ponent score (MCS). Linear regression analysis was conducted with PCS and MCS scores as dependent variables. Age, race and sex were included as baseline variables in all models while incorporating Charlson/D'hoore, Elixhauser, and HRQoL-CI measures one at a time. Adjusted R2 were compared to assess the comparative performances of risk-adjustment measures. **RESULTS:** The mean age was 68±13 years, with 80.63% non-Hispanic whites. The average PCS and MCS for HF patients were 45.53±12.28 and 30.64±11, respectively. HRQoL-CI (R2 = 0.2083) outperformed Elixhauser (R2 = 0.1784) and Charlson/D'hoore (R2 = 0.1359) in predicting PCS. Whereas, Elixhauser (R2 = 0.2184) had the best prediction of MCS compared to HRQoL-CI (R2 = 0.1920) and Charlson/D'hoore (R2 = 0.0918). **CONCLUSIONS:** No single comorbidity measure was best in predicting both PCS and MCS in HF patients; HRQoL-CI performed best in predicting PCS whereas Elixhauser measure had the best prediction for MCS. Selection of risk adjustment method should be based on the type of dimension used to evaluate HRQoL.

CARDIOVASCULAR DISORDERS – Health Care Use & Policy Studies

PCV87
IMPACT OF AN INTERACTIVE CARE PLAN ON PATIENT ACTIVATION IN HEART FAILURE INPATIENTS

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OBJECTIVES: Re-hospitalization in heart failure (HF) patients is often the result of a patient's inability to adequately self-manage the condition. The objective of this study is to determine if engaging inpatients in their care through technology is a solution to improving patient self-management. **METHODS:** Two hundred seventy-five patients with HF completed the HF interactive care plan while an inpatient at one of six hospitals throughout the United States. A pretest posttest design was used to evaluate a patient's activation using the 13-item Patient Activation Measure (PAM-13), a valid and reliable instrument to measure a patient's knowledge, skill, and confidence to perform self-management of their chronic disease(s). After completing the baseline PAM-13 following admission for a HF diagnosis, all 275 patients completed a self-paced set of interactive, educational modules throughout their inpatient stay. These modules were typically completed 3 or 4 days after admission, and then patients would complete the PAM-13 prior to discharge. The PAM-13 places individuals into activation levels 1 (lowest) through 4 (highest) based on an individual's responses. **RESULTS:** A two-tailed t-test between baseline and posttest scores of all participants showed a difference of 0.38 levels of activation ($p < .001$). Because 168 of the 275 participants were at level 4 on the PAM-13 at baseline, these individuals were removed and secondary analysis was performed on the remaining 107 individuals. A two-tailed t-test revealed a difference of 1.05 levels of activation ($p < 0.001$) after patients completed the interactive solution. **CONCLUSIONS:** Providing education through an interactive solution while in the hospital can improve activation scores in HF patients.

PCV88
EVALUATING OUTCOMES RELATED TO HYPERTENSION IN TOLEDO-LUCAS COUNTY CARENET PATIENTS

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OBJECTIVES: To determine blood pressure goal attainment levels and the factors influencing them for a low-income, uninsured population with hypertension. **METHODS:** A retrospective, cohort study was carried out by reviewing patient charts at three different sites where patients from CareNet, a Toledo based safety-net organization, received primary care. Eligible subjects were at least 18 years old and were CareNet members for a minimum duration of one year between the study period of January 1, 2003 to December 31, 2008. Descriptive statistics were utilized to determine goal attainment. Chi-square analysis was used to determine variables that had significantly different goal attainment. A binomial logistic regression model was used to predict goal attainment. Goal attainment at the last recorded visit served as the dependent variable and was classified as 'Yes' and 'No' (determined based on JNC-VII guidelines). Age, gender, race/ethnicity, BMI, tobacco use, number of primary care visits, and pharmacotherapy treatment were used as predictor variables. **RESULTS:** A total of 269 patients were included in the final analysis; 92 of these patients had diabetes while 177 didn't have diabetes as co-morbidity. The overall goal attainment was found to be 42.39% (n=39) in the patients with diabetes as co-morbidity and 60.45% (n=107) among the members without diabetes as co-morbidity. Chi-square analysis found patients the variables of co-morbidity ($p=0.05$) and number of visits ($p<0.01$) had significant differences in goal attainment. Patients who had primary care visits between 6-10 times were found to be significantly more likely (OR=3.705; CI: 1.670-8.218) to attain goal when compared to those who had just 1-5 visits. Notable trends were observed for other variables (co-morbidity,race/ethnicity,tobacco) but the effect was not significant. **CONCLUSIONS:** Goal attainment among CareNet members was found to be comparable to other studies and national statistics. Encouraging regular utilization of primary care services may further improve the clinical outcomes for a population utilizating a safety-net organization.

