characteristics of the orphan drugs (OD) with the non-Orphan drugs approved by the FDA in the period 1983–2007. METHODS: All new chemical entities (NCE) approved by the FDA in the study period were included in the study. Data derived from the FDA’s Orange Book (OB). Differences between group means were assessed using the t-test. Differences in proportions were evaluated using chi-square and Fisher’s exact test. RESULTS: Between January 4, 1983 and October 3, 2007 the FDA granted 1749 OD designations and 315 OD approvals for marketing. NCEs accounted for 19.7% of OD designations and 53.7% of OD approvals. The FDA approved 635 NCEs in the study period, out of which 17.5% had OD status at the first NDA approval. Sponsors of ODs were more likely (p < 0.01) to be US companies as compared to non-US companies (64.0% vs. 54.4%) and to have one NCE approval as compared to multiple NCE during the study period (43.2% vs. 17.6%). ODs were less likely (p < 0.001) to have at least one patent listed in the OB in comparison with non-ODs (62.2% vs. 82.8%). ODs had less patents listed in the OB than non-ODs (mean 1.7 vs. 2.3) (p < 0.005). Exclusivity period was longer than the patent period for 41.4% of the ODs and 21.4% of the non-ODs that had patents listed in the OB (p < 0.001). ODs had less generic competition than non-ODs (18.0% vs. 29.6%) (p < 0.05). CONCLUSION: US companies and companies with only one NCE approval were more likely to use the Orphan drug regulatory system. Orphan drugs have less number of patents, more exclusivity protection and less generic competition than non-orphan drugs.

RESEARCH ON MEDICARE PART D AND REIMBURSEMENT POLICIES II

MD5

HEALTH CARE UTILIZATION BY MEDICARE ADVANTAGE BENEFICIARIES IN THE ERA OF THE MEDICARE PART D DRUG BENEFIT COVERAGE GAP

Delate T1, Raebel MA2, Ellis JL2, Bayliss EA3

1Kaiser Permanente Colorado, Aurora, CO, USA, 2Kaiser Permanente Colorado, Denver, CO, USA

OBJECTIVE: To compare health care utilization changes between Medicare beneficiaries with two prescription drug benefit structures who did and did not reach their respective Part D drug benefit spend threshold in 2006. METHODS: A retrospective analysis of a cohort of 28,392 Medicare Advantage beneficiaries continuously enrolled into two distinct drug benefit structures for the year prior to and after implementation of the Medicare Part D benefit. Among both groups, beneficiaries who reached their threshold had greater morbidity burdens are at risk of increased health care utilization and the potential for adverse outcomes. It is imperative that strategies be developed that help safeguard vulnerable Medicare beneficiaries.

DIFFERENTIAL TAKE-UP OF THE MEDICARE PART D PRESCRIPTION DRUG BENEFIT

Rabbani A1, Yin W1, Zhang JX1, Sun SX2, Alexander GC3

1University of Iowa, Iowa City, IA, USA, 2USRDS Economic Special Study Center, The University of Iowa, Iowa City, IA, USA

OBJECTIVE: Little is known about how Medicare Part D utilization varies based on subjects’ pre-Part D prescription coverage and comorbidities. METHODS: We examined claims from a national pharmacy chain from 2005 and 2006 accounting for approximately 15% of the U.S. prescription drug market. We focused on beneficiaries ages 66–70 as of January 1, 2006. We focused on the association between pre-Part D insurance gener-
osity, comorbid burden using a method of risk adjustment based on pharmacy claims, and Part D uptake after adjusting for patients’ demographic characteristics, characteristics of pre-Part D prescription use (average 2005 annual copayments, number of prescriptions, drug utilization in pill-days, number of treatment classes as reported in the store data), pre-Part D Medicaid eligibility, and zip code linked USA Census data. RESULTS: After multivariate adjustment, each 10% increase in 2005 insurance generosity was associated with a 16% lower likelihood of Part D utilization and each standard deviation increase in comorbid score was associated with an 8% greater likelihood of Part D utilization. Beneficiaries with the lowest yet positive insurance generosity with the greatest comorbid burden were up to 2.5 times more likely to utilize Part D than people who had generous insurance and were the healthiest before the introduction of the program (60.65% vs. 37.56%, p < 0.001). Results were robust to numerous sensitivity analyses. CONCLUSION: We find significantly higher rates of benefit adoption among subjects with low pre-Part D prescription coverage and high pre-Part D comorbid burden. Our findings highlight the fact that implementation and uptake of changes in health policy are seldom uniform. These results also may be useful in welfare analyses of Part D, and they demonstrate the importance of considering non-random selection into Part D when considering the impact of Part D on processes or outcomes of care.

