switch (OR=1.6; 1.2-2.1) and discontinuation (OR=1.8; 1.5-2.1). Heart failure was associated with augmentation (OR=1.6; 1.0-2.5) and discontinuation (OR=1.7; 1.2-2.4). Age was inversely associated with augmentation and discontinuation and time since diabetes diagnosis was also inversely associated with augmentation. **CONCLUSIONS:** HbA1c is a clear driver of treatment regimen changes although there are other factors also independently related to change such as age, heart failure and baseline OAD.

PDB79

TREATMENT PATTERNS OF ORAL ANTI-DIABETIC DRUGS IN THE UK

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OBJECTIVES: In the UK, Oral Anti-Diabetic drugs "OAD" are administered to control hyperglycaemia in type 2 diabetes when HbA1c exceeds 48mmol/mol. Treatment guidelines determine initial OAD and subsequent changes in regimen depend on HbA1c response. Hence, the aim of this study is to quantify OAD treatment patterns. **METHODS:** All patients who initiated an OAD (except rosiglitazone) with first use as index date, in the GPRD database between 1/1/2006 and 25/2/2011 were included. Periods of continuous and overlapping prescribing (Rx) were used to define discontinuation, switching and augmentation; a gap of 60 days since expiry of Rx defined discontinuation. **RESULTS:** Of 63060 patients commencing OAD, 88% started on metformin and 8% on gliclazide both as monotherapy. Hence, all other OAD regimens comprised only 4% of all patients. Compared to metformin, the gliclazide patient group was older (mean age 67 vs. 61 years) and had higher median baseline HbA1c (70 (IQR 60-95) vs. 64 (IQR 56-74) mmol/mol). The rate of discontinuation of baseline OAD at one year was 32% whilst the discontinuation of all OAD was 26%. It was rare for discontinuation of OAD to be permanent; only 3.3% of patients who discontinued in the 1st 12 months did not restart during 4 years. The rate of switching was 6.4% and the rate of augmentation was 15% over the first year. These rates differed according to baseline OAD. Compared to metformin the discontinuation rate of gliclazide was higher (41% vs. 30%), as was switching (8.4% vs. 6.1%) and augmentation (23% vs. 14%). Lastly, insulin uptake was just 2% by one year since OAD initiation; again this was higher in the gliclazide group compared to metformin (7% vs. 1.4%). **CONCLUSIONS:** Most patients initiated on metformin, whilst for those initiating on gliclazide, discontinuation, switching, augmentation and insulin initiation were all higher. Most patients who discontinued OAD subsequently restarted.

SYSTEMIC DISORDERS/CONDITIONS - Clinical Outcomes Studies

PSY1

CARDIOVASCULAR AND CONGENITAL SAFETY EVALUATION OF ANTIOBESITY AGENTS, INCLUDING TOPIRAMATE: A PHARMACOVIGILANCE ANALYSIS OF THE ADVERSE EVENT REPORTING SYSTEM

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OBJECTIVES: A myriad of pharmacologic agents are developed in attempts to control obesity, including the extension of the antiepileptic topiramate as an antiobesity agent. However, concerns about the safety of such agents are mounting. This study aimed at evaluating the cardiovascular and congenital (CC) safety of marketed antiobesity agents, including topiramate. **METHODS:** A pharmacovigilance analysis of adverse event reports spontaneously submitted to the US Food and Drug Administration's Adverse Event Reporting System (AERS) from 2004 to 2011 was conducted. The Proportional Reporting Ratio (PRR) data mining algorithm is used to detect signals of CC adverse events that are reported for orlistat, phentermine, sibutramine, and topiramate. Safety signals are detected for PRR values >2. The values are compared within antiobesity class and to all drugs in AERS. **RESULTS:** A total of 41,930 adverse event reports for antiobesity agents were submitted to the AERS during the study period. About 4% and 1% of the reports were for cardiovascular and congenital problems, respectively. Compared to all drugs in AERS, antiobesity agents didn't show higher than expected reporting of cardiovascular events (PRR 0.71, 95%CI 0.68-0.74). However, they showed significant safety signals regarding congenital anomalies (PRR 7.45, 95%CI 6.82-8.0), which were mostly attributed by topiramate. Compared to other antiobesity agents, sibutramine was associated with higher cardiovascular reporting rates (PRR 4.42, 95%CI 4.0-4.85), e.g. cardiac arrhythmias, pulmonary hypertension, hypertension, coronary artery disease, and stroke. Phentermine was associated with valvular heart disease (VHD), pulmonary hypertension, and stroke. Topiramate was associated with congenital anomalies and VHD. **CONCLUSIONS:** Antiobesity agents should be prescribed with caution to patients with cardiovascular risk factors. Regulatory authorities should define cardiovascular safety surveillance requirements for antiobesity agents at postmarketing stages of product's lifecycle. An alternative to topiramate should be prescribed to females of childbearing age. Epidemiological studies are warranted to test the generated hypotheses.

