

period, FAST scores were significantly correlated with individual symptoms, impact on daily activities and sleep, and flushing-related dissatisfaction ($p < 0.01$). Changes in FAST scores were associated with treatment satisfaction ($p < 0.01$) and patient/physician-rated OTE ($p < 0.01$). Responders, defined by improved OTE ratings, experienced greater improvements than non-responders ($p < 0.01$) in maximum (1.85 points vs. 0.18 points) and mean (0.51 points vs. -0.15 points) overall flushing severity scores. Among patients with flushing, mean FAST scores differed between those who subsequently discontinued due to flushing (7.9/10 points) vs. those who did not (4.7/10 points; $p < 0.001$). The probable range in this study for a detectable change in flushing symptoms (MID) was 0.29–0.38 points for mean overall flushing severity and 0.41–0.54 points for maximum overall flushing severity. **CONCLUSIONS:** The FAST is a new instrument designed to assess the symptoms and impact of niacin-induced flushing. The FAST exhibited test-retest reliability and substantial evidence of construct validity among patients with dyslipidemia. Overall, flushing severity was responsive to change over time, suggesting that the FAST is a useful instrument for evaluating flushing symptoms induced by niacin therapy.

PCV87

IS MEASURING HEALTH STATUS BENEFICIAL IN HEART FAILURE PATIENTS?

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OBJECTIVES: Measuring patients subjective health status (HS) has become accepted in cardiology. However, the effect of these measurements on outcome and well-being of heart failure patients remains unclear. **METHODS:** The aim of this study was to investigate the impact of measuring HS on intermediate patients' well-being. In two Austrian heart failure outpatient wards 175 patients with documented heart failure were randomized into an intervention (IG) and control group (CG). Patients HS in the IG was measured prior to the physician contact using the Short-Form 36 and Hospital Anxiety and Depression Scale. IG-patients received feedback electronically feedback on their individual HS. The results were also made available to the treating physicians. They were encouraged to give additional feedback or to apply results for auxiliary treatment planning (e.g., counselling). Patients in CG received usual care without measuring HS prior to the physicians visit. After the visit, patients in both groups rated their health-related quality of life (HRQL) and general health on the MacNew Heart Disease HRQL Instrument. Patients were reassessed by postal questionnaire six months after initial visit. **RESULTS:** Complete 6-month follow-up data was available for 139 patients (79% response rate; 25.3% female; age: 58 ± 13.2 ; 64.2% retired; NYHA I: 14.7%, NYHA II: 53.9%, NYHA III: 24.5%, NYHA IV: 6.9%). Physical HRQL significantly deteriorated in both groups (IG: -0.3; CG: -0.4, both $p < .01$), whereas no significant deterioration for emotional and social HRQL was reported by the IG (IG: -0.1; -0.1, $p = ns$). Overall health improved in 34% of the IG patients, but only in 22% of the CG patients [ARR = 12%, $p = 0.09$; NNT of 9]. **CONCLUSIONS:** Routine assessment of patients subjective HS appears to be beneficial in helping maintain the well-being of heart failure patients (NNT = 9), which naturally decreases over time. These results, however, need to be replicated in an adequately powered study [N = 211, $\hat{\alpha} < .005$, $1-\hat{\alpha} = 0.89$].

PCV88

EVALUATION OF COMPARATIVE EFFECTIVENESS: A MODEL FOR GENERATING HYPOTHESES AND DETERMINING SAMPLE SIZE

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OBJECTIVES: Although payers are asking for comparative effectiveness data, risk of conducting studies is significant. One possible intermediary step is to leverage a validated instrument, the Treatment Satisfaction Questionnaire for Medication Version 1.4 (TSQM), to identify domains for separation and calculate sample size required for superiority in a comparative study. **METHODS:** We used data from iGuard.org, a consumer drug safety service totaling over 1 million members, whereby patients are randomly invited to complete the TSQM on an on-going basis. TSQM is a 14-item reliable and valid instrument providing scores on four scales—effectiveness, side effects, convenience and global satisfaction. For this study, we analyzed all responses from patients using lisinopril and metoprolol. For sample size evaluation, adjusted means (LsMean) and standard errors (SE) were generated for each treatment using an analysis of covariance model controlling for: patient age; gender; self-reported severity of disease; and use of other hypertensive, diabetes and heart failure medications. **RESULTS:** A total of 625 patients, 363 (58.1%) on lisinopril and 262 (41.9%) on metoprolol completed the TSQM between March and November 2008. TSQM domains had good internal consistency with Cronbach's alpha values over 0.85. There were significant differences between the two treatments on age; self-reported severity; and use of diabetes and heart failure medications. LsMean (SE) for lisinopril and metoprolol was 68.80 (1.46) and 66.01 (1.53) on effectiveness; 90.72 (1.83) and 85.66 (1.91) on side effects; 87.09 (1.28) and 81.55 (1.34) on convenience; and 67.67 (1.78) and 62.92 (1.86) on global satisfaction, respectively. Given differences observed, a sample size of 640 per treatment would be required to detect a statistically significant difference at a two-sided alpha of 0.05 with 80% power. **CONCLUSIONS:** This obtains feedback on comparative effectiveness study design and risk by conducting a pre-study that administers a validated instrument to an on-line community.

