PMS68
INFILTRATION OF LIPOSOMAL BUPIVACAINE (LB) DECREASES LENGTH OF HOSPITALIZATION FOLLOWING TOTAL KNEE ARTHROPLASTY (TKA)
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OBJECTIVES: Perioperative pain management is an important aspect of recovery from TKA, as severe pain can delay ambulation and hospital discharge. The objective of this study was to determine the impact of local infiltration analgesia using LB when compared to continuous femoral nerve catheter (FNC) following TKA. **METHODS:** This study enrolled consecutive patients who received a TKA between April 2011 and September 2014 into three study groups, excluding bilateral and revision TKA. Study Group A received adductor canal infiltration with bupivacaine and knee infiltration with LB. Study Group B received adductor canal infiltration with LB and knee infiltration with LB. The control group received a continuous FNC with an OnQ pump and ropivacaine. Numeric pain rating scores (NPRS), distance walked, and length of stay (LOS) were the primary outcomes. **RESULTS:** A total of 237 participants were enrolled in this study, including 98 in Group A, 34 in Group B, and 105 controls. On postoperative day (POD) 0, mean NPRS were similar between Group A (1.8±1.7), Group B (2.7±1.8), and the control group (2.3±2.4). Significantly ($p<0.05$) more patients in Group A (58%) and Group B (44%) walked on POD 0 than in the control group (0%); almost all patients walked on POD1. The mean distance walked was also significantly greater ($p<0.05$) on POD0 and on POD1 in Group A (33±42 feet; 193±203 feet) and Group B (42±82 feet; 211±144 feet) than in the control group (0 feet; 46.3±73 feet). LOS was significantly ($p<0.05$) shorter in Group B (2.2±1.7 days), than in the control group (3.2±0.7 days) and Group A (3.0±1.7 days). **CONCLUSIONS:** Local infiltration analgesia using LB improved ambulation and LOS following TKA when compared to continuous FNC with an OnQ pump and ropivacaine. The one-day decrease of hospitalization suggests an estimated cost savings to an Illinois hospital of $2,158 per patient.

PMS69
PATIENT-REPORTED PHYSICAL FUNCTION OUTCOME MEASURE FOR ADULTS WITH FIBRODYSPLASIA OSSIFICANS PROGRESSIVA: INTELLIGENT TEST DESIGN BASED ON PROMIS ITEM BANKS
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OBJECTIVES: Fibrodysplasia Ossificans Progressiva (FOP) is a rare and disabling genetic condition of progressive extraskeletal bone formation. Physical functioning declines as FOP progresses. The objective was to develop a measure of physical function (PF) in adults with FOP. **METHODS:** We reviewed the PROMIS PF item bank for relevant items for FOP, and 44 PF items were identified. We then conducted concept elicitation (CE) interviews in 21 patients diagnosed with FOP (with varying levels of disease severity) who attended the International FOP Association meeting. The selected PF items were administered after the CE interviews. Interview data were analyzed to identify categories of physical functioning that were impacted by FOP. Based on the CE findings and PF item data, 26 items were initially selected for the new measure. Clinical experts in FOP reviewed the proposed set of items. Five additional items were incorporated into the draft measure, and cognitive interviews (CIs) were conducted in 10 patients, and revisions were made to the final FOP-PF Questionnaire (FOP-PFQ; 28 items). **RESULTS:** For the CE interviews, mean age was 30 years (range 16–54) and 58% were female. For the CIs, mean age was 31 years (range 16–57) and 50% were female. CE interviews demonstrated substantial impacts of FOP on mobility, upper extremity function, and related activities. The CE findings, PROMIS PF item descriptive data, and discussion with clinical experts resulted in 31 relevant items which were included in the draft FOP-PFQ. Based on the CIs, the majority of patients understood the instructions, questions, and response scales; three items were deleted due to redundancy or item removal from the original PROMIS item bank. **CONCLUSIONS:** This qualitative research supports the content validity of the FOP-PFQ and illustrates the application of PROMIS item banks for efficient new instrument development in an ultra-rare and disabling genetic disease.

