PHS5

CHOOSING BETWEEN THE PROMIS GLOBAL AND EQ-5D FOR COMPARATIVE EFFECTIVENESS RESEARCH: ARE THEY REALLY DIFFERENT?

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OBJECTIVES: To inform the design of comparative effectiveness studies (CER), a head-to-head psychometric comparison of the PROMIS Global and EQ-5D instruments is needed. METHODS: In 2013, 2289 US adults completed an online survey including 15 items from PROMIS Global and Items from the 3 EQ-5D versions (EQ-5D-3L, EQ-5D-Y, and EQ-5D-5L) in random order. After testing for unidimensionality, across each of these 25 items, we conducted 3 separate exploratory factor analyses (EFAs) from the PROMIS Global version. Next, we performed an item-response theory (IRT) analysis for factors shared between the 2 instruments. Item levels with insufficient responses (n < 400) were collapsed. The relationship of each item was assessed using an unconstrained graded response model. RESULTS: All items were positively correlated (ρ = 0.32 to 0.98). Regardless of EQ-5D version, EFA analyses identified 3 factors (eigenvalue > 1): Physical Health (PH), Mental Health (MH), and Quality of Life (QL). Each item uniquely loaded to a single factor after rotation. Unlike PH and MH, QL included only PROMIS items. At a threshold of 0.5 in standard error, the IRT analyses showed similar PH information function ranges by instrument (-0.2 to 2.4 for EQ-5D-5L vs. -0.2 to 2.4 for PROMIS Global). However, the MH information range for EQ-5D-5L was substantially narrower than the range for the PROMIS Global (0.3 to 2.4 vs. -0.8 to 2.8). CONCLUSIONS: The PROMIS Global includes 5 items that extend the measurement of general health beyond the 2 factors shared with the EQ-5D. When comparing the remaining 5 items of the PROMIS Global to the EQ-5D, the instruments appear to share information ranges in PH, but the PROMIS Global has a broader MH range than the EQ-5D. These similarities and differences are important considerations when choosing between the PROMIS Global and EQ-5D for CER.

PHS51

IMPACT OF SYMPTOMATIC BURDEN AMONG WOMEN DIAGNOSED WITH UTERINE FIBROIDS ON HEALTH-RELATED QUALITY OF LIFE: AN ASSESSMENT USING UTERINE FIBROID SYMPTOM AND QUALITY OF LIFE QUESTIONNAIRE (UFS-QOL)

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OBJECTIVES: Uterine fibroids (UF) are associated with significant reduction in health-related quality of life (HRQoL). The impact of UF on HRQoL using a disease-specific instrument, the UFS-QOL. METHODS: An online survey of US women between 18 and 54 years was conducted using 3 large respondent panels as a sampling frame. Data collected included demographics, UF prevalence, symptoms, HRQoL and health-related productivity. Descriptive statistics were used to examine the impact of symptom presence, symptom severity, bothersomeness, and number of UF-related symptoms on multiple domains of HRQoL. Analyses were weighted to match the population distribution of age, education, region, and household income of US female population. RESULTS: 59,411 (15.5%) of the panel members who were contacted completed the prevalence screener; 5,879 met inclusion criteria for survey completion. Of those, 1,397 had UF and no hysterectomy. Mean age was 42.6 years, 65% were white, 62% were married or in a civil union. Among the most common symptoms experienced in the past 4 weeks, at least 49% rated each symptom as at least “moderate” severity and > 87% rated a symptom as at least “somewhat bothersome”. Mean UFS-Qol subscale scores were significantly (p < 0.05) worse among women who reported each UF symptom versus women in whom the symptom was absent. In particular, the presence of bleeding and also non-bleeding symptoms (pelvic pressure, low back pain, abdominal pain, bloating, and fatigue/weakness/anemia) was related to worse UFS-Qol subscale scores. Women who rated their UF symptoms as severe had significantly (p < 0.01) worse UFS-Qol scores versus women with mild or moderate UF symptoms. In addition, HRQoL, quality of life, and other domains of UF symptoms exhibited increased. CONCLUSIONS: Women who suffer from UF are more likely to report decreased or poor health. An increase in UF symptoms may result in decreased quality of life. Future research is needed to ascertain the impact of UF in a larger, national sample.

