burden of disease (>17). Registry-data was used in 3 studies to validate/assess generalizability. All modeling studies combined registry with non-registry data (e.g., RCT).

**CONCLUSIONS:** Registries provide a rich source of information on real-world patients which are being incorporated into health economic analyses. Although Nordic registry-data is being utilized in HE studies, many analyses important to HE are not currently available in the Nordic registries (EGBM) we examined. Several solutions are being developed to broaden the use and application of registry-data in the field of rheumatic disease. Given the gap in data required for an economic evaluation (e.g., modeling), researchers need to continue to be aware of potential issues associated with the synthesis of RCT and registry-data.

**PMS5 PRELIMINARY RESULTS OF MULTIDISCIPLINARY SYSTEMATIC FOLLOW-UP OF FRAILTY FRACTURES IN ORTHOPAEDIC CLINIC**


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**OBJECTIVES:** Despite the major health care impact worldwide of fragility fracture, there are few systems in place to identify and capture subjects to reduce future fracture risk and adverse outcomes. We implemented a multidisciplinary systematic follow-up of fragility fractures to close the care gap.

**METHODS:** We recruited 543 subjects over 40 years of age who sustained a fragility fracture at the orthopaedic clinic of Hôpital du Sacré-Cœur de Montréal or Hôpital Jean-Talon hospital from July 2010 to 2013. Demographic and clinical data were assessed over 18-months of follow-up. We analysed data of patients who have completed at least 18 months of follow-up (women: n=99; men: n=120). We described demographic data, BMD, perceived compliance to treatment, and subsequent fracture rates. We assessed the effect on bone mass, vitamin D levels using T-test. **RESULTS:** Mean age was at 61 years. The frequency was described in this retrospective cohort by the ankle and proximal humerus (13%), vertebral (10%) and hip (7%). Close to 41.7% of women and 20% of men perceived they were still persistent and adherent to treatment at 18 months in half of the cases.

**CONCLUSIONS:** Better diagnostic tools and systematic management of the fragility fractures and compliance monitoring can lower the fracture rates in the long term in this at-risk population.

**PMS5 TRENDS IN DMARD TREATMENT FOLLOWING THE INTRODUCTION OF A RHEUROPEUDEMYISTRIBUTION MANAGEMENT QUALITY MEASURE**

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**OBJECTIVES:** In 2005, a quality measure was added to the Healthcare Effectiveness Data and Information Set (HEDIS) that quantifies the proportion of rheumatoid arthritis (RA) patients who receive disease modifying anti-rheumatic drug (DMARD) therapy in a given year. This study describes annual trends in the HEDIS RA management measure that was first measured commercially in 2003 for U.S. RA patients from 2005 to 2012. **METHODS:** This was a retrospective observational study based on U.S. administrative claims data. Patients selected for study during a given measurement year were aged ≥18 years, had continuous insurance enrollment throughout the year, and had two outpatient claims, on different days, with a diagnosis of RA (ICD-9-CM codes 714.0, 714.1, 714.2, 714.81). Receipt of a biologic or non-biologic DMARD therapy was assessed annually from 2005 to 2012. Bivariate statistics were used to test for differences across the years. **RESULTS:** Annual sample sizes averaged ~95,000 RA patients. From 2005 to 2012, the RA quality measure was stable at approximately 83% of RA patients receiving DMARD therapy. Biologic DMARD utilization increased from 32% in 2005 to 39% in 2012 (p<0.001), whereas use of non-biologic DMARDs decreased slightly from 74% to 72% (p<0.001). Among the subset of patients aged ≥65 years with Medicare Supplemental insurance, the RA quality measure was slightly lower at approximately 78% receiving DMARD therapy. Fewer RA patients with Medicare Supplemental insurance received biologic DMARDs, however, utilization increased from 23% in 2005 to 29% in 2012 (p<0.001). In the same time period, non-biologic DMARD use decreased from 73% to 69% (p<0.001). **CONCLUSIONS:** Since the 2005 introduction of the HEDIS RA management quality measure, increases in the use of biologic DMARD therapy were offset by decreases in the use of non-biologic DMARD therapy. Findings suggest potential room for improvement in the quality of care for RA patients.

**NEUROLOGICAL DISORDERS – Clinical Outcomes Studies**

**PND1 COMPARATIVE PHARMACOVIGILANCE ANALYSIS OF BENZODIAZEPINE AND ANTICONVULSANT THERAPY AND SERIOUS SKIN EVENTS**

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**OBJECTIVES:** In late 2013, the FDA announced the public that clobazam is linked to serious skin reactions. This was significant as clobazam is included in the Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), and consequently approved changes to clobazam label and medication guide. However, no comparative pharmacovigilance analysis was conducted for other anticonvulsant benzodiazepines, including clonazepam, clobazapate, diazepam, and lorazeepam.

This study aims to detect and clarify signals of serious skin reactions associated with benzodiazepines and anticonvulsants in the FDA Adverse Event Reporting System (FAERS). **METHODS:** Cases reported to FAERS between 1997 and 2012 were reviewed. The MedDRA Preferred Terms were used to define serious skin reactions. Individual anticonvulsant benzodiazepines were identified by generic names. Empirical Bayes (Geo-Dash) odds ratio (OR) and 95% confidence interval (CI) were calculated as disproportionality measures. Drug-event combinations with EBR052 were considered signals that warrant further review.

**RESULTS:** 4,110 reports of serious skin reactions were submitted for all benzodiazepines (EBR052 = 75). No signals were found for other benzodiazepines, although adverse signals were found for clonazepam (EBR052 = 101). Clonazepam was significantly more frequent compared to other signal combinations (p<0.001). No more signals were found for SJS and TEN (p>0.05).

**CONCLUSIONS:** A total of 216 individuals (72% of whom females) were reviewed. Of the study population, 42% were diagnosed with MS, 38 years at start of natalizumab therapy. A significant decrease in mean ARR was seen after 12 months compared to baseline (N=216; Δ=0.76; p-value<0.001), and then again between the first and second years of treatment (N=208; Δ=0.06; p-value<0.030). The decrease was significant in both subgroups (N=216; Δ=0.76; p-value<0.001).

**NEO-DESIGN**

**OBJECTIVES:** Neodesign was a multicenter, observational, prospective, single-arm study conducted from January 2009 to January 2011. The main outcome measure was time to radiographic progression. Safety was evaluated throughout the study.

**RESULTS:** A total of 214 patients completed the study and were included in the safety analysis. No patients discontinued treatment due to serious infusion reactions. There were 40 serious adverse events reported during the study, none of which were considered related to the study drug. No drug-related serious adverse events were reported. Overall, 321 adverse events were reported, of which 31 were considered drug-related. There were no unexpected drug-related adverse events. No deaths occurred during the study.

**CONCLUSIONS:** Neodesign was well tolerated and safe in patients with relapsing–remitting multiple sclerosis who were naive to therapy with β-IFN or GA and had failed treatment with interferon β-1a or β-1b. No unexpected drug-related adverse events were reported, and no deaths occurred. Overall, natalizumab therapy was well tolerated and safe in patients with relapsing–remitting multiple sclerosis.