ous abstinence rate and intervention costs were estimated. a dynamic population model for COPD was used to project the long-term (cost-)effectiveness of one year implementation of minimal counseling, intensive counseling and intensive counseling plus pharmacotherapy for 50% of the smoking COPD patients compared to usual care. Time horizon was 25 years. Uncertainty and one-way sensitivity analyses were performed for variations in (the calculation of) the abstinence rates, the type of projection, intervention costs and discount rates. **RESULTS:** Nine studies were selected. The average 12 months continuous abstinence rates were estimated to be 1.4% for usual care, 2.6% for minimal counseling, 6.0% for intensive counseling and 12.3% for pharmacotherapy. Compared to usual care, the costs per QALY gained for minimal counseling, intensive counseling and intensive counseling plus pharmacotherapy were €16,900, €8,200 and €2,400, respectively. Results were most sensitive to variations in abstinence rates and discount rates. **CONCLUSIONS:** Compared to usual care intensive counseling and pharmacotherapy resulted in low costs per QALY gained with ratios comparable to results presented for smoking cessation in the general population. Compared to intensive counseling alone, intensive counseling plus pharmacotherapy was cost saving and dominated the other interventions.

PRS25

A COST-UTILITY ANALYSIS FOR TIOTROPIUM BROMIDE IN THE LONG TERM TREATMENT OF SPECIFIC SUBGROUPS OF ITALIAN COPD PATIENTS

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OBJECTIVES: The UPLIFT trial demonstrated in 5,993 patients with moderate to very-severe chronic obstructive pulmonary disease (COPD) that 4 years of tiotropium bromide were associated with improvements in lung function, quality of life, and exacerbations compared with placebo. The aim of this study is the economic assessment of tiotropium when included in COPD routine care (RC) for specific groups of Italian COPD patients. **METHODS:** A probabilistic patient-level simulation Markov model was developed over a lifetime horizon, with one-year cycles and a 3.5% annual discount rate. Patients were characterized by gender, age, height, smoking status and FEV1. FEV1 time trend was modelled based on the decline recorded in UPLIFT. The mortality of the general Italian population adjusted by smoking status and FEV1 was adopted. Health utilities derived from published Italian studies, while their variation from the UPLIFT. Exacerbation rates derived from an Italian observational prospective study and were adjusted for the relative risk (RR) reported in UPLIFT. Direct sanitary costs were considered. Health care resource consumption for RC, exacerbations and SAEs derived from Italian observational studies and were valued according to current price and tariffs. Cost-effectiveness was assessed for the overall cohort and for subgroups of patients by age, sex, GOLD stage and smoking attitude. **RESULTS:** In the whole cohort, patients treated with tiotropium gained an average (95%CI) 0.50 (−1.63−−6.27) LYs and 0.42 (−0.25−−3.05) QALYs with respect to RC. The incremental lifetime cost was €3,357 (−€10,669−−€29,820). The incremental cost-effectiveness ratio (ICER) was €7,916 /QALY. In the subgroups analysis the ICER ranged from a minimum of €6,627/QALY (females, GOLD III) to a maximum of €13,187/QALY (age <65 y, GOLD IV). **CONCLUSIONS:** The inclusion of tiotropium in RC for moderate to very severe COPD patients represents good value for money in Italy. The analysis across subgroups demonstrated a good stability of the model.

PRS26

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF MOMETASONE FUROATE AS MAINTENANCE TREATMENT IN PATIENTS WITH MILD TO MODERATE ASTHMA FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