PHS53

COMMON CHRONIC CONDITIONS, DISABILITY AND PERCEIVED HEALTH: EMPIRICAL SUPPORT OF A CONCEPTUAL MODEL

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OBJECTIVES: A predominant Health-Related Quality of Life Model (described by Wilson & Cleary) posits a sequential relationship from biological and physiological variables to perceived health and overall quality of life. We assessed the extent to which disability mediates the association between mental and physical conditions with perceived health. METHODS: Data come from the WHO World Mental Health Survey (WMH) 2004 in 22 countries (n = 1,364 respondents, 72.0% response rate). We assessed 9 common mental disorders with the WHO Composite International Diagnostic Interview v3.0 (CIDI), and 10 chronic physical with a checklist. Perceived health (PH) in the previous 30 days was assessed using a numerical scale (from 0, worst, to 100, best). Disability was assessed using a modified WHO Disability Assessment Schedule 2.0 (WHODAS). Path analysis and multigroup techniques were used to estimate total effects of physical and mental conditions on perceived health and their direct and indirect (through the latent and observed WHODAS dimensions) effects. RESULTS: 12-month prevalence was 14.4% for any mental and 51.4% for any physical condition. Disability was correlated with mental and physical conditions, 31.7% had both role functioning, 11.4% with mobility and 8.3% with Stigma. Overall perceived Health (FH) scores was 81. The model explained 36% of FH score variance and estimated a significant score decrement of 8.5 for individuals with a mental disorder and of -8.2 for those with a physical condition. Of those decrements, 7.7% (mental) and 59.0% (physical) were “indirect” effects (i.e., mediated by disability). Mediation importance of disability domains differed by mental and physical conditions. CONCLUSIONS: A large proportion of the decrement in perceived health associated with common conditions is mediated by disability. Disability mediation patterns are different for mental and physical conditions. These data support the validity of the Health-Related Quality of Life Model.

PHS54

HEALTH RELATED QUALITY OF LIFE IN PATIENTS USING COMPLEMENTARY ALTERNATIVE MEDICINE (HOMEOPATHY) IN QUETTA, PAKISTAN

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OBJECTIVES: To evaluate the health related quality of life among patients using complementary Alternative Medicine (homeopathy) in Quetta, Pakistan. METHODS: A cross sectional, descriptive study was undertaken among the patients visiting three major homeopathic clinics in Quetta City, Pakistan. Health related quality of life was assessed using Life scale (WHO QOL). Descriptive analysis was used to elaborate patients’ demographic characteristics while inferential statistics were applied to report the association among study variables. RESULTS: Out of 500 questionnaires distributed 486 were received with a response rate of 97.2%. Gender distribution was 264 (54.4%) males. Mean age of the study participants was 34.05 ± 13.0 years with 334 (68.7%) married and 431 (87.7%) having urban residency. The mean EQ-5D descriptive score and EQ-VAS score were 0.59 ± 0.22 and 60.19 ± 16.9 respectively. 32 patients related quality of life using Homeopathy is slightly low then the health related quality of life of general population of Quetta. This study provides baseline assessment for the health status of patients using Homeopathy and the results could be applied in clinical practice.

PHS55

FACTORS IMPACTING PERSONALIZED MEDICINE TEST ADOPTION: EVALUATING PATIENT PREFERENCES AND WILLINGNESS TO PAY

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OBJECTIVES: Personalized medicine tests (PMTs) are increasingly available in the healthcare marketplace. The diffusion of such technologies is in part a function of the collective preferences of patients, providers, and payers. The objective of our study was to identify the attributes of PMTs most important to patients and thus likely to impact individual decisions and population level adoption. METHODS: We used a mixed methods study design to identify the attributes of PMTs that impact patient decision-making. We recruited patients with and without prior PMT experience to participate in focus groups and interviews via flyers, provider contacts, and disease support groups. Patients completed an attributes rating exercise and a payment card scenario to estimate willingness-to-pay (WTP) for PMTs. Analysis of transcripts was performed using thematic coding, analysis of attribute ranking used a rank-ordered logit model, and payment card data was conducted using internal regression. RESULTS: We contacted 32 patients of which 20 ultimately participated (focus group: 16; interviews: 6). Analysis of the attribute rankings indicated that the most important attributes were: 1) ability to select the appropriate treatment, 2) benefit to family members, and 3) quality of life after testing. The rankings for these characteristics were all statistically significant. The average willingness-to-pay for a PMT was $1,528 (95%CI: $361-2,694). Patients making less than $25,000/yr had a statistically significant lower WTP ($373) compared to the population average. CONCLUSIONS: Patients showed a strong preference for the ability to select the appropriate treatment based on test results as well as the impact of test results on their family and their quality of life. Patients were willing to pay more than typically would be required in an insured population but less than the full cost of some commonly used PMTs. This work will ultimately be used to inform the development of a discrete choice experiment.

INDIVIDUAL’S HEALTH – Health Care Use & Policy Studies

PHS56

IMPACT OF PEDIATRIC REGULATION ON AVAILABILITY OF NEONATE DRUG INFORMATION

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OBJECTIVES: Regulatory policies, including economic incentivization through patent extensions, have been implemented to stimulate pediatric research, however, disparity exists for the neonatal subpopulation. This analysis was conducted to identify the availability of neonate-specific data for frequently used medications in Neonatal Intensive Care Units (NICUs) and to determine the extent to which pediatric exclusivity has increased information in neonatal populations.

