

model spending. We report adjusted relative risks (adjusted_RR) with 95% confidence intervals (CIs) for multivariable logistic regressions and adjusted coefficients with standard errors and p values for results from OLS models, controlling for covariates. **RESULTS:** In multivariable models, COPD maintenance medication discontinuation increased hospitalization risk (RR = 1.08, 95% CI 1.06, 1.10), while high MPR reduced hospitalization risk (RR = 0.93, 95% CI 0.91, 0.95) compared to low MPR. Medication discontinuation also increased total spending by \$2350 ($p < 0.001$), driven largely by Part A spending (\$4039; $p < 0.001$) and offset by Part D drug spending reductions (-\$1,833; $p < 0.001$). High adherence significantly reduced total spending by \$4273 ($p < 0.001$), while moderate adherence reduced spending by \$936 ($p = 0.05$) relative to poor adherence. **CONCLUSIONS:** Findings highlight the importance of adhering to prescribed pharmacologic regimens of COPD maintenance medication in reducing hospitalizations and associated costs.

PRS23

NON-ADHERENCE IN ISONIAZID TREATED PATIENTS AS MEASURED BY THE TEMPTATION TO SKIP THERAPY (TEST) SCALE

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OBJECTIVES: Isoniazid is highly effective and widely used for TB prevention and treatment; however it must be used consistently for 6 to 9 months to treat latent TB, which is usually asymptomatic. The combination of long-term therapy and lack of symptoms results in high risk for non-adherence. The cost of subsequent treatment for patients with isoniazid resistance is estimated at \$1 million per reactivation case prevented. These data highlight the need for more information about adherence with isoniazid in patients with latent TB. The specific aim of this study was to document adherence patterns in patients with latent TB and examine associations with patient characteristics. We also examined patient's attitudes toward intentional nonadherence in relation to medical doubts, lack of social support, and medication side effects by using the Temptation to Skip Therapy (TEST) scale. **METHODS:** Questionnaires were completed at baseline by 211 isoniazid treated patients (aged 18-66) at the Rhode Island Tuberculosis Clinic. Adherence was subsequently measured at 6 and 9 months. The average score was computed for each TEST subscale and the association with each subscale and the Morisky Medication Adherence Scale (MAS) was examined. **RESULTS:** Adherence to INH therapy was 45% (by MAS). Latent TB patients scored highest on the Side Effect (Mean=1.62) and lowest on the TEST Medical Doubt subscale (Mean = 1.47). Non-Whites exhibited higher mean scores on the Medical Doubt subscale indicating uncertainty toward the need for therapy. Patients with higher scores on the Medical Doubt and Side Effect subscales had higher non-adherence levels. **CONCLUSIONS:** Latent TB patients exhibited low adherence with isoniazid therapy. Fear of side effects and doubts about the need for medication were related to discontinuation of therapy. Better understanding of attitudes toward isoniazid therapy may be beneficial for improving adherence, and reducing costs associated with isoniazid treatment.

PRS24

IMPACT OF MORBIDITY, PSYCHOLOGICAL DISTRESS AND LUNG FUNCTION ON PHYSICAL FUNCTIONING IN A RETIRED POPULATION

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OBJECTIVES: Physical functioning scales have been used to assess risk for disability, propensity for healthcare utilization, and impact on quality of life (QOL) scores. Understanding related factors in a nationally representative older population is important for designing effective physical functioning improvement programs, potentially decreasing utilization and increasing QOL. **METHODS:** To measure impact of demographics, morbidities, psychological distress and lung function on physical functioning among the retired, a retrospective main effects analysis of data from the Health and Retirement Study (HRS) for subjects surveyed in 2006 and 2008 was performed on a sample of 13,129 patients aged >50 years (M = 66.14; 45.9% male) with lung function measurement (peak expiratory flow (PEF)), and psychological distress (symptoms of anxiety and depression) assessment (8 question Center for Epidemiologic Studies Depression Scale (CES-D8)), and self-reported confirmation of morbidity diagnoses. Morbidities were diabetes (19.4%), chronic obstructive pulmonary disease (COPD) (9.8%), heart disease (23.6%), cancer (13.7%), and stroke (6.0%). **RESULTS:** In a weighted multiple regression model of physical function difficulty score, 49% of the variance was explained by analyzed variables. In a weighted logistic regression model for difficulties with >4 physical functions (max=12), adjusted for age and race, odds were significantly higher for subjects reporting morbidities of frequent pain (odds ratio range (ORR) 6.0-7.7), COPD (ORR 2.4-3.4), stroke (ORR 2.0-2.8), heart disease (ORR 1.6-1.9), or diabetes (ORR 1.7-2.2). In addition, greater risk for physical function difficulties was associated with psychological distress (ORR 2.2-3.0) and low PEF scores (<80% of predicted, ORR 1.7-2.1). Among retirees with COPD, 59.3% had low PEF scores compared to 23.7% without; 34.8% had psychological distress compared to 19.6% without. **CONCLUSIONS:** The secondary database of longitudinal data from the HRS offers valuable information for understanding factors associated with functional limitations. Mental health and lung functioning are potential areas for focusing improvement efforts.