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OBJECTIVES: In the Brazilian public health care system, mometasone furoate (MF DPI) is not available and budesonide/formoterol (BUD/FF DPI) association is responsible for 86.9% of pharmacy claims for asthma. This study aimed to conduct cost-effectiveness and budget impact analysis (BIA) of MF versus BUD/FF for adult patients with mild to moderate asthma from the public payer perspective. **METHODS:** A decision tree was developed to compare MF and BUD/FF based on indirect comparison once head-to-head studies were not available. The final FEV1 values were converted into probabilities of hospitalization in the first two years in accordance with observational evidence of association between FEV1 and exacerbation requiring hospitalization. Only direct medical costs were considered and unit costs were obtained from Brazilian official lists. BIA assumed pharmacy claims data from the Ambulatory Information System as current scenario (Beclomethasone: 3.1%; BUD: 9.9%; BUD/FF: 86.9%) and a 20% initial market share for MF in substitution to equivalent doses of BUD/FF. **RESULTS:** Indirect comparison indicated 79 hospitalizations per 1000 patients for MF and 82 for BUD/FF during the first 2 years of treatment. Total cost of treatment was 832BRL and 655BRL per patient for MF200 mcg twice a day (bid) and MF400 mcg once a day and 840BRL for BUD/FF 400/12 mcg bid. These findings indicated MF as cost-saving in the proposed scenario with ICER of −2.608BRL and −61.959BRL per avoided hospitalization for MF200 mcg and MF400 mcg, respectively. The estimated budgetary impact for the first year showed a saving of 259,346,480BRL for MF 400 mcg and 10,919,299BRL for MF 200 mcg. **CONCLUSIONS:** MF is a clinically effective option to treat mild to moderate asthma and indirect comparison showed its clinical and economic benefit when compared to the most used anti-asthma medication in the Brazilian public setting. Further research to directly compare both medications and to measure finalistic outcomes alongside clinical trials is needed.

PRS27

COUNTRY ADAPTATION OF A HEALTH ECONOMIC MODEL: THE CASE FOR ROFLUMILAST IN THE NETHERLANDS

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BACKGROUND: The phosphodiesterase-4 enzyme (PDE4) inhibitor roflumilast is a new treatment that targets the underlying inflammation associated with COPD. When approved, roflumilast will be registered as an add-on to bronchodilator treatment in adult patients with severe COPD, with a history of frequent exacerbations. a health economic (HE) micro-simulation Markov model was used to support its submission in the United Kingdom (UK). Pharmaceutical companies can save significantly on the process of HE evidence development, if models can be adapted for use in more than one country. **OBJECTIVES:** To transfer an existing UK HE model to the The Netherlands in order to calculate the cost-effectiveness (CE) of roflumilast in patients with severe COPD from a societal perspective. **METHODS:** The model structure was adapted to include production loss using the friction cost method, and to separate heterogeneity from parameter uncertainty. All input parameters on health care use, costs, utilities, and COPD epidemiology were obtained from Dutch sources, except for the case-fatality rate of an exacerbation-related hospitalization. a direct comparison was made between a combination of a long-acting β2 agonist (LABA) plus roflumilast (ROFLU) and LABA alone. a second, indirect comparison was between LABA + ROFLU and LABA plus an inhaled corticosteroid (ICS). One-way and probabilistic sensitivity analyses were performed. **RESULTS:** From a societal perspective, the incremental CE ratio (ICER) for LABA + ROFLU compared with LABA alone, was €7900. The ICER of LABA + ROFLU versus LABA + ICS was €10,000. The probability that LABA + ROFLU was cost-effective when compared with LABA alone at a threshold of €20,000 versus LABA was 97%. Compared with LABA + ICS this probability was 68.3%. **CONCLUSIONS:** The original UK model was suitable for adaptation to the Dutch setting. The ICERs of roflumilast were below commonly referred threshold values of a QALY.

PRS28

ECONOMIC EVALUATION OF FLUTICASONE PROPIONATE/SALMETEROL COMBINATION THERAPY AND MONTELUKAST IN ADULT PATIENTS WHO ARE SYMPTOMATIC ON SHORT-ACTING BETA 2-AGONIST ALONE

