disease activity and lab measurements. RESULTS: 106 papers met our inclusion criteria. Studies were published between 2003 and 2015 and mostly from Europe. 39 included patients starting etanercept, 36 included patients starting rituximab and 32 patients starting tocilizumab. Mean age ranged between 42.9 and 63.3 years. 78.2% were female. The drugs were given in combination with methotrexate and/or other DMARDs. Study duration varied between 4 and 17.5 years, baseline disease activity scores between 4.3 and 7.0, and baseline health assessment questionnaire values between 1 and 2.9. The mean difference of rheumatoid-factor positive patients was 76.6%. Reporting of comorbidities and smoking status was generally poor, with only a few studies providing detailed data.

CONCLUSIONS: This systematic review of data from observational studies and clinical databases indicates that the characteristics of RA patients starting in clinical trials differ from those in real-world settings. Mean age, sex distribution, and disease duration varied between studies, and baseline disease activity scores were lower in real-world settings. Reporting of comorbidities and smoking status was generally poor.

PM136 EFFECTIVENESS OF A REFERRAL PROGRAM FOR EARLY ARTHRITIS DIAGNOSIS AT PRIMARY CARE CENTERS IN PORTUGAL - PRELIMINARY RESULTS FROM THE SARA Study

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OBJECTIVES: Early diagnosis and treatment of inflammatory arthritis can limit the impact of disease outcomes. We aimed to evaluate the effectiveness of a referral program on the identification of patients with suspected inflammatory arthritis (PSY2). (Referral Strategy Assessment: Systematic Review on Diagnosis and Referral of Axial Spondyloarthritis and Rheumatoid Arthritis Patients) is an observational prospective, randomized (by clusters of primary care centers) study to assess the impact of the referral of Referral Support Actions (RSA) consisting of a physician educational sessions about the disease and implementation of referral recommendations. The participating primary care centers (n=24) were randomly assigned to RSA or control group (with no intervention). Both RSA and control group patients were identified from patients suspected inflammatory arthritis in the rheumatology unit of the reference hospital (n=6). The main study outcome was the correct diagnosis of inflammatory arthritis / rheumatoid arthritis confirmed by the rheumatologist of the reference hospital. RESULTS: A total of 125 patients were referred to a rheumatologist (considering 4 hospitals): 61 RSA patients and 64 control patients. Mean age was 48.9 years (range: 19-73) and 88.8% were female (differences not statistically significant between groups). About 14.8% (n=9) of RSA patients and 4.7% (n=3) of controls had a confirmed diagnosis of arthritis (any type) by the rheumatologist (OR=3.5; 95%CI, 0.9-13.7; Chi-square p=0.056). Rate of confirmed rheumatoid arthritis was 4.9% in RSA patients and 1.6% in controls (p=0.287). The majority of the patients (82%) were referred in the 4 months after educational session (month 3.633%, month 6.967%). CONCLUSIONS: Although the study results still lack statistical significance, this preliminary data already suggests a positive impact of a referral program on the early identification of inflammatory arthritis, providing a better quality of care on these patients. The benefit of the implementation of RSA consisted of the reduction of the burden on patients, cost of treatment, and time on diagnosis, and also limitation of the impact of the disease on family and work at personal level. Further research is needed to determine the best way of including these recommendations and considered by healthcare deciders in order to improve health outcomes in inflammatory arthritis.

PM137 A WEB-BASED SURVEY TO INVESTIGATE THE EXTENT OF AWARENESS AND UNDERSTANDING FOR BIOSIMILAR AMONG JAPANESE PHYSICIANS AND PHARMACISTS

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OBJECTIVES: Several biosimilar products have been developed and marketed in Japan. However, the degree of understanding of biosimilars among healthcare professionals is uncertain. The objective of this study was to investigate the extent of awareness and understanding of biosimilars among Japanese physicians and pharmacists. METHODS: This was a non-interventional, web-based survey conducted in May 2015. Japanese physicians (rheumatologists/oncologists) and pharmacists voluntarily participated and provided their thoughts via questionnaires. Rheumatologists who have seen > 30 patients with RA will be further analyzed.

