PIH42

RESULTS OF AN OBSERVATIONAL STUDY IN 574 COMMUNITY PHARMACIES IN SPAIN CHARACTERIZING PATIENT PROFILES OF MEN ASKING FOR ERECTILE DYSFUNCTION MEDICATION

Martí B[1], Ibañez J[2], Machuca M[3], Pol-Yanguas E[4], Schnetzler G[5], Pascual Renedo V[6]
[1]Health Outcomes Research, Pfizer, Spain, [2]Ibañez Pharmacy, Barcelona, Barcelona, Spain, [3]Machuca Pharmacy, Seville, Seville, Spain, [4]Pharmacy, Alicante, Alicante, Spain, [5]Pfizer International Operations, Paris, France, [6]Pfizer Spain, Madrid, Madrid, Spain

OBJECTIVES: To characterize patient profiles of men asking for an erectile dysfunction (ED) treatment at the pharmacy. **METHODS:** Multi-center, observational, cross-sectional study carried out in community pharmacies in Spain. Each investigator recruited one patient with a prescription for an ED treatment (Rx-group) and one patient that came into the pharmacy without prescription but asking for an ED treatment (Non-Rx group). Study pharmacists completed a questionnaire asking the patient demographic, clinical and behavioral questions including the SHIM (Sexual Health Inventory for Men). **RESULTS:** A total of 574 pharmacists recruited 1147 patients, whereof 1113 (97%) were included for analysis. Mean age was 58.5 (age range 28–91) years for the Rx-group and 54.8 (age range 21–88) years for the Non-Rx group ($p < 0.001$). There was no statistical difference between the groups regarding weight, BMI, known hypertension, diabetes mellitus, hypercholesterolemia, dyslipidemia, depression and stress. Median SHIM score was 13.9 (95%CI = 13.5–14.4) and 14.0 (95%CI = 13.6–14.4) for the Rx and the Non-Rx group, respectively ($p = 0.7892$). In the Non-Rx group, 85.1% of men asked for a PDE5 inhibitor and the remaining men asked for herbal remedies, food supplements or vitamins. Patients of both groups take about 25 months since the first symptoms until they present with a health care professional. In the Non-Rx group 60,2% stated that this visit in the pharmacy was the first time they had spoken with a Healthcare Professional about their erection problems. **CONCLUSIONS:** Men without a prescription for ED treatment have the same degree of ED and an equal co-morbidity profile as men who have a prescription for a PDE5 inhibitor. Therefore community pharmacists should be actively trained on this condition as they may play a relevant role by educating men about ED and encouraging them to seek further medical care, because ED might be a sign of underlying conditions.

PIH43

EARLY ASSESSMENT OF A NEW TREATMENT FOR ADOLESCENT IDIOPATHIC SCOLIOSIS

Boomkamp IS, Hummel JM, IJzerman MJ, Verkerke GB
University of Twente, Enschede, The Netherlands

OBJECTIVES: Adolescent idiopathic scoliosis (AIS) reduces the quality of life. It can lead to back pain, reduced back function and socio-psychological problems. Left untreated it may induce cardio-vascular and pulmonary problems, and even death. Current treatment of severe forms of idiopathic scoliosis are based on fusion of the vertebrae. These treatments restrict back function and growth of the adolescents. This study aims to conduct an early technology assessment of a new non-fusion scoliosis correction system. **METHODS:** The early assessment of this new treatment is supported by the Analytic Hierarchy Process (AHP), a technique for multi-criteria decision analysis. The AHP quantifies the comparison between the performances of decision alternatives under a finite set of decision criteria. An expert panel composed of six technological engineers and medical specialists compared the expected performance of the new non-fusion treatment to the performance of posterior fusion surgery for patients with severe AIS. They regarded criteria related to the quality of life, complications, user friendliness and costs. **RESULTS:** The expert panel considered the influence of the treatment on the quality of life to be most important (weight 0.46) followed by complications (0.35), user friendliness (0.11) and costs (0.09). They expected the new non-fusion treatment to particularly have a more positive influence on the quality of life (priority 0.73) than posterior surgery has (priority 0.27). Main disadvantage was considered to be the relative high costs of the new treatment (priority 0.37 versus 0.63). In overall, the new treatment is expected to slightly outperform the current treatment (priority 0.63 versus 0.37). **CONCLUSIONS:** In the absence of clinical evidence, this method provides a valuable means to systematically predict a new technology's clinical value. The outcomes provide clear directions for medical industry to improve the future cost-effectiveness of new treatments.

PIH44

VARIATIONS IN CHANGES OF PRESCRIBING BEHAVIORS AMONG PHYSICIANS AFTER THE RELEASE OF WHI REPORT

Chen WC, Tang CH, Pwu RF, Shen WC, Hung ST
Taipei Medical University, Taipei, Taiwan

