“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” period (0.87 vs. 0.72). For the statins, there was an 18% decrease 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

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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 >50 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

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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

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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...
HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PRIMARY CARE PATIENTS WITH TYPE 2 DIABETES MELLITUS AND DEPRESSION

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OBJECTIVES: To (1) determine the prevalence of depression in primary care patients with type 2 diabetes mellitus (T2DM) and (2) compare HRQoL in diabetic patients based on the severity of depressive symptoms. METHODS: Primary care patients with T2DM were recruited during their scheduled clinic appointments. Self-reported data on demographic characteristics were collected via a survey. Data on Hemoglobin A1C values and comorbid conditions were collected from patient charts. The Zung self-rating depression scale was used to measure depressive symptoms and the SF-8 was used to measure HRQoL. Analysis of variance (ANOVA) was used to compare HRQoL summary scores and domain scores for general health (GH), physical functioning (PF), role physical (RP), bodily pain (BP), vitality (VI), social functioning (SF), mental health (MH) and role emotional (RE) in diabetic patients based on the severity of symptoms. RESULTS: A total of 217 surveys were collected with a usable response rate of 93%. The mean age of the overall sample was 57.3 years (SD = 11.9), 62.2% were female and 61% were Hispanic. The Zung self-rating depression scale indicated that 72.1% of patients met criteria for depression. Scores for the domains of GH, PF, RP, BP, VI, SF, MH and RE decreased significantly (p < 0.001) as the severity of depressive symptoms increased. Similarly, ANOVA results showed that summary scores for PCS-8 (F = 24.16, p < 0.001) and MCS-8 (F = 40.00, p < 0.001) decreased significantly as depressive symptom severity increased. Post-hoc analyses revealed significant differences between groups. CONCLUSION: Patients with T2DM were found to have a high prevalence of depressive symptoms, including symptoms of severe depression. Mental as well as physical HRQoL decreased significantly as the severity of depressive symptoms increased. Detection and treatment of depression may help to improve HRQoL in patients with type 2 diabetes mellitus.

HEALTH-RELATED QUALITY OF LIFE AND UTILITIES OF RESPONDENTS WITH TYPE 2 DIABETES COMPARED TO THOSE WITH DIFFERING LEVELS OF CARDIOMETABOLIC RISK

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OBJECTIVES: Understanding the impact of diabetes on quality of life may provide impetus for education and prevention. This study assessed differences in health-related quality of life (HRQoL) across respondents with type 2 diabetes (T2D) and groups with varying levels of cardiometabolic risk for developing T2D. METHODS: The Study to Help Improve Early evaluation and management of risk factors leading to Diabetes (SHIELD) is a US longitudinal study of individuals with or at risk for T2D. Respondents without diabetes but with 3–5 cardiometabolic risk factors for T2D (abdominal obesity, BMI ≥28 kg/m2, reported diagnosis of cholesterol problems, hypertension or coronary heart disease or stroke) were classified as high risk and respondents with ≤2 of these risk factors as low risk. HRQoL was measured by the EQ-5D visual analog scale (VAS) and index utility score. Baseline mean VAS and utility scores (using US population values) were compared across the three respondent groups using analysis of variance with post-hoc testing. RESULTS: Mean VAS scores for T2D and high-risk respondents (66.8 and 70.4, respectively) were significantly reduced compared with low-risk respondents (79.6, p < 0.001). Mean index utility scores for T2D and high-risk groups (0.78 and 0.79, respectively) were substantially lower than those for low-risk group (0.87, p < 0.001). Additionally, the mean VAS and utility scores for T2D respondents were significantly lower than those of high-risk respondents (p < 0.001). Greater decrements were reported in all domains by T2D and high-risk respondents compared with low-risk respondents, with the largest difference in decreased mobility (47.9%, 43.4%, 17.1%, respectively). CONCLUSION: SHIELD results demonstrated that respondents with or at higher risk for T2D report decreased overall HRQoL, resulting from lower scores in every domain, compared with those at low risk. Even before T2D diagnosis, reducing cardiometabolic risk levels may lead to significant improvement in HRQoL.

VALIDATION OF THE 25-ITEM NATIONAL EYE INSTITUTE VISUAL FUNCTION QUESTIONNAIRE (VFQ-25) IN PATIENTS WITH DIABETIC RETINOPATHY

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OBJECTIVES: The 25-Item National Eye Institute Visual Function Questionnaire (VFQ-25) was designed to assess the influence of visual impairment on health-related quality of life (HRQL). The instrument has been developed and validated in samples of patients with various vision problems, but it has not previously been validated specifically for use in patients with diabetic retinopathy (DR). The purpose of this study was to assess the reliability and validity of the VFQ-25 in patients with DR. METHODS: Data were from a multicenter study on vision loss in patients with type 1 or type 2 diabetes and moderate to severe nonproliferative DR. Visual acuity was defined at each time point as each individual’s best corrected vision as determined by the ETDRS visual acuity chart score. Patients completed the VFQ-