PMS70
RAPID ACQUISITION OF DATA ON THE PATIENT PERSPECTIVE IN RHEUMATOID ARTHRTIS THROUGH A DIGITAL PORTAL
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OBJECTIVES: Rheumatoid arthritis (RA) is an autoimmune disease characterized by significant morbidity related to systemic and joint inflammation. With the availability of more targeted therapeutic approaches and the potential of disease remission, there is increased focus on utilizing patient reported outcomes to better evaluate RA treatment impact. Collecting such data efficiently, i.e., with relatively low cost and time expenditures, can be challenging. Our objective was to implement digital direct-to-patient methodology to collect and incorporate United States (US) RA patient data into the Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) project to study the patient perspective on remission. **METHODS:** Leveraging a known community (MediGuard.org) of approximately 40,000 US RA patients with pre-existing consent to contact for research purposes, patients were contacted in December 2014 to obtain 50 responses to the OMERACT survey through a direct-to-patient digital communications platform. Patients did not receive any honoraria for survey completion. **RESULTS:** The first survey was completed within seven minutes of initial digital outreach and the fiftieth within three hours. RA patients from 23 continental US states were represented. Of the 50 patients, 82% were female, mean age 54.8 years; male patients were older, mean age 61.7 years. RA diagnosis duration was 11.3 years average (range 1-40). Comorbidities including other autoimmune and musculoskeletal conditions, diabetes, cardiovascular disease, malignancies were reported by 70%; 76% reported synthetic (72%) and/or targeted (44%) disease-modifying antirheumatic drug use; 84% reported current RA disease activity. Additional usable data were obtained including those on education, employment, health insurance, income, remission state, health assessment questionnaire, and patient global for the project. **CONCLUSIONS:** This analysis documents the feasibility of gaining rapid and relevant responses from a representative community RA patient population regarding their perspective on RA remission through our digital direct to patient portal.

PMS71
CONTENT VALIDITY EVALUATION OF A NEW DIARY DEVELOPED TO EVALUATE SYMPTOMS IMPORTANT TO PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS
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OBJECTIVES: Patient-reported outcome instruments are used in clinical trials of rheumatoid arthritis (RA) treatments to evaluate treatment benefits. A growing body of evidence suggests that joint pain, tiredness, and morning joint stiffness are among the most important symptoms for RA patients. A 7-item electronic daily diary was developed to assess these key symptom concerns of patients with RA for use as efficacy endpoints in clinical trials. The aim of this study was to evaluate the content of the diary and to ascertain whether patients with RA found items in the diary interpretable and relevant through concept elicitation and cognitive interviews. **METHODS:** A cross-sectional qualitative interview study was conducted in adults with moderate-severe RA in the US and UK. Interviews were conducted using a standardized interview guide to elicit information about ways patients with RA experience and talk about their symptoms followed by a cognitive interview on the dairy. Data were analyzed utilizing a qualitative analysis software program, Atlas.ti. **RESULTS:** The study sample included 28 participants (US n=22, UK n=6; 29% male; mean age 58.41 years; RA mean duration 13.92 years). Total HAQ-DI mean scores were 0.84 (US) and 1.50 (UK). Morning joint stiffness (n=19), joint pain (n=28), and tiredness (n=7) were among the most commonly experienced and reported symptoms; saturation of these concepts was achieved in the second interview. These results demonstrated that the diary includes appropriate content and terminology. Cognitive interviews indicated that participants found the diary items and response options clear, easy to understand and relevant to their RA experiences. No differences in qualitative results were noted between the two country samples. **CONCLUSIONS:** Results of this qualitative study suggest that the 7-item electronic daily diary includes content relevant to patients and is suitable for assessing RA symptoms in clinical studies of patients with moderate to severe RA.

PMS72
DOES ORAL CHOLECALCIFEROL SUPPLEMENTATION IMPROVES PAIN INTENSITY AND DISABILITY IN PATIENTS WITH CHRONIC LOW BACK PAIN?
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OBJECTIVES: In the past decade many studies established relationship between vitamin D deficiency and chronic musculoskeletal pain including low back pain. Present study aimed to examine the effect of vitamin D3 supplementation in patients with chronic low back pain with low level of vitamin D. **METHODS:** This single arm, open label study was conducted in a public tertiary care teaching hospital in India after obtaining approval from the Ethics Review Board of the hospital. Adult patients of either gender, aged 18 to 65 years, with a diagnosis of CLBP and low serum 25(OH) D3 levels (<30 ng/mL) and not responding to medications and physical therapies, having a pain score of at least 50 as assessed on 0 – 100 Visual Analogue scale (VAS) at baseline were eligible for study recruitment. Cholecalciferol (active vitamin D3) in a dose of 60,000 IU/week for a period of 8 weeks was given to the enrolled subjects according to standard guidelines. Study endpoints include change in pain score and disability as measured by modified Oswestry disability questionnaire (MODQ). Patient information and outcome measures were collected at baseline, 2, 3 and 6 months. **RESULTS:** A total of 68 chronic low back patients were included in the trial. Mean baseline vitamin D level is found to be 12.80+5.73 ng/ml. After treatment it significantly ($P<0.01$) increased to 36.07+12.51. VAS (81.03+18.57) and MODQ (44.83+15.47) were high at baseline. Pain intensity has significantly reduced to 44.71+18.96 (<0.05) and 35.74+17.75 (<0.05) at 3 and 6 months respectively. Disability has significantly reduced to 30.94+12.48 (<0.05) and 26.10+10.03 (<0.05) at 3 and 6 months respectively. **CONCLUSIONS:** Present study shows that vitamin D supplementation can improve the pain and disability in patients with CLBP. Study results should be carefully interpreted as it is a single arm open label study and concomitant medication usage was not assessed.

