that condition) and increases the mortality probability as time progresses (reflecting patients that entered the trial with less severe and undetected 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 curve without mortality phase-in, at all times t before 60 months the simulated and actual curves had a statistically significant difference ($0 < p < 0.04$). 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.

PCV158

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 suffered 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 surgery were identified from the 100% Medicare Inpatient 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, 3.98 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.

PCV159

COMPARATIVE EFFECTIVENESS INDEX: A CONCEPTUAL APPROACH TO COMPARATIVE EFFECTIVENESS RESEARCH

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OBJECTIVES: The Comparative Effectiveness Index (CEI) provides a quantitative method of transforming efficacy data into effectiveness indices. In lieu of head-to-head randomized controlled trials, the CEI uses efficacy, adherence, and safety data to facilitate the drug evaluation process by providing a single value index for each therapeutic alternative. **METHODS:** Efficacy data from clinical trials serve as 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 and B = 7.2. Adverse events (AE) reported in the clinical trials are ranked based on severity, the scale is anchored at 0 and 100 where 0 = No AE and 100 = Death. Each AE is assigned a value depending on its severity then multiplied by the probability of its incidence. This is repeated for each AE and summed. The inverse of the sum, the Adverse Events Score (AES), is used in the final computation so that both MES and AES modifiers have a direct relationship with the CEI. The AES for the drugs are: A = 3.33 and B = 5.00. The MES is multiplied by the AES to calculate the CEI. Consequently, the CEI would be: A = 19.98 and B = 36.00. Although drug A was more efficacious, drug B is more effective. **CONCLUSIONS:** The CEI provides health care decision-makers with valuable comparisons between therapeutic alternatives, but it requires further development and validation. Incorporating measures of dispersion for efficacy and compliance in a sensitivity analysis can generate more comprehensive indices.

INDIVIDUAL'S HEALTH – Clinical Outcomes Studies

PIH1

THE NATIONAL BURDEN OF PEDIATRIC ADVERSE DRUG EVENTS: A CASE-CONTROL STUDY USING THE 2006 KIDS' INPATIENT DATABASE

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OBJECTIVES: Pediatric adverse drug events (ADEs) lead to substantial burden on patients, caregivers, and payers. The objective of the current study was to quantify the extent of the national pediatric ADE burden by determining (1 the frequency of ADE occurrence; (2 excess length of stay (LOS) and excess cost associated with hospitalization; and (3 the hospital, patient, and ADE characteristics that predict excess LOS and excess cost. **METHODS:** Using the 2006 Kids' Inpatient Database, ADEs were identified using ICD-9 and supplemental Ecodes; ADE frequencies were computed. A hospitalization with an ADE was matched with 1 hospital visit without an ADE; matching criteria included the All Patient Refined-Diagnosis Related Group, which accounts for severity of illness and risk of mortality, and gender and age. Excess LOS and excess cost (totals and means) were calculated for case-control pairs. An ordinary-least-squares regression was run, with the case-control pairs as observations, to determine significant predictors of excess LOS and excess cost. **RESULTS:** In 2006, 118,779 ADEs occurred in 99,320 visits out of 7,558,812 total pediatric hospitalizations. The mean excess LOS was 0.98 days ($p < 0.0001$), while the mean excess cost was \$2,252 ($p < 0.0001$). Adverse effects from benzodiazepine-based tranquilizers, certain anticonvulsants, adrenal corticosteroids, and various antibiotics led to the highest excesses (all with $p < 0.0001$). The mean excess LOS and excess cost, respectively, for neonates aged 0–7 days were 6.4 days ($p < 0.0001$) and \$26,417 ($p < 0.0001$). Statistically significant predictors included age, hospital region, insurance coverage, hospital size, urban versus rural hospital location, major diagnostic category for hospital admission, and severity of illness. **CONCLUSIONS:** A substantial share of the pediatric ADE burden is accounted by adverse effects rather than accidental poisoning. Variation across regions, drug classes, and diagnoses suggests that efforts to reduce the ADE burden can be targeted to have the greatest impact.