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OBJECTIVES: To estimate the incremental cost-effectiveness of SFC verus montelukast in adult patients with persistent asthma. **METHODS:** A decision-analytic model was developed from a randomized, double-blind, double-dummy, 12-week clinical trial were analyzed. Efficacy end points included, symptom-free days (SFDs) during the 12-week period. The study assumed the Mexican health care perspective with costs in 2010 US dollars, and hence only direct costs were included in the analysis. Direct costs included those related to study drugs, emergency room department visits, unscheduled physician visits, and rescue medication. The incremental cost-effectiveness ratio (ICER), which is the mean difference in average costs divided by the mean difference in average effectiveness, was calculated for the effectiveness outcomes (SFDs). Issue of uncertainty was addressed by means of a probabilistic Monte Carlo simulation, which attributed stochastic distributions to model inputs. **RESULTS:** Treatment with FSC resulted in a significantly greater improvement in the mean percentage of symptom-free days compared with MON 48.9 and 21.7 respectively (p 0.001). In the base case, patients initiated on SFC displayed a 45% reduction in overall cost as compared with patients initiated on MON US $186 versus $US258, respectively, respectively). SFC dominated the use of MON because of previously demonstrated lower incidence of *Asthma exacerbations* and rescue free days. Sensitivity analyses determined that univariate changes in all model variables, including medication cost, and cost of treating exacerbation, did not impact overall results. a Monte Carlo simulation analysis found that use of SFC remains the best overall treatment strategy when taking into consideration the potential variance in all model assumptions. Compared with MON, SFC is estimated to be both more effective and more economically favourable, with a probability of almost 92%. **CONCLUSIONS:** The decision model indicated that use of SFC as treatment in patients with asthma should result in lower overall treatment costs relative to the cost of MON.

PRS29

COST-EFFECTIVENESS OF SALMETEROL/FLUTICASONE PROPIONATE COMBINATION VERSUS LEUKOTRIENE MONTELUKAST FOR THE CONTROL OF PERSISTENT ASTHMA IN CHILDREN

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OBJECTIVES: To assess the incremental cost-effectiveness of SFC compared with MON for the control of persistent asthma in children. **METHODS:** We conducted an economic evaluation on a 12-week prospective randomized open-label parallel-group

comparison of SFC versus MON in children with symptomatic asthma receiving inhaled corticosteroids and short-acting β2-agonists. Asthma-related medication, unscheduled physician contacts and hospitalizations were collected prospectively. The main effectiveness measure was percentage of asthma-controlled week with no short-acting β2-agonist use during the study period. The analysis was conducted from the Mexican health care perspective using 2010 unit cost prices, and only direct costs were considered, all costs are reported in US dollar. The model was made fully probabilistic to reflect the joint uncertainty in the model parameters. **RESULTS:** Over the whole treatment period, the median percentages of asthma-controlled weeks were 83.3% in the SFC group and 66.7% in the MON group (SFC-MON difference, 16.7%; 95% CI, 8.3–16.7; P < 0.001 in favor of SFC). The mean total cost of the SFC regimen was US$186 compared with US$271 for the MON regimen. The SFC was the dominant strategy (both more effective and less expensive) using the SFC was associated with an incremental cost per additional asthma-controlled of $US (513). Probabilistic sensitivity analysis tested numerous assumptions about the model cost and efficacy parameters and found that the results were robust to most changes. **CONCLUSIONS:** This analysis demonstrates that, compared with MON, SFC may be cost saving from the Mexican health care perspective for the treatment of pediatric patients with asthma. SFC provided a reduction in the number of severe exacerbations, frequent asthma symptoms and rescue medication use. Incremental cost-effectiveness analysis indicated the dominance of SFC because of both lower costs and greater efficacy.