Abstracts

THE IMPACT OF MEDICARE NEW DRUG BENEFIT (PART D) ON THE UTILIZATION OF PSYCHOTROPIC MEDICATIONS AND CONSEQUENT OUT OF POCKET EXPENDITURE FOR ELDERLY

Chen H1, Nwangwu A1, Aparasu R1, Sun SX2, Lee KY2
1University of Houston, Houston, TX, USA, 2Walgreens Health Services, Deerfield, IL, USA

OBJECTIVE: To evaluate the effect of Medicare new drug benefit (Part D) on utilization of psychotropic medications and the consequent financial burden for elderly. METHODS: The effect of Medicare Part D was measured using 24 months pharmacy claims collected from 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. Segmented regression of interrupted time series analysis was employed to evaluate population level changes in the utilization of three most commonly used psychoactive classes as reported in the store data), pre-Part D Medicaid eligibility, and zip code linked USA Census data. RESULTS: After Part D came into effect, the proportion of out-of-pocket payment in total pharmacy reimbursement decreased 18% for antidepressants (net saving: $4.5 per prescription) and 21% for antipsychotics (net saving: $5.7 per prescription). In contrast, the out-of-pocket share the elderly paid for benzodiazepines increased 19% (net increase: $2.8 per prescription). Part D implementation was associated with significant month-to-month increase in use of antidepressants [1679 prescriptions per month (95% CI: 719, 2639)] and antipsychotics [567 prescriptions per month (95% CI: 413, 720)]. By December 2006, the antidepressant and antipsychotic prescriptions filled by seniors grew 7% (from 273,166 to 293,590 prescriptions per month, P < 0.001) and 18% (from 41,079 to 48,276 prescriptions per month, P < 0.001) respectively as compared to the expected level estimated based on prior Part D trend. In contrast, Part D led to an immediate and sustained drop of 5% (from 238,961 to 226,622 prescriptions per month, P < 0.001) in benzodiazepine prescriptions filled by elderly. CONCLUSION: Our findings revealed that Medicare Part D improved the access to psychotropic medications covered under plan through reducing out-of-pocket expenses. However, the financial burden related to psychotropic medications excluded from the Part D formulary, such as benzodiazepines, has significantly increased.

RESEARCH ON PATIENT REPORTED OUTCOMES METHODS

RASCH RATING SCALE ANALYSIS OF THE EQ-5D USING THE 2003 MEDICAL EXPENDITURE PANEL SURVEY (MEPS)

Gu NY, Doctor JN
University of Southern California, Los Angeles, CA, USA

The aim of this study was to assess the Rasch measurement properties of the EQ-5D in respondents with most prevalent chronic conditions. Medical Expenditures Panel Survey (MEPS) respondents’ age ≥ 18 with complete EQ-5Ds from 2003 were extracted (n = 19,439). Eleven subgroups were identified using the primary ICD-9-CM code for the top 10 chronic conditions (hypertension, diabetes, depression, back disorder, arthropathy, cholesterol, asthma, sinusitis, anxiety and joint disorder) as well as healthy persons (n = 8021). Respondents with perfect scores demonstrating ceiling (n = 3911) and floor effects (n = 3) were removed to ensure uncertainty in the responses. Coding reflected that higher scores represent healthier respondents. The Rasch rating scale model was used to estimate one set of thresholds for all items. Unidimensionality was assessed using a z-score fit statistic, point-biserial correlations and Rasch residual factor analysis. Differential item functioning (DIF) was investigated in a pooled analysis of the 11 subgroups. Qualitative advances of the thresholds and positive point-biserial correlations were found on the EQ-5D items in all subgroups. Residual factor analysis revealed that a single factor explained between 74.9% and 94.4% of the variance. Further, respondents with different diseases demonstrated different orders of item difficulty. However, the item “anxiety/depression” consistently showed misfit (z-score > 2.0) in all subgroups. Overall, differential item functioning was found across the 11 subgroups, suggesting that respondents with different health conditions endorsed items with different frequency. For the most part, items in the EQ-5D contribute to a single underlying construct and may be used to evaluate different disease conditions. However, consistent item misfit of the “anxiety/depression” item in all subgroups suggests that a possible modification on this item may be needed.

WHAT PATIENTS SAY VS. WHAT PATIENTS MEAN: QUALITATIVE RESEARCH IN PRO DEVELOPMENT

Lasch KE1, Marquis P1, Vigneux M1, Abetz L1, Arnould B1, Bayliss MS1, Crawford B1, Rosa K1, Scott J1
1Mapi Values, Boston, MA, USA, 2Mapi Values, Lyon, France, 3Mapi Values Limited, Bollington, UK

The value of qualitative research in the development of Patient-Reported Outcome (PRO) measures has been recognized for many years. Very little information is available, however, in the PRO field on the conduct and analysis of qualitative research compared to the plethora of literature that is readily available on psychometrics. More recently, the focus has been placed on the concepts being measured and their meaning, and not in terms of correlation coefficients or factorial structure, but in their authenticity for patients. This paper that is authored by an international, interdisciplinary group of psychologists, psychometricians, regulatory experts, a physician, and a sociologist presents a method for developing PROs that are based on a foundation of