A search was conducted utilizing the FDALabels database to identify all FDA-approved NDA, BLA and ANDAs from 01/01/1980 to 08/01/2013 searching for the terms “neonate”, “newborn” and “infant” present in any of the following label sections: “Indication and Usage”, “Dosage and Administration” and “Pediatric Use.” The results were cross-referenced with a recently published list of 100 frequently prescribed drugs in NICUs and drugs granted pediatric exclusivity by the FDA as of August 31, 2013. RESULTS: A total of 373 unique labels for 110 distinct drugs were identified (including 18 combination products and 15 modified versions of previously marketed drugs). “Newborn” was identified in 450 labels, “infant” in 414 labels and “neonate” in 76 labels. More than one of these terms was found in 294 labels. Only 19% of drugs frequently used in NICUs mentioned neonates, newborns or infants on their labels. Mention of neonates, newborns or infants occurred in 4.5% (n=9) of the drugs with pediatric exclusivity, while 8.7% (n=17) of drugs granted pediatric exclusivity did not mention any of these terms. OBJECTIVES: To evaluate fracture-related expenses and health care resource utilization among post-menopausal women in the U.S. MEDICARE POPULATION. METHODS: Female patients diagnosed with fractures (International Classification of Disease, 9th Revision, Classification [ICD-9-CM] codes: 733.1-3, 800.0, 805.2, 805.4, 805.6, 808.5, 808.8, 808.3, 810.0, 810.2, 812.2, 812.4, 813.3, 813.2, 813.4, 813.8, 814.0, 820.0, 820.2, 820.8, 821.0, 821.2, 823.2, 823.3, 823.4, 823.8) were identified using U.S. Medicare data from 01/01/2000 through 12/31/2005. The initial diagnosis date was designated as the index date. A control cohort that included patients without fractures of the same age, race, region and baseline Charlson Comorbidity Index score was created. The index date for the control cohort was randomly assigned to minimize duration bias. Patients in both cohorts were required to be age ≥50 years, with continuous medical and pharmacy benefits for 1 year pre- and post-index date. Propensity score matching (PSM) was used to compare health care costs and utilization among post-menopausal women in the U.S. Medicare population.

CONCLUSIONS: Only a total of 18 (30%) patients were prescribed with at least 1 PIM according to STOP Criteria. Most commonly prescribed PIMs were systemic corticosteroids (29%) followed by hypnotics (22%), anticoagulants (11%), antihypertensives (10%), antibiotics (7%) and anti-arrhythmics (5%). On multiple regression, important predictors for PIM prescribing were found to be polypharmacy, number of diagnoses. CONCLUSIONS: The results show that PIMs prescribing is high in Indian elderly inpatients STOP and START criteria, it is more effective in identifying the PIMs. This study is ongoing and we will present the data up to 250 patients before the presentation.

PHS99 EVALUATION OF THE POTENTIAL IMPACT OF DRUG-GENE INTERACTION RISK (DGIR) ON HEALTH RESOURCE UTILIZATION (HRU) OBJECTIVES: To assess the relationship between DGIR and HRU in elderly patients to evaluate potential benefit from pharmacogenetic testing. METHODS: A retrospective cohort of patients age ≥65 years was identified through Innovan's MORE2® registry with continuous enrollment, taking ≥3 prescription medications (July 1, 2012 - March 31, 2013) and on ≥1 drug metabolized by a polymorphic drug metabolizing enzyme. Patients were stratified into zero, low, medium, and high DGIR groups via a diagnostic test (Genelex Youscript®). Counts of HRU during 9 months follow-up post index-date (date of first claim for ≥1 drugs with pharma-cogenetic implications) included all-cause hospitalizations, emergency-room and clinic visits. Poison prescription was used to test the association between DGIR and HRU counts. The model was adjusted for age, gender, race, Charlson Comorbidity Index (CCI) and number of known drug-drug interactions. RESULTS: A total of 452,102 patients were assigned to each of the four categories—zero, low, medium, and high DGIR groups. The median DGIR score was 8.7% [95% CI 2.3%-4.4%]. There were 59,559 (23.6%) with a DGIR score of zero, 82,224 (32.6%) with low risk (0-20%), 33,139 (13.3%) with moderate risk (20-40%) and 100,080 (38.8%) with high risk (>40%). Multivariable analysis revealed that the low and medium DGIR groups were associated with a 9% (95%CI 8.4% to 9.7%, p < 0.0001), and 8% (95%CI 7.7% to 9.2%, p < 0.0001) increase in the rate of HRU, compared to zero risk. The high DGIR group was associated with a 17% (95%CI 15.6% to 18.3%, p < 0.0001) increase in the rate of HRU compared to zero risk.

CONCLUSIONS: Among elderly patients, low and medium DGIR groups were associated with increased rates of HRU. In contrast, high DGIR was associated with lower HRU rates. This may be explained by a time-dependent effect of changing DGIR as a result of medication changes over time.