A573



At 18 months, drug survival rate of the mix of first-line biologics was 71.8% [95% CI: 60.1% - 80.6%]. **CONCLUSIONS:** Claims database is a useful tool to describe the  $medical\ management\ of\ RA\ patients.\ These\ observations\ suggest\ that\ BA\ clinical$ use in RA disease management in France is similar to other existing European registries data.

## ETANERCEPT 25 MG ONCE WEEKLY COULD BE A COST-EFFECTIVE OPTION FOR RHEUMATOLOGY PATIENTS IN SUSTAINED CLINICAL REMISSION

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OBJECTIVES: Etanercept 50mg/week (ETN50) has demonstrated efficacy in rheumatoid arthritis (RA), psoriatic arthropathy (PA) and ankylosing spondylitis (AS) patients. In certain patients in sustained clinical remission, a dose reduction to etanercept 25 mg/week (ETN25) could be done. Determine the economic impact of ETN25 in RA, PA and AS patients in sustained clinical remission. METHODS: Observational, retrospective cohort of patients treated with ETN50 that achieve and maintain clinical remission (DAS28<2.6 or BASDAI<2) during 1 year and slow worsening of structural changes, enrolled in an off-label program (January 2006-June 2013) to switch ETN50 to ETN25. Economical impact was assessed using Enbrel® Spanish official prices. **RESULTS:** From January 2006 to June 1, 2013, 98 RA, 40 PA, 47 AS patients were treated with ETN50; 39 (24%) patients (18 women; age 53±7 years; 24 RA, 7 PA, 8 AS) received ETN25 for at least 0.5 years (2.6±2.0 years; range 0.5-7.3 years). At June 1, 2013, 29 (74%) patients continued on ETN25. RA patients: 17 continued on ETN25, 5 patients discontinued due to reactivation of RA (4 switched to ETN50 and 1 switched to adalimumab, all regained clinical remission) and 2 patients due to adverse reactions. PA patients: 4 continued on ETN25, 2 patients discontinued due to reactivation of PA (switched to ETN50 regaining clinical remission) and 1 patient due to adverse reaction. All AS patients continued on ETN25. Total associated savings with ETN 25 throughout the 7-year observation period were 622.073€, leading to treat 52 additional patients with ETN50 for a year without increasing ETN total costs. CONCLUSIONS: ETN25 produces cost savings when used in patients in clinical remission for at least 1 year with ETN50. At a time when therapy cost is an unavoidable component of health care treatment decisions, ETN25 could be a cost-effective option for selected RA, PA and AS patients.

## BURDEN OF DOSE ESCALATION WITH BIOLOGICS IN RHEUMATOID ARTHRITIS: A REVIEW OF FREQUENCY AND COSTS

Moots  $R^1$ , Mays  $R^2$ , Li  $C^2$ , Stephens  $J^2$ , Tarallo  $M^3$ 

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OBJECTIVES: Switching or dose escalation of TNF inhibitors is an option for rheumatoid arthritis (RA) patients unresponsive or with a partial response to first-line treatment. Drug costs increase with higher dosing but the frequency and impact of dose escalation on other costs is not well known. A literature review of biologic dose escalation in RA was conducted to assess how often it occurs and the economic impact to payers. METHODS: A search of PubMed, EMBASE, Cochrane, and Centre of Disseminated Reviews was conducted for TNF inhibitors in inflammatory arthritis diseases. Searches were focused on dose escalation and economic terms in RA. Limits were Human, English and time frame (2003 to 2013). A weighted proportion of dose escalators in RA was calculated for each drug as an alternative to reporting ranges. RESULTS: Forty-one publications were identified with 36 reporting values for dose escalation in RA. The proportion of dose escalators varied widely: adalimumab 7.5 to 36%, etanercept 0 to 22%, and infliximab 0 to 80%. Various definitions of dose escalation led to the wide range. The weighted proportion of dose escalators  $\,$ for each drug was adalimumab 14.9%, etanercept 4.9%, and infliximab 41.7%. Six studies reported economic data comparing dose escalators to non-dose escalators. Adalimumab drug costs increased 27 to 43% with total costs increasing 28 to 34%; infliximab drugs costs increased 6 to 75%, RA-related costs increased 25 to 54%, and total costs increased 15% to 35%. Lowest costs were reported with etanercept: drug costs increased 3.2 to 19%, RA-related costs increased 4.5%, and total costs increased 2.2 to 15%. CONCLUSIONS: Pooled results demonstrated dose escalation in RA occurred most frequently with infliximab and least frequently with etanercept. Not only were biologic costs increased, but also RA-related and total costs. Etanercept was associated with the lowest cost increases.