PCV89
PATIENT-, HOSPITAL-, AND COUNTY- LEVEL PREDICTORS OF DISCHARGES AND READMISSIONS AMONG PATIENTS WITH CARDIOVASCULAR DISEASE

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OBJECTIVES: The role of patient- and hospital-level factors in predicting hospital readmissions in the cardiovascular disease (CVD) setting is established, while the contribution of community-level factors is less clear. We determine the contribution of county-level characteristics in predicting discharge and readmission outcomes. **METHODS:** This retrospective analysis of hospital discharge data included adult patients discharged alive from nonfederal acute care hospitals between 2000 and 2005. Merged hospital- and county- level data characterized the admitting hospital in terms of quality of care and the patients' residence county in terms of income, crime, medical social services, and private transportation. Multinomial logistic and logistic regression models examined, respectively, the likelihood of 1) 3 discharge outcomes (home, unauthorized discharge, or further medical care), and 2) 31-day same-hospital readmission. The likelihood ratio (LR) test and Akaike Information Criterion (AIC) compared 3 models: Model 1: patient-level, Model 2: patient- and hospital-level, and Model 3: patient-, hospital- and county-level. **RESULTS:** Application of inclusion criteria resulted in 348,572 discharges with a primary-listed discharge diagnosis of CVD. In the discharge outcomes models, results from the LR tests that compared Model 2 to Model 1, and Model 3 to Model 2 were statistically significant ($\chi 2 = 773.38$, $p<0.0001$; $\chi 2 = 1346.80$, $p<0.0001$), suggesting no data support for the implied restrictions in Models 1 and 2. The AIC for Models 1, 2, and 3 were 309139, 308378, and 307047, favoring Model 3. In the 31-day readmission models, results from the LR tests that compared Model 2 to Model 1, and Model 3 to Model 2 also were statistically significant ($\chi 2 = 34.73$, $p<0.0001$; $\chi 2 = 89.62$, $p<0.0001$). The AIC for Models 1, 2, and 3 were 144041, 144012, and 143931. **CONCLUSIONS:** Prediction models examining discharge and readmissions outcomes can benefit from the inclusion of patient-, hospital, and area (e.g. county) – level measures.

PCV90
THE QUALITY OF ANTICOAGULATION THERAPY IN PATIENTS WITH ATRIAL FIBRILLATION

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OBJECTIVES: The aim of this research was to assess the quality of anticoagulation therapy of patients with atrial fibrillation (AF) in a real life setting and to identify the causal factors explaining anticoagulation quality deficits. Furthermore, clinical consequences of suboptimal anticoagulation therapy (strokes, TIA, bleedings, embolism, myocardial infarcts) are identified. **METHODS:** The INR values as well as other clinical events concerning AF patients recruited into a prospective cohort study (observation period of 12 month) were documented at every visit to the treating doctor. Using the Rosendaal linear trend method, the time in therapeutic range (TTR) of 2.0-3.0 was estimated. Additionally, the squared INR deviation was investigated. To identify causes of INR-values below/above 2.0-3.0, a logistic regression on the basis of a TTR < 60% as the dichotomous outcome was conducted. **RESULTS:** For 525 patients from 71 study centers, at least two INR values were available over a median observational period of 228.9 days (SD: 106.1 days). The average TTR was 68.1 % (SD: 26.3 %). The average deviation of INR value from the mean of the INR target range (2.5) was 0.44 (SD: 1.29). The results of the multivariate regression (R2=0,179) show that the most important factors explaining a poor quality of anticoagulation therapy are bridging periods and patients self-reported need of help regarding medication therapy without getting that help. In the group of patients with a TTR<60 %, the occurrence rate of clinical outcomes was higher ($p=0.031$) than in the group of patients with a TTR>60 %. **CONCLUSIONS:** Labile INR values lead to negative clinical outcomes. In order to improve the situation, the main identified causes of poor anticoagulation quality should be addressed.

