

reference measure) and one fingerstick analyzed by the Hemochron POC device. Consistent with published FDA recommendations, the previous standard QA analysis included linear regression, correlation and Bland Altman analysis. The novel QA analysis features thorough descriptive analysis and a validated method to estimate when INR measures lead to the same clinical decision. **RESULTS:** 1,666 paired INRs were collected. Standard QA analysis deemed the Hemochron device acceptable. Notably, the correlation between the Hemochron and laboratory was 0.9. Our novel analysis revealed the Hemochron never reported seven INR values: 2.1, 2.7, 3.1, 3.5, 3.8, 4.1, and 4.4. Furthermore, the Hemochron systematically inflated lower INRs and deflated higher values. Consequently, 30% (503 / 1,666) of clinical decisions were predicted to differ using the Hemochron. The laboratory was nearly twice as likely to report an INR below the target range (RR: 1.9, 95% CI: 1.7–2.1) than the Hemochron. **CONCLUSIONS:** Standard QA analysis missed clinically important deficiencies in the Hemochron device. Our novel analysis revealed the Hemochron does not report all INR values and leads to incorrect clinical decisions an unacceptably large proportion of times. The Hemochron device has been replaced in our institution. QA analyses should be reported in explicitly clinical terms so decision-makers understand the implications to patient care.

PCV148

RELATIONSHIP BETWEEN VENOUS THROMBOEMBOLISM AND HOSPITAL QUALITY

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OBJECTIVES: To examine the association between venous thromboembolism (VTE) events and hospital quality for patients who underwent major orthopedic surgery. **METHODS:** Based on 2005–2007 national Medicare claims, all patients who underwent major orthopedic surgery were identified. Rates for patients who had a VTE event during their initial hospitalization were calculated. By using the CompQual™ scoring algorithm, every provider in the Medicare dataset was ranked according to their quality. This algorithm, with an empirical Bayesian approach, combines volume and mortality rate of hospitals to create an index score. Hospitals are ranked in quintiles. Logistic regression was used to see the effect of quality on VTE event rates. **RESULTS:** We obtained a sample that included 642 patients in the pulmonary embolism (PE) only group, 1950 patients in the deep vein thrombosis (DVT) only group, and 153 patients in the both PE and DVT group. After controlling for patients' demographic and clinical factors, VTE events in low quality hospitals were almost 2.5 times higher than VTE events in high quality hospitals ($p = 0.000$). **CONCLUSIONS:** Any policy implementation that would decrease the variation in hospital quality would have a direct effect on the rates of VTE events.

PCV149

QUALITY OF PHARMACEUTICAL CARE PROVIDED IN A CHRONIC DISEASE: GEOGRAPHIC VARIATION, PROCESS OF CARE MEASURES AND CLINICAL OUTCOMES

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OBJECTIVES: To determine association of recommended pharmacotherapy in CHF with geographic variation in clinical outcomes. **METHODS:** Veterans with at least one outpatient visit with CHF diagnosis from FY2000–2001 were included in a cohort. Patients with non-utilization of VA for two years were excluded. Twenty-two Veteran Integrated Service Network (VISNs) of the VA were geographic units of analyses. Outcomes evaluated were: death, all-cause hospitalization and heart failure hospitalization. Recommended pharmacotherapy was measured by use of ACE inhibitors, ARBs and Beta-blockers. Follow up period was one year post index date of CHF diagnosis. We accounted for patient factors (gender, race, age, co-morbidities, severity of illness, co-medications, adherence) and process of care measures (prescription of recommended pharmacotherapy). Multivariate logistic regression models were used to calculate observed-to-expected (O/E) ratios across VISNs. Separate models were constructed accounting for patient factors, process of care measures and structure (VISNs). We ranked the outliers and interpreted, in context of, the quality of pharmaceutical care provided. **RESULTS:** We analyzed 125,239 CHF cases with enough power to detect differences across VISNs. About 60% patients were on ACE inhibitors, 8% on ARBs and 49% on Beta Blockers. Factor of variance in prescription rates ranged from 1.11 to 2.79. Strong correlation was observed between prescription rates and outcome rates (–0.48 to –0.54). c-indexes for all the models were above 0.7. Change in the outlier status, from the model containing patient factors versus the model with patient factors and process of care factors, indicated change in the quality of pharmaceutical care provided by the VISNs. **CONCLUSIONS:** In 1998, VA implemented Quality Enhancement Research Initiative (QUERI) to systemize quality improvement. During FY2000–02, significant variations were observed in prescription and outcome rates, despite efforts to synchronize quality of care. Differential prescription rates and differential adherence rates led to the variations in the outcomes.