PRS25

FACTORS INFLUENCING SATISFACTION WITH COPD MAINTENANCE MEDICATION: CONCEPTS ELICITED THROUGH QUALITATIVE INTERVIEWS WITH PATIENTS

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BACKGROUND: Patients with COPD have demonstrated poor adherence and persistence with inhaled maintenance medications, suggesting low satisfaction with existing therapies. An understanding of the factors driving treatment satisfaction from the patient perspective is necessary to develop or modify therapies to address patients' concerns. **OBJECTIVES:** To examine factors influencing patients' satisfaction with COPD maintenance medications. **METHODS:** Fifty-two one-on-one semi-structured telephone interviews were conducted with COPD patients to gather information about attributes that influence satisfaction with COPD maintenance medication and delivery devices. Participants were selected from two sources: patients who recently exited one of two trials with acclidinium bromide via the Genair™ inhaler (n=32) or non-trial patients recruited from clinics who recently received treatment with tiotropium bromide via the HandiHaler™ (n=20). A coding scheme for categorizing responses was developed and interview transcripts were analyzed using qualitative software. **RESULTS:** Focus group participants had a mean age of 66.5 years; were 51.9% female; and had a diagnosis of moderate (GOLD II) to severe (GOLD III) COPD. Four components of patients' satisfaction were identified: ease of use/convenience, efficacy, onset of action, and side effects. Regarding ease of use/convenience, patients most frequently cited the importance of device portability (31%), device simplicity (27%), and whether the device indicated that a dose had been received (25%). For efficacy, patients most frequently mentioned whether the product made them feel that their airways were open and they could catch their breath (42%), that the medication kept symptoms from worsening (33%), and that the medication improved ambulatory ability (29%). Nearly half of patients (46%) noted onset of action as important. Finally, thirty-five percent of patients noted that side effects affected their satisfaction with treatment. **CONCLUSIONS:** Ease of use/convenience, efficacy, onset of action, and side effects drive patients' satisfaction with inhaled COPD maintenance medications. COPD medications and delivery devices that address these factors may improve patient adherence and persistence.

PRS26

RELIABILITY AND VALIDITY OF THE EXACT-RESPIRATORY SYMPTOMS (E-RS) SCORE TO QUANTIFY THE SEVERITY OF RESPIRATORY SYMPTOMS OF COPD

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OBJECTIVES: Although respiratory symptoms are a defining feature of COPD, a standardized method for assessing their day-to-day severity suitable for testing treatment effects in clinical trials has not been established. This study examined the reliability and validity of the E-RS (EXACT-Respiratory Symptoms), a respiratory symptom score derived from the 11 respiratory items of the 14-item EXACT, a daily diary assessing exacerbations of COPD. **METHODS:** Content validity was assessed through analyses of qualitative data from 84 patients with COPD, including secondary analyses of data collected during EXACT development (n=63) and data from four new focus groups with patients without recent history of exacerbation (n=21). Quantitative properties were tested through secondary analyses of data from 188 stable COPD patients gathered over 7 days during the first EXACT validation study. **RESULTS:** Qualitative: Sample mean (SD) age=65(10), 44% male, mean FEV₁=1.2(0.4) L. Patient descriptions of respiratory symptoms during stable disease were consistent with the E-RS content, wording, and structure. Quantitative: Sample mean (SD) age=66 (10), 50% male, mean FEV₁=1.2(0.5) L. Factor analysis showed three subscales: RS-Breathlessness (5 items), RS-Cough & Sputum (3 items) and RS-Chest (3 items). For RS-Total and subscale scores, respectively: Reliability, internal consistency (alpha) =0.88 0.86, 0.73, 0.80; test-retest (ICC) Day 1 to 7 (n=171) =0.73; 0.71; 0.69; 0.62. Validity: Correlations (Spearman's) with St. George Respiratory Questionnaire - COPD (SGRQ-C) =0.75; 0.69, 0.58, 0.52, modified Medical Research Council dyspnea scale (mMRC) =0.33; 0.38, 0.24, 0.16, and rescue medication use =-0.32; 0.34, 0.26, 0.17 ($p \leq 0.05$ to 0.0001). **CONCLUSIONS:** Results suggest the E-RS is a valid and reliable method for evaluating severity of respiratory symptoms in COPD; the daily diary structure permits assessment of day-to-day variability and severity over time. Further research is needed to evaluate performance over longer assessment periods and in response to treatment, and to refine score interpretation.

PRS27

THE DEVELOPMENT OF A PATIENT-REPORTED OUTCOME INSTRUMENT TO EVALUATE NIGHTTIME SYMPTOMS OF COPD

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OBJECTIVES: There is currently no validated tool to evaluate nighttime symptoms in patients with COPD. The purpose of this study was to develop and test a patient reported outcome (PRO) self-administered questionnaire for evaluating COPD symptoms experienced during the night. **METHODS:** A review of the literature and interviews with six clinical experts informed the development of a framework for exploring patients' experience with nighttime symptoms of COPD. Four focus groups were conducted with twenty-seven subjects who experienced COPD symptoms at night or in the early morning. Trained interviewers used a semi-structured interview guide, starting with open ended questions. Grounded theory was applied using qualitative analysis software to identify key concepts and determine concept saturation. A conceptual framework was developed to depict patients' experience with COPD symptoms at night. Items and response options were generated based on the qualitative data. Subsequently, one-on-one cognitive debriefing interviews were conducted with 10 COPD patients to assess item readability, comprehensive-