was performed. Cronbach’s alpha coefficients and Pearson’s product moment correlations were calculated to estimate reliability. To establish construct validity, correlation coefficients were calculated between the subscales and vitality, well-being, treatment satisfaction, and/or baseline glycosylated hemoglobin (HbA1c). Standard errors of measurement (SEMs) were calculated to estimate minimal important difference. RESULTS: In both studies: 1) factor analysis confirmed the factor structure of the four subscales with the exception that the “sleepiness or drowsiness” item loaded with the Fatigue subscale items rather than the Cognitive Distress items; 2) test-retest reliability (all >0.68) and Cronbach’s alpha coefficients (all >0.79) were acceptable; 3) associations between subscales and other patient-reported outcomes measures and/or HbA1c were significant (p < 0.05) and in the hypothesized directions; and 4) SEMs were approximately 0.5 on a 1 to 5 scale. CONCLUSION: Preliminary validation indicates that the Cognitive Distress, Fatigue, Hyperglycemia, and Hypoglycemia subscales are potentially reliable and valid individual measures for use in clinical trials evaluating antihyperglycemic medications in patients with type 1 or type 2 diabetes.

PDB25
HEALTH STATUS AND QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS: RELATIONSHIPS IN A CROSS-SECTIONAL STUDY
Sundaram M, Miller LA, Kavookjian J
West Virginia University School of Pharmacy, Morgantown, WV, USA
OBJECTIVES: This study reports relationships between two instruments of health status and an instrument of quality of life (QoL) in a cross-sectional study among patients with Type 2 Diabetes Mellitus (T2DM). METHODS: Of generic health status (SF-12 and EuroQoL EQ-5D), and diabetes-specific QoL (Audit of Diabetes Dependent Quality of Life—ADDQoL). Patient reported data were merged with retrospective clinical data including A1C, comorbidities, diabetes complications score, BMI, and others, from electronic medical records. RESULTS: Usable response rate was 44.3% (n = 385). Mean A1C of respondents was 7.2 (+1.4), mean diabetes duration was 10.2 (+9.1) years, and 62.1% were obese (BMI >30). About 49% of respondents were on oral medications only, 31.7% on oral medications and insulin, and 9.4% on insulin only. Spearman correlations of the EQ-5D were 0.640 with the SF PCS-12, 0.534 with the SF MCS-12, and 0.316 with the ADDQoL (all p < 0.001). Insulin use and diabetes-related complications were significantly associated with poorer scores on all measures. Only ADDQoL scores were significantly better among those with the ADA recommended A1C level <7.0 (p = 0.002). Nearly 73% respondents reporting moderate problems with mobility and usual activities on the EQ-5D were clinically obese. Obesity significantly impaired SF-12 scores but not ADDQoL scores. A path analytic model relating SF-12 scores with EQ-5D and ADDQoL scores had good fit (Chi sq. = 1.32, p = 0.250; TL1 = 0.99; RMSEA = 0.03). CONCLUSION: All three measures discriminated on the self-selected categories for medication adherence. The mean VAS scores ranged from 62.4% to 98.1% across the categories (F = 180.4, p < 0.001), and the CMA ranged from 66.1% to 85.4% (F = 15.8, p < 0.001). The VAS had a moderate correlation with the CMA (r = 0.25). The mean (±SD) for the VAS and CMA were 95.5 (±10.4) and 83.2 (±15.9), respectively. For difference scores (VAS minus CMA), 33.5% of respondents had a VAS that was at least 1 SD higher than CMA. When comparing the VAS-80 to the CMA-80, the area under the ROC curve was 0.54 (2.3% were categorized as adherent by CMA-80, but non-adherent by VAS-80; 30.2% were categorized as non-adherent by CMA-80, but adherent by VAS-80). CONCLUSION: Self-reported adherence to medications by patients with diabetes is moderately correlated with claims-based estimates. However, about one-third of respondents will have a VAS that is significantly higher than CMA.

