A166


PHH61

AN OVERVIEW 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 drug products. This study aimed to evaluate the evidence required for orphan drug label approvals compared to non-orphan drugs. This study analyzed all PRO label claims for orphan drugs approved between 2006 and 2013 in the US Food and Drug Administration (FDA) database. A total of 28 PRO label claims were reviewed. The evidence required for orphan drug label approvals was compared to the evidence required for non-orphan drug label approvals.

RESULTS: PRO label claims required evidence from literature reviews and clinical studies. Evidence was required from at least 3 clinical studies in most cases. The average number of clinical studies was 4.1 (range 1-11). The evidence required for orphan drug label approvals was similar to the evidence required for non-orphan drug label approvals.

CONCLUSIONS: The evidence required for orphan drug label approvals was similar to the evidence required for non-orphan drug label approvals. Therefore, the study found no evidence to support the claim that orphan drugs require more rigorous evidence than non-orphan drugs.

PHH70

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

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OBJECTIVES: The objective of this study was to assess the quality of life associated with erectile dysfunction (ED) among the US adult population, both among diagnosed ED sufferers and non-sufferers. METHODS: A representative (US) sample of 1,000 adults (502 males, 498 females) completed an online survey about their own (for men) or partner’s (for women) ED experiences. RESULTS: Men and women who had been diagnosed with ED had lower levels of quality of life compared to non-ED suffers. CONCLUSIONS: ED is a common condition and has a significant impact on quality of life. Health care providers should be aware of the impact of ED on patients’ lives and provide appropriate care.

PHH68

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 little known about the health outcomes associated with use of prohormones. The objective of this study was to assess the relationship between health outcomes and self-reported prohormone use.

METHODS: A self-administered survey was developed and deployed via two e-mails 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. Analysis was performed using STATA 11.0.

RESULTS: Eight hundred and ninety-five participants completed the survey. A total of 65 respondents reported using prohormones. Users reported an average of 2.69 (SD=0.60) cycles in their last prohormone cycle. Comparison showed that 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 are 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.

CONCLUSIONS: The 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.

PHH69

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 the morbidity and mortality of adverse events, resulting in increased health care costs. METHODS: The first part of this project was to review the ADRs reporting system in Pakistani hospitals, to determine the factors contributing to the ADRs reporting rate and benchmark with the current system of reporting ADRs. Data was collected by self-administered questionnaires of 48 doctors, 24 (80%) hospitals have no proper ADRs system, five (16.7%) hospitals are targeting the improvement of ADRs reporting system, one (3.3%) hospital has a proper ADRs policy. Results: The ADRs reporting rate was 19.7% (24/121), and 19.7% (24/121) know how to report ADRs. The per reporting rate was 7.7% (3/40). ADRs with serious reaction (56.2%), unusual reaction (44.1%), reaction to a new treatment (66.6%) reaction to a new treatment were more common. CONCLUSIONS: The study concluded that the ADRs reporting rate was low and the ADRs reporting system needs improvement.

PHH72

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 major dialect groups dominate the language. This study evaluated the translation between English and Spanish for conducting linguistic validation for US-based sites to ensure the most appropriate Spanish language is used. METHODS: Past studies that required US Spanish were conducted in 4 locations and 20% of respondents were Spanish-speaking 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-speaking locations yielded the best results as the site location was communicated to the linguistic validation provider. When this information was not available at project commencement, it is necessary to consider the array of national backgrounds and subsequent cultural correlations that are present throughout the US when selecting translators and cognitive interviewing respondents. When site locations were throughout the US, the most inclusive and universal US Spanish was achieved with the following cognitive debriefing recruitment formula for a 5 respondent interview: 2 Mexican respondents, 1 South American respondent, 1 Central American respondent, and 1 Caribbean respondent. If site locations are being concentrated in one area, selecting a team that represents the largest population in that region is ideal. 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.

PHH73

ASSOCIATION BETWEEN PERCEIVED AND ACCULTURATIVE 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, acculturative stress, coping mechanisms, and health-related quality of life among pharmacy students. METHODS: A self-administered questionnaire was sent to ISPOR student network members. RESULTS: The final sample was 39 (39.3% n=39) and 67 (67.3% n=67) for hospital pharmacists. Thirty three (39.3%) doctors and thirty four (65.4%) pharmacists knew how to report ADRs within the hospital and 7 (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 treatment (66.6%) reaction to a new treatment were more common. CONCLUSIONS: 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 the improvement of ADRs reporting system. Training and integration of ADRs reporting into the clinical activities would definitely improve the patient outcome.