A166

P1H76
A REVIEW OF PATIENT-REPORTED OUTCOME ORPHAN DRUG LABELS IN THE UNITED STATES FROM JANUARY 2006-SEPTEMBER 2013: ANALYSIS OF EVIDENCE FOR ORPHAN DRUG PRO LABEL CLAIMS

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OBJECTIVES: Previous reviews of patient-reported outcome (PRO) label claims did not include orphan designation. Prior analyses were limited. Here, we describe, assess, and analyze PRO claims in the orphan drug literature.

METHODS: Using the Drugs@FDA database, new molecular entities and biologic licensed agents approved between January 2006 and September 2013 with orphan designations were identified. We evaluated PRO label reviews for PROs with clinical trials, and summary review sections from FDA drug approval packages were reviewed to identify reviewing division, indication, review designation (priority, standard), PRO endpoint status, PRO measure type, number of phase 3 trials supporting claims, and PRO frequency. Analysis was limited to orphan drugs with PROs.

RESULTS: Of 43 orphan products identified, 5 (12%) included PRO label claims. Five orphan products achieved 7 PRO claims. Priority and standard review prevalence were similar (44% vs. 40%, respectively) for orphan products; the majority (4 of 5) of products with PROs claimed priority review. A slight majority (60%; 3 of 5 orphan products) included PRO claims supported by ≤ 1 phase 3 trial. Signs/symptoms measures and secondary PRO endpoints were most common (57% each). FDA reviewing division varied. One product received PRO-related SEALD comments. CONCLUSIONS: For the time period evaluated, orphan products rarely included a PRO label claim. These claims may not be forthcoming for the ED health state due to the rareness that they are for non-orphan products. PRO claims achieved for orphan products appear to require less supporting evidence for approval than non-orphan products, consistent with orphan drug approval expectations but in contrast to FDA PRO guidance criteria.

P1H80
HEALTH OUTCOMES ASSOCIATED WITH THE USE OF PROHORMONE NUTRITIONAL SUPPLEMENTS

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OBJECTIVES: Anabolic prohormones, similar to anabolic-androgenic steroids, are sold as dietary supplements in the United States. There is very little known about the health outcomes associated with exposure to prohormones. The objective of this study is to systematically review the health outcomes and other perceptions associated with prohormone use.

METHODS: A self-administered survey was developed and deployed via two e-talks dedicated to prohormone use. Questions included information about health outcomes, beliefs about the commonality of side effects in users, and prohormone use characteristics including number of substances taken, number of cycles completed in a year, and taking the recommended or excess dosage. Outcomes were correlated with beliefs. Logistic regressions were used to measure the association between dose categories and self-reported outcomes. A multiple risk factor analysis looked at the association between higher than average number of self-reported outcomes and several combined risk indicators. Combining results of each risk indicator were compared to analyzing each above recommended dose method in combination with highest number of substances per cycle, highest number of cycles per year and having also taken AAS in the last year, respectively.

RESULTS: Eighty one respondents were enrolled (92% men, 8.5% women) of 65 respondents. Users reported an average of 2.49 (SD = 0.65) outcomes in their last prohormone cycle. Correlations showed those who experienced no outcomes believe adverse events are uncommon (R = 0.26, P = 0.04). Conversely, those who experienced the highest number of outcomes were not correlated with the belief that outcomes are common (R = 0.17, P = 0.16). No outcome was significantly associated with taking more than the recommended dose. Multiple risks showed no significant association with an above average number of reported outcomes. CONCLUSIONS: This study is a pilot in an understudied population. Despite having a small sample, this study is the first of its kind in compiling self-reported outcomes in prohormone users.