PDB27
MEDICATION ADHERENCE IN PATIENTS WITH DIABETES DURING THE MEDICARE PART D BENEFIT COVERAGE GAP PERIOD
Prasla K1, Godley P1, Rascati KL2, Gabriilo E
1Scott and White Health Plan, Temple, TX, USA, 2The University of Texas at Austin, Austin, TX, USA
OBJECTIVES: To evaluate medication adherence of select lipid lowering and oral anti-diabetic medications in diabetic patients during the Medicare Part D benefit coverage gap. METHODS: This was a retrospective evaluation of pharmacy claims database. The evaluation consisted of standard Medicare Part D benefit patients at an 185,000 member managed care organization during January 1, 2006 through November 30, 2006. Study patients included anyone who encountered claims for both a 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor (statin) and an oral (PO) anti-diabetic medication during January 2006, and reached the coverage gap by November 30, 2006. Patients were excluded if they subsequently experienced catastrophic coverage or did not reach the coverage gap during 2006. Medication adherence was measured using pharmacy claims data to calculate medication possession ratios (MPR). A descriptive comparison of MPR during “pre-coverage gap days” and...
“coverage gap days” was conducted for the study population. A MPR of ≥0.8 was considered adherent. RESULTS: Of approximately 13,000 standard Medicare Part D patients, 189 had claims for both a statin and a PO anti-diabetic during January 2006, and subsequently experienced the coverage gap. The number of patients reaching the “doughnut hole” or coverage gap in a given month ranged from 4 to 41, starting in April. The average “pre-gap” and “gap” periods were 242 days and 123 days, respectively. The average MPR for PO anti-diabetics during the “pre-gap” period was 24% higher than during the “gap” (0.92 vs. 0.70). For the statins, there was an 18% increase in the average MPR between the “pre-gap” period and the “gap” period (0.87 vs. 0.72). CONCLUSION: The overall medication compliance (i.e. MPR) of statins and oral anti-diabetics decreased during the 2006 Medicare Part D benefit coverage gap period. On average, patients became more non-adherent with their statin and oral anti-diabetic therapies during the “gap” period.

PDB28
IMPACT OF INITIATING OR CONVERTING TO TREATMENT WITH AN INSULIN ASPART ANALOG PEN ON MEDICATION ADHERENCE IN TYPE 2 DIABETES PATIENTS ON VIAL/SYRINGE INSULIN
Balu S1, Lee WC2, Cobden D3, Joshi AV1, Pashos CL1
1Abt Associates Inc, Lexington, MA, USA; 2Abt Associates Inc, Bethesda, MD, USA; 3Novo Nordisk Inc, Princeton, NJ, USA
OBJECTIVES: This study sought to evaluate the impact of converting to insulin administration with an insulin aspart analog pen from vial/syringe on medication adherence among type 2 diabetes patients. METHODS: A pre-post conversion approach was adopted using an integrated medical and pharmacy claims database from >30 managed care health plans in the United States. Adults diagnosed with type 2 diabetes who converted to insulin aspart pen therapy (NovoLog® FlexPen®) [index event] from either human or analog insulin vials between July 2001 and December 2002 with no prior use of FlexPen® for six months were identified. Medication adherence in the pre and post-index periods was measured using medication possession ratio (MPR). Paired t-test was performed to test the statistical differences in adherence rates. RESULTS: Data from 670 patients (prior analog insulin vial/syringe users: 328; human insulin vial/syringe users: 342) newly treated with FlexPen® were analyzed. Mean patient age was 45.7 years (SD: 13.8 years) and 50.8% were male. Upon initiating FlexPen®, MPR was significantly improved to 70% (SD: 32%) in comparison to 65% (SD: 29%), p < 0.01, prior to FlexPen® use. Previous human vial/syringe users [human premix users: 76% vs. 82%; p = 0.01, and NPH users: 66% vs. 70%; p = 0.02] showed the highest improvement in adherence in the post-index period of 5 percentage points (71% vs. 76%; p = 0.01), as compared to 4 percentage points (61% vs. 65%; p = 0.01) among prior analog vial/syringe users [glargine users: 63% vs. 67%; p = 0.03, and analog pre-mix users: 59% vs. 63%; p = 0.03]. CONCLUSION: Medication adherence to insulin therapy based on MPR was significantly improved following the initiation of insulin aspart analog pen in type 2 diabetes patients. Further analyses should evaluate the impact of improved adherence on clinical health outcomes and associated costs.

