OBJECTIVES: To assess the relative efficacy of umeclidinium bromide 62.5 mcg OD (UMEC) versus tiotropium bromide 18 mcg OD (TIO), aclidinium bromide 400 mcg BID (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-analyses were performed by pooling results of each treatment vs. placebo on 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 treatment comparison (ITC) within a frequentist framework 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 change from baseline in trough FEV1 compared to TIO [18.06mL (95%CI: -19.11, 55.23, p=0.341)], AB [35.77mL (95%CI: -7.84, 79.38, p=0.108)] and GLYCO [27.86mL (95%CI: -8.74, 64.45, p=0.136)]. At 24 weeks, UMEC resulted in comparable trough FEV1 values vs. TIO (p=0.854), AB (p=0.663) and GLYCO (p=0.777). UMEC also resulted in comparable TDI focal scores and rescue medication use at both time points compared with TIO, AB and GLYCO. UMEC resulted in numerically lower (better) change from baseline at 12 weeks in SGRQ total score compared with TIO [-2.65 (95%CI: -7.09, 1.79, p=0.242)], AB [-2.68 (95%CI: -7.12, 1.75, p=0.235)] and GLYCO [-2.15 (95%CI: -6.60, 2. 31, p=0.345)]. At 24 weeks there was no statistically significant difference in change from baseline in SGRQ total score between UMEC, TIO, AB and GLYCO. **CONCLUSIONS:** UMEC showed comparable efficacy to TIO, AB and GLYCO on trough FEV1, SGRQ, TDI and rescue medication use at 12 and 24 weeks.

PRS6

SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES AND RCTS OF OMALIZUMAB IN SEVERE PERSISTENT ALLERGIC ASTHMA AND META-ANALYSIS FEASIBILITY ASSESSMENT

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OBJECTIVES: To compare the effectiveness of omalizumab versus standard of care (SOC) based on randomized controlled trials (RCTs) compared with 'real-world', single cohort, observational studies that assess patients 'before and after' the use of omalizumab. **METHODS:** A systematic literature review was conducted to identify RCTs and observational studies that assessed omalizumab in patients with severe persistent allergic asthma. Study and patient characteristics, outcome definitions, and differences in baseline risk and observed study effects were compared in terms of exacerbations and hospitalizations across the RCTs and observational studies. **RESULTS:** 11 RCTs and 24 observational studies were identified. A wide range of clinically significant exacerbation rates was observed across RCTs in terms of baseline risk (SOC: 0.40–2.86) and the treatment effect (rate ratio [RR]: 0.39–0.75). This differed from observational studies in terms of baseline risk (before omalizumab: 3.48–6.00) and the treatment effect (RRs: 0.12–0.46). A limited range of severe exacerbation rates was observed in RCTs regarding baseline risk (SOC: 0.42–0.48) and the treatment effect (RR: 0.50–0.56). However, considerable differences were identified in observational studies in terms of baseline risk (before omalizumab: 2.20–4.50) and the treatment effect (RR: 0.05–0.39). In terms of hospitalization rates, a limited range was observed for RCTs with respect to baseline risk (SOC: 0.12–0.17) and the treatment effect (RR: 0.12–0.54). Again, a wider range was observed across the observational studies in terms of baseline risk (before omalizumab: 0.32–4.45) and the treatment effect (RR: 0.09–0.71). **CONCLUSIONS:** 'Real-world' evidence reinforces the efficacy of omalizumab in patients with severe allergic asthma derived from RCTs, although differences in potential treatment effect modifiers were identified. Patients in observational studies may represent a more severe population compared with those in RCTs.

PRS7

IMPACT OF OMALIZUMAB ON POOR ASTHMA CONTROL EVENTS AND MEDICATION UTILISATION IN PATIENTS WITH MODERATE OR SEVERE PERSISTENT ASTHMA