P1H73
ADVERSE DRUG REACTION REPORTING SYSTEM AT DIFFERENT HOSPITALS OF LAHORE: AN EVALUATION AND PATIENT OUTCOME ANALYSIS

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OBJECTIVES: ADRs are known to be a major cause of morbidity and mortality. However, only a very little proportion is reported. ADRs contribute to two-thirds of adverse effects, resulting in increased health care costs. METHODS: The first part of this project was to review the ADRs reporting system in Pakistan hospitals, to determine the factors contributing to the ADR reporting rate and benchmark with WHO Data. Then, following the ADR reporting systems, a study was conducted in 24 hospitals. 20,428 ADRs were collected and administered. RESULTS: Out of 24 hospitals, 20 (80%) hospitals have no proper ADR system, five (16.7%) hospitals are targeting few of the drugs for ADRs reporting while only one (3.3%) hospital has a proper ADRs management system. During the study, 2000 questionnaires were given to hospital personnel and 2000 questionnaires were given to ADRs reporting to Ministry of Health. Factors that would encourage respondents to report ADRs included seriousness of reaction (75.8%), unusual reaction (63.6%), reaction to a new product (66.6%) and patients’ education (51.5%). However, the discouraging factors are uncertain association (65.7%), awareness (57.6%), and concern about legal liability (51.4%). CONCLUSIONS: It is observed that awareness of ADRs program need special attention with some concrete steps should be taken for education of ADRs reporting to Ministry of Health. The training and integration of ADRs reporting into the clinical activities would definitely improve the patient outcome.

P1H70
ASSESSMENT OF HEALTH STATES AND ERECTILE DYSFUNCTION-ASSOCIATED QUALITY OF LIFE AMONG ADULT UNITED STATES MALES AND UNITED STATES FEMALES WITH MALE PARTNERS

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OBJECTIVES: To determine the quality of life associated with erectile dysfunction (ED) among the U.S. adult population both among diagnosed ED sufferers and non-sufferers. METHODS: A representative (U.S.) sample of 1,000 adults (502 males, 498 females) completed an online survey about their own (for men) or partner’s (for women) ED. Of the 276 samples (11.3% of males report having been diagnosed with ED and 6.4% of females that report their male partner has been diagnosed. Overall, the SG and VAS measures yield very similar but not identical utility estimates for the ED health state. The mean utility estimates across all eligible respondents are 0.41 (0-1 scale) for the SG and 0.44 for the VAS. Looking just at SG, males have lower utility on average (0.37) for the ED health state than do females for their partner’s ED health state and there was no difference between males who are healthy and those diagnosed with ED. Women whose partners are healthy express lower utility (0.37) for their ED health state (described as “significant difficulty in achieving an erection/penis gets hard but not hard enough for penetration”) than women with a partner diagnosed with ED. Younger respondents also have lower utility for the ED state for their partner respondents, than for the VAS the utility of this health state is linear. CONCLUSIONS: The fact that males who have not been diagnosed with ED have the same utility for the ED health state as those who have been diagnosed indicates that otherwise healthy males accurately anticipate quality of life decline associated with ED. Females with a diagnosed partner seem more willing to accept living with that partner’s ED health state.

P1H72
SPONSORING SPANISH LANGUAGE TRANSLATIONS IN UNITED STATES-BASED CLINICAL TRIALS

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OBJECTIVES: The accuracy of clinical trial data can be jeopardized if the translations used in the study are not regionally appropriate, particularly if the COAs (Clinical Outcomes Assessments) record direct feedback from patients whose first language is not English. Ensuring regional sensitivity in translations can be difficult in countries like the United States, where four major dialect groups dominate the population. To manage this challenge, we present the post project experiences of conducting linguistic validation for US-based sites to ensure the most appropriate Spanish language is used. METHODS: Past studies that required US Spanish were performed with COAs (Clinical Outcomes Assessments) translating US-based patients. Consideration was given to studies incorporating multiple site locations around the country, as well as to studies targeting a specific region. RESULTS: US Spanish translations yielded the best results when sites were regionally appropriate, particularly if the Spanish-speaking patients. CONCLUSIONS: Determining US site location prior to translation is recommended to ensure a more comprehensive translation that is tailored toward the target population, therefore yielding the most accurate responses. If sites have not been confirmed within the US, a recruitment formula developed to account for major Spanish populations in the US is recommended.