PCV91
DEVELOPMENT OF METHODOLOGICAL RECOMMENDATIONS FOR COMPARATIVE EFFECTIVENESS RESEARCH ON THE TREATMENT OF ATRIAL FIBRILLATION

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OBJECTIVES: Atrial fibrillation (AF) has been identified by the Institute of Medicine as one of the top research priorities for comparative effectiveness research, yet there is limited methodological guidance on how to meet the evidentiary needs of patients, clinicians, and payers. The Center for Medical Technology Policy (CMTP) managed a stakeholder-driven process to develop an effectiveness guidance document that issued guidance for trial designers on study design considerations to best answer decision-makers' needs in AF research. **METHODS:** The AF team reviewed the literature and conducted interviews with researchers, patients and methodologists to scope the project needs. Open-question interviews were conducted with 25 individuals from the clinical research, clinical practice, regulatory, payer, professional organizations, and patient communities. An eight-person multi-stakeholder technical working group worked in collaboration with CMTP staff to establish and refine the recommendations. The methods recommendations were guided by the objective of achieving an acceptable balance across a number of desirable dimensions, including internal validity, relevance, feasibility and timeliness. The document was posted on CMTP's website for a 30-day public comment period as part of the broader dissemination and translation strategy. **RESULTS:** The final recommendations provide guidance on the design of prospective studies in Atrial Fibrillation, rationale for their inclusion, specifics on implementation and data analysis/reporting considerations. The final list included five research design recommendations, and three priority research areas that would synergistically benefit stakeholders' evidentiary needs and improve health outcomes. **CONCLUSIONS:** The meaningful engagement of patients, providers, and decision makers to prioritize the questions and develop the methods to answer

them is an essential component of CER. The Atrial Fibrillation methods guidance was developed in a unique process to improve the future quality of evidence with a balance between internal validity and external generalizability.

PCV92

DRUG APPROVAL STRATEGIES IN GERMANY

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OBJECTIVES: The German legislator introduced early benefit assessments of almost all new drug approvals in 2011. Within one year after approval, the pharmaceutical manufacturer and the Statutory Health Insurance funds negotiate a rebate based on the early benefit assessment. For each new drug, a common rebate for all indications is negotiated. Therefore, the manufacturer needs to analyze whether or not to seek approval for each potential indication. We aim to analyze the manufacturer's decision. **METHODS:** We develop a binary decision model to determine profitability of each indication. Profitability is defined as a positive contribution to the manufacturer's global revenue. We apply our model to Ticagrelor as an example. Ticagrelor was the first drug that was subject to an early benefit assessment. The assessment is publicly available and delivers information for four indications. **RESULTS:** The approval decision for a specific indication depends on five factors: 1) Expected benefit as determined by the early benefit assessment; 2) Expected DDDs in Germany; 3) Willingness for off-label use in the indication in Germany; 4) Expected DDDs globally; and 5) Impact of the German price on the mean global price. **CONCLUSIONS:** The approval decision proves to be complex. Ticagrelor's early benefit assessment has shown the important role of the comparator used in the assessment. The manufacturer named no trials to prove benefit over the adequate comparators for STEMI (percutaneous coronary intervention) and STEMI (coronary artery bypass grafting). Willingness for off-label use, however, is high, as currently observed for Clopidogrel. For such a case, our model shows that it is profitable to just seek approval for the indication with the greatest additional benefit (unstable angina/NSTEMI). Based on the best indication, the manufacturer can negotiate a smaller rebate. Additional revenue is generated if off-label prescriptions are common in other indications.