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OBJECTIVES: Poor asthma control is associated with increased health care cost in patients with moderate or severe asthma. Here we evaluate the impact of omalizumab on poor asthma control events (PACE) and medication utilisation (MU) in a case-crossover study of US patients with moderate or severe persistent asthma. **METHODS:** Truven MarketScan database was used to compare PACE (hospitalisation, ER visit, corticosteroid [CS] burst or ≥7 short-acting beta-agonist [SABA] fills) and MU for 1 year pre/post omalizumab exposure, during the period 1-January-2007 to 30-September-2012. Included in the analysis were patients aged ≥12 years who had 1 inpatient or 2 outpatient Asthma claims (ICD-9=493. XX) and used omalizumab continuously for 1 year, with 2 years continuous coverage (1 year pre/post omalizumab index date). Patients were categorized as Moderate or Severe based on their most recent 8 weeks of continuous, NHLBI-guideline-recommended, therapy preceding omalizumab. **RESULTS:** In total, 429 patients (mean age, 46.6 years; female, 59.0%; Moderate=340, Severe=89) were included in the analysis. Omalizumab was associated with reductions in proportions of All, Moderate, and Severe asthma patients with PACE (41.3%, 48.3%, 17.2%, respectively; all p<0.05). Specifically, reductions in patients with ≥1 asthma-related hospitalisation, ≥1 asthma-related ER visit, ≥2 CS bursts, and ≥7 SABA fills in the Moderate group (Moderate: 55.9%, 77.8%, 53.8%, and 40.6%, respectively; all p≤0.0196) drove reductions in All patients (all p≤0.0159). Reductions in patients with ≥1 OCS fill and ≥1 SABA fill were observed in All and Moderate patients (20.3%–26.1%; all p<0.0001); 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 Severe patients (20.1%; p=0.0328). **CONCLUSIONS:** Omalizumab initiation was associated with significant reduction in PACE and MU in patients with moderate or severe persistent asthma.

PRS8

INDIRECT COMPARISON OF EXACERBATION FREQUENCY BETWEEN ACLIDINIUM AND TIOTROPIUM IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: The purpose of this study is to compare the frequency of exacerbations between aclidinium and tiotropium 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 exacerbation frequency of aclidinium 200µg and 400µg twice a day and tiotropium 18µg once a day regimens compared to placebo. Inclusion criteria were at least 12 weeks of treatment from January 1990 to January 2014, an age over 40, current or former smokers, and diagnosis with moderate to very 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 200µg and 400µg BID and 16 trials of tiotropium 18µg QD. tiotropium 18µg 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 200µg (OR 0.73; 95% CI 0.53 to 1.01) and aclidinium 400µg (OR 0.72; 95% CI 0.52 to 1.00). Aclidinium 200µg (OR 0.84; 95% CI 0.603-1.167) and aclidinium 400µg (OR 0.83; 95% CI 0.592 -1.156) BID showed the similar frequency of exacerbation to tiotropium 18µg QD. **CONCLUSIONS:** Our study substantiates that tiotropium 18µg provides superior effects on lowering the risk of exacerbation compared with placebo but there was no significant difference in the frequency of exacerbations between aclidinium and tiotropium.

PRS9

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 Doxofylline (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, taking into account the prescriptions of other drugs associated 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, dispenced between 5 days before and 5 days following the prescription of ATC codes. The price of prescriptions has been calculated using the information "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 Doxofylline (4.81€ vs 6.37€ per prescription); however, Theophylline was more associated than Doxofylline (34.4% 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 Doxofylline 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.

PRS10

A DATABASE STUDY TO INVESTIGATE THE INCIDENCE OF ANAPHYLAXIS AND THE PRESCRIPTION RATE OF SELF-INJECTION EPINEPHRINE 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 (MinaCare Co. Ltd) was used for this retrospective study. In order to identify actual anaphylaxis/shock precisely, diagnosis recorded in the claims based on ICD-10 code (T78.0, T78.2 and T88.6) was combined with claim records of medical practice and prescriptions. Specifically, prescription for epinephrine/adrenaline or oxygen inhalation therapy was required for "anaphylactic shock" and the use of an infusion therapy or venous catheter was required for detecting "anaphylaxis (except for anaphylactic shock)". For this study, the data associated with events occurring in fiscal years 2010 to 2013 (2010/4/1 to 2013/3/31) were included. **RESULTS:** Of approximately 2.9 million person-years of observations, 13.3 anaphylactic shock events per 100,000 person-years (crude rate) were identified. The rate was 42.9 per 100,000 person-years when non-shock anaphylaxis events were considered. The age-specific anaphylactic shock event rates (per 100,000 person-years) were: 27.6 (0-6 years), 12.8 (7-12 years), 11.0 (13-18 years), and 11.9 (>18 years). Among the 389 anaphylactic shock events, etiologies of anaphylaxis were food 113

(29.0%), venom 31 (8.0%), drug 28 (7.2%), other/unknown 217 (55.8%). The prescription rate of self-injection epinephrine immediately after the anaphylaxis was 10.9% (after the insurance started to cover the service in 2011/9). **CONCLUSIONS:** This is the first report on the incidence of anaphylaxis in general population in Japan; the rates were consistent with those reported in the West. The prescription rate of self-injection epinephrine was notably low even among those who experienced anaphylaxis, indicating the importance of increasing the awareness of the availability of life-saving anaphylaxis management.