### RATIONALE FOR INITIATING AND SWITCHING BIOLOGIC THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS OF A EUROPEAN CHART REVIEW STUDY

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OBJECTIVES: This study aimed to describe the rationale for selection of initial biologic therapy and changes in biologic therapy among patients with RA in Germany, Spain, and the United Kingdom (UK). METHODS: This retrospective, observational medical chart review captured patient data via 118 Spanish, German, and British rheumatologists. Patients(  $\geq$ 18 years) had a confirmed diagnosis of RA between January 2008 and December 2010, and received a biologic therapy for  $\geq$ 3 months and had ≥12 months of follow-up. Physicians recorded all RA regimens and rationale for drug selection. **RESULTS:** The 656 patients (n=328; Germany: n=111, Spain: n=106, UK: n=111) were 71.3% female, had a mean (standard deviation) age of 48.3 (12.6) years at diagnosis and mean 28-joint Disease Activity Score of 5.1±1.2 at biologic initiation. Patients most frequently initiated biologic therapy with adalimumab (41%) or etanercept (38%). The most common reason for initial biologic treatment

was inadequate response from traditional disease-modifying anti-rheumatic drugs (DMARDs) alone (54.9%), followed by symptom control (13.4%). Among the remaining responses, clinical data (e.g., results from clinical trials) was cited most frequently in the UK (17.1%) compared to Germany/Spain (9.0%/4.7%), while personal experience was cited most in Germany (15.3%) vs. UK/Spain (2.7%/0.9%). Inadequate response to DMARDs was most frequently reported for adalimumab (61.5%) vs. etanercept (46.9%) or other biologics (40.2%); inadequate DMARD symptom control was more cited for etanercept (18.8%) vs. adalimumab (11.1%) or other biologics (9.8%). Among the 23 patients who switched to a second biologic agent, 72.7% were switched due to inadequate response to the first biologic agent. CONCLUSIONS: Across the three study countries, prescribers most frequently initiated biologic therapy due to inadequate response or lack of symptom control on traditional DMARDs. Other reasons varied by country, however differences across biologic agents prescribed

### PMS103

### BURDEN OF DISEASE OF CERVICAL DYSTONIA IN THE UNITED KINGDOM

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OBJECTIVES: Cervical Dystonia (CD), the most common adult-onset dystonia, is characterised by involuntary contractions of the cervical muscles that result in abnormal, sustained, and painful postures of the head, neck and shoulders. Annual prevalence rate of CD in Europe is approximately 117 per million. To date, very few studies assessed the burden of the disease, and those published focused on costs of specific treatments. The objective of this study was to describe health care resource utilisation of patients with CD during the first year after diagnosis in the UK. METHODS: In this retrospective cohort study, adult patients with a first ever diagnosis of primary or secondary CD (Read code: F138200 Spasmodic torticollis) between January 2007 and December 2011 were selected from The Health Improvement Network (THIN), a large UK Primary Care database. Patients were required to have a follow-up time of at least 24 months after diagnosis. Analyses performed described demographic and clinical characteristics at diagnosis and all-cause utilization of CD-related health care resources including treatment during follow up. **RESULTS:** This study included 4,497 patients, 65.40% were female, median age at diagnosis was 41 years old and 8.05% were diagnosed with depression. During that first year, patients had on average 6 visits to the GP (SD: 5.45) and were newly referred most frequently to the orthopaedist (5.09%); less than 2% of patients had an all-cause hospitalisation and less than 1% underwent neurosurgery; 80.23% were managed with pharmacological treatment for CD, and the most commonly prescribed drugs were analgesics (69.85%) and benzodiazepines (41.23%); 14.65% received physical therapy. **CONCLUSIONS:** This study provides first-time estimates of the health care resource utilisation related to management of patients with CD in UK during the first year. To describe the complete burden of CD further research will have to investigate secondary care data and longer time horizon.