PCV150

UTILIZATION OF SECONDARY PREVENTIVE MEDICATIONS FOLLOWING ACUTE MYOCARDIAL INFARCTION (AMI): A RETROSPECTIVE COHORT ANALYSIS OF A MEDICAID POPULATION

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OBJECTIVES: To assess the utilization of secondary preventive medications after an acute myocardial infarction (AMI) in a state Medicaid population. **METHODS:** The study was a retrospective cohort analysis using a state Medicaid claims database. The study cohort was identified based on inpatient claims for discharges with either a primary or secondary diagnosis code for AMI (ICD-9 code: 410.XX) between January 1, 2002 and December 31, 2006. The study cohort was restricted to patients who were < 65 years old and were enrolled in the traditional fee-for-service program. Utilization of secondary preventive medications was considered appropriate if patients filled at least 1 prescription for each of the recommended medications (angiotensin-converting enzyme (ACE) inhibitors/angiotensin-receptor blockers, beta-blockers, and statins) in the 90 days after discharge. Logistic regression analysis was used to identify demographic and clinical predictors associated with the recommended utilization of secondary preventive medications. **RESULTS:** The final study cohort consisted of 752 patients discharged following hospitalization for AMI. The mean age of the cohort was 53±7.9 years and there were a higher proportion of females (59%) and whites (84.6%) in the study sample. Only 43.25% of the patients appropriately utilized all the recommended medications after AMI. Regression analysis indicated that use of percutaneous transluminal coronary angioplasty (PTCA) procedures during the hospitalization (OR = 2.64; 95% CI:1.78–3.89); having a diagnosis of hyperlipidemia (OR = 1.71; 95% CI:1.17–2.51), hypertension (OR = 2.00; 95% CI:1.18–3.39) or asthma (OR = 0.56; 95% CI:0.37–0.87); and utilization of the recommended medications prior to hospitalization (OR = 2.42; 95% CI:1.30–4.50) were significant predictors of appropriate utilization of secondary preventive medications. **CONCLUSIONS:** Post-AMI patients in a state Medicaid program had sub-optimal utilization of secondary preventive medications; however, the utilization rates were higher than in previous studies that primarily focused on an older cohort of patients.

PCV151

ASSESSMENT OF MEDICATION UTILIZATION PATTERN OF PATIENTS WITH SYSTOLIC HYPERTENSION AND COMPELLING INDICATIONS IN A PRIMARY CARE PRACTICE