PRS30

DISCREPANCY BETWEEN ANALYTIC APPROACHES IN THE CLINICAL AND ECONOMIC EVALUATION OF THE SAME TRIAL: EXPERIENCE IN COPD

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OBJECTIVES: Clinical and economic evaluations of the same trial often use different statistical analyses and methods to handle missing data. This leads to different results for the same health outcome. We aimed to study how the combination of multiple imputation (MI) with frequently used advanced methods of clinical analysis affect estimates of cost-effectiveness. **METHODS:** Data from a two-year RCT of an INTERdisciplinary COMmunity-based COPD management program (INTERCOM) versus usual care were used. Five outcomes, SGRQ, EQ-5D, 6MWD, total and severe exacerbations measured at 4, 12 and 24 months or continuously (exacerbations) were selected. These outcomes were re-analyzed using the same methods used in the clinical paper, i.e. with repeated measurement analysis or negative bionomial regression, but now after missing data have been imputed using MI. The resulting estimates were compared with 1) the estimates in the original clinical paper before MI and 2) the estimates obtained after MI based on simple averages before any further statistical analyses based on maximum likelihood. **RESULTS:** A total of 175 patients were included in the analysis of which 158 completed the trial. The cost difference of €2751 between INTERCOM and usual care was kept constant. The number of severe exacerbations avoided varied from 0.014 to 0.077 resulting in ICERs from €35,700 to €196,500, depending on the approach used. The improvement in SGRQ ranged from 2.2 to 2.6 units, but the ICERs were all around €1000. The gain in QALYs varied from 0.062 with an ICER of €44,400 to 0.085 with an ICER of €32,400 per QALY gained. The probability that the INTERCOM program was cost-effective at a threshold value of €50,000 ranged from 56% to 74%. **CONCLUSIONS:** This study showed that the combination of analytic approaches of the clinical and economic evaluations does alter the cost-effectiveness ratios.

PRS31

SHOULD SALMETEROL/FLUTICASONE PROPIONATE (SAL/FP) BE ADDED TO ROUTINE COPD TREATMENT WITH FENOTEROL/IPRATROPIUM BROMIDE (FEN/IB)? PHARMACOECONOMIC ASSESSMENT OF COPD TREATMENT BASED ON OBSERVATIONAL RESEARCH (PHACTOR)

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OBJECTIVES: To assess cost-effectiveness of adding SAL/FP to routine COPD treatment with Fen/IB. **METHODS:** Depersonalized patient database was created in multicenter observational research of severe and very severe COPD. Patients were subdivided into two groups: 1- Fen/IB-based therapy without SAL/FP (N = 245); 2- Fen/IB-based therapy with SAL/FP (N = 84). Prices of drugs were up to Q1 2010 for Moscow city (from Farmexpert market monitoring). Unit cost of inpatient-day, outpatient-visit and emergency-visit was derived from Moscow city government regulation #290 from 04.2010 (about medicare). Direct medical costs within one year time horizon were assessed as health care perspective was taken. **RESULTS:** Number of COPD exacerbations per patient was 3.9 with and 6.8 without SAL/FP. Sum of yearly direct medical costs was 31,607 RUB (€832) with and 55,179 RUB (€1452) without SAL/FP. Incremental cost per one prevented exacerbation (ICER) was 1237 RUB (€32.5). Average cost of treatment of one exacerbation was 8 056 RUB (€212). Results were sensitive to unit cost of inpatient-day (25% increase leads to cost-saving in with SAL/FP arm). Indirect cost inclusion lead to considerable cost-saving in with SAL/FP arm (7952 RUB = €209). **CONCLUSIONS:** Adding SAL/FP to routine treatment of severe and very severe COPD with Fen/IB is cost-effective.

PRS32

REGIONAL DIFFERENCES AS A BASIS FOR SENSITIVITY ANALYSIS OF COST-EFFECTIVENESS OF SALMETEROL + FLUTICASONE PROPIONATE (SAL/FP) VS. INHALED CORTICOSTEROIDS (MONO-ICS)