OBJECTIVES: Findings from the Women's Health Initiative (WHI) gave rise to the concerns of risk of hormone therapy (HT). This study aimed to compare physicians' prescribing behavior before and after the release of WHI report in Taiwan. **METHODS:** The data source for this study comes from the outpatient claims records of the National Health Insurance (NHI). A cohort of 57,958 women aged 40–69 who were regular estrogen users for menopausal symptom were identified during January 1, 2001 to June 30, 2001. Proportion of estrogen use, number of outpatient visits with estrogen prescription, and dosage of estrogen were compared on an annual basis, between the pre-WHI period (July 1, 2001–June 30, 2002), and the post-WHI period (Januray 1, 2003-December 31, 2003). Multiple logistic regressions and generalize estimating equation (GEE) were performed, to examine the effects of physicians' characteristics on the changes in HT prescribing behavior. **RESULTS:** Probability of prescribing estrogen, number of outpatient visits with estrogen prescriptions and total dosage of estrogen prescription were significantly reduced after WHI. However, the extents to which this consulting and prescribing behavior changes varied by physicians' characteristics: physicians of younger ages, affiliated with medical centers, and located in urban areas were less likely to prescribe estrogen, less frequently to be consulted at outpatient visits with estrogen prescription, and prescribed less dosages of estrogen, compared to their counterparts. **CONCLUSIONS:** The dissemination of information on drug safety seems to be varied by physicians' characteristics. Strategies on improving the dissemination of information on drug safety,speficially targeting on less informed physician groups, were warranted to avoid the misuse of drug with safety concerns.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PRS1

A COMPARISON OF EFFICACY AND SAFETY OF FLUTICASONE WITH BUDESONIDE AND BECLOMETHASONE IN 1:2 DOSE RATIO IN THE TREATEMENT OF BRONCHIAL ASTHMA

Pankiewicz O, Nadzieja-Koziol A, Kwaskowski A, Jaros P, Jagodzinska K, Lach K, Rys P, Jarczewska D, Plisko R, Wladysiuk M
HTA Consulting, Krakow, Poland

OBJECTIVES: This study compared efficacy and safety of fluticasone (FL) with budesonide (BUD) and beclomethasone (BDP) in 1:2 dose ratio in the treatment of bronchial asthma. **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines and Agency for Technology Assessment in Poland. The most important medical databases (EMBASE, MEDLINE and CENTRAL) were searched. Two reviewers independently selected trials, assessed their quality and extracted data. Head-to-head comparisons were performed. **RESULTS:** The systematic search retrieved 15 RCTs for comparison FL vs. BUD and 18 RCTs for FL vs BDP, respectively. FL was significantly more effective than BUD in respect to the risk of asthma exacerbations (RR = 0.73 [0.59; 0.91]), change in morning Peak Expiratory Flow (PEF) (WMD = 8.02 L/min [5.20; 10.85]) and proportion of symptoms-free days (MD = 8.00 [2.00; 14.00]). Asthma Symptom Score (ASS) score didn't differ between groups (WMD = –0.24 [–0.52; 0.03]). Safety analysis showed that FL in comparison with BUD increased the risk of hoarsness (RR = 1.97 [1.07; 3.62]) and rhinitis (RR = 1.90 [1.07; 3.36]) but the incidence of other adverse events was comparable between those drugs. There was no statistically significant difference in risk of asthma exacerbations between FL and BDP (RR = 0.84 [0.61; 1.14]). FL was associated with better improvement than BDP in respect to morning PEF (WMD = 5.59 L/min [1.84; 9.34]), proportion of symptoms-free days (WMD = 6.43 [0.47; 12.39]) and statistically significant reduction in ASS score (WMD = –0.11 [–0.19; –0.03]). No significant differences in safety outcomes were found between FL and BDP. **CONCLUSIONS:** Fluticasone in comparison with budesonide and beclomethasone in dose ratios 1:2 provides improvement in spirometric parameters and in comparison to budesonide descreases risk of asthma exacerbations. Safety profiles of fluticasone seems to be comparable both with budesonide and beclomethasone.

PRS2

SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY OF VARENICLINE FOR SMOKING CESSATION COMPARED WITH PLACEBO, NICOTINE REPLACEMENT THERAPY OR SUSTAINED-RELEASE BUPROPION

Walczak J, Nogas G, Czarny I, Baginski P, Borowiack M
Arcana Institute, Cracow, Poland

OBJECTIVES: The aim of this study was to compare efficacy and safety of varenicline compared with placebo, nicotine replacement therapy or sustained-release bupropion for smoking cessation in adults. **METHODS:** Systematic review of randomized controlled trials was performed to assess clinical effectiveness of varenicline according to guidelines of Cochrane Collaboration and HTA Agency in Poland. **RESULTS:** The clinical effectiveness analysis of varenicline compared with placebo for smoking cessation in adults showed statistically significant difference between groups in continuous abstinence. Abstinence rate for weeks 9 through 12, 9 through 24 and 9 through 52 was superior for varenicline vs placebo. The clinical effectiveness analysis of varenicline in smoking adults in the context of maintaining their abstinence showed significantly greater continuous abstinence rate in weeks 13 to 24 compared with placebo. This advantage was maintained through the follow-up to week 52. The clinical effectiveness of varenicline compared with NTZ for smoking cessation in adults showed that continuous abstinence rate for the last 4 weeks of 12 weeks treatment was significantly greater for varenicline (55.9%) than NRT (43.2%). In clinical effectiveness analysis of varenicline compared with BP, varenicline was found to be more efficacious in continuous abstinence rates. For weeks 9 through 12, the odds ratio was 1.86(95% CI: 1.49; 2.33); for weeks 9–24 OR: 1.65(95% CI: 1.29; 2.11); for weeks 9–52 OR: 1.59(95% CI: 1.21; 2.10). **CONCLUSIONS:** The performed analysis shows that varenicline is effective therapy for smoking cessation. Varenicline was more efficacious than placebo, NTZ and bupropion SR at continuous smoking abstinence outcomes for the last 4 weeks of study, from weeks 9 through 24 and weeks 9 through 52. Varenicline more often than placebo, NTZ and bupropion SR causes nausea, insomnia, abnormal dreams and headache. Varenicline more effectively reduces urge to smoke, depressed mood, anxiety and smoking satisfaction.