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.

PRG56

**PUBLICATION MANUAL OF BUDGET IMPACT ANALYSIS (BIA) BY THE DEPARTMENT OF SCIENCE AND TECHNOLOGY OF THE MINISTRY OF HEALTH (DECIT)**

Enquiry CDU1, Elias FTS2

1FPE - Fundação de Ensino e Pesquisas Econômicas, Brasília, Brazil, 2Ministry of Health of Brazil, Brasilia, Brazil

The epidemiological and economic methods applied to health technologies evaluations had a significant development in the last two decades. The need to balance the investments in health technologies in health and limited budget have 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 SNS. In order to comply with the 2011, the National Agency of Surveillance (ANVISA) and DECIT, in partnership Institute for Health Technology Assessment (IA TS) for drawing up of this guideline. In the first stage of development were used international recommendations of Canada, Australia, the UK and Poland, the recommendations of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the methods used in studies of budgetary impact that had already been published. Afterwards, drafted a preliminary version of the Guidance and was used as a standard tool - Excel worksheets - to estimate the uptake of monetary resources required for adoption of new technologies. Revisions were carried out by technicians DECIT and health agencies, and the proposal was submitted to the World Group on Development of Methodology EKKBRT, 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 DIAGNOSIS (IVD) TO PARENTS OF CHILDREN WITH SUSPECTED FOOD ALLERGY IN ALLIN**

Hermandson L1, Khorosen K2, Silven M3, Rantanen S4, Isabo R3, Savolainen J1

1Theoretica Ltd, Uppsala, Sweden, 2Hälsan Primary Care Center, Lieto, Finland, 3University of Turku, Turku, Finland

**OBJECTIVES:** According to Finnish Allergy Program 2008-2018, to decrease food avoidance diets by 50%. Focus in algorithm with patient history IV D in school children with suspected food allergy and reason for declining re-diagnosis. NICE clinical guideline (Food Allergy Diagnoses, 2013) suggested further work made on effect of diagnosing allergies in realistic population and cost-effectiveness of retesting. METHODOLOGY: A prospective trial with patients from Finnish primary care database (2885 school children). School kitchen had allergy restricted diets for 175 children. In the pilot phase, 179 families were contacted by telephone. Of the 24 who were not allergic, 12 were not allergic (70%). In this family studies were reviewed by telephone. Of 156 families 107 agreed to participate in this study and 47 children will be diagnosed by component resolved diagnostics (CRD) and 60 with sIgE and CRD. **RESULTS:** Prevalence of food avoidance diets: 6.2%. Reasons for declining re-testing were not allergic, 9 were busy, 9 have own physician, 3 did not believe allergy tests, 8 scared of needles, 7 already tested, 4 tested often due to health problems, 2 in pilot study and 7 did not recognize a benefit. **CONCLUSIONS:** Telephone consultation by nurse decreased special diets for 23 children (13%) and 39 (22%) had non-medical reason to decline retesting. Nurse consultation to introduce retesting with IVD can be considered as cost effective approach in decreasing food avoidance diets in children.

**PRS2**

**EFFECTIVENESS OF MONTELUKAST ON ASTHMA CONTROL IN INFANTS: A CLA IMS DATA**

Belhasmen M1, Ginoux M, Maigle V, chaunet-Vogel C2, Lamezec L3, de Blic J4, Rauxoux B5, de Pouvoirouille C7, Laforet L, Van Gans E5

1University of Lyon, Lyon, France, 2Université de Cote d’Azur, Nice, France, 3Centre Hospitalier Saint-Jean, Royan, France, 4“ESSEC Business School, Crepy, France

**OBJECTIVES:** Montelukast 4mg (MLT-4) is an add-on therapy for asthmatic infants. Given the quality and exhaustivity of the data, French claims data (SNIIR-AM) is a realistic population and cost effectiveness of dual-therapy with Montelukast and ICS appears to be comparable therapeutic strategies, with similar effects on exacerbation and equivalent costs. The SNBAM allows conducting comparative effectiveness research.

**PRS3**

**CLINICAL TRIAL-BASED COST-EFFECTIVENESS ANALYSIS OF INDACEROL (ONBREZ® 150 MCG) VERSUS TISI TROP IUM (SPIRIVA®) IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN TURKEY**

