patients with and without dose escalation, respectively, and CDN$29,504 and CDN$25,449 for infliximab in patients with and without dose escalation, respectively. **CONCLUSIONS:** Results of this RAMQ database analysis illustrate that, in a real-world setting and over a long period of time, CD patients treated with infliximab had a significantly higher proportion of dose escalation compared with patients treated with adalimumab. In both recommended and adjusted dosing, adalimumab demonstrated significant cost savings over infliximab.

PGI29

THE USE OF REPEAT SCREENING COLONOSCOPY IN A NATIONWIDE PRIVATELY INSURED POPULATION

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OBJECTIVES: Assess the frequency and appropriateness of early repeated colonoscopy **METHODS:** Patients undergoing a colonoscopy in 2005 were identified using paid claims data from a nationwide privately insured population. Patients were screened to be between the ages of 50 and 64 years with at least one year continuous enrollment. Colonoscopies with evidence of positive results [e.g., paid claims for biopsy, fulguration, snare, etc.], or with evidence suggesting clinical indications three months prior to the screening were defined as non-screen tests. The cumulative probability of repeated screening colonoscopy was then documented and the related risk factors for appropriate and inappropriate repeat screening tests were assessed using survival analysis and Cox proportional hazard regression models. **RESULTS:** A total of 51,400 colonoscopies were identified from the paid claims in 2005 for patients age 50-64. The majority of these procedures were found to have either positive results [25,029 (48.7%)] or evidence of clinical indications for the procedure [17,842 (34.7%)]. Among 8,529 apparent screening colonoscopies with negative results, 8% had a repeated colonoscopy within six years, the majority of which were associated with evidence that the repeated test could be justified (78.7% with indications and 21.3% without indications). The initial regression analysis identified risk factors of repeated colonoscopy with indications including age over 55 (HR: 1.2; 95%CI: 1.0–1.5) and having at least one comorbidity (HR: 1.2; 95%CI: 1.0-1.5). The risk factors of repeated colonoscopy without indications include male (HR: 1.53; 95%CI: 1.07-2.20) and having at least one comorbidity (HR: 1.57; 95%CI: 1.04-2.31). **CONCLUSIONS:** The majority of all colonoscopies in 2005 were found not to be routine screening exams. The risk of a repeated screening colonoscopy within 6 years is low [8%]. Among these repeat procedures, the majority was done because of the existence of clinical indications.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

FLUOROQUINOLONE-ASSOCIATED TENDON-RUPTURE: A SUMMARY OF REPORTS IN THE FOOD AND DRUG ADMINISTRATION'S (FDA'S) ADVERSE EVENT REPORTING SYSTEM

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OBJECTIVES: Tendon rupture is associated with fluoroquinolones and listed in boxed warnings. We reviewed and summarized reports of tendon rupture associated with fluoroquinolones as reported in the FDA's Adverse Event Reporting System (FAERS) through September 26, 2012. **METHODS:** We queried the FAERS for reports of tendon rupture involving each fluoroquinolone. Signal detection consisted of empiric Bayes geometric mean (EBGM), with 95% confidence intervals from initial marketing date for each drug. For a signal to be considered significant, minimum criteria are: reports of 3 or more cases, the low end of the 95% confidence interval must be 2.0 or greater. **RESULTS:** There were 2539 tendon rupture cases. Most cases were reported with levofloxacin (61.25%) followed by ciprofloxacin (23.87%) and moxifloxacin (9.05%). Signal detection results for fluoroquinolones were: ciprofloxacin (EBGM=20.0, 95%CI=18.2-21.6), enoxacin (EBGM=13.2, 95%CI=4.2-29.7), gatifloxacin (EBGM=5.0, 95%CI=3.5-7.0), levofloxacin (EBGM=55.2, 95%CI=52.3-58.0), moxifloxacin (EBGM=13.3, 95%CI=11.7-15.1), norfloxacin (EBGM=9.6, 95%CI=6.5-13.5), ofloxacin (EBGM=8.2, 95%CI=6.3-10.2), gemifloxacin (EBGM=1.9, 95%CI=0.7-4.5), lomefloxacin (EBGM=2.3, 95%CI=0.94-5), and trovafloxacin (EBGM=0.3, 95%CI=0.08-1.1). FAERS event date timelines suggest lower risk of tendon rupture for gemifloxacin (n=5), lomefloxacin (n=5), and trovafloxan (n=1), with initial reports in 2006, 2005, and 2000, respectively. The mean age was 59.6± 5.1. The most common concurrent drugs were corticosteroids (levofloxacin=27.1%, enoxacin=20%, gatifloxacin =18.2%, moxifloxacin=14.7%, ciprofloxacin=10.4%, ofloxacin=5.3%, and norfloxacin=2.4%). Analysis by the reporting country revealed that most cases were reported from the US (70%) followed by Japan (8.2%), Great Britain (3.7%), France (.9%) and Canada (.42%). **CONCLUSIONS:** Tendon rupture was reported with most fluoroquinolones. Significant signals existed for all flouroquinolones except gemifloxacin, lomefloxacin, and trovafloxacin, which potentially have lower risks. However, FAERS data are dependent upon utilization and MedWatch reporting rates. As stated in the boxed warning, as stated in the boxed warning, concurrent corticosteroids increases risk of tendon rupture