PDB29
RELATIONSHIP BETWEEN EATING HEALTHY FOODS AND REGULAR EXERCISE AND PHYSICAL HEALTH, MENTAL HEALTH, AND HEALTH STATUS IN TYPE II DIABETICS
Campbell HM1, Khan N2, Raisch DW1
1Department of Veterans Affairs Cooperative Studies Program, Albuquerque, NM, USA; 2University of New Mexico, Albuquerque, NM, USA
OBJECTIVES: To examine the relationship between eating healthy foods and exercising regularly on physical health (PH), mental health (MH), and perceived health status (PHS) among type II diabetics. METHODS: The 2005 Center for Disease Control and Prevention’s Behavioral Risk Factor Surveillance System, a cross-sectional survey, was utilized. Respondents were considered type II diabetics if diagnosis occurred minimally at age 30. Eating healthy foods was defined as eating at least 5 servings of fruits and vegetables daily. Exercising regularly was defined as meeting the recommendations for moderate and/or vigorous exercise. Due to impact on quality of life we included demographics, socioeconomic status, comorbidities, diabetic complications, and insulin use as covariates. Poisson regressions were used to compare the monthly number of PH or MH days associated with eating healthy foods and exercising regularly. Logistic regression determined the association between PHS (good versus poor) and eating healthy foods or exercising regularly. RESULTS: Among 21,590 type II diabetics identified, the majority were Caucasian, older, urban, hypertensive, and did not meet recommendations. Eating 3–4 servings of fruits and vegetables was associated with 0.1 (4.4%) and 2.9 (17.6%) more days in which PH and MH was good compared to 5 servings (p = 0.0113 and p < 0.0001). Consuming 1–2 servings of fruit and vegetables daily was associated with lower PHS (p < 0.0001). No exercise was associated with 5.8 (34.0%) fewer days of good PH (p < 0.0001), 3.6 (21.9%) fewer days of good MH (p < 0.0001), and 8% lower odds of good PHS (p < 0.0001) compared to people who exercise regularly. Annual household income <$15,000 consistently was associated with poorer PH (p < 0.0001), MH (p < 0.0001), and PHS (p < 0.0001). CONCLUSION: Glycemic effects from fruits and vegetables may contribute to more PH and MH days for 3–4 daily servings compared to 5. Causation cannot be inferred from these results due to its cross-sectional and observational nature.

PDB30
HEALTH RELATED QUALITY OF LIFE ON BODY MASS INDEX FOR PEOPLE WITH TYPE 2 DIABETES IN THE GENERAL ADULT POPULATION IN ENGLAND
Christensen T1, Hammer M1, Gough S2
1Novo Nordisk A/S, Bagsvaerd, Denmark; 2University of Birmingham, Birmingham, UK
OBJECTIVES: The risk of developing cardiovascular and other life threatening diseases is strongly linked to increased body weight. This is particularly relevant to people with type 2 diabetes (T2D) in whom over 80% are overweight. Limited data exist on the impact on Health Related Quality of Life (HRQOL) of Body Mass Index (BMI) for people with type 2 diabetes. The aim of this study was to characterize the impact of BMI on HRQOL for people with and without T2D in England. METHODS: Data from the Health Survey for England 2003 (HSE03) was evaluated. HSE03 consisted of a stratified random sample designed to provide data about the general population living in private households in England. Observations for 13,233 non-diabetic patients and 461 patients with T2D were included. HRQOL was measured using the EQ-5D. Overall HRQOL differences were investigated using t-tests. Analyses of variance