PMS73
MINIMALLY IMPORTANT DIFFERENCES FOR PATIENT-REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM (PROMIS) FATIGUE AND PAIN INTERFERENCE SCORES
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OBJECTIVES: Interpretation of patient-reported outcomes (PROs) requires some definition of an important or meaningful difference. This study aimed to estimate minimally important differences (MIDs) for the Patient-Reported Outcomes Measurement Information System (PROMIS®) Fatigue and Pain Interference scale scores in rheumatoid arthritis (RA). **METHODS:** The responsiveness of several PROs was assessed in an observational cohort of 521 RA patients in the Arthritis, Rheumatism and Aging Medical Information Systems (ARAMIS) cohorts. PROMIS Fatigue and Pain Interference instruments were administered at baseline, 6 months, and 12 months. Self-reported retrospective changes in fatigue and pain over the previous 6 months were obtained at

the follow-ups (a lot better/worse, a little better/worse, stayed the same). We estimated MIDs using the mean change in PROMIS scores for people who rated their change 'a little better' or 'a little worse.' **RESULTS:** At 6 months, 41 patients reported their fatigue was a little better compared to baseline (mean change [SD]: -2.6 [4.8]), 119 a little worse (1.7 [5.6]). Pain was a little better for 60 patients (-1.9 [6.1]) and a little worse for 126 (0.6 [5.7]). At 12 months, fatigue was a little better compared to 6 months prior for 31 patients (-1.3 [6.5]) and a little worse for 133 (0.9 [5.6]). Pain was a little better for 53 patients (-1.8 [5.7]) and a little worse for 122 (1.5 [5.0]). Thus, the MID range was 1-2 points for both Fatigue and Pain Interference. Correlations between change scores and retrospective ratings were low (0.13-0.29), indicating that these analyses may underestimate the MID. **CONCLUSIONS:** The MID for PROMIS Fatigue and PROMIS Pain Interference, estimated from this cohort of RA patients, is roughly 2 points and corresponds to a small effect size. This is consistent with earlier work in this cohort demonstrating an MID of 2 points for PROMIS Physical Functioning.

PMS74

OUTCOMES VALIDATION OF THE ASES, DASH, EQ5D, AND VR6D IN A POPULATION OF ORTHOPEDICS PATIENTS WITH UPPER EXTREMITY MORBIDITY

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OBJECTIVES: We sought to identify whether region-specific (American Shoulder and Elbow Surgeon (ASES) and Disabilities of the Arm, Shoulder, and Hand (DASH)) or generic (EuroQOL 5D (EQ-5D) and Veterans Rand 6D (VR-6D)) patient-reported outcomes instruments perform best in an orthopedics population with upper extremity morbidity (hand/wrist, elbow, or shoulder). **METHODS:** New patients presenting to our institution with complaints of upper extremity morbidity completed the ASES, DASH, EQ5D, and the Veterans Rand-12 (from which the VR-6D is derived). We oversampled patients at the initial visit to ensure adequate sample size for the six-month follow-up. Based on standard of care, patients received conservative (e.g., casting), operative, or no treatment. Six-months after the initial appointment, patient-outcomes were reassessed. Performance of the instruments was examined, and compared over time, body parts, and treatment modality. **RESULTS:** A total of 294 patients provided responses at the first visit and six-months later. Of these patients, 21.4% reported to our institution for elbow morbidity, 40.5% for shoulder morbidity, and 38.1% for hand/wrist morbidity. The mean age of respondents was 56.5 years (hand/wrist: 57.3 years, elbow: 52.2 years, shoulder: 57.9 years; $p<0.01$). Mean initial scores were determined for the ASES: 60.9/100; DASH: 26.6/100 (reverse scored), EQ5D: 0.79/1, and VR6D: 0.70/1. Significant differences in the initial and six-month scores were found for all instruments. Initial scores were poorer in the operative group for the VR6D, but the difference was not significant. Significant improvements were detected using the ASES and EQ5D, but not in the DASH or VR6D. Ceiling effects were noted for the DASH and EQ5D. The ASES and VR6D scores were normally distributed. **CONCLUSIONS:** We determined that a region-specific instrument, the ASES, had the most desirable psychometric properties in our patient population. To expand our findings, we are currently developing mapping algorithms between the generic preference-based and disease-specific measures to estimate health utilities.