PSY2

PRELIMINARY VALIDATION OF COLLECT SCALE: A CO-MORBIDITY ASSESSMENT TOOL FOR PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA

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OBJECTIVES: COLLECT scale was developed to assess the level of comorbidity with an impact on treatment decision for patients with Chronic Lymphocytic Leukaemia (CLL) in 5 steps: 1.-Literature review, 2.-Focus Group, 3.-Pilot study to evaluate scale feasibility, 4.-Scale design, 5.-Scale validation in an observational, prospective phase IV study (evaluating safety profile of Rituximab in CLL). This communication presents the preliminary validation of the COLLECT scale. **METHODS:** A total of 219 patients were included. The scale is to be fulfilled before initiating CLL treatment and it collates and rates the presence of 11 relevant comorbidities. The range of the score goes from 0 to 57 points. Four scoring clusters were predefined: 0-3 points (low comorbidity), 4-6 (mild comorbidity), 7-10 (moderate comorbidity) and >10 (high comorbidity). **RESULTS:** Data from 218 patients of 47 hospitals were analyzed. Most frequent therapeutic scheme was Rituximab-Fludarabine-Cyclophosphamide (R-FC) (41.3%), followed by Rituximab-Bendamustine (R-B) (29.6%) and Rituximab-Chlorambucil (R-Cl) or schemes including alkylating agents (21.1%). COLLECT median score (SD) was 4 (0-21) with a mean of 4.8 (3.1) points. 39.2% of patients scored between 4-6 and 33% between 0-3. Statistically significant differences were observed in COLLECT score according to age ($p<0.01$) and EGOG ($p<0.01$): the greater the age and ECOG, the greater the score. The election of inmunochemotherapy treatment differed depending on the score cluster ($p=0.002$): 50.6% and 32,9% of patients treated with R-FC had low and mild comorbidity level respectively. 40,0% of patients receiving R-B had medium and 26.5% high comorbidity level. 50% of patients treated with R-Cl scored between 4-6 and the 23.5% between 7-10. **CONCLUSIONS:** COLLECT scale allows defining 4 levels of comorbidities, with a very good correlation to age and ECOG status. Although the aim of the scale is not to drive treatment decision, the study shows a trend to associate comorbidity score with intensity of treatment.

PSY3

DISEASE ACTIVITY INDICES (DAIS) IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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OBJECTIVES: Review the development and properties of systemic lupus erythematosus (SLE) disease activity indices (DAIs) used in clinical trials, observational studies, and case studies. **METHODS:** A structured search was conducted to identify published articles in 2005-2011 through key literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from targeted rheumatology, outcomes research and quality-of-life scientific meetings in 2009-2011 were included. SLE therapy clinical trials within the past five years were identified through the ClinicalTrials.gov database. **RESULTS:** The search resulted in more than 15 different DAIs, with the most frequently used being the British Isles Lupus Assessment Group Scale (BILAG), European Consensus Lupus Activity Measure (ECLAM), Systemic Lupus Activity Measure (SLAM), SLAM-revised (SLAM-R), Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), SLEDAI-2K, Safety of Estrogen in Lupus Erythematosus National-SLEDAI (SELENA-SLEDAI), and SLEDAI-2K-50 (SRI-50). The number of items (24-97), time to complete (5-20 mins; >20 mins for some tools in case of less physician training/familiarity), scoring (no global score or 0-105), organ/systems assessed (8-24), and subscales observed in these measures varied widely. These eight DAIs all demonstrated substantial inter-rater reliability (ICC=.61-1.0) and had moderate to strong correlations with each other (r=0.43-0.97). Measures in all but BILAG were weighted. All of these tools require periodic laboratory assessments such as hemoglobin, white cell count, complement levels, or increased DNA binding. Ability to discriminate between-patient and between-visit differences varied across the tools. **CONCLUSIONS:** BILAG and SELENA-SLEDAI or instruments derived from these tools are used widely in SLE clinical research. However, given the complexity, clinician time required for accurate completion, and need for lab assessments to complete these tools, further investigation is needed to assess their feasibility for use outside of the research arena in routine clinical practice for optimal SLE management.

PSY4

LENALIDOMIDE OR BORTEZOMIB FOR THE TREATMENT OF RELAPSED/REFRACTORY MULTIPLE MYELOMA (MM): A COMPARATIVE EFFECTIVENESS ANALYSIS USING INDIRECT STATISTICAL TECHNIQUES

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OBJECTIVES: Lenalidomide (LEN) and bortezomib (BORT) are both effective for the treatment of relapsed/refractory MM. The former is administered 25 mg/day orally on days 1-21 of repeated 28-day cycles. The latter as a 1.3 mg/m^2 intravenous dose on days 1, 4, 8 and 11 for eight, three week cycles. Currently, there are no data from head to head randomized trials comparing LEN and BORT. In the absence of such data, an indirect comparison between LEN and BORT was performed in the relapsed/refractory MM setting. Such an analysis was feasible because comparable controls were used in the pivotal randomized trials and patients had similar baseline characteristics. **METHODS:** Three pivotal randomized trials with LEN (n=2) and BORT (n=1) in the relapsed/refractory setting were identified. Patients within each trial had similar disease characteristics. Data in terms of response rate (RR), time to progression (TTP) and overall survival (OS) were extracted from the pivotal trials. An indirect statistical comparison between LEN and BORT was then performed on these endpoints using the method of Bucher et al. (1997), which partly maintains the benefits of randomization on the magnitude of benefit. **RESULTS:** The analysis identified significant differences in efficacy between these drugs. Patients treated with LEN were significantly more likely to achieve a disease response (OR=1.92; 95%CI: 1.15 - 3.20) and to have a prolongation in TTP (HR = 0.64; 95%CI: 0.44 - 0.91). The analysis also identified a trend for an OS benefit in patients receiving treatment with LEN over BORT (HR = 0.71; 95%CI: 0.46 - 1.11). **CONCLUSIONS:**