P1H74
PERCEIVED (PERCEIVED AND ACCUMULATIVE) AND HEALTH RELATED QUALITY OF LIFE AMONG STUDENTS IN THE ISPOR STUDENT NETWORK: A PILOT STUDY

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OBJECTIVES: The objective of this pilot study was to investigate the associations among perceived stress, accumulative stress, coping mechanisms, and health-related quality of life among students. METHODS: A self-administered questionnaire was used to collect data. RESULTS: 387 questionnaires (69%) were completed. A response rate of 93.5% was achieved. Among the participants, 39.3% were doctors and thirty four (65.4%) pharmacists knew how to report ADRs within the hospital while 9 (10.7%) doctors and 13 (25%) Pharmacists knew about the ADRs reporting to Ministry of Health. Factors that would encourage respondents to report ADRs included seriousness of reaction (75.8%), unusual reaction (63.6%), reaction to a new product (66.6%) and patients’ education (51.5%). However, the discouraging factors are uncertain association (65.7%), awareness (57.6%), and concern about legal liability (51.4%). CONCLUSIONS: It is observed that awareness of ADRs program need special attention with some concrete steps should be taken for education of ADRs reporting to Ministry of Health. The training and integration of ADRs reporting into the clinical activities would definitely improve the patient outcome.
Brief COPE Scale (higher scores = better coping); 4) Acculturative Stress (ASSIS) (higher scores = lower acculturative stress); 5) demographic information. RESULTS: The mean age of the 19 participants was 28.9 years ± 4.6. A majority of the respondents were Asian (47.4%), female (73.7%), enrolled in the PhD program (73.7%), single (52.6%), international students (57.9%) and lived with family (47.4%). Mean PIH74 was 49.97 ± 9.3 among participants. We observed that both the physical health and mental health summary scores were comparable to the general population. Overall, participants reported low stress (GSI-8) levels (mean = 56.2 ± 10.3; range 21 – 147) and engaged in mid-range levels of coping mechanisms to deal with stress (mean = 71.42 ± 7.1; range 28 – 140). Among international students, acculturative stress levels (mean = 51.10 ± 27.9; range 36 – 180) were low. CONCLUSIONS: There is a paucity of quantitative data for perceived stress among graduate students. The results from this pilot study will be used to implement a future survey among a larger and more diverse sample of graduate students.

PPIH47

A SIMPLE AND EFFECTIVE APPROACH FOR ANALYZING MULTIVARIATE LONGITUDINAL HEALTH OUTCOMES IN OBSERVATIONAL STUDIES

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OBJECTIVES: The purpose of this paper is to propose a simple and efficient approach for analyzing multivariate longitudinal data (MLD), such as longitudinal health-related quality of life (HRQoL) assessments in observational studies. This will be accomplished using the combination of two popular statistical methods for causal inference and multivariate data, namely the inverse probability-weighted (IPW) estimator and principal component analysis (PCA). METHODS: Multivariate outcomes at each time point will be converted to the first principal component score (FPS) for each subject. Then all FPSs will be composited into a numerical observation using the area under a curve (AUC). The IPW estimator is used to compare the difference between regression coefficients in terms of the AUC of FPS. The principal component score (PCS) of FPS is the statistically rigorous approach for a total score (TSCORE) that contains covariates. RESULTS: The statistical results show that the 95% bootstrap percentile confidence interval (BPCI) is (-3.06, -3.59). Since the BPCI was not contained in the 95% CI, we claim that the treated group (M = 95%) had a significantly higher stratum cost than the control group (OG = 71.42 ± 7.1; range 28 – 140). Among international students, acculturative stress levels (mean = 51.10 ± 27.9; range 36 – 180) were low. CONCLUSIONS: There is a paucity of quantitative data for perceived stress among graduate students. The results from this pilot study will be used to implement a future survey among a larger and more diverse sample of graduate students.