PMS75

ACCUMULATED ONE YEAR HEALTH UTILITY LOSS AFTER SUSTAINING A HIP FRACTURE IN MEXICO

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OBJECTIVES: Hip fractures are common in older people and incur substantial pain and suffering, disability, increased risk of death and high costs. The burden of hip fractures is expected to grow considerably during next years due to population aging. We aimed to describe the health-related quality of life (HRQoL) and the determinants in patients sustaining a hip fracture in Mexico. **METHODS:** Data from Mexican patients enrolled in the International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS) was gathered. Patients had to be diagnosed with a low-energy-induced hip fracture and to be at least 50 years old. HRQoL was prospectively collected in three phases over 12 months after fracture using the EQ-5D instrument. The UK preference weights were used to determine health utility at different times. The accumulated HRQoL loss in the first year after fracture was calculated using the trapezoid method. Multivariate regression analysis was conducted to identify determinants of HRQoL reductions. **RESULTS:** 200 patients were evaluated. Mean (±SD) age was 77.4 ±9.9 years and 80% were women. A 15.5% of the sample reported a prior fracture in last 5 years; 54% had a job before fracture and 78% were classified into the low level of income category. Mean (95%CI) utility value before fracture was 0.64 (0.59—0.68). Utility dropped to 0.01 (0.01—0.02) immediately after fracture and then improved to 0.46 (0.42—0.50) and 0.59 (0.55—0.63) at month 4 and 12 post-fracture, respectively. Accumulated utility loss over the first year was 0.35 (0.31—0.39). HRQoL before hip fracture and age at fracture were the two most relevant characteristics associated with the accumulated utility loss. **CONCLUSIONS:** Hip fractures impair HRQoL in a significant way leading to utility values close to death shortly after fracture. Mean utility value elicited after one year follow-up was lower than before sustaining the fracture.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS76

HIGH-COST BIOLOGICS FOR RHEUMATOID ARTHRITIS: HOW ARE PAYER-LED COST-TAMING STRATEGIES IMPACTING BRAND UPTAKE IN THE UNITED STATES?

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OBJECTIVES: As pharmaceutical pipelines begin to churn out specialty products at a higher rate than traditional therapies, payers are experiencing double-digit growth in costs for biologics and other high-cost specialty drugs. Such agents are expected to consume half of the drug spend by 2018. Focusing on rheumatoid arthritis (RA), this study explored current uptake of biologics, and examined evolving payer prescribing controls. **METHODS:** A total of 40 managed care organization (MCO) pharmacy and medical directors, and 103 rheumatologists who prescribe biologics for RA were surveyed regarding prescribing and reimbursement. **RESULTS:** Surveyed rheumatologists reported that 59% of their drug-treated RA patients currently receive a biologic, with extensive use of Enbrel and Humira, especially, as first-line therapy. MCO tier coverage currently favors such TNF-α inhibitors, but surveyed payers indicated that, in one year's time, newer biologics and non-TNF-α inhibitors that have previously been formulary-excluded will move to coverage tiers. More than 80% of surveyed rheumatologists encounter strong-to-moderate payer control of RA biologics prescribing, with reports of increasing control and consequent decreased prescribing of specific agents. A large majority of payers confirmed using at least some form of restrictions, mostly prior authorization, and also step therapy and quantity limits. Higher copays for biologics versus other drugs are also encountered, and about half of payers reported a specialty pharmacy is commonly used to acquire biologic for RA. More than one-third of payers also reported that their contracting arrangements with drugmakers include rebating and price protection for RA biologics. **CONCLUSIONS:** As the biologics/specialty drug market for RA grows, increased prescribing controls by MCOs are likely. Furthermore, as competition increases, so will the demand for more extensive data and greater discounts/rebates to justify preferred coverage. Achieving preferred coverage is vital to avoid losing patient share to competitors achieving more favorable reimbursement terms.