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OBJECTIVES: The study evaluated medication utilization pattern of patients aged 50 years and older with systolic hypertension (SH) in a primary care setting. Specific objectives were: 1) to assess the prevalence of comorbid conditions by patient demographics, and 2) to study the utilization of antihypertensive classes based on compelling indications. **METHODS:** Retrospective analysis was conducted using GE Centricity electronic medical records (EMR) from a large primary care physician group. Patients with SH (ICD-9-CM 401.xx) with systolic blood pressure (SBP) >140 mmHg, diastolic blood pressure (DBP) <90 mmHg, 50 years and older, continuously enrolled in the database and having 12 months pre- and post-index date observations were identified. Patients on dialysis were excluded from the study. Demographics, office visits, clinical measures, compelling indications for antihypertensive treatment and comorbidities, drug regimens over a 2-year period were collected. Descriptive analysis was performed using SPSS version 17. **RESULTS:** A total of 22,074 patients had hypertension out of which 1,616 met the inclusion/exclusion criteria for SH. Mean age was 68.88±11.38 years; 59.03% females, and 78.4% had one or more compelling indications/comorbidities. Hyperlipidemia was the most prevalent comorbid condition (70.9%, n = 1,145), followed by diabetes (24.7%, n = 399) and coronary artery disease (15.6%, n = 252). A total of 16.4% of SH patients were on statins, followed by CCBs (16.2%) and ACEIs (15.3%). By compelling indications (top medication class), 18.8% patients with diabetes were taking CCBs, 16.9% patients with hyperlipidemia were taking CCBs, and 15.8% patients with CAD were taking ACEIs. **CONCLUSIONS:** Evidence from large clinical trials demonstrate that appropriate use of antihypertensive therapy in patients with SH and compelling indications reduces the incidences of stroke, myocardial infarction, and heart failure. Thus, it is important for physicians to follow the Seventh Joint National Committee (JNC 7) guidelines to improve quality of care and health outcomes in patients with SH.

PCV152

TREATMENT PATTERNS, RESOURCE UTILIZATION AND COSTS OF PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION IN THE US

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OBJECTIVES: Oral therapies that target nitric oxide signaling (sildenafil) or endothelin signaling (bosentan and ambrisentan) are used to treat pulmonary arterial hypertension (PAH). We studied the treatment patterns, resource utilization, and costs associated with these three oral therapies in a US population of commercially insured patients. **METHODS:** This was a retrospective study using claims from a large health insurance database. Commercial and Medicare Advantage patients with claims indicating PAH between January 2006 and December 2008 and whose first PAH treatment was for ambrisentan, bosentan, or sildenafil were selected for study inclusion. PAH treatment patterns, PAH-related utilization, and PAH-related costs were assessed during a minimum 6 month follow-up period. **RESULTS:** A total of 727 patients were

identified for study inclusion. Sildenafil was the most common initial treatment (n = 455 patients), followed by bosentan (n = 251 patients) and ambrisentan (n = 21 patients). On average, ambrisentan patients received one pill/day with a daily dose of 7 mg, bosentan patients received 2 pills/day with a daily dose of 222 mg, and sildenafil patients received 2.3 pills/day with a daily dose of 61 mg. Approximately 44% of ambrisentan, 35% of bosentan, and 25% of sildenafil patients experienced a dose increase (p = 0.013) during the follow-up period. PAH-related inpatient and emergency department utilization were similar among the groups, while ambulatory visits differed among the groups, with average monthly counts of 1.2, 0.8, and 0.5 visits for ambrisentan, bosentan, and sildenafil patients (p < 0.001). Follow-up total PAH-related costs were significantly different among the groups, with average monthly costs of \$6820, \$5332, and \$3632 for ambrisentan, bosentan, and sildenafil patients (p = 0.020). Cost differences were primarily driven by PAH-related pharmacy costs, which were significantly lower in sildenafil patients (p < 0.001). **CONCLUSIONS:** Of the three oral PAH treatments studied, sildenafil was the most frequently prescribed, and was associated with lower pharmacy and overall costs than either ambrisentan or bosentan.