## THE COST SAVING POTENTIAL OF UTILIZING BIOSIMILAR MEDICINES IN BIOLOGIC NAIVE SEVERE RHEUMATOID ARTHRITIS PATIENTS

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<sup>1</sup>GfK Bridgehead, Melton Mowbray, UK, <sup>2</sup>Sandoz Biopharmaceuticals, Holzkirchen, Germany OBJECTIVES: To analyze the potential cost savings associated with utilization of a quota for biosimilar RA medicines in a biologic naïve but potentially biologic eligible population (those defined as severe). METHODS: High patient numbers in rheumatoid arthritis (RA) and biologic therapy costs place significant pressures on health care budgets. Currently biologic therapies are underutilized in severe RA (DAS Score  $\geq$  3.7) patient populations that may be eligible for treatment. Biosimilar treatments are expected to reach the market (for the top 3 molecules adalimumab, etanercept and infliximab) by 2017 and may provide an avenue to reduce treatment costs and increase patient access to these agents. Biologic naïve RA populations were estimated for France, Germany and the UK as severe RA patients are assumed to be eligible for biologic therapy. Total cost of applying biologic treatment to a 50% quota of the estimated eligible patient population was compared to a situation of initiating patients on a biosimilar equivalent with a price point 30% lower than the originator. Reinvestment potential was calculated, defining how many more patients could be treated with yearly savings. RESULTS: By 2017, when all 3 biosimilars are expected to be available, the assumed 50% quota resulted in yearly savings of  $\epsilon$ 98 million for the UK,  $\epsilon$ 351 million for Germany and  $\epsilon$ 26 million for France compared to the budget impact of using the originator. If these savings were reinvested potentially 40%, 36% and 39% of the remaining biologic naïve patients could be initiated on biosimilar treatment in the UK, Germany and France respectively. CONCLUSIONS: The cost savings from biosimilar adoption in naive severe RA patients presented potentially increase access by removing budgetary pressures from health care systems. Proactive payer encouragement for biosimilar utilization is necessary through the use of guidelines and prescription quotas so that health care systems can realize significant savings.

# THE RESOURCE USE RELATED TO HIP FRACTURES BASED ON DATA FROM

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OBJECTIVES: The International Costs and Utilities Related to Osteoporotic fractures Study (ICUROS) is an ongoing 18 months prospective observational study with the objective of estimating resource use and health related quality of life related to osteoporotic fractures. This study aims to describe the resource utilization for hip fractures (sustained during 2007-2012) pooled from 10 countries: Australia, Austria, Estonia, France, Italy, Lithuania, Mexico, Russia, Spain, and the UK. **METHODS:** Patients studied were ≥ 50 years and lived at home prior to fracture. Data were collected through patient interviews and review of medical records: at baseline and 4, 12, and 18 months after fracture. Only resource use related to the fracture event was collected. RESULTS: There were 1,795, 1,435, 1,256 patients available for analysis at 4, 12 and 18 months follow-up, respectively. The mean age ( $\pm$ SD) at fracture was 77 $\pm$ 10 years and 79% were women. 96% of patients were hospitalized. Mean hospital length of stay (LoS) (±SD) was 17.2±20.4 days during months 0-4 and 1.2±6.8 during months 5-18. Mean LoS varied from 9.3 days to 26.5 days during months 0-4 across countries. The mean number of physician visits (±SD) was 2.8±3.1 during months 0-4 and 2.5±5.6 between months 5-18. The mean number of nurse visits (±SD) was 2.4±9.6 and 3.8±31.9 during corresponding periods, respectively. During months 0-4, 65% of patients used analgesics, 41% calcium/vitamin D, and 27% pharmacological interventions for osteoporosis. The respective uptakes for months 5-18 were 47%, 46% and 25%. **CONCLUSIONS**: Almost all patients were hospitalized after fracture and the mean number of inpatient days is high, although there is a large variation. The vast majority of health care consumption in relation to fracture occurs during the first 4 months but substantial consumption persists up to 18 months after fracture.