PMS77

BIOLOGIC BRANDS AND BIOSIMILARS FOR RHEUMATOID ARTHRITIS IN THE EU5: CONTENTION FOR COST-EFFECTIVENESS

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OBJECTIVES: As EU5 healthcare budgets tighten and cost-containment strategies become ever-more convoluted, the threat of biosimilars looms large for the rheumatoid arthritis (RA) biologic brands. With the first biosimilars for RA set to penetrate these markets in 2015, this study explored their likely uptake as payers and prescribers balance clinical need with limited funds. **METHODS:** In September/October 2014, 253 rheumatologists across the EU5 were surveyed regarding their views on biosimilars for RA, and on current and expected biologics prescribing patterns. In addition, 15 payers who influence reimbursement at national/regional level were interviewed. **RESULTS:** At least three-quarters of surveyed rheumatologists in each country (>90% in Germany and Italy) plan to prescribe biosimilars of infliximab, etanercept, and rituximab within two years of launch, more frequently to new biologics patients than existing brand patients. Overall, however, in 2017, respondents expect less than half of their RA patients, on average, receiving any of these molecules to be on a biosimilar version. Interviewed payers in France, Italy, Spain, and the UK will encourage but not mandate biosimilar prescribing, largely due to anticipated modest discounts and corresponding price cuts to the brands. In Germany, however, payers believe that biosimilar prescribing targets and financial penalties for physicians who do not adhere will induce hefty discounts on biosimilars as robust uptake will compensate. **CONCLUSIONS:** EU5 rheumatologists expect to prescribe biosimilars for RA; however, brand dominance is likely through 2017 at least, due partly to modest discounts on the biosimilars resulting in lack of incentive for payers to promote their prescribing. Both prescribers and payers are also likely somewhat wary given the dearth of long-term RA biosimilar safety data. Over time, however, increasing confidence in biosimilars is probable, as are more aggressive payer policies encouraging prescribing across the EU5, especially as a favorable price-uptake ratio looks certain in Germany.

PMS78

PATIENT, HEALTH PLAN AND COMMUNITY FACTORS ASSOCIATED WITH RECEIPT OF DISEASE-MODIFYING ANTIRHEUMATIC DRUGS AMONG PATIENTS WITH RHEUMATOID ARTHRITIS IN MEDICARE MANAGED CARE PLANS

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OBJECTIVES: To identify factors associated with disease modifying antirheumatic drugs (DMARDs) receipt among Medicare beneficiaries enrolled in Medicare Advantage (MA) plans. **METHODS:** This study used a large nationally representative administrative claims data, supplemented by new sources of socioeconomic and community resource data (i.e., market source (at zip+4 levels) and area health resource files) in addition to CMS published contract information and Monthly Membership Report. The sample consisted of MA members (≥18 years) who were diagnosed with rheumatoid arthritis (RA) during 2013. The generalized linear mixed model was used to determine factors associated with DMARD receipt. **RESULTS:** A total of 12,835 RA patients were identified, of which 9,850 (76.74%) received DMARD. Factors associated with less likelihood of receiving DMARD were male gender (OR: 0.72), increasing age (80-84 years, OR: 0.67; ≥85 years, OR: 0.45; vs. 18-54 years), more comorbidities (Charlson Comorbidity Index, OR: 0.96; HCC Risk Score, OR: 0.89), living in South Atlantic region compared to Mid-Atlantic (OR: 0.76), and percent households with 1st Individual who completed college (1-15% vs. 0%, OR: 0.82). Factors associated with more likelihood of DMARD receipt were Hispanic compared to White (OR: 1.38), use of glucocorticoids (OR: 2.22), living in New England region compared to Mid-Atlantic (OR: 1.82), median household income ($50,000-$74,999, OR: 1.31; $75,000 - $99,999, OR: 1.34; $100,000+, OR: 1.42; vs. $0-$15,000), end-stage renal disease (OR: 2.77), enrolled in employer group waiver plan (OR: 1.40), MA plans market penetration rate in service area (3-4%, OR: 1.26; 5-8%, OR: 1.45; 9-100%, OR: 1.60; vs. 0-2%). **CONCLUSIONS:** The probability of receiving DMARD is correlated with sociodemographic, clinical, health plan and community characteristics. This study provides new evidence that can be used to identify subgroups of members to