CARDIOVASCULAR DISORDERS – Conceptual Papers & Research on Methods

FAILURE OF THE BLAND-ALTMAN METHOD TO IDENTIFY CLINICALLY IMPORTANT DISAGREEMENT BETWEEN MEASURES OF THE INTERNATIONAL NORMALIZED RATIO

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OBJECTIVES: The Bland-Altman method is often upheld as the optimal method to assess agreement between alternate measures of the same clinical parameter. However, recent research by our group demonstrates the Bland-Altman method does not report agreement in a clinically meaningful way. The objective was to determine if the Bland-Altman method distinguished between two point-of-care (POC) INR devices. These devices were previously shown to have significantly different levels of agreement with our core laboratory. **METHODS:** In a previous experiment, 170 patients provided three separate INR measures at the same clinic visit—two by POC (Avosure™ and ProTime™ devices) and one venous sample analyzed at our core laboratory (considered the standard measure). Agreement was achieved when the POC and lab INR values led to the same clinical decision. Differences in agreement between the POC devices and laboratory were assessed by McNemar's test. In the current study, we applied the Bland-Altman method to determine if inferences regarding agreement between the POCs and laboratory were identical to the previous experiment where clinical decisions defined agreement. **RESULTS:** The Avosure device was significantly more likely to lead to the same clinical decision as the laboratory versus the ProTime device (80% vs. 66%, respectively, p < 0.001). However, the Bland-Altman method produced virtually identical mean bias (0.4 and 0.5 INR units, respectively) and did not distinguish between the devices. Statistical analysis of the Bland-Altman method produced the same findings for each device: significantly different standard deviations between the POC and the laboratory (p < 0.001), significant bias in each device (p < 0.001), and high correlations between the POCs and the laboratory (0.925 and 0.926, respectively). **CONCLUSIONS:** The Bland-Altman method did not detect clinically important differences between the POC INR devices. Clinically meaningful agreement between measures of INR is optimally assessed by a method that directly observes or explicitly estimates clinical decisions.

USING DIFFERENT MEASURES TO DETERMINE TIME IN THERAPEUTIC INR RANGE AMONG WARFARIN-TREATED PATIENTS FOLLOWING TOTAL HIP OR KNEE REPLACEMENT

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OBJECTIVES: To determine the proportion of the post-surgery prophylaxis period that warfarin-treated patients undergoing total hip or total knee replacement (THR/TKR) spent in the American College of Chest Physicians (ACCP)-recommended therapeutic international normalized ratio (INR) range using two methods: within-patient proportion and Rosendaal linear interpolation. **METHODS:** Using an electronic database, patients undergoing total THR/TKR between January 1, 2004 and January 31, 2009 who received warfarin within 3 days after surgery were identified and followed for up to 90 days. Analysis focused on Day 5 onward since warfarin takes several days to reach therapeutic effect and on patients with at least 2 measured INR levels during this period. INR results were categorized based on ACCP guidelines: in range (2–3), below range (<2), or above range (>3). The proportion of INR levels within each range was determined for each patient, and the distribution of these within-patient proportions computed. Time within each range was imputed using the Rosendaal method, which assumes a linear interpolation between observed measurements, applying an INR level to each treatment day. **RESULTS:** A total of 653 THR and 871 TKR patients were identified; both groups had a median of 5 INR measurements from Day 5. Median within-patient percentages of in-range INR values were 33% for the average THR patient and 29% for the average TKR patient. Using the Rosendaal method, THR patients spent a median 29% and TKR patients a median 28% of within-patient proportion of time within the INR 2–3 range. **CONCLUSIONS:** The within-patient proportion of actual INR values and the proportion of imputed days

spent in the ACCP-recommended therapeutic range (2–3) were similar in this post-surgical cohort of THR/TKR patients. Regardless of the method, the majority of INR values among all patients were outside of the ACCP-recommended INR therapeutic range.

