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concerning the long-term safety and effectiveness of the drugs when used on larger populations. Pharmaceutical companies face big challenges for the coming years, especially in EU and there is an increase need for local regulatory knowledge. There’s still need to increase awareness for the importance of real world studies and the impact it has on the patient’s life.

PMRG5

PUBLIC MANUAL OF BUDGET IMPACT ANALYSIS (BIA) BY THE DEPARTMENT OF SCIENCE AND TECHNOLOGY OF THE MINISTRY OF HEALTH (DEICT)

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The epidemiological and economic methods applied to health technologies evaluations had a significant development in the last two decades. The need to balance the introduction of new technologies in health care, and the financial limitations in limited healthcare systems, has promoted the construction and application of instruments supporting the decision making of health technology. The requirement Budget Impact Analysis formally stated in Law 12.401/2011 establishing the incorporation process technologies in SIS, was limited to the introduction of new technologies. Revisions were carried out by technicians DEICT and health agencies, and the proposal was submitted to the World Health Organization (WHO). Methodology BIA (BIA), composed of experts and academic researchers from several Brazilian states. Were also carried out workshops for the application of spreadsheets. In 2012, the first edition of the Guidelines was published two thousand copies in Portuguese in order to provide best practice recommendations for studies of budget impact.

DISEASE - SPECIFIC STUDIES

RESPIRATORY-RELATED DISORDERS - Clinical Outcome Studies

PRS1

PROSPECTIVE STUDY ON COST-EFFECTIVENESS OF NURSE INTERVENTION INTRODUCING RETESTING WITH IN VITRO DIAGNOSTICS (IVD) TO PARENTS OF CHILDREN WITH SUSPECTED FOOD ALLERGY IN Gdynia

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OBJECTIVES: To evaluate the effect of an intervention that included nurse follow-up of children with a possible food allergy, identifying the parents of children with a suspected food allergy, and implementing a cost-effective strategy to reduce food allergy in children.

METHODS: A prospective, randomized controlled trial, including 120 children aged 6 months to 18 years, and their parents. Children were observed for 1 year. Parents were assigned to either the intervention group (IG) or the control group (CG). The intervention group received nurse follow-up, including retesting with in vitro diagnostics (IVD) to confirm or exclude a food allergy. The control group received usual care. The primary outcome was the number of hospitalizations for food allergy.

RESULTS: The number of hospitalizations for food allergy was significantly lower in the intervention group compared to the control group (9 vs. 16, respectively, p = 0.033). The cost per hospitalization was also lower in the intervention group compared to the control group (200 € vs. 400 €, respectively, p = 0.01). The cost per positive IVD test was lower in the intervention group compared to the control group (50 € vs. 100 €, respectively, p = 0.04). The intervention group had a significantly lower number of hospitalizations for food allergy, and a lower cost per hospitalization, compared to the control group.

CONCLUSIONS: The nurse intervention, including retesting with in vitro diagnostics to confirm or exclude a food allergy, was effective in reducing hospitalizations for food allergy and was cost-effective.
OBJECTIVES: To assess the relative efficacy of umecitidinium bromide 62.5 mcg OD (UMEC) versus tiotropium bromide 18 mcg OD (TIO), aclidinium bromide 400 mcg OD (AB) and glycopyrronium bromide 50 mcg OD (GLYCO). METHODS: A systematic literature review was performed to identify RCTs ≥ 12 weeks duration comparing TIO, AB, GLYCO or UMEC to placebo in adult patients with COPD. Random effects meta-analysis was performed pooling results of each treatment group and comparing change from baseline at 12 and 24 weeks in trough FEV1, SGRQ total score, TDI focal score and rescue medication use. The results were synthesized by using an indirect meta-analysis with a common comparator based on the Bucher method. Scenario analyses were performed to evaluate the robustness of the results to variations in the included studies and assumptions. RESULTS: At 12 weeks, ITC results show that treatment with UMEC resulted in a comparable but numerically higher increase from baseline in trough FEV1 vs. TIO (RR = 1.11, 95%CI: 1.09, 1.13, p < 0.0001), AB (RR = 1.14, 95%CI: 1.11, 1.17, p = 0.0002) and GLYCO (RR = 1.0, 95%CI: 0.97, 1.02, p = 0.75) compared to placebo (RR = 1.0, 95%CI: 0.98, 1.02, p = 0.53). At 24 weeks, UMEC resulted in comparable improvement in trough FEV1 vs. TIO (RR = 0.98, 95%CI: 0.95, 1.01, p = 0.42), AB (RR = 0.97, 95%CI: 0.93, 1.01, p = 0.43) and GLYCO (RR = 0.93, 95%CI: 0.90, 0.96, p = 0.02). Significant improvements in trough FEV1 were observed in all patient subgroups compared to placebo (RR = 0.98, 95%CI: 0.97, 1.00, p = 0.10). Across all RCTs, a significant improvement in trough FEV1 was observed with UMEC vs. placebo (RR = 0.97, 95%CI: 0.95, 1.00, p = 0.07). Significant reductions in SABA fills were observed in all patient subgroups compared to placebo (RR = 0.97, 95%CI: 0.95, 0.99, p = 0.009). Significant reductions in mean OCS fills and mean SABA fills were observed in All and Moderate patients (20.4%–26.1%; all p < 0.0001), whereas reductions in mean OCS fills and mean SABA fills were observed in All and Moderate patients (26.0%–42.5%; p < 0.0001), while reductions in mean SABA fills were also observed in moderate patients (28.7%–43.0%; p < 0.001). CONCLUSIONS: Omalizumab initiation was associated with significant reduction in PACE and MU in patients with moderate or severe persistent asthma.

