

optimal market access. **METHODS:** Across the EU5, 16 payers who influence reimbursement nationally or regionally were interviewed, and 255 pulmonologists were surveyed. **RESULTS:** All interviewed payers demand unequivocal proof of added benefit from new agents for favorable reimbursement terms. Those in Germany highlight the G-BA's determination of no added benefit for mepolizumab (GlaxoSmithKline's Nucala) to exemplify the penalty for using an inadequate comparator regimen and flawed trial design when superiority in head-to-head studies is required. The importance of clinically relevant end-points is also stressed across countries, with rate of exacerbation for severe asthma rather than surrogates such as FEV1 specifically mentioned. Likewise, 57% (Italy) to 78% (UK) of surveyed pulmonologists select reducing exacerbations as a top-five prescribing driver for asthma biologics. In all countries, clinical performance trumps treatment cost among surveyed physicians' prescribing drivers overall; however, interviewed payers everywhere also seek substantial price discounts or managed entry agreements at national and subnational levels in exchange for optimal reimbursement and positioning. These payers stress that, despite different mechanisms of action and use of different biomarkers, asthma biologics will ultimately compete for the same small, largely overlapping population of severe, refractory asthma. The opportunity to ease payers' cost concerns with positive pharmaco-economic data is also pinpointed. **CONCLUSIONS:** Emerging asthma biologics face the modern day EU5 market access reality of frugal payers increasingly reliant on health technology assessment and pharmaco-economic results as a lever to stringent reimbursement negotiations, and increasingly seeking cost-cutting opportunities. Realistic prices, meaningful discounts/entry agreements, well-designed clinical trials, and persuasive pharmaco-economic data will help float the asthma biologics' market access boat.

#### PRS64

##### COST AND TREATMENT OF ASTHMA AND COPD IN THE REAL PRACTICE: A REGIONAL SEGMENTATION

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**OBJECTIVES:** Italian recommendations for the management of Asthma and Chronic Obstructive Pulmonary Disease (COPD) are respectively GINA and GOLD international Guidelines, with some local documents available for COPD. The aim of this research was to investigate the variability concerning the pharmacotreatment of respiratory treatments among Italian Regions. **METHODS:** A desk research was conducted to gather international and local guidelines. The research integrated hospitals and territory data supplied by QuintilesIMS (i.e. LRx and Monitor Spesa Databases) and Ministry of Health data (epidemiologic data at local and regional levels), in order to achieve a comprehensive overview of the current drug utilization scenario. The analysis included 13 different molecules, both branded and generics, belonging to the following respiratory drug classes: long-acting antimuscarinics (LAMA), long-acting beta2 antagonists (LABA)/LAMA and inhaled-corticosteroids (ICS)/LABA. The analysis included 90% of all prescriptions delivered in 2016, within all the 21 Italian Regions. **RESULTS:** Prevalence and incidence in the use of respiratory drugs included in the analysis showed a positive correlation; no difference among Regions in North, Centre and South of Italy were observed. Nonetheless, the research highlighted intra-regional variability in terms of treatment cost per-capita and per-patient. In addition, costs per-patient varied significantly among Regions, with a statistical reduction in Southern vs Northern ones ( $p < 0.05$ ). Southern Regions showed a higher generic dispensing ratio (GDR) compared to Northern Regions, both considering prevalent and naïve patients. **CONCLUSIONS:** The research highlighted a great tendency to prescribe generic drugs in Southern Regions, especially in naïve patients. Indeed, the per-patient cost of drugs was lower in Southern Regions, and this finding can be explained with the presence of a financial plan, agreed with the Government to settle regional debts (i.e. Repayment plan). On the contrary, in Northern Regions drug prescriptions are reduced in terms of volumes, but not in terms of values, probably due to the lower GDR.

#### PRS65

##### ANALYSIS OF CONSUMPTION OF ANTI-TB MEDICINES IN UKRAINE DURING 2012-2016

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**OBJECTIVES:** According to the statistics of the Ministry of Health in Ukraine in 2016 about 700 thousand people were ill with tuberculosis, 600 thousand of them were on the dispensary record, including 142 thousand with an open form of tuberculosis. Currently, an important task for the treatment of patients with tuberculosis in Ukraine is to provide them with anti-TB drugs, as needed. **METHODS:** AT /DDD-method developed by WHO. **RESULTS:** During 2012-2016 in the pharmaceutical market of Ukraine the number of INNs of anti-tuberculosis drugs decreased from 11 to 6, and TNs from 25 to 19. It was established that in 2012, 28.84 DIDs of anti-tuberculosis drugs were consumed; in 2013 - 30.92 DIDs; in 2014 - 9.00 DIDs; in 2015 - 5.90 DIDs; in 2016 - 22.36 DIDs. The Ukrainian protocol for TB treatment indicated three schemes: I - 4 drugs for 2 months, II - 2 drugs for 4 months and III - 5 drugs for 2 months. In terms of 700000 patients with TB, the prescribed treatment regimens for the years are as follows: in 2012 - all patients received I and II regimens, 441714 patients received also III treatment regimen; in 2013 patients received I+II treatment regimens during the year, and 586890 patients also received the III scheme; in 2014 only 578755 patients received one of the treatment regimens I or II; in 2015 there was also little use of drugs, I or II schemes for only 384196 patients, and in 2016 the volume of drug use increased and they were again enough to fully support all patients during the I+II treatment regimens, and 38671 patients also got the III scheme. **CONCLUSIONS:** Thus, the treatment of patients with tuberculosis in Ukraine takes place at state funds, and starting from 2016 we observe the sufficient provision of TB patients with medicines.