CARDIOVASCULAR DISORDERS – Health Care Use & Policy Studies

PCV89

DIABETES MANAGEMENT AND KNOWLEDGE IMPROVEMENTS AS A RESULT OF PATIENT EDUCATION: A COMMUNITY BASED, RANDOMIZED CLINICAL TRIAL

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OBJECTIVES: The purpose of this study is to assess: 1) the impact of different education modules (class education, mail education or both) on Hemoglobin A1c control in diabetic patients with hypertension; 2) determine which education module was the most effective for patient disease process awareness based on Knowledge Tool Test scores. **METHODS:** Adult patients with type-2 Diabetes with concomitant hypertension were recruited from community based primary care physician offices. The study was composed of 825 diabetic patients, a subset of those enrolled in the Baltimore Partnership Programs to Reduce CVD Disparities project based on a minimum of one year of follow-up. Intervention patients received education either by class, mail, or both. HbA1c was measured at baseline and patients were followed-up every six months. Multiple regression models were used to assess the effects of 1) Different education modules on HbA1c change, defined as percent change of HbA1c from baseline; 2) different education modules on change of patients' disease process awareness, defined as change of Knowledge Tool Test score from the baseline. The model was adjusted for sociodemographic variables. **RESULTS:** The majority of the diabetic patients were African American (88.61%), females (65.62%), and the mean age was 65 years. The mean HbA1c reduction was -0.8. As compared to the control patients (-0.7), the HbA1c reduction was larger in intervention patients (-0.9). Males (-0.82 vs. -0.78) had a higher reduction in HbA1c values than females. Opposite trends were found on patient disease process awareness. **CONCLUSIONS:** In this patient sample, decreased trend in HbA1c level and an increased trend in Knowledge Tool Test score is seen among intervention patients, with class education module being more effective in patient disease process awareness. These results may help guide future patient intervention programs for diabetes and hypertension management.

PCV90

PHARMACEUTICAL SPENDING ON CHRONIC DISEASES IN CONSUMER DIRECTED HEALTH PLANS

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OBJECTIVES: Consumer directed health plans (CDHP) are aimed at reducing moral hazard due to insurance coverage. How do CDHP plans affect the consumption of pharmaceuticals for chronic diseases such as hypertension, high cholesterol and diabetes? **METHODS:** We obtained data on all employees from a large private U.S. employer for the 2005 to 2007 time period. All enrollees in the CDHP plan in this study are initially provided an employer funded Health Reimbursement Account (HRA) from which they can purchase medical care. Funds in these accounts range from \$1000 to \$2000 depending on whether the enrollee is in an individual or a family health plan. After the HRA funds are exhausted, there is a second phase in which enrollee spending is completely out of pocket (range from \$500 to \$2000), after which time the insurance plan begins coverage. We compare average daily pharmaceutical spending for individuals with diabetes, hypertension and high cholesterol as they move through each of the different coverage thresholds (HRA, Out-of-Pocket and Full-Coverage). **RESULTS:** Using Icd-9 codes we identified 27,644 individuals diagnosed with diabetes, hypertension or high-cholesterol. For each of these diseases average daily pharmaceutical expenditure was substantially lower when individuals were in the HRA and out-of-pocket sections of their CDHP plan as compared to when they were in the Full-Coverage part of their insurance plan. Average daily expenditure on pharmaceuticals was approximately \$2.60 for individuals in the HRA section of the plan, \$1.00 for individuals who moved into the out-of-pocket part of the insurance plan and \$4.00 for individuals who were covered by insurance. **CONCLUSIONS:** Findings from this study suggest that cost-sharing levels in CDHP plans affect pharmaceutical spending on the treatment of chronic diseases. Reductions in chronic disease pharmaceutical expenditures have the potential to negatively affect enrollee health outcomes.

