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 1.2 pills/day with a daily dose of 61 mg. Approximately 35% of bosentan, 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 < 0.001). Cost differences were primarily driven by PAH-related pharmacy costs, which were significantly higher in ambrisentan, 35% of bosentan, and 25% of sildenafil patients compared to the base case ($5332, and $3632 for ambrisentan, bosentan, and sildenafil patients (p < 0.001)).

Follow-up total PAH-related costs were 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 virtually identical mean bias (0.4 and 0.5 INR units, respectively).

Cardiovascular Disorders – Conceptual Papers & Research on Methods

PCV153

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 has illustrated that agreement assessed with the Bland-Altman method does not necessarily mean 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™) and one venous sample analyzed at our core laboratory (considered the standard measure). Agreement was achieved when the POC and lab INR values fell within the same clinically defined range. Agreement in the ProTime and Avosure 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 agreement was achieved. 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.

PCV154

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 (ACCOP)-recommended therapeutic international normalized ratio (INR) range. METHODS: Using an electronic database of patients undergoing total THR/TKR between January 1, 2004 and January 1, 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 was 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. Medians within-patient percentages of in-range INR values were 33% for the average cumulative percentage = 29%. We compared 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 therapeutic range.

PCV155

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 datasets 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-403.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 57 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/day 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.

PCV156

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) as a random 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 weighted 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.

PCV157

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 because they have systematic and clinical characteristics related to excess mortality. OBJECTIVES: To capture the effect that clinical trial exclusion criteria have on intermediate-term (i.e., one- to five-year) death probabilities in clinical studies with substantial asymp- tomatic or 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