PIH2

THE PREVALENCE AND USE OF POTENTIALLY INAPPROPRIATE MEDICATION IN ELDERLY POPULATION USING NATIONAL NURSING HOME SURVEY

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OBJECTIVES: The aim of the study is to determine the prevalence and use of potentially inappropriate medication in elderly population according to the Beer's criteria. **METHODS:** Data for the present study was obtained from National Nursing Home Survey (NNHS) 2004. Patients of the age 65 and above were taken as sample. The use of potentially inappropriate medication was assessed by ranking the rate of usage of the 48 medications listed in the Beer'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 top five most used drugs were ferrous sulfate (54.33%), Clonidine (7.8%), Lorazepam (6.9%), Biscodyl (6.9%) and Amioderone (5.7%). Other more used drugs were Nifedipine (2.6%), Amitryptyline (2.5%), Alprazolam (2.2%), Fluoxetine (1.6%), Naprozen (1.4%), Temezepam (1.1%), Diazepam (0.95%) and Nitrofurointoin (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 (17.9%) and 75 to 84 (39.1%). There were 2208 (91.8%) elders using at least one of the 48 medications and 181(8.1%) elders using two of these 48 medications. **CONCLUSIONS:** The use of potentially inappropriate medication listed under Beer'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, accept 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.

PIH3

RISK OF WEIGHT GAIN WITH THE USE OF SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRI) AND ATYPICAL ANTIPSYCHOTICS (SGA) 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 (SGA) 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 SGA, where at least 14 days of treatment overlap 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 follow up 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

adolescents (13–18 years). The effect of combination therapy on risk of weight gain was observed against both SSRI monotherapy and SGA monotherapy in multivariable logistic regression analyses. Likelihood of gaining weight with combination therapy was higher against both SSRI monotherapy (OR = 1.88; 1.69–2.10) and SGA monotherapy (OR = 1.52; 1.37–1.68). Long-term combination therapy (>60 days of treatment overlap) resulted into increased risk of weight gain (OR = 1.64; 1.30–2.07) as compared to short term uses (> = 14 days and <60 day). **CONCLUSIONS:** The effect of combination therapy on increased risk of weight gain was suggested in the study, especially when the combinations were used for long term maintenance. Comprehensive evaluation of other psychotropic combinations on risk of other adverse events is needed to be conducted in future.

PIH4

ASSESSMENT OF MATERNAL MORBIDITY DURING LABOR AND DELIVERY: EVALUATION OF LENGTH OF DELIVERY HOSPITALIZATION STAY OF WOMEN WITH PRE-EXISTING MEDICAL CONDITIONS

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OBJECTIVES: Monitoring maternal morbidity is essential as per Healthy People 2010 objectives. Maternal morbidity due to pre-existing medical conditions (PEC's) is found to be an important determinant of delivery complications. With limited literature for the influence of PEC's on obstetric hospitalization, the objective of this study was to assess the effects of PEC's on length of stay (LOS) during child delivery. **METHODS:** The 2006 National Hospital Discharge Survey (NHDS) was used as the data source. PEC's included diagnosis of chronic hypertension, diabetes mellitus, anemia, asthma, thyroid disorder or cardiac disease before conception. Cox Proportional Hazards Model was performed to ascertain the relationship between PEC's and LOS in the presence of other covariates. The data analysis was conducted using SAS 9.1. **RESULTS:** The 2006 NHDS included records of 39,751 women hospitalized for child birth; of which 15.25% (N = 6,063) had diagnosis of one or more PEC's in contrast to 4.9% in early 2000's. PEC's group had higher proportion of older women (≥35years) (20.32% vs. 16.43%, $p < 0.0001$) and African-Americans (23.50% vs. 15.79%, $p < 0.0001$) compared to the non-PEC's group. Presence of PEC's was found to be associated with prolonged LOS (hazard ratio = 0.840, $p < 0.0001$). Among hospital characteristics, women delivering in large hospitals (≥500beds) (hazard ratio = 0.880, $p < 0.0001$) and northeastern and southern regions (hazard ratio = 0.813, $p < 0.0001$) had extended LOS. In addition, African-American race (hazard ratio = 0.863, $p < 0.0001$) and cesarean delivery (hazard ratio = 0.383, $p < 0.0001$) were also associated with longer LOS. **CONCLUSIONS:** Women with PEC's impose significant health care burden in terms of length of stay during child birth. Access to appropriate pre-conception and prenatal care should be ensured to childbearing women, especially due to the rising prevalence of PEC's. Racial and geographical disparities need to be examined by policy-makers while framing prophylactic strategies. Future research should assess the health care resource utilization due to maternal morbidity from pre-conception to postpartum period.