PMS2

RISK AND COST-EFFECTIVENESS ANALYSIS OF ADVERSE ATRIAL FIBRILLATION OUTCOME IN TREATING OSTEOPROSIS

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OBJECTIVES: The purpose of this study was to investigate the risk of getting atrial fibrillation in a year after receiving the first medication and analyze cost-effectiveness in avoiding the adverse event among alendronate, raloxifene, and hormone replacement therapy. **METHODS:** We used the 2000-2008 National Health Insurance Research Database (NHIRD) to identify 10,353 patients who had the first medication with drugs and classify them into three groups (7439 patients defined as those who used alendronate and 2077 patients with raloxifene as well as 837 patients with hormone replacement therapy). Cox proportional hazard model was used to estimate the hazards of getting atrial fibrillation among three drugs. Also, this study used the cost-effectiveness analysis to estimate the incremental cost effective ratio in avoiding the adverse event as they were treated by different treatments. **RESULTS:** The Cox regression analyses demonstrated that alendronate group (HR=1.52, 95%CI: 0.55-4.19) and raloxifene group (HR=1.38, 95%CI: 0.46-4.21) had higher risk in getting atrial fibrillation than hormone replacement therapy group, but there were not statistically significant. As to the cost-effectiveness analysis in avoiding 1% chance of the adverse event, the average medication expenditure of hormone replacement therapy group would increase 2,916.7 USD (ICER=2,916.7, 95%CI: 1063.3–5,102.9) and 2,266.7 USD (ICER=2,266.7, 95%CI: -411.5–5,068.1), comparing to alendronate group and raloxifene group respectively. **CONCLUSIONS:** People with osteoporosis that were treated by bisphosphonate or raloxifene are better in terms of overall economic cost than those who used hormone replacement therapy.

PMS3

SYSTEMATIC REVIEW AND META-ANALYSIS OF OPEN SPINE FUSION VERSUS MINIMALLY INVASIVE SPINE FUSION FOR THE DIAGNOSIS AND TREATMENT OF LUMBAR SPINE CONDITIONS

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OBJECTIVES: Transforaminal Lumbar Interbody Fusion is used to treat mechanical back-pain and radicular pain associated with spondylolisthesis due to arthritis, herniated disc or spinal stenosis. This procedure is performed either in the traditional open technique (o-TLIF) or using minimally invasive (m-TLIF) techniques. The goal of this study was to conduct a meta-analysis to compare various outcomes when comparing treatments for lumbar spine conditions using the “standard” open fusion (o-TLIF) versus minimally invasive surgical fusion (m-TLIF). **METHODS:** Prospective and retrospective cohort studies comparing o-TLIF to m-TLIF were identified by searching PubMed, EMBASE, the Cochrane libraries, and reference lists from selected studies. Of the 15 selected for full-text review, 4 were excluded because they used the wrong surgical technique, did not include m-TLIF, or did not measure the desired outcomes. Effects sizes (relative risks and standardized mean differences) were calculated using both fixed- and random-effects models. **RESULTS:** Eleven cohort studies (N=554 patients) were included in the review (N=259, o-TLIF; and N=294, m-TLIF). Average follow-up ranged from 12 – 24 months. Random-effects models were used due to the high heterogeneity across studies for each outcome (53.1%-93.5%). Use of m-TLIF was associated with a 420 mL decrease in blood loss when compared to o-TLIF (standardized mean difference (SMD) = -1.57, 95% CI: -2.14 to -0.99, p<0.0001). Operating Room (OR) time was significantly longer with a 33 minute increase for those undergoing m-TLIF (SMD=0.90, 95% CI: 0.24 to 1.55, p=0.007). **CONCLUSIONS:** While most outcomes did not differ between the two procedures, m-TLIF was associated with significantly lower blood loss despite longer OR time. In the appropriate clinical population, m-TLIF may be the favorable TLIF procedure for treatment of back pain and radicular pain in patients with spondylolisthesis due to arthritis, herniated disc or spinal stenosis.

