitivity analysis results agreed with the primary findings (odds ratio: 0.831; 95% CI: 0.622-1.110). CONCLUSIONS: The risk of hospitalization for VTE was found to be similar for users of typical and atypical anticoagulant medication in this elderly Medicare population.

PCV4: TREATMENT PATTERNS, CLINICAL AND ECONOMIC BURDEN OF VENOUS THROMBOEMBOLISM IN ABDOMINAL SURGERY PATIENTS

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OBJECTIVES: To examine prophylaxis use as it relates to the clinical and economic burden of venous thromboembolism (VTE) in abdominal surgery patients.

METHODS: A retrospective study (January 1, 2005 to December 31, 2007) was conducted using a subset of the MarketScan Commercial and Medicare Supplemental Claims database. Patients' demographics, clinical and discharge statuses were compared using Chi-square testing and standardized difference. Risk-adjusted healthcare visits and costs were estimated using the General Linear Model. Potential risk factors for VTE events were selected using the Cox Proportional Hazard Regression Model.

RESULTS: In patients who underwent abdominal surgery (n = 49,355), 24,473 (49.59%) received anticoagulant therapy during their hospitalization and until 30 days after discharge. VTE events for patients who received anticoagulant prophylaxis were 4.63% versus 7.02% for patients who did not receive anticoagulant prophylaxis. Compared with patients without VTE in the 6-month follow-up period, patients with VTE were more likely to be older, have comorbid conditions including previous VTE, major and minor bleeding, and cancer, and to have higher baseline health care visits and costs. After risk adjustment for pre-specified covariates, inpatient costs ($16,677 vs. $10,774), outpatient costs ($15,426 vs. $7,424), pharmacy costs ($2,541 vs. $1,862), and readmission rates (0.23% vs. 0.12%) were higher in patients who had VTE. In the multivariate analysis, appropriate anticoagulant prophylaxis was significantly associated with the reduced risk of VTE (HR: 0.515).

CONCLUSIONS: The VTE event rate was lower for patients who received prophylaxis compared with those who did not. Since the health care costs of patients with an event were significantly higher than those of patients without an event, prophylaxis use is associated with lower health care costs.

PCV5: PREVALENCE, INCIDENCE, AND OUTCOMES OF CRITICAL LIMB ISCHEMIA IN THE MEDICARE POPULATION IN THE UNITED STATES

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Critical limb ischemia (CLI) is a severe obstruction of the arteries that seriously decreases blood flow to the extremities resulting in amputation of the affected limb if left untreated. Despite the severity of the disease, there is a lack of data on prevalence, incidence and outcomes of CLI in the United States.

OBJECTIVES: We conducted a large population-based study to directly estimate prevalence, incidence and outcomes of CLI in the United States. METHODS: Data from January 2006 to December 2008 were extracted from the U.S. Medicare database. We estimated 1) age, gender, race and diabetes-specific CLI prevalence and incidence rates using the direct standardization method, and 2) factors associated with CLI outcomes (leg revascularization, non-atheromatous amputation, and mortality) among the CLI population, using the Cox proportional hazard regression model.

RESULTS: A total of 68,074 patients were identified with eligible CLI ICD-9 codes in 2007 of whom 51,259 were analyzed. A Cox model evaluating 2 years of data, CLI prevalence and mortality, and leg revascularization incidence rates in this elderly population were 0.23% (0.28% for male and 0.20% for female patients) and 0.20% (0.23% and 0.17%), respectively. Just as with prevalence, incidence increased sharply among beneficiaries aged 65-69 (0.33%) to ≥85 (0.31%), was around 2.3 times higher in black patients compared to white patients, and 8.6 times higher in diabetic patients compared to non-diabetic patients. The overall incidence rates of leg revascularization and non-atheromatous amputation in the year after CLI diagnosis were 29.7% and 25.2%, respectively. Compared to revascularization, patients who are older, male, black, and have diabetes had a higher incidence of amputation. 30.3% of the patients died within the first year after CLI diagnosis. CONCLUSIONS: This first U.S. nationwide-based study shows that prevalence, incidence and outcomes are different according to patients' socio-demographic characteristics and comorbidities, suggesting that CLI patient management varies among the U.S. population.

PCV6: ANALYSIS OF MYOCARDIAL INFARCTION RELATED CLINICAL OUTCOMES, HEALTH CARE UTILIZATION AND COSTS OF PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

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OBJECTIVES: To estimate clinical outcomes, healthcare utilization and cost burden of patients who suffered a myocardial infarction during the 180 days after diagnosis of non-valvular atrial fibrillation (NVAF) and compare it with patients who did not suffer a myocardial infarction.

METHODS: Based on 2005-2007 U.S. Medicare advantage insurance claim files, patients aged 65 years and older who had two or more primary diagnoses for NVAF occurring within 30 days of one another were selected. The 180-day follow-up event rates, healthcare facility use and costs for patients with a myocardial infarction and those without were compared. Risk adjustment was performed using the propensity score matching method with the ProbChoice™ algorithm.