PCV91

DISPARITIES IN CORONARY ARTERY DISEASE CARE AMONG ENROLLEES WITH AARP MEDICARE SUPPLEMENT INSURANCE

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OBJECTIVES: Discover if age-, gender-, race-, or income-related disparities in care for coronary artery disease (CAD) exist among Medicare enrollees with supplement plan coverage (i.e. Medigap). **METHODS:** Data were obtained from UnitedHealth Group's database of AARP Medigap enrollees. Patients were selected into the study if they had one or more medical claims with a diagnosis of CAD from July 1, 2006-June 30, 2007. Logistic regression analyses tested for age-, gender-, race-, or income-related differences in the likelihood of receiving an office visit, coronary angiography, or surgical intervention. The regression models controlled for socioeconomic, health

status, type of supplement plan, and residential location. **RESULTS:** Of the 2.2 million Medigap insureds eligible for the study, 25.4% (570,711) had CAD. Males were 60% ($p < 0.001$) more likely than females to have an office visit, but gender was not a significant predictor for the other services. Patients residing in high-minority neighborhoods were about 8% ($p < 0.001$) less likely to receive any services for CAD. Older individuals were significantly less likely ($p < 0.001$) to have invasive procedures (angiography and surgery). Patients residing in lower-income areas were about 9% ($p < 0.001$) more likely to receive any of the CAD services. Patients with mental health problems were about 45% ($p < 0.001$) less likely to receive any CAD services. Additionally, CAD-related care varied significantly by state of residence and urban versus rural location. Insureds with policies that covered more out-of-pocket costs were more likely to receive an office visit, however, policy type was not a significant predictor for invasive CAD procedures. **CONCLUSIONS:** Disparities in CAD-related care existed by age, income, and race, but the magnitude was relatively small (about 10%). Larger disparities were found by residential location and for those with mental health problems. AARP and UnitedHealth Group are designing interventions to address these disparities; such interventions will begin in mid-2009.

PCV92

HOW DOES THE OUT-OF-POCKET PAYMENT MATTER TO HYPERTENSIVE PATIENTS' CHOICES OF ACCESSING DIFFERENT MEDICAL FACILITIES IN TAIWAN? THE PRELIMINARY STUDY OF A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: With generous coverage and patients' full freedom to access different tiers of medical facilities, Taiwan's single payer national health insurance system is facing difficulties of escalating utilization and cost of out-patient care. Recently, out-patient co-payment has been largely increased in order to control unnecessary medical demands and encourage patients with minor illness of initial contact in primary care, but this policy has only shown limited impacts. To determine the relative importance of factors (attributes) associated with patients' choices on accessing different tiers of medical facilities, we conducted a qualitative study on hypertensive outpatients. **METHODS:** Focus groups were conducted on hypertensive outpatients from different tiers (clinics, local, regional hospitals and medical centers) of medical facilities in Southern Taiwan. **RESULTS:** Nine focus groups were conducted at local community (1), local hospital (2), regional hospital (2) and medical center (4), including 40 hypertensive participants. The saturated opinions indicated doctors' reputation and friendliness, tiers of hospitals, and transportation convenience as the three main considerations for participants to access different hospitals. Participants tend to visit a fixed doctors and hospitals because they believe hypertension needs a long-term, consecutive and quality treatment. Higher-tier medical facilities are symbolized as better medical care, drugs and equipments, yet the out-of-pocket payment is considered affordable, especially doctors prescribed continuous prescriptions to save patient's co-payment charge. Participants dislike being transferred from lower to higher tiers of medical facilities due to the inconvenient process and lack of price incentive. **CONCLUSIONS:** By identifying attributes to hypertensive outpatients' choices of accessing medical facilities, we found the current co-payment policy does not impact on hypertensive patients' affordability and accessibility in Southern Taiwan. Future study is going to determine the relative importance of attributes and whether and how much higher co-payment charge can influence on patients' decisions to access different tiers of medical facilities.

PCV93

CARDIOVASCULAR RISK (ACCORDING TO FRAGMINHAN) FOLLOW-UP OF A COHORT INSCRIBED IN THE DE TODO CORAZON (DTC) DISEASE MANAGEMENT PROGRAMME OF MUTUAL SER HMO IN COLOMBIA, 2004-2007

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OBJECTIVES: Top describe the tendency of cardiovascular risk and the determining factors of a cohort of patients enrolled in the De todo corazón disease management (DM) programme. **METHODS:** The DTC programme was begun in Colombia in 2004 and 19,697 patients have benefitted up to December 2007; it seeks to control cardiovascular risk (CVR) using a DM model. The present study represents a first approach to evaluate the programme's effectiveness by analysing the tendency of CVR marker variables, such as blood-pressure and lipid profile by CVR group. The population being studied consisted of patients who had formed part of the programme since 2004 and who had uninterrupted annual follow-up visits up to 2007. A descriptive analysis was made, annual CVR level was calculated using the methodology described by ATPIII and tendency was described by both variables and CVR groups. **RESULTS:** Average age for the final population to be analysed (5174) was 63.74 years (11.76 S.D) and mainly consisted of females (72%). A decreasing tendency in the high risk group was observed in analysis by CVR group, accompanied by a corresponding increase in patients classified in latent and intermediate levels. Similarly, analysing tendency by variable revealed how systolic blood-pressure tended to decrease consistently throughout the time spent on each visit in each risk group. LDL-cholesterol revealed a similar tendency in high and intermediate risk groups, less stable behaviour

being seen in the latent risk group. HDL-cholesterol presented stable tendency in the three risk groups during successive visits. **CONCLUSIONS:** The results suggested that the De todo corazón DM programme had a positive impact during the period being studied, affecting modifiable risk factors such as TA and lipid profile and CVR control. Such tendencies should be compared with a control group for establishing whether they have really been produced by the DM programme.