PMS4

PATIENT OUTCOMES OF HIP RESURFACING COMPARED TO TOTAL HIP ARTHROPLASTY: A SYSTEMATIC REVIEW

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OBJECTIVES: Hip resurfacing (HR) was developed for younger, more active patients, as a surgical alternative to total hip arthroplasty (THA). The safety of metal-on-metal HR is controversial with concerns expressed over adverse events and early device failure. We conducted a systematic review comparing primary HR to conventional THA for patients with hip osteoarthritis (OA). Outcomes of interest were adverse event rates, early failure (revision/reoperation within 5 years), and post-operative component alignment. **METHODS:** Studies were identified through electronic databases, grey literature and reference lists of included studies. Inclusion criteria were: English language studies published after 1996 reporting adverse events, complications, safety issues or revision rates with respect to adults with primary hip OA, who underwent either primary HR or THA. Outcomes of interest included: revision, reoperation, dislocation, infection/sepsis, femoral neck fractures, time to revision, rates of early failure, mortality, and post-operative component alignment. Results were reported per 1000 person years for comparability and stratified by age, publication date and market status (in-use and discontinued). **RESULTS:** A total of 7421 abstracts were identified and screened. Of these 384 full text articles were reviewed, 236 of which were included in this analysis. For all devices, those in-use and discontinued, dislocations were more frequent in THA, while revisions and reoperations were more frequent in HR. An analysis of only devices currently in-

use determined that early revisions/reoperations were more frequent in HR than in THA (range 3.1-13.1 vs. 1.9-7.5 per 1000 person years, respectively). **CONCLUSIONS:** This systematic review provides clinicians and health policy makers with information on adverse events based on device type and market status. Rates of adverse events vary by device type, making it challenging to conclude which device is more effective. Findings highlight the importance of differentiating market status and standardizing exposure time by 1000 person years to facilitate comparisons between studies.

PMS5

ADVERSE EVENTS ASSOCIATED WITH COLCHICINE DRUG INTERACTIONS: ANALYSIS OF THE PUBLIC VERSION OF THE FDA ADVERSE EVENT REPORTING SYSTEM

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OBJECTIVES: Colchicine was originally used, and continues to be used, to treat rheumatic diseases. It is used most frequently for the treatment of gout but is also used to treat familial Mediterranean fever, pericarditis, and Behcet's disease. However, because of its pharmacokinetics, colchicine can interact dangerously with other drugs. The objective of the study was to analyze the association between drug-drug interactions involving colchicine and major adverse events as reported in the U.S. FDA Adverse Event Reporting System (FAERS). **METHODS:** All major adverse events (including death, initial or prolonged hospitalization, and persistent or significant disability) related to colchicine between 2004 and 2011 were retrieved from FAERS. Then, events evidently caused by interactions with drugs (such as atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, cyclosporine, and ranolazine) were distinguished from events evidently caused by colchicine as the primary suspect drug. Major adverse event rates were calculated. **RESULTS:** Between 2004 and 2011, a total of 2655 adverse event reports involving colchicine interactions with other drugs were found in the FAERS database, of which 718 reported a death (implying a fatality ratio of 27.0%), 762 reported a hospitalization (giving a 28.7% hospitalization rate), 78 referred to life-threatening events, and 56 reported disability. Pancytopenia, renal failure, vomiting, drug toxicity, and diarrhea were the most common reported events. There were 4,717 reports involving colchicine as the primary suspect drug, of which 527 reported a death (fatality ratio of 11.2%). A statistically significant ($p<0.001$) difference between the two fatality ratios was found. **CONCLUSIONS:** When combined with certain other drugs, evidence suggests that colchicine may be associated with a relatively high death rate, especially if not dosed appropriately. In light of the current data, physicians should be keenly aware of all potentially fatal drug-drug interactions and follow therapeutic guidelines on using colchicine.