RESULTS: In patients who were identified with NVAF (n = 18,575), 258 (1.39%) suffered a myocardial infarction during the 180 days after NVAF diagnosis. Patients were not significantly different in terms of gender, region, and baseline comorbid conditions. After risk-adjustment for pre-specified covariates, mortality (10.08% vs. 3.9% p < 0.0001), outpatient emergency room (ER) visits (82.56% vs. 48.06% p < 0.0001), acute coronary syndrome (63 vs. 2/100 person years), ischemic stroke (31 vs. 4/100 person years), major bleeding (4 years) and non-major clinical relevant bleeding (24 vs. 6/100 person years) were all higher for patients who suffered a myocardial infarction compared to those who did not. Besides inpatient costs ($26,646 vs. $9,393), risk-adjusted outpatient ER costs ($1,176 vs. $863) were also higher for myocardial infarction patients. The overall adjusted difference in health care costs is significant ($16,584 vs. $10,366 p < 0.0001). CONCLUSIONS: Most of the adverse events analyzed were higher for patients who suffered a myocardial infarction after NVAF relative to patients who did not. Total health care utilization and costs were also significantly increased.

PCV7: ANALYSIS OF TREATMENT PATTERNS AND COSTS FOR VENOUS THROMBOEMBOLISM, MAJOR AND MINOR BLEEDING EVENTS IN HOSPITALIZED MEDICALLY-ILL PATIENTS

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OBJECTIVES: To examine the prophylaxis use, incidence of VTE, major bleeding, minor bleeding and associated economic burden over 90 days in hospitalized medically-ill patients.

METHODS: A retrospective study (January 1, 2005 to December 31, 2007) was conducted using a subset of the MarketScan Commercial and Medicare Supplemental Claims database. Patients' demographics, clinical and discharge statuses were compared using Chi-square testing and standardized difference. Risk-adjusted healthcare visits and costs were estimated using the General Linear Model.

RESULTS: Model.

CONCLUSIONS: Patients' demographics, healthcare visits and costs were compared using Chi-square testing and standardized difference. Risk-adjusted total healthcare costs between patients with events and without were estimated using the General Linear Model.

RESULTS: In patients who were identified as medically ill (n = 12,077), 6,646 (53.52%) received anticoagulant therapy during their hospitalization and until 30 days after discharge. Compared with patients who did not receive any anticoagulant prophylaxis, patients who received anticoagulant prophylaxis had significantly lower VTE events (1.47% vs. 3.58%, p < 0.0001). Although there was no significant difference in rates of major bleeding and minor bleeding, after risk-adjustment for pre-specified covariates, patients with outcome events were significantly associated with higher total health care costs (VTE: $40,523 vs. $17,698 p < 0.0001; Major bleeding: $27,430 vs. $18,137 p < 0.0001; Minor bleeding: $25,696 vs. $17,410 p < 0.0001). CONCLUSIONS: Despite existing guidelines, few medically-ill patients are receiving anticoagulant prophylaxis. Appropriate anticoagulant prophylaxis use results in lower VTE event rates and total follow-up health care costs in hospitalized medically-ill patients.

PCV8: EVALUATION OF A SAFETY INITIATIVE AND OUTCOMES FOR PATIENTS ON STATIN-FIBRATE COMBINATION THERAPIES IN THE VETERANS AFFAIRS POPULATION

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OBJECTIVES: To determine the reported higher incidences of adverse events in patients on combination statins and fibrates compared to statins alone, the Veterans Affairs (VA) San Diego initiated an intervention to reduce the number of patients on combination therapies. This study aimed to evaluate the effectiveness and safety of statin-fibrate combination therapies within the VA population.

METHODS: This was a retrospective cohort study of VA medical, pharmacy, and laboratory data. Patients on a statin and fibrate combination in June 2008 were selected and stratified based on continuation or discontinuation of combination therapy by June 2009. Hyperlipidemic measures, safety measures, and adverse events were obtained pre- and post-intervention. Chi-square and ANOVA tests were utilized to test between-group differences and paired t-tests were conducted to analyze within-group differences at pre- and post-intervention. Repeated measures regressions were used to assess longitudinal differences between groups over time.

RESULTS: No differences in rates of cardiovascular disease were found between patients who continued and discontinued combination therapy at baseline and one year later. No incidences of rhabdomyolysis and pancreatitis were reported. Compared to those who continued combination therapy, those who discontinued combination therapy had significantly lower total cholesterol (184 versus 172 mg/dL, p < 0.029), high density lipoprotein (HDL) cholesterol versus 132 mg/dL, p < 0.006), and lower levels of triglycerides (LDL) (82 versus 115 mg/dL, p < 0.006) at pre-intervention. There were no significant longitudinal differences between groups over time. Within the patients who discontinued combination therapy, AST and ALT were significantly lower after the intervention while total cholesterol and LDL levels were higher post-intervention. Within those who continued, ALT was lower while triglyceride, HDL, and CK were higher post-intervention. CONCLUSIONS: Discontinuation of statin-fibrate combination therapy did not have a significant impact on the management of hyperlipidemia measures and no differences in adverse events were observed. Further studies should be done to assess the long-term effects of statin-fibrate combination therapy.