Savian M, Beykoz V, Kesevlislan A

Novartis Pharma, Istanbul, Turkey

**OBJECTIVES:** COPD is a disease that is characterized by chronic and progressive restriction of the airflow. The cost of COPD medications can be reduced significantly by implementing a treatment algorithm that is consistent with the GOLD guidelines. Indacaterol and tiotropium administered by inhalation are indicated for maintenance treatment of COPD in Turkey. We aimed to compare, from the perspective of the Turkish social security institution, the cost-effectiveness of indacaterol 150 mcg once daily and long-acting tiotropium 18 mcg once daily at months 3 and 6 in patients with moderate to severe COPD aged 30 years and above. METHODS: From randomized clinical trials and a pilot study, a cost-effectiveness analysis based on two separate clinical trials (INTENSITY-once daily indacaterol and tiotropium vs. placebo and INHANCE-indacaterol vs tiotropium) was performed. The primary endpoints of the clinical trials were COPD exacerbations (COPD exacerbation Rate in Exposed Patients [SGRQ]), included in the cost-effectiveness analysis. Incremental cost effectiveness ratio (ICER) of indacaterol vs. tiotropium for different treatment success rates (week 12 FEV1 increase, 12% increase in SGRQ score) were compared. Incremental cost effectiveness ratios were calculated over incremental differences versus placebo. Probabilistic sensitivity analysis was performed using the Bootstrap method. **RESULTS:** FEV1 success rates at month 3 for indacaterol and tiotropium were 26.5% and 44.9%, respectively. At month 3, ICERS of indacaterol versus tiotropium were -1002TL for FEV1, -434TL for TLC and -878TL for SGRQ. At month 6, FEV1 success rates were 58.4% and 47.4%, TLC success rates were 58.7% and 54.0% and SGRQ success rates were 81.8% and 77.1%, respectively. ICERS of indacaterol versus tiotropium at month 6 were -616TL for FEV1, -1049TL for TLC and -1014TL for SGRQ. **CONCLUSIONS:** Based on this clinical trial-based analysis, indacaterol was cost effective treatment and cost reducing choice vs. tiotropium in COPD treatment.

**PRS4**

**A NETWORK META-ANALYSIS COMPARING THE EFFICACY AND SAFETY OF CEFTEBISPOROLE AND SELECTED COMPARATORS IN THE TREATMENT OF HOSPITAL-ACQUIRED PNEUMONIA**

Boele W1, Chadda S, Madrigal AM2, Kuehner D, Posthumus J2


**OBJECTIVES:** Hospital-acquired pneumonia (HAP) is a severe respiratory tract infection which develops more than 48h after hospital admission. Ceftebispore, the active moiety of its prodrug ceftebispore medacolar, is a new cephalosporin with bactericidal activity against a broad spectrum of pathogens including resistant bacteria such as methicillin-resistant 5 aureus (MRSA), penicillin-resistant pneumococci (PRSP) and extended spectrum beta-lactamase (ESBL) producing ger- nass. Ceftebispore was shown safe and effective for the treatment of HAP (excluding ventilator-associated pneumonia), when compared with linezolid plus cephalazin in a large-scale, phase III clinical trial (NCT0112096). METHODS: MEDLINE, EMBASE, Medline-In-Process and the Cochrane Library were searched for randomised controlled trials that included ceftebispore and/or comparators ceftepime, meropenem, imipenem/clastatin, piperacillin/tazobactam, ciprofloxacin, levofloxacin, moxifloxacin and gentamicin as intervention in the treatment of HAP. The efficacy of ceftebispore was compared to comparators using a random effects model implemented within a fully Bayesian framework. Primary outcome was clinical response after end of treatment in the clinically evaluable (CE) population. **RESULTS:** Eleven studies (2413 patients) with HAP were included in the analysis, 1618 patients were eligible for analysis of clinical response in the CE population. The comparative efficacies odds ratio, 95% credible interval of ceftebispore to each comparator were 0.920 (0.892-0.948) (cefazidime), 1.0, 0.954-19 (piperacillin/tazobactam), 1.9, 0.012-30 (meropenem), 0.83, 0.019-52 (levofloxacin), 0.96, 0.047-16 (imipenem/clastatin), and 0.87, 0.025-22 (ciprofloxacin). No comparison was possible to gentamicin or moxifloxacin due to a lack of comparative studies against other comparators. No significant difference was seen between ceftebispore and any comparator in clinical response or in any of the secondary outcomes, including mortality and adverse events. **CONCLUSIONS:** The clinical and bacteriologic outcomes support the use of ceftebispore to replace currently used comparators in the treatment of HAP. This analysis was limited by the small number of available studies, and by the fact that among the drugs compared, only ceftebispore provides coverage of MSSA.

**PRS5**

**COMPARATIVE EFFICACY OF UMECLIDIMIN BROMIDE VERSUS OTHER LONG-ACTING ANTICHOLINERGIC MONOTHERAPIES AS TREATMENTS FOR COPD PATIENTS**

Ismailia A1, Huisman E2, Punekar Y3

1University of Lyon, Lyon, France, 2Research Triangle Park, NC, USA, 3Mapi – HEOR & Strategic Market Access, Houten, The Netherlands, 4ClaisSmithKline, Uxbridge, UK