PCV93

MARKET RESPONSE TO FOOD AND DRUG ADMINISTRATION'S SAFETY WARNINGS: A CASE STUDY USING AN INTERRUPTED TIME SERIES ANALYSIS OF THE MEDICARE DATABASE FOR 2006-2008

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OBJECTIVES: To evaluate the impact of Food and Drug Administration (FDA) safety warning on the utilization rates of thiazolidinedione oral anti-diabetes medications using an interrupted time series analysis. **METHODS:** The analysis used data from the five percent national sample of Medicare Part D beneficiaries. Beneficiaries were included if they were diabetic, continuously enrolled in Part D and had filled a prescription for a thiazolidinedione medication at any time during the period of January 2006 through December 2008. Beneficiaries were classified each month into appropriate-use, at risk, and contraindicated groups based on the presence of certain comorbid conditions. Data were aggregated to monthly utilization rates. Analyses examined the effects of the May 2007 FDA safety warnings about the ongoing review of rosiglitazone's potential to increase cardiovascular risks on thiazolidinedione utilization rates for the different appropriateness of use categories using an interrupted time series consisting of 32 data points (13 months before and 19 months after the safety warning). **RESULTS:** There was an increasing trend in the total utilization rates of thiazolidinediones before the safety warning. Significant decline in drug utilization rates were observed at the end of the study period for all patient groups on rosiglitazone (relative difference -74.78%, -79.93%, and -90.21% in appropriate-use, at risk and contraindicated patient groups, respectively). The intervention did not have significant immediate effects on the post-intervention utilization rates of pioglitazone. However, after the intervention, a general decline in utilization of thiazolidinediones, including pioglitazone, was observed. **CONCLUSIONS:** The initial safety warning about rosiglitazone's cardiovascular safety was effective in decreasing rosiglitazone's utilization in the targeted population and thus appeared to achieve the desired safety effects. The safety warning, however, also had spillover effects by reducing utilization of drugs in other patient cohorts not targeted by the warning.

PCV94

UNPACKING THE RAPID GRWOTH OF PHARMACEUTICAL SPENDING GROWTH: A CASE ANALYSIS OF CHINESE HOSPITAL

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OBJECTIVES: Pharmaceutical expenditure is rapidly growing and accounts for 40-50 percent of total medical care expenditures. In order to contain drug expenditure growth effectively, we need to understand what the drivers are. This study aims to answer the question by decomposing the pharmaceutical expenditure changes into prices, volume, and product substitution effects. **METHODS:** By using quarterly drug sales records from 2006-2011 of a large public hospital in Sichuan province, we analyze the pharmaceutical expenditure changes for two therapeutic groups: antibiotics (249 products molecules with 2491 records) and cardiovascular(130 products molecules with1668 records). After standardizing volume and price recommended by DDD (WHO), a statistic index factor analysis is employed. Specifically, Laspeyres price index (LPI) and chained LPI are employed to calculate the price changes with and without entry and exit of products over time. We also take a closer look at the substitution pattern, including shift among therapeutic groups, shift between brand and generic drugs, and shift between old and new drugs. **RESULTS:** Our results show that both antibiotics and cardiovascular drug expenditures increased over 30% in the past 5 years. Interestingly, prices are continuously dropping and the volumes are slightly increasing for both antibiotics and cardiovascular drugs. Relatively speaking, substitution effect plays the most important role in expenditure growth. Specifically, proportions of brand-name drugs, new drugs, and more therapeutic advanced drugs are increasing over time. **CONCLUSIONS:** Our study indicates that the key factor that contributes to the expenditure growth is product substitution effect. Thus, price control policies may not be an effective way to control the rapid pharmaceutical expenditure growth. Instead, more attention should be paid on how to control the substitution shifts, which may be caused by prescriber behavior and consumer demand. Further analysis should also be on the impact of substitution shift on quality of health care.