LINKING CLAIMS AND ELECTRONIC MEDICAL RECORD (EMR) DATA FOR A HYPERTENSION STUDY

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OBJECTIVES: To develop a methodology to link patients from two de-identified databases and leverage unique data from both to measure the impact of blood pressure and clinical findings on total costs. **METHODS:** Hypertensive patients (ICD-9 diagnosis 401.xx-405.xx) were identified from the MarketScan Commercial and Medicare Supplemental administrative claims databases (MarketScan) and the GE Centricity Electronic Medical Record (EMR) database (Centricity) for the years 2004–2008. A hybrid approach of deterministic and probabilistic matches was developed to identify common patients. Patients were included if they matched on zip code, gender and month of birth, and had at least three matching office visit dates at a rate of 75% or higher. Patients were followed for 12 months after the initial diagnosis. MarketScan provided data on enrollment, all reimbursed services (medical and drug) and costs, and Centricity provided clinical and biometric details, such as body mass index (BMI) and blood pressure. **RESULTS:** Among the 3 million MarketScan and 1.5 million Centricity patients with hypertension, 31,786 met the matching criteria. Mean age was 58 and 54% were female. The demographic and clinical characteristics of these patients did not vary substantially from those of the two data sources. Among the 31,786 patients, 84% received drug treatment, 56% had a BMI over 30 and mean systolic and diastolic values were 134 and 81, respectively. Mean unadjusted costs were \$9,338 for patients with consistently controlled (first and last systolic <140 and diastolic <90) hypertension and \$8,773 for patients not consistently controlled. **CONCLUSIONS:** A combined probabilistic and deterministic approach of linking patients yielded a sample size large enough to conduct a study and leverage the strengths of administrative and EMR data. Initial findings suggest that controlled patients incur higher costs, however, adjustments have not been made for additional demographic, clinical, and treatment characteristics.

MODELING TRANSFORMED HEALTH CARE COSTS WITH UNKNOWN HETEROSKEDASTICITY

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OBJECTIVES: Log models are widely used to deal with skewed outcomes, such as health care costs. They improve precision of estimates and diminish the influence of outliers. Smearing estimation suggested in literature only works with homoskedastic or heteroskedastic errors due to categorical variables. Generalized linear models (GLM) have been proposed as an alternative to deal with any kind of heteroskedasticity but recent literature shows that log models are superior to GLM under certain conditions. We present a method using log transformation that accounts for any kind of heteroskedasticity in the estimation of health care cost. **METHODS:** Assume there is a population represented by the random vector of explanatory variables (ex. patient and clinical characteristics) and with the scalar response variable (ex. health care costs) and we want to estimate unknown parameters. Assume that error terms are in function of explanatory variables, and therefore heteroskedasticity exists. By modeling heteroskedasticity separately, we created a weight function and using this weight in an outcomes model, we corrected the heteroskedasticity in the log transformed model. Retransformation was done by adjusting for heteroskedasticity. **RESULTS:** As a case study, we calculated the burden of illness of venous thromboembolism (VTE). The difference between the cost of VTE and non-VTE patients is estimated to be \$6,345 and \$8,239 depending on whether the proposed or a GLM model is used. The standard errors changed significantly depending on the model. The difference was significant with the log transformed model with heteroskedasticity-adjusted standard errors and the GLM model. However, the difference was insignificant when the adjustment was not done. **CONCLUSIONS:** Log transformation provides more efficient estimators than GLM models under certain conditions (ex. if there is excess kurtosis) and heteroskedasticity can be adjusted even if its form is unknown.

ACCOUNTING FOR TRIAL-EXCLUDED MEDICAL CONDITIONS WHEN SIMULATING MORTALITY IN CLINICAL TRIAL POPULATIONS

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BACKGROUND: Clinical trials frequently exclude patients likely to die within the trial timeframe. Thus, these highly-selected patients have lower initial mortality probabilities relative to the age- and gender-matched general population. **OBJECTIVES:** To capture the effect that clinical trial exclusion criteria have on intermediate-term (i.e., one- to five-year) death probabilities in study subjects with substantial asymptomatic carotid artery stenosis. **METHODS:** We “phased-in” certain relevant death probabilities in a microsimulation model using data from the Asymptomatic Carotid Atherosclerosis Study (ACAS). The phase-in process initially eliminates or greatly reduces the mortality probability from a condition (reflecting patients excluded with