### PMS106

# METHODOLOGY OF AN OBSERVATIONAL STUDY TO EVALUATE THE CARE MAP OF WOMEN WITH POSTMENOPAUSAL OSTEOPOROSIS (PMO) IN SWITZERLAND Lippuner $\rm K^1$ , Pendl $\rm G^2$ , Biteeva $\rm I^2$ , Murigande $\rm C^2$ , Schwenkglenks $\rm M^3$

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Basel, Basel, Switzerland OBJECTIVES: The diagnosis and management of PMO involves multiple specialists and referrals. To better understand patient management, an ongoing observational study will evaluate the care map of women with PMO treated in routine clinical practice in Switzerland, and estimate the 2-year treatment cost of parenterally administered medications (denosumab, ibandronate, zoledronate). Here, we describe the study design and methodology. **METHODS:** Of 52 specialist centers across Switzerland operating a DXA machine, 22 agreed to participate in the study. Women diagnosed with PMO and initiated on parenteral antiresorptive treatment were enrolled in the study between June 18, 2012 and May 31, 2013. To minimize selection bias, treatment initiation must have occurred within 6 months before study initiation visit at the participating center. The planned follow-up period is 24 months. Patients may be followed by the specialist or referred back to the general practitioner. Where available, the following data will be collected: demographics and patient history, co-morbidities and co-medications, DXA T-scores, osteoporosis risk factors, PMO treatment and rationale, bone turnover markers, vitamin D level, and costs related to PMO diagnosis and treatment. These parameters will be recorded at baseline and at any visit in the 24-month observation period as available from routine practice. Continuous outcomes will be summarized by descriptive statistics. For categorical outcomes, the number and percentage of patients in each category  $will be \ presented. \ Baseline \ covariates \ (demographic, patient \ characteristics \ and \ site$ characteristics) will be described overall and by treatment received. **RESULTS:** As of May 31, 2013 at least 280 eligible women were enrolled into the study. Full study results will be reported at a later date. **CONCLUSIONS:** The recruited number of patients confirms the feasibility of the planned methodology. Data from this study will provide valuable information regarding the care map of women with PMO in

## PMS107

# AGE AND GENDER DISTRIBUTION OF OUTPATIENT CARE PHYSIOTHERAPY SERVICES FOR DORSOPATHIA DISEASES IN HUNGARY

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routine clinical practice in Switzerland.

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OBJECTIVES: To assess the utilization of out-patient care physiotherapy services related to dorsopathia diseases of the musculoskeletal and connective tissue diseases according to age and gender. **METHODS:** The data come from the financial data base of the National Health Insurance Fund Administration (in Hungarian: OEP) involving the year of 2009. The activity list was provided by the rulebook on the application of the activity code list in out-patient care. The dorsopathia diseases of musculoskeletal and connective tissue diseases (M00-M99) are listed in the International Classification of Diseases (ICD) with code of M40-M54. The number of cases in physiotherapy activities were determined per 10,000 persons by age and gender in outpatient care. RESULTS: The total number of the provided 151 different types WHO-classified physiotherapy services was 32.318.413 in the year of 2009; 19.095.614 (59,09%) of them with the musculoskeletal and connective tissue diseases. The prevalence of the dorsopathia diseases were 51,17% in the group of the muskuloskeletal and connective tissue diseases. The average number of cases of physiotherapy activities per 10,000 persons accounted for 12.015 cases in 2009. The average number of cases per 10,000 persons for males and females were 15.589 cases for males and 8.061 cases for females. The number of cases increase from the 20. age groups in the men and women patients. The highest number of physiotherapy treatment is provided for both gender in the age group 50 to 59 followed

by age groups of 60 to 74. **CONCLUSIONS:** The physiotherapy services occurred with the highest incidence in cases of the 'diseases of the musculoskeletal system and connective tissue' ICD group. The dorsopathia diseases at the ICD groups show the highest prevalence, indicating the importance of prevention.