PRS11

EPIDEMIOLOGY AND SEVERITY OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN THE UNITED KINGDOM (UK)

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OBJECTIVES: In 2013, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommendations on COPD management and prevention were updated to include additional therapeutic options for patients based on severity using a combined assessment of symptoms, degree of airflow limitation and number of exacerbations. The objective of the present study was to quantify the prevalence and incidence of COPD in the UK and estimate disease severity by 2013 GOLD categories A/B (low risk) and C/D (high risk). **METHODS:** Patients with a diagnosis of COPD aged ≥40 years were identified in the population-based Clinical Practice Research Datalink. Point prevalence was calculated on December 31, 2013. Incidence was estimated using newly diagnosed patients between 2009-2013. Rates were standardised using 2011 UK population age and gender. % predicted FEV_1, modified British Medical Research Council grade and exacerbations defined by Read codes and prescriptions were used to classify patients by GOLD categories. Patient characteristics were reported. **RESULTS:** 49,286 prevalent patients were diagnosed with COPD with mean age of 70 years; 51% were male. Median time since diagnosis was 5 years. Overall prevalence was 33.0 per 1,000 people (95% CI: 32.7-33.4). Of these, 66.4% were classified as GOLD A/B and 33.6% as GOLD C/D. 27,224 newly diagnosed patients were identified with mean age of 67 years at first diagnosis; 53% were male. Incidence was 2.2 per 1000 person-years (95% CI: 2.1-2.2). **CONCLUSIONS:** A third of COPD patients in the UK are considered high-risk according to the 2013 GOLD categories. Classification of patients is key to identifying appropriate treatment options to reduce symptoms and the frequency of COPD exacerbations.

PRS12

INCIDENCE AND PREVALENCE OF COPD BY GOLD 2013 CLASSIFICATION IN THE NETHERLANDS

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OBJECTIVES: To quantify the five-year incidence (2008-2012) and 2012 prevalence of COPD in The Netherlands by the Global initiative for chronic Obstructive Lung Disease (GOLD) 2013 combined assessment categories. **METHODS:** Using the General Practitioners Database of the PHARMO Database Network, the five-year incidence (2008-2012) and prevalence at July 1, 2012 of COPD (ICPC code R95) by GOLD 2013 combined assessment categories among individuals ≥40 years of age was assessed. Based on degree of airflow limitation (using post-bronchodilator FEV_1) and risk of exacerbations (based on medication or as recorded by the GP) patients were classified as low-risk COPD (FEV_1 ≥50% and/or ≤1 exacerbations) or high-risk COPD (FEV_1 <50% and/or ≥2 exacerbations). **RESULTS:** Using a source population of 813,800 individuals ≥40 years of age the five-year (2008-2012) incidence (95% CI) of COPD among patients ≥40 years of age was 0.50 (0.49-0.50) per 100 person years; this was 0.54 (0.53-0.55) among males and 0.45 (0.44-0.46) among females. The 2012 prevalence of COPD in a source population of 805,112 individuals ≥40 years of age was 3.7 (3.6-3.7) per 100 persons; this was 4.0 (3.9-4.1) among males and 3.4 (3.3-3.4) among females. Mean (± sd) age of incident and prevalent COPD patients was 65 ± 12 and 67 ± 12 years, respectively. The distribution of low-risk COPD and high-risk COPD was 90% versus 10%. For patients treated by their GP this distribution of low-risk and high-risk COPD was similar, while patients treated by a specialist had a distribution of 82% versus 18%. **CONCLUSIONS:** This study describes the epidemiology of COPD in the Netherlands. Results on the distribution of low-risk and high-risk COPD depend on the population studied and the definitions used. Additional information on symptoms would allow a more detailed classification of patients.

PRS13

ESTIMATING SMOKING CESSATION RATES AND SMOKING PREVALENCES USING PUBLIC DATA AND A PUBLISHED DYNAMIC MODEL

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OBJECTIVES: Mendez *et al*[1] developed a dynamic forecasting model to predict the prevalence of smoking. They use initiation and prevalence rates (data from 1965-1993) and estimate cessation rates for that period. Further, they assume the persistence of the cessation rates and predict future prevalence of smoking. We re-created the Mendez et al model in order to estimate smoking cessation rates (n) and updated cessation rates for 2000-2012 using newly available data on smoking prevalence (R). Further, smoking prevalences for the decade 2012-2024 were predicted based on a couple of alternate hypotheses of smoking initiation **METHODS:** We re-created the Mendez model in Excel, including the mathematical manipulations for estimates of mean rates of cessation from the years 1970-1994 and used the re-created Mendez model set-up and newly available data on smoking prevalence (R), initiation etc. to estimate cessation rates between 2001 and 2012. Further, we predicted smoking prevalences for 2012-2024 and explored a couple of different scenarios of smoking initiation. Birth and death rates of the general population are assumed to be the average of the previous decade. Relative Risk of mortality is assumed to be the same. **RESULTS:** Smoking prevalence in 2024 is estimated to be 18.5%, even with alternate hypotheses around smoking initiation in the 2012-2022 decade. **CONCLUSIONS:** Aging of smoker population will continue to contribute to reducing prevalence of smokers. Existing dynamic forecasting models were re-created and used to estimate smoker prevalence using recent data.

