that condition) and increases the mortality probability as time progresses (reflecting patients that entered the trial with less severe and untreated cases of the condition or who developed the condition during the trial). Mortality was phased-in for four conditions reflective of their high prevalence and consistency with exclusion criteria: CHD, malignant neoplasms, chronic lower respiratory disease, and liver disease.

RESULTS: To statistically compare the ACAS simulated versus actual mortality survival curves, we calculated the absolute differences between the curves and performed a standard equality of probabilities test on the curves at 12, 24, 36, 48, and 60 months. For the ACAS, without mortality phase-in, at all times t before 60 months the simulated and actual curves had a statistically significant difference (0.0 < p < 0.04). With mortality phase-in, there was no evidence at any time t that the simulated and actual curves had a statistically significant difference (0.62 < p < 0.95). CONCLUSIONS: Phasing in mortality probabilities for trial-excluded conditions can simulate mortality survival curves that reflect the control arms of clinical trials.

RARE EVENT BIAS IN RETROSPECTIVE ANALYSIS OF OUTCOMES MEASURES

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OBJECTIVES: It is well documented that standard logit regressions are biased in rare events. We wanted to illustrate how to analyze rare events in observational analysis using Medicare claims data. In particular, we compared the operational mortality for patients who underwent hip fracture surgery and survived venous thromboembolism (VTE). METHODS: We applied two correction methods to address possible rare event bias. The first method involved obtaining information about the fraction of those in the population and the observed fraction of those in the sample. We estimated the adjusted constant coefficient in the logit model. In the second method, we weighted the proportion of ones and zeros in the sample to equal the true proportion in the population. We tested for differences in predicted probabilities using a non-parametric test. The Mann-Whitney U test and Kolmogorov-Smirnov two sample test can both be used on predicted probabilities of logit regression to see whether differences exist.

RESULTS: To apply the methodology, we constructed a retrospective cohort study comparing the operational death rate between patients who underwent hip replacement surgery who suffered VTE and patients who did not suffer VTE. 60,245 patients with hip fracture were identified from the excluded conditions dataset. Mortality was rare (0.81% vs. 3.34% for patients with non-VTE vs. VTE). Using Monte Carlo simulation, the unadjusted rate was 0.97% for non-VTE patients and 4.36% for VTE patients. The odds ratio was 3.98 for the standard model, 3.99 for the prior correction method, and 4.37 for the weighted mechanism. The predicted event probabilities were significantly different. CONCLUSIONS: Standard logit regression is proven to underestimate probabilities with rare events. We examined two correction methods. The predicted event probabilities adjusted for rare event bias were significantly different from the unadjusted ones.

COMPARATIVE EFFECTIVENESS INDEX: A CONCEPTUAL APPROACH TO COMPARATIVE EFFECTIVENESS RESEARCH

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OBJECTIVES: A comparative effectiveness (CE) index provides a quantitative method of transforming efficacy data into effectiveness indices. In lieu of head-to-head comparisons and surrogate markers of effectiveness. In analyzing two hypothetical anti-hypertensive drugs, A and B, the efficacy of each drug is ranked on a nominal scale based on the literature: A = 10 and B = 8. The drug with the highest nominal value is the most efficacious. However, this value needs to be moderated by adherence and safety data. Adherence rates, calculated from claims databases for example, are: A = 60% and B = 90%. The formula for calculating the Modified Efficacy Score (MES) of each drug is the (adherence rate × efficacy score)/100: A = (6 × 60) + (8 × 72). Adverse events (AE) reported in the two drugs were ferrous sulfate (54.3%), Clonidine (7.8%), Lorazepam (6.8%), Bisolvon (6.4%) and Amiodarone (5.2%). Other more used drugs were Nifedipine (2.6%), Amtryptilnine (2.5%), Alprazolam (2.2%), Fluoxetine (1.6%), Naproxen (1.4%), Temeparin (1.1%), Dizaprazin (0.95%) and Nitrofurantoin (0.90%). The usage was more in female (73.7%) as compared to male (26.3%), it was more in the age group 85 to 100 (43.1%) compared to 65 to 74 (39.1%) and 55 to 84 (39.1%). There were 2208 (91.8%) elders using at least one of the 48 medications. The use of potentially inappropriate medication was assessed by ranking the rate of usage of the 48 medications listed in the CE’s criteria that should be avoided in elderly patients and assessing the medication usage across demographics like gender and age. Descriptive statistics were carried out using SPSS 17. RESULTS: The total number of cases of the age 65 and above using the potentially inappropriate medication was 2209. The topmost five used drugs were ferrous sulfate (54.3%), Clonidine (7.8%), Lorazepam (6.8%), Bisolvon (6.4%) and Amiodarone (5.2%). Other more used drugs were Nifedipine (2.6%), Amtryptilnine (2.5%), Alprazolam (2.2%), Fluoxetine (1.6%), Naproxen (1.4%), Temeparin (1.1%), Dizaprazin (0.95%) and Nitrofurantoin (0.90%). The usage was more in female (73.7%) as compared to male (26.3%), it was more in the age group 85 to 100 (43.1%) compared to 65 to 74 (39.1%) and 55 to 84 (39.1%). There were 2208 (91.8%) elders using at least one of the 48 medications. The use of potentially inappropriate medication listed under the CE’s criteria is highly prevalent among the elderly. There is more usage in females compared to males and more in the age group 85 to 100. Among the top 12 drugs used, acceptable for Ferrous sulfate and Clonidine which has the low Beer’s severity rating, all other drugs have a high BEER’s severity rating and causes Adverse Drug Events.

RISK OF WEIGHT GAIN WITH THE USE OF SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRI) AND ATYPICAL ANTIPSYCHOTICS (AAP) COMBINATION TREATMENT IN CHILDREN AND ADOLESCENTS

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OBJECTIVES: To estimate the risks of gaining weight, with the use of selective serotonin reuptake inhibitors (SSRI) and atypical antipsychotics (SA) in combination among children and adolescents. METHODS: A retrospective cohort study was conducted using 2003–2005 Medicaid Analytic eXtract (MAX) data from four U.S. states. Combination pharmacotherapy was operationalized as the concurrent prescribing of SSRI and SA, where at least 14 days of treatment overlapped occurred. Long-term combination use is defined as an overlap beyond 60 days. Children and adolescents aged 6–18 years, and enrolled in Medicaid during 3 months prior and 1 year post the treatment initiation were selected. Multivariable logistic regression models were employed to estimate the risks of gaining weight during the one-year overlap period. RESULTS: Among 118,126 children and adolescents received SSRI or SGA, 56,091 (12.5%) were on combination treatment and of which approximately 80% were on long-term therapy (>60 days). Vast majority (63%) of these recipients were