PCV94

ASSESSMENT OF THE STATUS OF HYPERTENSION MANAGEMENT IN NEWLY DIAGNOSED AND ESTABLISHED HYPERTENSION PATIENTS IN PRIMARY CARE PRACTICE

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OBJECTIVES: This study compared hypertension management in newly treated and previously treated (established) adult patients (≥ 18 years) with hypertension. **METHODS:** A retrospective study was conducted using the GE Centricity electronic medical record database which contains ambulatory electronic health record data for over 7.4 million patients in the US. Patients were classified as newly treated hypertensives if they had no antihypertensive treatment within 24 months prior to the index date (date of the first anti-hypertensive prescription in 2006). Otherwise, patients were classified as established hypertensives if they received antihypertensive treatment during 24 months prior to index date. These two groups were compared to assess differences in comorbid conditions, proportion of patients treated per JNC-7 guidelines, distribution of index drugs, likelihood of achieving BP goal and changes in the antihypertensive therapy during 13 months follow-up period from the index date. **RESULTS:** A total of 28,276 newly treated patients (mean age 58.6 years; 55.7% women) and 78,450 (62.1 years; 57.1% women) established patients were identified. Newly diagnosed patients had fewer comorbidities (mean number 0.74 vs. 1.85; $p < 0.001$), less changes in anti-hypertensive medications (1.6 vs. 1.7; $p < 0.001$), less likely to be treated per JNC-7 guideline (52.7% vs. 60.2%; $p < 0.001$), and more likely to be treated on monotherapy at index (66.2% vs. 39.9%; $p < 0.001$) than established patients. Among the newly diagnosed patients, ACE inhibitors (ACEi) (30.6%) and diuretics (19.2%) were the most commonly prescribed first-line treatments, while ACEi (22.3%) and the combination of ACEi and diuretics (9.2%) were more commonly prescribed in the established patients. After controlling for age, gender, race, comorbid conditions, baseline BP, adherence to JNC-7, newly diagnosed patients were 38% more likely to achieve BP goal at follow-up ($p < 0.001$). **CONCLUSIONS:** Newly treated hypertensive patients tend to be younger, with less comorbidities, more likely to be treated on monotherapy and achieve BP goal compared with established patients.

PCV95

ELECTRONIC MEDICAL RECORD USE AND WARFARIN DRUG-DRUG INTERACTIONS DURING AMBULATORY VISITS IN THE UNITED STATES, 2003-2006

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OBJECTIVES: Elevated warfarin levels caused by drug-drug interactions (DDIs) increase the risk of gastrointestinal bleeding and vascular accidents. Electronic medical records (EMRs) have been associated with a greater potential for identifying DDIs. We evaluated the influence of EMR use on trends in prescribing potentially harmful drug combinations involving warfarin from a nationwide survey of ambulatory care office visits. **METHODS:** Data were derived from the 2003-2006 National Ambulatory Medical Care Survey (NAMCS), a public-use, nationwide probability sample survey of office visits by ambulatory patients to non-Federally employed physicians. Warfarin and interacting drugs prescribed within the same visit were identified. We evaluated the proportion of interaction-related encounters comparing visits with and without the availability of EMRs. Subgroup analyses were performed by combining 2-years of data (2003-2004 and 2005-2006) for more precise estimates. All analyses were weighted to reflect the sampling design of NAMCS to reflect representative ambulatory care use in the U.S. with appropriate variances. **RESULTS:** Total warfarin-related visits increased from 11.8 million in 2003 to 16.6 and 15.4 million in 2005 and 2006, respectively. In 2003-2004 (period 1) the proportion of warfarin visits in which an interacting drug was co-prescribed was 34.4% (95% CI: 21.4%-47.4%) with EMRs available and 32.0% (95% CI: 27.5%-36.5%) with no EMRs available. In 2005-2006 (period 2), the proportions were 36.7% (30.9%-42.4%) with EMRs and 33.5% (28.6%-38.3%) without EMRs. We observed no significant differences in the proportions of interaction-related encounters between EMR and non-EMR visits in both periods. **CONCLUSIONS:** Between 2003 and 2006, the rates of warfarin prescribing in ambulatory care increased by 27%. The proportions of interaction-related encounters were unaffected by EMR use, due possibly to the limited implementation of EMRs during that period. Further studies as newer data become available are needed.