PS8 INDIRECT COMPARISON OF EXACERBATION FREQUENCY BETWEEN ALCIDINUM AND TIOTROPUM IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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OBJECTIVES: The purpose of this study is to compare the frequency of exacerbations in patients with chronic obstructive pulmonary disease (COPD). METHODS: Through a systematic literature search in Medline (PubMed), we included randomized controlled trials that evaluated the efficacy of aclidinium bromide 400 mcg OD (ACLIO) and tiotropium bromide 18 mcg OD once a day in patients with moderate or severe COPD. The main outcome is the frequency of exacerbation. Indirect comparison analysis was performed to estimate the odds ratio of exacerbation between aclidinium and tiotropium. RESULTS: After screening 278 full-text articles, we identified 19 clinical trials that total 19,741 COPD patients were participated. 3 trials of aclidinium 200mcg and 400mcg OD and 16 trials of tiotropium 18mcg OD tiotropium 18mcg was associated with a significant reduction in exacerbation compared with placebo (OR = 0.90; 95% CI 0.84 to 0.96). Other two anticholinergic agents showed comparable effects in reducing exacerbation compared with placebo (aclidinium 200 mcg (OR = 0.93; 95% CI 0.90 to 0.96) and aclidinium 400 mcg (OR = 0.97; 95% CI 0.95 to 1.00)). Aclidinium 200 mcg (OR = 0.84; 95% CI 0.63-1.16) and aclidinium 400 mcg (OR = 0.83, 95% CI 0.59 -1.15) showed the similar efficacy for exacerbation and both agents were found to be 0.77 and 0.75, respectively. CONCLUSIONS: We found that aclidinium 18mcg OD has comparable efficacy to tiotropium in patients with moderate or severe COPD. Aclidinium 18mcg OD once daily is associated with a significantly reduced exacerbation compared to placebo and tiotropium.

PS9 TREATMENT PLAN COMPARISON: AN OBSERVATIONAL STUDY OF THE MARCHE REGION
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OBJECTIVES: to estimate the number of users of Theophylline (ATC: R03DA04) and Doxoflamine (ATC: R03DA11) for the treatment of chronic asthma in adults, in the Marche Region. Moreover, we wanted to estimate the cost of the two treatments across the region and to compare the different results obtained with them. METHODS: The drug prescriptions were extracted from the Information System of the Pharmaceutical Prescriptions of the Marche Region (PHARM), containing all the recipes sent by pharmacies within the region and reimbursed by the National Health System. The number of prescriptions per year has been obtained by selecting all the recipes for each ATC code in the years 2008-2012, while the number of users has been estimated by identifying the subjects who received at least one prescription of the ATC codes of interest. The number of concomitant prescriptions was estimated by selecting all the recipes for potentially associated ATC, then differences between before and after the dates following the prescription of ATC code were calculated using the “price” contained in the PHARM record. RESULTS: For both drugs, the users are approximately 5,000 per year in the study period. Theophylline had a mean base price lower than tiotropium (4.88 € vs 6.33 €), however, theophylline was more associated with Daxid (4.44 € vs 23.7 €) with other drugs for the treatment of Asthma. Consequently, the total treatment cost for Theophylline was equal to 33.65 € vs a total cost for Daxid equal to 22.49 € (49.6%). CONCLUSIONS: The PHARM allows the estimate of drugs’ utilization, taking into account the overall patient’s treatment plan. In our study, the prescription of the first ATC code is more associated with prescriptions of other drugs, and this implies an increasing in the cost of the treatment plan despite a lower average initial price.

PS10 A DATABASE STUDY TO INVESTIGATE THE INCIDENCE OF ANAPHYLAXIS AND THE PRESCRIPTION RATE OF SELF-INJECTION EPIFEPINE IN JAPAN
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OBJECTIVES: A database research was conducted to investigate the incidence of anaphylaxis/shock using a Japanese health-claims database (HDB). In addition, the prescription rate of self-injection epinephrine was investigated among those patients with anaphylaxis for the management of future reactions. METHODS: A Japanese HDB which contains approximately 1.8 million subjects covered by employment-based health insurance (MinaCo Ltd. Co. Ltd) was used for this retrospective study. In order to identify actual anaphylaxis/shock precisely, diagnosis recorded in the database was cross-referenced with ATC codes. As a result, anaphylaxis claim records of medical practice and prescriptions. Specifically, prescription for epinephrine/aspirin or oxygen inhalation therapy was required for "anaphylactic shock (anaphylaxis)" for Japan. RESULTS: The prescription rate for epinephrine (0.23% vs 2.37%) and aminophylline (0.9% vs 10.9%) were significantly lower in the HDB than in the Marche Region. CONCLUSIONS: The prescription rate of self-injection epinephrine was investigated among those patients with anaphylaxis for the management of future reactions.