PCV95

PREVALENCE AND DETERMINANTS OF PHARMACOTHERAPY IN MYOCARDIAL INFARCTION PATIENTS

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OBJECTIVES: To assess the prevalence and determinants of pharmacotherapy in patients with myocardial infarction. **METHODS:** The Medical Expenditure Panel Survey (MEPS) data from 2004 to 2008 were used to conduct a retrospective cross-sectional study. Study sample included adults ≥ 18 years with myocardial infarction. Pharmacotherapy was defined as the use of aspirin, beta-blockers, statins or ACEI/ARB. Descriptive characteristics were used to describe the study sample and utilization patterns. The predictors of pharmacotherapy use were modeled based on the Andersen Behavior Model using logistic regression. The year variable and the Charlson's comorbidity index score (CCI) was also included in the analyses. A p-value of 0.05 was considered to be statistically significant. **RESULTS:** According to the MEPS, 55% of the patients received ACEI/ARBs, 68% received beta-blockers, 64% received statins and 75% received aspirin. Individuals who had a usual source of healthcare were twice as more likely to receive ACEI/ARBs (OR: 2.15; CI: 1.20 – 3.84). Also, patients who were publicly insured (OR: 0.50; CI: 0.28 – 0.90), those who resided in metropolitan region (OR: 0.69; CI: 0.50 – 0.95) and patients having a CCI score of 2, 3 or 4 were less likely to receive ACEI/ARBs. Females (OR: 0.63; CI: 0.44 – 0.91), blacks (OR: 0.45; CI: 0.30 – 0.66) and individuals who had a CCI score of 10 (OR: 0.22; CI: 0.08 – 0.58) were less likely to receive beta-blockers. Also, as age increased, the likelihood of taking beta-blockers (OR: 1.22; CI: 1.11 – 1.34) and aspirin (OR: 1.24; CI: 1.11 – 1.39) increased. Patients who had a usual source of healthcare were 3 times as likely to receive statins (OR: 3.05; CI: 1.53 – 6.10). **CONCLUSIONS:** Analyses of national level data revealed suboptimal utilization of evidence-based pharmacotherapy for management of myocardial infarction. Concerted efforts are needed to optimize pharmacotherapy in patients with myocardial infarction.

PCV96

TRENDS IN UTILIZATION FOR RATE-CONTROL AND RHYTHM-CONTROL DRUGS FROM 2001 TO 2009: RESULTS FROM THE NATIONAL AMBULATORY MEDICAL CARE SURVEY

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OBJECTIVES: Results from several clinical trials have showed that rhythm-control drugs, which have serious adverse events, have no survival advantage over rate-control drugs in patients with atrial fibrillation (AF). The objective of the study was to determine 1) the trends in utilization for rate-control and rhythm-control drugs from 2001 to 2009; and 2) if the utilization of rhythm-control drugs decreased over time. **METHODS:** The physician's-office and outpatient data components of the National Ambulatory Medical Care Survey (NAMCS) from 2001 to 2009 were used. Visits with AF were identified by ICD-9 diagnosis code, '427.31'. From these visits, visits with mentions of rate-control drugs, beta blockers (e.g. metoprolol, propranolol, carvedilol, etc.) and non-dihydropyridine calcium channel blockers (verapamil and diltiazem) and visits with mentions of rhythm-control drugs (e.g. amiodarone, disopyramide, propafenone, etc.) were identified using drug codes provided by NAMCS. Trends in utilization were calculated as total number of visits with prescriptions divided by total number of visits with AF for each year. **RESULTS:** From 2001 to 2009, visits with AF rose from 6.83 million to 11.56 million. The prescription rate for rate-control drugs increased from 24.28% to 62.31% from 2001 to 2009. The prescription rate for rhythm-control drugs remained the same, 5.31% in 2001 and 5.14% in 2009. The prescription rate for any pharmacotherapy for AF increased from 29.32% to 67.44% from 2001 to 2009. **CONCLUSIONS:** The utilization of rhythm-control drugs remained constant while that of rate- control drugs increased from 2001 to 2009. Previously, the treatment approach for AF was to achieve normal sinus rhythm with rhythm-control drugs and direct current cardioversion, rather than use the rate-control drugs. Following the trials on rate-control and rhythm-control drugs, the use of rate-control strategy increased.

PCV97

REAL WORLD PATIENT PROFILE OF PATIENTS WITH REDUCED EJECTION FRACTION HEART FAILURE (HF-REF) IN 5 REGIONS OF CHINA

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