PMS6

INTENSIVE CARE UNIT ADMISSION AMONG TRUMA PATIENTS AT A LARGE TRAUMA CENTER IN SAUDI ARABIA

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OBJECTIVES: Despite risk of mortality, traffic-related injuries place a significant financial burden on the health sector, especially due to costs like intensive care unit (ICU) admission and prolonged hospital stays. The aim of the study is to investigate risk factors of admission to the ICU among injured-patients admitted to a large urban trauma center in Saudi Arabia. **METHODS:** This analysis was performed using a dataset from King Abdulaziz Medical City in Riyadh, Saudi Arabia. 7,859 patients met the inclusion criteria during the study period (injured due to falls or traffic crashes and admitted to the hospital between years 2001-2010). Backward-stepwise logistic regression, with admission to the ICU as the outcome, was performed. Variables with p-values<0.1 were included in the final model. Model discrimination was evaluated using the Area Under the Curve (AUC). **RESULTS:** A total of 1833 injured individuals (23.3%) were admitted into the ICU during the study period. They had longer hospital stay and were more likely to be males, sustain head injuries, and to undergo surgery. Multivariate analysis identified injury severity score, Glasgow coma scale, injury mechanism, head injury, and direct transfer to surgery as significant predictors of admission to the ICU. The results indicate that compared to falls, all traffic-related injuries were significantly more likely lead to ICU admission (occupants OR=2.5, [95% CI: 2.0-3.0]; pedestrians OR=2.7, [95% CI: 2.1-3.4]; motorcycle OR=1.7, [95% CI: 1.1-2.7]) adjusting for other covariates. The model showed excellent discrimination ability as shown by [AUC=0.90]. **CONCLUSIONS:** This model can facilitates the triage process of injured patients by assisting in identify those at higher risk of ICU admission. Unlike the U.S, emergency health care services are free in Saudi Arabia and costs are mostly absorbed by the admitting hospital. Therefore, public health interventions are needed to alleviate the burden traffic injuries place on health care settings and improve population health.

PMS7

ORAL GLUCOCORTICOID USE IN RITUXIMAB-TREATED RHEUMATOID ARTHRITIS PATIENTS WITH PRIOR EXPOSURE TO ANTI-TUMOR NECROSIS FACTOR-ALPHA THERAPY

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OBJECTIVES: Long-term use of oral glucocorticoid (OGC) therapy may be associated with adverse effects; thus, OGC-sparing approaches to treatment of rheumatoid arthritis (RA) may benefit patients. This study examined OGC use in rituximab-treated RA patients with prior exposure to anti-tumor necrosis factor-alpha (anti-TNF) therapy. **METHODS:** Administrative claims-based retrospective study. Study patients met the following criteria: initiated rituximab between March 1, 2006-March 31, 2011 (initiation date=index) after exposure to anti-TNF therapy, aged ≥18 years, had a medical claim with a diagnosis code for RA (ICD-9-CM 714.0x) between January 1, 2004-March 31, 2011, continuously enrolled for 12 months before and ≥90 days after index, had no medical claims with diagnosis codes for non-RA indications of biologic disease modifying antirheumatic drugs (BDMARDs) within 12 months before index. Using rituximab infusion dates and the recommended administration frequency schedule, rituximab exposure periods were constructed. Exposure periods commenced upon index and terminated at the first occurrence of switch to a different BDMARD, 90-day gap in rituximab treatment, loss to follow-up, or follow-up of 36 months. Outcomes were any OGC use and mean daily OGC dose expressed in prednisone equivalent and averaged among all patients, measured throughout the exposure period in sequential 90-day intervals. Multivariable generalized estimating equation models tested for statistically significant changes in OGC use over time. **RESULTS:** Study included 1,763 rituximab exposure periods (1,718 unique patients); mean age 54.9 years, 81.5% female, 54.0% with OGC use within 30 days before index. Between the first and last 90-day intervals, the probability of OGC use and the mean daily OGC dose decreased significantly: from 0.56 to 0.36 ($p<0.001$) and from 3.5mg/day to 2.7mg/day (primarily driven by OGC discontinuation) ($p<0.001$), respectively. Sensitivity analyses subset to exposure periods lasting a full 36 months yielded similar results. **CONCLUSIONS:** Statistically significant decreases in OGC use were observed in rituximab-treated RA patients with prior exposure to anti-TNF therapy.