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OBJECTIVES: To assess cost-effectiveness of SAL/FP vs. mono-ICS in different Russian regions using OPTIMA pharmacoeconomic model. **METHODS:** Description and calculation steps of OPTIMA model were published in ISPOR Twelfth Annual European Congress Research Abstract #PRS8. Variable region-specific input data: drug prices and dosage proportion (from Farmexpert monitoring as of Q4 2009), medical tariffs (from regional government regulations), GDP per capita and average salary (from statistics service). Constant disease-specific data: frequency of controlled/uncontrolled asthma in arms (from clinical trial), number of unscheduled resources utilization and QoL in controlled and uncontrolled asthma (from prof. I.V.Demko's observational study). Fixed combination SAL/FP (Seretide) was compared with mono-ICS (Beclomethasone, Fluticasone and Budesonide). ICERs (cost per QALY) were assessed for each 84 Russian regions. Regional WTP was assumed as three regional GDP per capita. 1 EUR = 38 RUB. **RESULTS:** Weighted average monthly pharmacotherapy cost varied from 1410RUB (in Kostroma) to 3376RUB (in Tula) for SAL/FP, and from 430RUB (in Kostroma) to 1524RUB (in Khanty-Mansi) for MonoICS. The differences were driven by proportion of low/medium/high doses. Medical tariffs varied dramatically as well: tariffs of outpatient visit varied from 107RUB (in Ivanovo and Dagestan) to 975RUB (in Yamal-Nenets), bed-day cost varies from 500RUB (in Kurgan) to 3123RUB (in Yamal-Nenets). GDP per capita were from 38110RUB (in Ingush) to 928374RUB (in Tyumen); average salary—from 9 125 RUB (in Dagestan) to 46480RUB (in Yamal-Nenets). SAL/FP was cost-saving (dominating) in 18 regions, cost-effective in 62 regions (ICER < WTP; in this regions ICERs were from 3210RUB (84EUR) to 639480RUB (16828EUR) per QALY), and disadvantageous (ICER > WTP) in 4 regions (Ivanovo, Kabardino-Balkaria, Ingush, and Dagestan; mainly due to low WTP). **CONCLUSIONS:** In general case SAL/FP was cost-effective in most Russian regions, in some regions SAL/FP was cost-saving, and in few regions—not cost-effective. To assess cost-effectiveness in particular cohort of patients additional analyses are needed.

PRS33

ECONOMIC EVALUATION OF ILOPROST, EPOPROSTENOL AND TREPROSTINIL FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION

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OBJECTIVES: To analyze the eficiency of three alternative treatments (inhaled iloprost (ILO), intravenous epoprostenol (EPO) and subcutaneous treprostinil (TRE)) for patients suffering from pulmonary arterial hipertensión (PAH) iniciating therapy with a prostanoid. **METHODS:** A Markov model was built to simulate a PAH patient cohort in functional class III of the New York Heart Association (NYHA). The model had four health states, those of the functional classes, plus death. Treatment changes were allowed when patients worsened from class III to IV. Time horizon was three years and transition cycles were of 12 weeks. Perspective was that of the National Health System (NHS) in Spain. Data sources were: 1) literature review, 2) costs databases and 3) expert opinion. Costs were expressed in euros 2009. Costs and effects were discounted at a 3% rate following Spanish recommendations. Both, deterministic and probabilistic analyses were performed to check for robustness of results. **RESULTS:** At three years, results for initiating prostanoid therapy with ILO, EPO and TRE were, respectively: total cost—€143,092, €430,271 and €360,387 -; efficacy—2.695 LYG, 2.729 LYG and 2.690 LYG -; —1.737 QALY, 1.780 QALY and 1.728 QALY -; mean cost per LYG—€53,092, €157,678 and €133,997; mean cost per QALY—€82,376, €241,667 and €208,595 -. Incremental cost-effectiveness ratios and cost-utility ratios of EPO vs. ILO were: >8.5M€/LYG and >6.5M€/QALY, and vs. TRE were: >1.5M€/LYG y > 1.3 M€/QALY, much above the usually accepted threshold in Spain of 30,000 €/LYG or QALY. ILO was dominant vs. TRE. Sensitivity analyses confirmed these results. **CONCLUSIONS:** Initiating prostanoid therapy in class III PAH patients with intravenous epoprostenol is slightly more efficacious than the alternatives. At a three-year time horizon, inhaled iloprost shows to be the less costly alternative for the NHS in Spain.

PRS34

IMPROVED PREDICTION OF FINDING COPD PATIENTS BY LUNG FUNCTION PRE-SCREENING IN PRIMARY CARE

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OBJECTIVES: To investigate if easily accessible pre-screening of individuals at risk for COPD leads to a more accurate selection of patients for ordinary spirometry, thereby improving the incidence of pathological test results. **METHODS:** Primary care