PIH5

DIAGNOSIS AND TREATMENT OF WOMEN WITH HYPOACTIVE SEXUAL DESIRE DISORDER AND DEPRESSION/ANXIETY

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OBJECTIVES: The goal of this study is to describe the timing of the Hypoactive Sexual Desire Disorder (HSDD) diagnosis with that of depression/anxiety in a subgroup of women suffering from both disorders and determine which diagnosis came first—depression/anxiety or HSDD. In addition it describes the use of both antidepressants and anxiolytics in this subgroup. **METHODS:** Marketscan® Research Databases were used to identify women aged 18–64 with an ICD-9-CM coded diagnosis of HSDD (302.71) from January 1, 1998-December 31, 2007 who also had an ICD-9-CM coded diagnosis of depression or anxiety (293.84, 296.2x, 296.3x, 300.0x, 300.4, 309.1, 311, v79.0). The first physician visit with an HSDD diagnosis was the index date. Antidepressant and anxiolytic use was examined in the 24-month study period (12-months before and following index). **RESULTS:** A total of 957 (24.1%) of 3,975 women identified with HSDD also had a diagnosis of anxiety or depression in the study period. In this group, 34.7% (n = 332) had a depression/anxiety-coded claim appear after their HSDD-coded claim (after cohort), conversely, 65.3% (n = 625) had a depression/anxiety-coded claim appear on or before their HSDD-coded claim (before cohort). The majority of women in both the after and before cohorts were prescribed an antidepressant or anxiolytic in the study period, 78.3% (n = 260) and 86.1% (n = 538) respectively. Sixty percent (n = 156) and sixty-five percent (n = 351) of these women went on to discontinue use of the same. **CONCLUSIONS:** Over 24% of women with HSDD also suffer with depression/anxiety. More than one-third of these women developed their depression/anxiety diagnosis after being diagnosed with HSDD. A larger proportion of women had a diagnosis of depression and/or anxiety on or before that of HSDD. This may be evidence that both depression/anxiety and HSDD often present in tandem and that doctors feel competent to make such diagnoses concurrently. Additionally, intervention with antidepressants or anxiolytics appear inadequate to treat this population.