#### PRS66

##### PRIMARY DATA COLLECTION VERSUS USE OF RETROSPECTIVE CLAIMS DATA: METHODOLOGY LESSONS LEARNED FROM A LINKED DATABASE STUDY IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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**OBJECTIVES:** Primary data collection either by a retrospective medical chart review, as part of a prospective observational study or use of retrospective claims data, are common methods in non-interventional health care research. By using a linked dataset, the aim of this study was to assess strengths and limitations of primary data (PD) and claims data (CD) with data obtained from a population of German COPD patients. **METHODS:** Prospectively collected PD from 536 patients (04/2013-11/2014) were linked to CD from a German sickness fund (AOK Nordost) on a patient level, covering the same observation period. Characteristics of both datasets were assessed by (1) an analysis of value differences in (1a) patient characteristics, (1b) documented exacerbations and (1c) prescriptions of bronchodilators (ATC codes: R03\*), and (2) a comparison of patient characteristics between both datasets. **RESULTS:** 536 patients were included in this post-hoc analysis (mean age 67.98 years; 36.38% female). The percentage of comorbid patients reported in PD was lower than in CD (e.g., depression 6.7% vs. 29.3%,  $p < 0.001$ ). Based on PD, 20.9% experienced at least one exacerbation versus 29.1% based on CD. Mean number of COPD prescriptions per patient year was 3.7 prescriptions (PD) versus 10.3 (CD), for 440 patients with drug treatment data available in both datasets. In terms of generalizability, we observed that patients in the complete claims dataset (74,916 patients) were three years older and to a higher percentage female than PD patients. Moreover, they were less comorbid and less frequently visiting physicians than PD patients. **CONCLUSIONS:** Even if the same patient population and follow-up period is observed, substantial differences on values of key variables between PD and CD exist. Data linkage may provide a more complete and precise overview and could thereby provide an opportunity to improve external and internal validity.

#### PRS67

##### OBSERVED REDUCTION OF HEALTHCARE UTILIZATION AFTER OMALIZUMAB INITIATION AMONG PATIENTS WITH PERSISTENT ASTHMA FOLLOWED IN CANADIAN CLINICAL SETTINGS

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**OBJECTIVES:** The primary objective was to evaluate the health care utilization (HCU) following omalizumab (OMA) initiation as assessed by the reduction in number of hospitalizations, emergency room (ER) visits, and oral corticosteroid (OCS) use in patients covered in Ontario. The number of night awakenings was an exploratory endpoint. **METHODS:** This study is a retrospective, pre-post cohort, observational study. The data was collected from the patient support program. Individuals were enrolled to the Ontario Trillium Drug Program and had access to OMA through Exceptional Access Program (EAP). Individuals were identified and their OMA EAP claims for the relevant period. The data extract included patients with an enrollment form receipt date greater than July 17th 2013 or a reactivation form receipt date greater than July 17th 2013. The end date of data collection was May 5th, 2016. **RESULTS:** 148 patients (mean age 57.6; female 62.2%) formed the study population. Omalizumab was associated with a 74.4% reduction in the number of hospitalization (pre vs post-omalizumab's 12 month treatment period: 0.7 vs 0.2  $p < 0.001$ ). 89.9% of patients did not have any asthma related hospitalization. There was a reduction of 87.5% in ER visits (7.3 vs 0.9  $p < 0.001$ ), 66.2% of patients did not have any emergency visit. A 74.7% reduction of the number of high dose OCS by (4.23 vs. 1.07  $p < 0.001$ ), 52.7% of patients did not need to take any courses of high dose OCS. The mean number of night awakenings / per week decreased from 6.1 (8.03) to 1.3 (2.79) following 12 month treatment with omalizumab. **CONCLUSIONS:** There was an observed reduction in the number of hospitalizations, ER visits, and high-dose OCS courses post-omalizumab use in patients with severe uncontrolled asthma in a Canadian real-world setting. The results are consistent with outcomes observed in previous large real-world trials such as the eXperience registry.

#### PRS68

##### IMPACT OF GLOBAL BUDGET ON PERSONAL MEDICAL EXPENSE FOR INPATIENT WITH RESPIRATORY DISEASE: AN INTERRUPTED TIME SERIES ANALYSIS

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**OBJECTIVES:** Soaring medical expense has been a global issue for a decade, and China is confronted with an even greater burden. Increasing medical expense brings great economic burden for patients. From 2009, Global budget payment system (GBPS) was introduced in Shanghai for public hospitals instead of fee-for-service (FFS) payment system to curtail medical expense, and fully implement from 2011. The aim of this paper is analysis to evaluate impact of GBPS in medical expense per capita of inpatients of respiratory disease in Shanghai. **METHODS:** Daily number of hospitalizations and medical expense of respiratory disease of residents participated in Urban Employee's Basic Medical Insurance (UEBMI) in Shanghai from April 1, 2009 to March 31, 2012 was collected by Shanghai Health Insurance Bureau (SHIB). An interrupted time-series analysis (ITS) was used to evaluate the impact of GBPS pilot extended from 2010 and fully implement from 2011 compared to baseline in medical expense. **RESULTS:** A Segmented autoregressive integrated moving average (ARIMA) was used to evaluate model medical expense per capita. Our study showed GBPS could retard the monthly increasing speed of medical expense per capita. The monthly increment of total medical expense, medical insurance coverage service expense and self-paying service expense per capita were decreased by CNY 0.08 thousand, 0.07 thousand and 0.01 thousand in 2010 and CNY 0.07 thousand, 0.05 thousand and 0.02 thousand in 2011. But the instant effect of CBPS