regulatory requirements on efficacy and safety. Target product profiles (TPPs) are developed to evaluate critical assumptions underlying these parameters. Subsequently, hedonic market research tools (e.g., conjoint analysis) may be used to evaluate informally pricing/reimbursement potential based on the TPP. We explore a more direct approach: applying a minimal cost-effectiveness threshold used by health technology assessment agencies (such as the UK’s NICE) to derive formally a minimally acceptable clinical TPP vector and a maximally acceptable value-based price. METHODS: A generalizable, hypothetical data-based, Markov decision model was developed to compare experimental treatment, A, to exisiting standard treatment, B, in a chronic disease. Three sets of clinical parameters were assigned: treatment A was assumed to offer better efficacy, a worse AE profile, and a higher risk of relapse (presumably due to its lesser suitability in maintenance treatment) than treatment B. Plausible quality-adjusted life years (QALYs) and medical costs were assigned based on time in each of the health states of remission, progressive disease/relapse, and death. RESULTS: Using Markov cohort analysis, at a base case TPP, one-way sensitivity analysis yielded the maximum justifiable value-based price premium for A vs. B. For a hypothetical A vs. B price premium, multi-way sensitivity generated minimally acceptable TPP vectors for A that met the reimbursement threshold. A tornado diagram analysis yielded key uncertainty drivers. Using Markov micro-simulation, we generated expected net monetary benefit (NMB) acceptability curves for A vs. B, varying the key drivers. For TPPs that yielded convergent NMBs across treatments, the expected value of acquiring additional information (VOI) with a clinical trial was generated. CONCLUSIONS: TPPs that are explicitly derived from required cost-effectiveness thresholds should be used to guide drug development and to help determine price expectations.

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MD1 NONADHERENCE WITH ORAL HYPOGLYCEMICS AMONG MEDICARE PART D ENROLLEES WITH DIABETES

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OBJECTIVES: The objective was to examine the association between nonadherence to oral hypoglycemic agents and subsequent all-cause hospitalization, emergency room (ER) visit, and mortality among Medicare Part D enrollees with diabetes. METHODS: This is a longitudinal retrospective cohort study. The study sample consisted of Medicare Part D enrollees with diabetes from six states (Alabama, California, Florida, Mississippi, New York, and Ohio) who had filled at least one prescription for oral hypoglycemic agents during the first 6 months of 2006. Adherence was measured using proportion of days covered (PDC). Subjects were classified as adherent (PDC ≥ 0.8), poor adherent (0.5 < PDC < 0.8), and very poor adherent (0 < PDC < 0.5). Medicare Part D records and beneficiary files from July 1, 2006 to March 31, 2007 were evaluated for all-cause hospital admissions, ER visits, and mortality. Multivariate regression analyses were performed to assess the independent association between medication adherence and outcomes. RESULTS: Data were available for 1,101,533 patients. Among them, 58.4% were females and the mean age was 71.7 years. About 64.9% were adherent, 11.2% were poor-adherent, and 24.0% were very poor-adherent with oral hypoglycemics. After controlling for age, gender, race, and comorbidities (Charlon comorbidity index), in comparison to adherent patients, the odds for all-cause hospital admission, ER visit, and mortality were 17.9% (OR: 1.179; 95% CI: 1.156–1.204), 6.3% (OR: 1.063; 95% CI: 1.048–1.077), and 7.1% (OR: 1.071; 95% CI: 1.037–1.106) higher for poor-adherent patients. Compared to adherent patients, the odds for a poor-adherent patient to die were 13.9% (OR: 1.229; 95% CI: 1.214–1.247), 17.1% (OR: 1.171; 95% CI: 1.160–1.183), and 10.4% (OR: 1.104; 95% CI: 1.079–1.129) more likely to be hospitalized, have visited ER, or die during outcome measurement. CONCLUSIONS: The results suggest that nonadherence to oral hypoglycemic agents is relatively common and appears to be associated with adverse clinical outcomes. Medicare prescription drug plans should consider developing targeted interventions to improve adherence to oral hypoglycemic agents.

MD2 RACIAL DISPARITIES IN ANTI-DEMENTIA MEDICATION, ANTI-DEPRESSANT, AND ANTIPSYCHOTIC USE AMONG MEDICARE BENEFICIARIES WITH ALZHEIMER’S DISEASE AND RELATED DEMEN TIAS