PMS8

ASSESSMENT OF THE INCIDENCE OF FLARES FOR GOUTY ARTHRITIS PATIENTS WITHIN THE SCOTT & WHITE HEALTH CARE SYSTEM

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OBJECTIVES: To identify features that characterize difficult-to-treat gout patients based on the number of flares experienced within a 12-month period. **METHODS:** A retrospective database analysis was conducted using electronic medical records, laboratory reports and demographic data files. Eligible patients were above 18 years, with at least one diagnosis of gout and/or a gout-related medication between January 1, 2005 and December 31, 2010. Patients with at least one serum uric acid value and at least one flare were followed for 12 months from the date the first flare was reported. Eligible patients who had no flares within the study period were also included. **RESULTS:** A total of 266 patients met study criteria, the mean age (±SD) was 61.2 years (±15.7), the majority were males (n=180; 67.7%), the mean annual flare rate was 1.80 (±1.11), and the mean serum uric acid value was 7.24mg/dl (±2.07). Based on three categories of flare rates, 110 patients (41.4%) had no flares, 107 patients (40.2%) had one or two flares, and 49 patients (18.4%) had at least 3 flares. ANOVA tests detected significant differences in mean serum uric acid values by flare rate ($F=18.34$; $df=2$; $p<0.0001$). Kruskal-Wallis results indicated a significant relationship between serum uric acid level categories (<6.0 mg/dl, ≥6.0-<9.0 mg/dl and ≥9.0 mg/dl) and flare rates; $X^2=32.26$; $df=2$; $p<0.0001$. There was no significant difference in flare rate by age ($F=0.31$; $df=2$; $p=0.7355$). Although Wilcoxon results showed a significant relationship between serum uric acid level categories and gender ($X^2=7.10$; $df=1$; $p=0.0077$), no significant relationship between flare rates and gender ($X^2=1.67$; $df=1$; $p=0.1959$) was observed. **CONCLUSIONS:** More information is required to be able to identify and characterize difficult-to-treat gout patients.

PMS9

COMPARISON OF DISEASE STATUS AND OUTCOMES OF PATIENTS WITH ANKYLOSING SPONDYLITIS (AS) RECEIVING THEIR FIRST BIOLOGIC IN UK, GERMANY, FRANCE, ITALY AND SPAIN (5EU)

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OBJECTIVES: To compare the disease status and outcomes of patients with AS receiving their first biologic in 5EU. **METHODS:** A multi-country multi-center medical chart-review study of AS patients was conducted among physicians (rheumatologists:97%) in hospitals and private practices to collect de-identified data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30 yrs) and patient volume (incl. >5AS biologic patients/month) and recruited from a large panel to be geographically representative in each country. Eligible patient charts (>3) were randomly selected from a sample of prospective patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns/dynamics and patient symptomatology/disease status/outcomes. **RESULTS:** In 1Q2012, 1095 eligible AS patient charts were abstracted; 935 (85%) patients were on their first biologic (mean-age:42.6yrs, female:20%). Geographic distribution of patients were – UK:20%, Germany:18%, France/Italy:21%, Spain:19%. Time-to-1st biologic from diagnosis (range:28month (Italy)-59month (France)) and time-on-current biologic (range:24month (UK/Germany/Italy)-27month (France)) differed within 5EU. Among the top-3 reasons for biologic treatment initiation, 'mechanism of action' & 'improve signs/symptoms' were observed across 5EU, whereas 'positive personal experience' (UK/Germany/France) and 'preservation of structural damage' (Italy/Spain) were also observed. Key lab measures documented were: ESR