PIH6

PREVALENCE AND PREDICTORS OF POLYPHARMACY AMONGST ELDERLY PATIENTS: A POPULATION-BASED COHORT STUDY

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OBJECTIVES: We sought to evaluate the prevalence of polypharmacy, and to determine patient characteristics that are predictive of exposure to polypharmacy in the elderly population of Emilia-Romagna, Italy. **METHODS:** We conducted a retrospective cohort study of the 2007 Emilia-Romagna outpatient pharmacy database linked with patient information available from a demographic file of approximately 1 million Emilia-Romagna residents aged ≥65 years. The cohort was comprised of 887,165 elderly patients who had at least one prescription filled during the study year. Using the World Health Organization's Defined Daily Dose (DDD) to determine the duration of treatment for a given drug, we defined a polypharmacy episode as overlapping treatment with 5 or more medications occurring for at least one day. The prevalence of polypharmacy was measured together with patient characteristics found to be predictive of polypharmacy exposure. **RESULTS:** A total of 349,689 elderly in the population (39.4%) were exposed to at least one episode of polypharmacy. The prevalence of polypharmacy substantially increased with age, (32.7% for those ages 65–74, over 45% for those ages 75+). Over 35% of those exposed to polypharmacy were exposed for 101 or more days of the year. The top three classes of medications involved in polypharmacy were antithrombotics, peptic ulcer disease and gastroesophageal reflux disease agents, and angiotensin-converting enzyme inhibitors. Compared to unexposed subjects, elderly exposed to polypharmacy were older, were more likely to be male, and had a greater number of chronic conditions. **CONCLUSIONS:** This study provides evidence that the prevalence of polypharmacy in the elderly in Emilia-Romagna is substantial. Educational programs targeting primary care physicians should be developed to make them aware of the magnitude of polypharmacy phenomenon, as well of patient characteristics associated with polypharmacy to ensuring safe, effective, and appropriate use of medication in the elderly population.

PIH7

PREDICTORS OF NON-MEDICAL USE OF PRESCRIPTION DRUGS AMONG PREGNANT WOMEN IN THE UNITED STATES

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OBJECTIVES: Non-medical use of prescription drugs (NMPUD) is a serious problem in the US. This problem is even more concerning among pregnant women since non-medical use of prescription drugs has the potential to harm both mother and fetus. However, our knowledge about the prevalence of NMPUD among pregnant women and its predictors is limited. This study attempted to fill these gaps. Objectives of this study were: 1) To estimate the prevalence of NMUPD among pregnant women, and 2) To determine various predictors of NMUPD among pregnant women. **METHODS:** This study used data from 2007 National Survey on Drug Use and Health (NSDUH). Sample consisted of non-institutionalized, pregnant women who were 12 years or older. Multiple logistic regression analyses which adjusted for the complex survey design were conducted to estimate the relationship between NMUPD among pregnant women and demographic characteristics. **RESULTS:** The sample consisted of 956 respondents out of which 92 (9.62%) had engaged in NMUPD in the past year. Among different categories of prescription drugs, prevalence of non-medical use was highest for pain relievers (5.27%), followed by tranquilizers (1.65%), stimulants (1.93%), and sedatives (0.51%). Results from the logistic regression showed significant relationships between past year NMUPD and poor health status (O.R. = 5.28, 95% CI: 1.37–20.28), past year use of tobacco (O.R. = 2.28, 95% CI: 1.003–5.226), and African American race (O.R. = 0.19, 95% CI: 0.06–0.52) or other nonwhite races (O.R. = 0.08, 95% CI: 0.02–0.29) at $\alpha = 0.05$. **CONCLUSIONS:** Pain relievers are used most frequently non-medically by pregnant women when compared to the other prescription drugs. Pregnant women, who are white, have poorer health and those who smoke are more likely to engage in NMUPD than the others. This study highlights the group of pregnant women that are more vulnerable to NMUPD. Physician need to be careful while prescribing medication to these high risk groups.

PIH8

DOES TRIAL PARTICIPATION IMPACT ON THE PSYCHOMETRIC PROPERTIES OF SELF-REPORT DEPRESSION IN POSTNATAL WOMEN?

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OBJECTIVES: It is assumed within the context of clinical trials that the measurement characteristics of self-report outcomes are equivalent. However, little work has been conducted to determine if this assumption is supported. The goal of the current study was to determine trial allocation may significantly impact on the psychometric properties of a commonly used self-report postnatal depression screening questionnaire. **METHODS:** Utilising data from a prospective randomised controlled trial (RCT) investigating the impact of antenatal exercise on psychological well-being, postnatal depression was assessed using the Edinburgh Postnatal Depression Scale (EPDS) at the 12–16 weeks following birth. Structural equation modeling approaches were used to investigate the assumption of measurement invariance of the EPDS using a two-