### PMS108

# AGE AND GENDER DISTRIBUTION OF OUTPATIENT CARE PHYSIOTHERAPY SERVICES FOR HIP AND THIGH INJURIES IN HUNGARY IN 2009

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**OBJECTIVES:** The medical aspects of injuries of the lower extremity is well known, however, limited information is available on physiotherapy treatment of these diseases. The aim of our study is to assess amount and frequency of the physiotherapy services in hip and thigh injuries based on age and gender distribution. METHODS: Data were derived from the countrywide database of Hungarian Health Insurance Administration (HHIA), based on official reports of outpatient care institutes in 2009. The total numbers of different physiotherapy services were determined by selecting the reported specific diagnoses codes and counting the number treatments provided for that specific diagnosis code. The different types of treatment codes are listed in the chapter of the Guidelines of HHIA for 'Physiotherapists, massagetherapists, conductors and other physiotherapy practices'. The number of cases in physiotherapy activities related to for hip and thigh injuries (BNO S70-79) were determined per 10,000 persons by age and gender in outpatient care. RESULTS: The total number of the 151 different physiotherapy services was 353.260 cases at the hip and thigh injuries in the year of 2009 at the. In 2009 the average number of cases of physiotherapy activities per 10,000 persons accounted for 351.91 cases. The average number of cases per 10,000 persons for males and females were 443.7 cases for males and 249.75 cases for females. The number of cases of the hip and thigh injuries were higher in the 15-49 age group in males, and in the age group of elderly females. CONCLUSIONS: In case of the hip and thigh injuries, the highest demand of the outpatient care physiotherapy services occurred older injured patients. The differences in young males vary with the physical activity and the type of recreation activities, and with the condition of osteoporosis in elderly females.

### PMS109

# BONE EVALUATION STUDY (BEST): PREVALENCE AND TREATMENT RATES OF MALE PATIENTS WITH OSTEOPOROSIS (OP) IN GERMANY

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**OBJECTIVES:** With an aging population, prevalence of OP and OP-attributable fractures (OAF) is expected to rise dramatically. We evaluated prevalence and treatment rates for male OP (MOP) in Germany. METHODS: BEST, a retrospective analysis of de-identified claims data from a German sickness fund, included male and female OP patients, aged  $\geq$ 50 years and insured  $\geq$  1 day between 01/2006-12/2009. Two populations were defined. Inclusion criteria for population B were: 1) OP diagnosis (M80.x, M81.x), and/or 2) prescription for OP-related medication (OPM), and 3) exclusion of diagnoses M88.x, E83.5x, and M90.7x (ICD-10). Population A included population B plus patients solely experiencing OAF. **RESULTS:** Population A included 104,938 men. In 2009, prevalence of MOP was 6%. While 67% of men experienced ≥1 OAF during observation period, with the highest rate in those aged 50-54 years (78%), only 15% received OPM. Population B included 47,694 men. In 2009 prevalence of MOP was 4.8%. 27.2% of those diagnosed experienced  $\geq$ 1 OAF, with the highest rate in men aged ≥ 75 years (2006-2009). Only 41.8% of men with ≥ 1 OAF received OPM during the observation period. **CONCLUSIONS:** While prevalence of MOP is lower than that of postmenopausal OP (6% vs. 24% in 2009), high fracture rates in OP-patients represent a significant burden to the German health care system. The low treatment rates reported may lead to suboptimal outcomes, and must be optimized to reduce risk of follow-up fractures in MOP.

## RESEARCH POSTER PRESENTATIONS – SESSION V RESEARCH ON METHODS STUDIES

## RESEARCH ON METHODS - Clinical Outcomes Methods

## PRM1

# THE BENEFIT-HARM FRONTIER OF DIFFERENT PRIMARY SCREENING STRATEGIES FOR CERVICAL CANCER IN GERMANY

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OBJECTIVES: Using a benefit-harm frontier (BHF) approach, we systematically compared benefits and harms of different HPV- and cytology-based primary cervical cancer screening strategies in Germany. METHODS: A previously validated and published Markov modelwas used to analyze the trade-off between benefits and harms of different screening strategies differing by length of screening interval and test algorithms, including cytology alone, HPV testing alone, in combination with cytology or with cytological triage of HPV-positives. We used published German clinical, epidemiological and international test accuracy data from meta-analyses. Predicted outcomes included reduction in cervical cancer incidence and unnecessary treatment (defined as conizations of lesions <CIN3). RESULTS: Overall, comparing identical screening