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 (9.5 vs. 1.8 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). This is a probable change in this study, as 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 maca-induced flushing, and to maintain interest in the disease. Our findings substantiate the evidence that flushing is a valid symptom 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 maca 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 HF 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, in patients groups their health-related quality of life (HRQL) and general health on the MacNew Heart Disease HRQL Instrument. Patients were reassessed by postal questionnaires six months after visit. RESULTS: Complete 6-month followup was available for 139 patients (79% response rate; 25.3% female; age: 58 ± 13.2 ± 64.2% retired; NYHA E 14.7%, NYHA II: 53.9%, NYHA III: 24.5%, NYHA IV: 6.7%). Physical HRQL significantly deteriorated in both groups (IG: -0.3; CG: -0.4, both p < 0.01), whereas no significant deterioration for emotional and social HRQL was reported by the 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 = 0.099, NNT = 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 = 214, t < 0.05, 1α = 0.89).

PAV98 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 Guard.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 (LaMean) 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 (42.9%) 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. LaMean (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 67.47 (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 administered a validated instrument to an on-line community of consumers.

PCV99 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) the relationship between patient knowledge and the most effective for patient disease process awareness known to Knowledge Tool Test scores. METHODS: Adult patients with type-2 Diabetes with concomitant hypertension were recruited from community based primary care physicians 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 (38.61%), 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 in patient disease process awareness. CONCLUSIONS: Our study sample, decreased trend in HbA1c level and an increased trend in Knowledge Tool Test score was 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) sometimes come with substantial financial hazards 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 lsd-c9 codes we identified 27,644 individuals diagnosed with diabetes, hypertension or high-cholesterol. For each of these diseases daily average 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