PPIH5

ASSESSMENT OF MEDICAL AND PHARMACY STUDENTS’ KNOWLEDGE AND PERCEPTIONS ABOUT GENERIC MEDICINES AND THEIR QUALITY AND PRICES IN KABUL – AFGHANISTAN

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OBJECTIVES: To assess medical and pharmacy students’ knowledge and perception about generic medicines and its quality and prices in Kabul-Afghanistan. METHODS: A questionnaire based convenience sample of 255 was applied and study was conducted at Kabul Medical University and Pharmacy Faculty of Kabul University. The questionnaire had 19 questions and was designed in two sections (definition of generic and branded medicine and perception towards generic medicine). A total of 95 pharmacy and 125 medical students had voluntarily participated in the survey. SPSS version 16 was used for data analysis purposes. RESULTS: Among the total target n = 220 (response rate 86.27%) students voluntarily participated in the survey of which 75 (33.9%) were female and 145 (66.1%) were male. The PCs was to provide generic medicines in the private pharmacy outlets. In reference to the knowledge about generic medicines n = 173 (67.84%) of the respondents had knowledge about generic medicines. The interviewees n = 205 (80.39%) expressed that the quality is their major concern, when buying generic medicines. Both groups have shown unanimity n= 216 (84.70%) that prescription of generic medicines promotes cost containment among the patient. CONCLUSIONS: The current study emphasizes that awareness and knowledge about generic medicines by including special topics in the medical and pharmacy curriculum is important and further promoting culture of prescribing generic medicines in daily practice.

INDIVIDUAL’S HEALTH – Health Care Use & Policy Studies

PPIH6

MOMSB2: IMPROVING BIRTH OUTCOMES THROUGH USE OF CELL PHONES, TEXTING, AND INTRINSIC CASE MANAGEMENT

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OBJECTIVES: Out of 200 of the most populous U.S. counties, Philadelphia has the fifth highest infant mortality rate. Keystone First partnered with Verizon Wireless to launch a pilot program providing free cell phones and minutes to directly deliver cell phones and minutes to high-risk pregnant women. The goals are to engage Keystone First’s high-risk pregnant Medicaid members. The targets are to improve prenatal care and health outcomes, and keep members connected to the phone. METHODS: The Intrinsic Case Management team contacted participants on the cell phones to provide coaching and care coordination during pregnancy and postpartum. Participants also received text messages with nutritional and clinical information specific to gestational diabetes. In addition, they received encouragement and gift incentives to maintain scheduled prenatal/postpartum care, along with information about screenings and educational and community-based programs. Seventeen participants actively engaged in Moms2B (intervention group) were compared to 17 non-participating high-risk pregnant members (control group: CQ). Matching variables included age group (<18, 18–34, 35+), race, ethnicity, number of high-risk diagnosis codes, obesity status, gestational diabetes, hypertension, multiple gestations, and incompetent cervix—are known predictors of low birth weight and premature delivery. RESULTS: Thirty-one participants at high-risk for premature delivery received cell phones and text services. Twenty-six (84.6%) successfully delivered to term (<31 days from expected delivery date). Babies born in the IG had higher birth weights than those born in the CG (mean, 38, 71g), lower rates of low birth weight babies (7% vs. 13%). CONCLUSIONS: Results of this pilot study will be used to implement a future survey among a larger and more diverse sample of graduate students. The results from this pilot study will be used to implement a future survey among a larger and more diverse sample of graduate students.

PPIH80

HEALTH CARE UTILIZATION AND COSTS AMONG PRIVATELY INSURED CHILDREN WITH OROTIFEN

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OBJECTIVES: Orotifene clefts (ORF) are among the most common birth defects and affect upwards of 1 in 3,000 early children. To implement care and support for these children, a database of health care utilization and costs for children during 2010. METHODS: Data were extracted from the 2006-2010 MarketScan Commercial claims databases to identify children with ≥1 outpatient claims or ≥1 inpatient claim for ORF during those five years to maximize case ascertainment. Healthcare utilization and costs during 2010