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PRS14

PATIENTS WITH COPD WHO INITIATE ROFLUMILAST IN SWEDEN

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OBJECTIVES: In Sweden, reimbursement for roflumilast is limited to eligible patients with severe to very severe chronic obstructive pulmonary disease (COPD) who are intolerant to inhaled corticosteroid therapy. Therefore, patients being treated with roflumilast in Sweden may differ by their characteristics to patients in other countries. Our aim was to describe demographic and disease characteristics of patients with COPD prescribed roflumilast in Sweden, at time of first prescription. **METHODS:** Patients with diagnoses of COPD or chronic bronchitis (CB) who initiated use of roflumilast at age ≥40 during 2011 were identified from the Swedish Hospital Discharge Register and Swedish Prescribed Drug Register. Summary statistics were calculated for demographic and disease characteristics at time of first prescription. The Charlson comorbidity index (CCI) was used to score the presence of comorbidities. **RESULTS:** 1,161 patients (42.8% male) with COPD/CB initiated roflumilast. Mean age at time of first prescription was 70.8 (SD±8.3) years. Mean time since first COPD diagnosis was 6.1 (SD±3.8) years. 640 (55.1%) patients were hospitalized at least once in the year prior; 99 (8.5%) had ≥5 hospitalisations in this period. 21.7% of patients had congestive heart failure, 13.5% myocardial infarction, 17.1% diabetes, and 9.1% a mood disorder indicated in their medical records. 37.2% of patients had a CCI score ≥ 3 at time of first roflumilast prescription. **CONCLUSIONS:** Patients who are prescribed roflumilast carry a very severe disease burden. Appropriate methodology should be used when making comparisons between patients who are exposed to roflumilast to those who are not, using real world data in Sweden.

PRS15

THE PREVALENCE OF TOBACCO SMOKING IN PATIENTS WITH DIABETES IN HOSPITAL PULAU PINANG, MALAYSIA

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Widespread evidence has demonstrated the negative effects of tobacco smoking in patients with diabetes. Although many studies have explored the prevalence of tobacco smoking in the general population, data are lacking regarding its prevalence in a specific population with a chronic disease such as diabetes.**OBJECTIVES:** This study aims to determine the prevalence of tobacco smoking among patients with diabetes in Hospital Pulau Pinang, Malaysia. **METHODS:** A cross-sectional survey was conducted to study diabetic patients who attended the endocrine clinic at Hospital Pulau Pinang in Malaysia from March to August 2012. All the diabetic patients who attended the endocrine clinic during that period were asked about their smoking status, and their medical records were reviewed. A total of 1,118 patients with diabetes were reviewed to determine the prevalence of tobacco smoking in diabetic patients at the endocrine clinic of Hospital Pulau Pinang. **RESULTS:** The majority of the study population was male, with Malay and Chinese patients in almost equal proportions and a smaller proportion of Indian patients. Most of these patients had started smoking before they were diagnosed with diabetes. Among the 1,118 diabetic patients, only 108 patients smoked; therefore, the prevalence of tobacco smoking in our patients with diabetes was 9.66%. **CONCLUSIONS:** A low prevalence of tobacco smoking was estimated in this study. This prevalence is close to the corresponding value in the general population in Malaysia.

PRS16

CURRENT ANNUAL COST CALCULATION IS THE BEST PREDICTOR OF MORTALITY AT THREE YEARS IN COPD

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OBJECTIVES: Chronic Obstructive Pulmonary Disease (COPD) is a progressive condition which is characterized by a dramatic socio-economic impact. Sensitivity of clinical signs and lung function in predicting death is variable in different COPD phenotypes. **AIM:** To assess the predictive value of COPD annual cost on mortality. **METHODS:** Gender; age; smoking habit, clinical data, and complete lung funtion were assessed in 275 consecutive COPD patients aged >40y together with the annual cost calculated over the last twelve months. **STATISTICS:** t test for comparing means ± sd; linear regression for checking any relationship between each variable and mortality ($p<0.05$ was accepted). **RESULTS:** The whole mortality was 40.4% over three years (n=12; 47, and 52 subjects, respectively). Subjects still survived after three years (n=164) proved originally different from those (n=111) who died in terms of mean age; FEV1 (in l); RV; TLCO/VA; 6' walking test; BODE index, and Charlson index (all $p<0.001$), but not of FEV1% pred. and FEV1/FVC (p=ns). Mean total