PM158 AGREEMENT OF RISK SHARING AGREEMENTS (RSAs) IN SELECT GLOBAL MARKETS WITH SPECIFIC FOCUS ON ACTIVITIES SURROUNDING IMMUNOMODULATORS

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OBJECTIVES: To understand current Risk Sharing Agreements (RSAs) for immunomodulators for rheumatoid arthritis, psoriasis, and psoriatic arthritis in 11 markets aimed to optimize specific RSA strategies/payer partnerships. METHODS: Review of publicly available health authority websites and peer-reviewed journals. Interviews with payers and stakeholders who influence RSA decisions and pharma executives for validation and gap filling. RESULTS: USA manufacturers negotiated RSAs with private health insurers and states. Payers in USA integrate high financial risks with manufacturers using outcome based agreements (OBAs). Canada established RSAs with Provinces and use financial based agreements (FBAs) but some exclusion. France requires fixed based price to limit budget impact. Germany uses FBAs at the sickness fund level rather than the Gemeinsamer Bundesausschuss (G-BA) level because sickness funds manage their own budgets. Some OBAs exist with clearly defined outcomes. Italy negotiates FBAs which is mainly for orphan diseases and OBAs which often require clearly defined outcomes. Germany prefers FBAs where manufacturers are accountable for limiting budget impacts. In the UK, FBAs with few OBAs are used affecting product price but are not rebate based. Australian RSAs are mostly FBAs and are referred to as “Deeds of Agreement”. CONCLUSIONS: With high-cost immunomodulators, authorities are shifting towards integrating RSAs in price negotiations to optimize budget expectations prior to launch. Europe prefers FBAs to OBAs which often require clearly defined outcomes.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1 ASSOCIATION OF ADVERSE EVENTS AND HEALTH SERVICE USAGE WITH TAPENTADOL PROLONGED-RELEASE TREATMENT COMPARED WITH MORPHINE CONTROLLED-RELEASE (CR) AND OXYCODONE CR: A UK PRIMARY CARE OBSERVATIONAL STUDY

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OBJECTIVES: This study compared adverse outcomes and resource use in patients treated with tapentadol prolonged-release (PR) with those treated with morphine controlled-release (CR) and oxycodone CR. METHODS: Data were from the Clinical Practice Research Datalink, a database derived from UK primary-care. Patients prescribed tapentadol PR between May 2011 and December 2014 were matched to two groups of controls treated with either morphine CR or oxycodone CR on gender, age, pain relief, Charlson disease index. Two diagnostic conditions. Rates of adverse events (constipation and nausea/vomiting) were compared by adjusted hazard ratio (aHR). Rates of primary-care contacts, accident and emergency contacts for recent clinic letters and prescriptions. RESULTS: 1,167 patients prescribed tapentadol PR were matched with 2,334 patients prescribed CR and 2,334 patients prescribed oxycodone CR. Compared with controls, adverse events with tapentadol PR treatment were reduced: aHR=0.643 (95% CI 0.459-0.901; p=0.019) versus morphine CR and 0.505 (0.335-0.763; p=0.002) versus oxycodone CR. Compared with morphine CR, primary-care contacts (IRR=0.817; 0.786-0.850), accident and emergency attendance (0.699; 0.560-0.870) and outpatient letters (0.715; 0.543-0.939) were also reduced. For oxycodone CR, the respective figures were 0.776 (0.706-0.840), 0.840 (0.639-1.043) and 0.954 (0.800-0.739). For the subset of HES-linked patients the rates of inpatient admissions were 0.723 (0.590-0.884) and 0.458 (0.357-0.585) vs. morphine CR and oxycodone CR, respectively. CONCLUSIONS: Tapentadol PR was associated with significantly fewer adverse gastrointestinal events than morphine CR or oxycodone CR. There was also significantly reduced primary and secondary-care resource use. As with all observational studies, potential bias due to residual confounding and confounding by indication should be considered.

PSY2 CLINICAL AND ECONOMIC BURDEN OF PULMONARY EXACERBATIONS IN PATIENTS WITH CYSTIC FIBROSIS WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION

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OBJECTIVES: To assess the clinical and economic burden of pulmonary exacerbations (PEx) in patients with cystic fibrosis (CF) and homozygous for the F508Del (delta F508) mutation. METHODS: Retrospective chart review of patients ≥ 12 years old were collected in France, Germany, Italy, Spain, Australia and Canada. Demographics, clinical characteristics, and selected resource utilization were obtained for a 12-month baseline period and a follow-up period ranging from 2-36 months. The frequency of late health interventions and exacerbations were assessed overall and by age (12-17, ≥ 18 years) and lung function (percent predicted forced expiratory volume in 1-second [ppFEV1]) ≥ 70%, 41-69%, <40%. Descriptive analyses were conducted. RESULTS: Data for 523 patients were included. Baseline mean ± SD age was 24.8 ± 9.5 years and mean ± SD ppFEV1 was 67.1 ± 22.9%. During