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OBJECTIVES: Although racial disparities in the prevalence and associated costs of Alzheimer’s disease and related dementias (ADRD) have been documented in the elderly, no data examine whether these differences translate into differences in drug treatment. The objective of this study was to investigate racial disparities in the drug therapy for ADRD and its main manifestations, depression and psychotic disorders. METHODS: Community-dwelling elderly Medicare beneficiaries with ADRD were identified from the 2000–2004 Medicare Current Beneficiary Survey Cost and Use files linked with Medicare claims in n = 2,865. Generalized estimating equations were employed to calculate prevalence ratios (PRs) for use of anti-dementia medications, anti-depressants, and anti-psychotics by race, controlling for demographic characteristics, functional status, prescription drug insurance, and comorbidities. RESULTS: The prevalence of ADRD was significantly higher in minority beneficiaries than in non-minority beneficiaries (8.1% vs. 5.7%, p < 0.001), whereas anti-dementia medication use was 28.5% lower among minorities (OR = 0.72, 95% CI: 0.64–0.80). Depression was common in both groups (68.4% in minorities vs. 70.8% in non-minorities, p = 0.32), but minority beneficiaries were less likely to receive anti-depressant therapy (OR = 0.60, 95% CI: 0.42, 0.85). No racial differences were observed in prevalence of psychiatric disorders (11.7% vs. 20.8%, p = 0.096) or the use of antipsychotic drug use (OR = 1.06, 95% CI: 0.78, 1.44). CONCLUSIONS: Although minority Medicare beneficiaries were more likely to suffer from ADRD, they were significantly less likely to receive drug therapy for the condition and the coexisting depression. Under-use of appropriate drug therapy may lead to expensive inpatient hospitalization and nursing home care, resulting in poorer health outcomes and substantial burden on the health care system. The identification of clinically-modifiable factors associated with under-treatment is critical to improve health outcomes and reduce cost.

MD3 EFFECT OF LIPID LOWERING DRUG USE ON HOSPITALIZATIONS, EMERGENCY ROOM VISITS, AND MORTALITY IN MEDICARE DIABETIC POPULATION

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OBJECTIVES: To describe utilization patterns of lipid lowering drugs (LLD) and to examine the relationship between LLD use and all-cause hospitalizations, between LLD use and emergency room visits and mortality among Medicare patients with diabetes. METHODS: This is a longitudinal retrospective cohort study. The study sample consisted of diabetic Medicare Part D beneficiaries from six states, including Alabama, California, Florida, Mississippi, New York and Ohio. Beneficiaries was identified as diabetic using a combination of ICD9 code for diabetes (250.xx) and NDC codes for oral hypoglycemic agents. Utilization of LLDs in Medicare Part D records during the first 6 months of 2006 was evaluated and the measure was dichotomized as not using and using LLD. The primary outcomes of interest were all-cause hospitalization, all-cause emergency room (ER) visits and all-cause mortality. Multivariable regression analysis was performed to assess the association between LLD utilization and outcomes. RESULTS: The study sample constituted of 1,888,682 Part D enrollees with diabetes. Fifty percent of them were users of LLD. None of the enrolled patients were over 65 years of age and 67% were white. In unadjusted analysis, patients who used LLD had lower all-cause hospitalizations (OR: 0.761; 95% CI: 0.754–0.767), lower ER visits (OR: 0.909, 95% CI: 0.903–0.914) and lower all-cause mortality (OR: 0.567; 95% CI: 0.559–0.574). When adjusted for age, gender, race and comorbidities in multivariable analysis, LLD utilization remained significantly associated with lower risks for all-cause hospitalizations (OR: 0.862, 95% CI: 0.854–0.869), lower ER visits (OR: 0.801, 95% CI: 0.796–0.806) and lower all-cause mortality (OR: 0.646, 95% CI: 0.637–0.655). CONCLUSIONS: In conclusion, approximately 50% of the patients with diabetes received LLDs in the study period and utilization of LLDs are shown to be associated with improved outcomes in patients with diabetes after controlling for patient demographics and comorbidities.

MD4 THE EFFECT OF MEDICARE PART D ON INAPPROPRIATE PSYCHOTROPIC MEDICATION USE IN THE ELDERLY

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OBJECTIVES: The purpose of the study was to examine the impact of Medicare new drug benefit (Part D) on the utilization of inappropriate psychotropic medications (IPM) in the elderly. METHODS: The effect of Part D was measured using 24 months (2003–2006) pharmacy claims data provided by one of the largest retail pharmacy chains in the United States. Among the approximately 70 million individuals who filled prescriptions at the pharmacy chain in 2006, 11% were 65 years or older. IPM was defined based on Beers’s Criteria. Segmented regression of interrupted time series analysis was applied to evaluate changes in the monthly prevalence of IPM that were excluded and included in the Part D formulary in the elderly population 65 years or older. RESULTS: Among the 2.52 million elderly who filled psychotropic medications in the retail pharmacy chain in 2005, 0.72 million (28.5%) filled at least one IPM. The implementation of Part D caused a sudden [1.21% (P < 0.0001)] and a sustained drop [0.05% per month (P = 0.037)] in the prevalence of IPM. The seniors who enrolled in Part D were affected more than those who did not. Of 0.74 million seniors who filled IPM in 2006, only 12.81% were Part D enrollees. The reduction in IPM utilization was mainly due to the decrease in use of those medications excluded in the Part D formulary. The number of benzodiazepine and barbiturate prescriptions (medications excluded from Part D formulary) dispensed in 2006 dropped 6.16% compared to 2005. There is no statistically significant change in the use of IPM among patients and antipsychotics that were not excluded in Part D formulary. CONCLUSIONS: The implementation of Medicare Part D resulted in a decrease of IPM and thereby improving the quality of care in the elderly. Further study is warranted to assess the long term effect of Part D on IPM.