hemophilic joint health (0.67 vs. 0.73, p<0.01) or disability (0.65 vs. 0.70, p<0.01) as similar as in the results of Haemo-Qol. With patients who were on a job or students (467, 77.2%), LPT was estimated at 127.81 hours per month on average. Of 467, patients with inhibitor or disability showed higher LPT compared to those without inhibitor (130.6 vs. 126.61 hours per month, p=0.486) or disability (132.27 vs. 126.11 hours per month, p=0.056). Patients’ clinical characteristics were patients’ clinical characteristics should take into account for the management of hemophilia given patient-reported outcomes differed by clinical manifestations.

PSY92 BURDEN OF LUPUS NEPHRITIS (LN) AMONG PATIENTS MANAGED IN ROUTINE CLINICAL PRACTICES IN EUROPE (EU)

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OBJECTIVES: To assess the burden of LN in comparison to SLE patients without LN. To qualitatively assess the impact of Psoriasis on patient quality of life. To assess the burden of LN in patients with Psoriasis compared to SLE patients without LN.

Methods: A multi-center medical chart-review of adult (16-69yrs) SLE patients was conducted among rheumatologists and internal medicine physicians in France/Germany/Italy/Spain (SEU). Physicians were recruited from a geographically representative sample in each country. Approx. 5 consecutive eligible persistent active or relapse remitting (SLE) cohorts were compared using descriptive statistics. Results: 168 LN patients and 569 non-LN patients with SLE were analyzed. Patient characteristics included (LN/Non-LN): age (yrs): 40-42.7%, Female: 82.7/94%, Caucasian: 82.7/98.8%, full-time employment: 32/13/6.0%, part-time employment: 19/0.0/22.0%. Among LN/Non-LN, frequency of SLE diagnosis was 9.5/6%, 10.6/6%, respectively. SLE activity was 28.5/25.0, 5.0/10.0, respectively. Frequency of SLE-related complications was 0/0.9%, 15/14.8, respectively.

Conclusions: LN patients had higher clinical and humanistic burden in EU compared to their SLE counterparts. Factors influencing the observed burden, including the therapeutic strategies used in these geographies warrant further investigation to manage SLE, and in particular, optimally.

PSY93 QUALITY OF LIFE (QOL) WITH PSORIASIS: ETHNOGRAPHY STUDY EVALUATING THE IMPACT OF PSORIASIS ON MODERATE TO SEVERE PATIENTS IN EUROPE (EU), FROM A PATIENT’S PERSPECTIVE

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OBJECTIVES: To qualitatively assess the impact of Psoriasis on patient QoL.

Methods: An ethnographic study with moderate/severe Psoriasis patients was conducted in 4EU (UK/Spain/Italy) and the US to explore patients’ views on treatment options. Individuals with Psoriasis impacted by the disease were contacted by phone or email to see if they were interested in participating. Participants were asked to complete a survey and schedule an interview. Interviews were conducted by telephone and lasted between 60-90 minutes. Interviews included open-ended questions such as how the disease affects you personally and professionally, as well as questions on the burden of the disease. Interviews were transcribed and coded. Results: 1Ipsos HealthCare, Columbia, MD, USA

Qualitative data from 26 interviews were analyzed using a phenomenological approach. The analysis process involved identifying themes and patterns from the data, and then organizing and interpreting the data. The following themes emerged from the data: challenges of living with Psoriasis, impact on daily life, treatment experiences, and future perspectives.

Conclusions: Living with Psoriasis can have a significant impact on daily life, and patients experience challenges in managing the disease and its effects on their personal and professional lives.

PSY94 HEALTH RELATED QUALITY OF LIFE OF PATIENTS AND THEIR CAREGivers IN RARE DISEASES RESULTS OF THE BURQOL-ROD PROJECT IN HUNGARY

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OBJECTIVES: The Social Economic Burden and Health-Related Quality of Life in Patients with Rare Diseases in Europe (BURQOL-ROD, http://www.burqol-rod.com) project aims to investigate disease burden and self-perceived health outcomes of patients and their caregivers in rare diseases in 8 EU countries (Bulgaria, France, Germany, Hungary, Italy, Sweden, Spain, UK).

Methods: An online questionnaire survey was developed for patients (adults/children) and caregivers. Patients were recruited in 11 participating centers in cystic fibrosis (CF), ataxia telangiectasia (AT), Prader-Willi syndrome (PWS), haemophilia (HMO), Duchenne muscular dystrophy (DMD), epidermolysis bullosa (EB), fragile X syndrome (FXS), scleroderma (SCL), mucopolysaccharidosis (MPS), juvenile idiopathic arthritis (JIA) and histiocytosis (HIS). Demographic and main clinical characteristics were collected. Quality of life (QoL) was assessed by the EQ-5D-5L, disability and caregivers’ burden by the Barthel Index and Zarit Burden Interview questionnaires.

Results: In Hungary, 296 Hungarian patients (male: 161, 55%) and 211 caregivers were enrolled. Patients and caregivers’ burden was assessed by the EQ-5D-5L, disability and caregivers’ burden by the Barthel Index and Zarit Burden Interview questionnaires.

Conclusion: The study findings suggest that patients and caregivers in rare diseases in Hungary experience significantly lower quality of life and impose burden on caregivers. Taking an integrated approach our study results can impact the future research and implementation in other orphan diseases.

PSY95 THE DISEASE-SPECIFIC LUPUS QoL INDEX: SENSITIVE TO CHANGES OF DISEASE ACTIVITY IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS AFTER TREATMENT OF A FLARE

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OBJECTIVES: To assess the disease-specific LupusQoL sensitive to changes of disease activity in SLE patients after treatment of a flare.

Methods: Patients with SLE experiencing a flare (baseline) & requiring an increase in treatment were recruited. Assessments were undertaken at baseline & monthly for 9 months & included BILAG-2004 disease activity index & the LupusQoL & scores range from 0-100 (best HRQoL). LupusQoL domain scores when disease activity improved or deteriorated between consecutive time points are reported as mean changes, with 95% CI constructed using robust standard errors to account for repeated patient assessments. Results: Mean change in SLE-QoL from baseline to 9 months was 49.4/29.7; mean # of organ manifestations was: 4.5/3.9.

Conclusions: Disease activity after treatment of a flare is significantly sensitive to disease activity change in other orphan diseases.

PSY96 THE QUALITY OF LIFE OF PATIENTS TREATED WITH ROBOTIC VERSUS TRADITIONAL SURGERY RESULTS FROM AN ITALIAN OBSERVATIONAL MULTICENTER STUDY

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OBJECTIVES: To assess the Quality of Life (QoL), focusing on level of pain, of patients submitted to surgical interventions with robotic technique in comparison with traditional approach in the Italian setting. Methods: The prospective multicenter study analyzed the QoL of 699 patients submitted to surgical interventions, enrolled in 8 Italian Hospitals for the period February 2011-May 2014. The specialties were: thoracic, gynecological, thoracic surgery performed with open, laparoscopic or robotic technique. Patients completed two questionnaires: one related to pain intensity during the hospitalization and one fulfilled at home related to pain intensity and its impact on daily activities, mood, relationship, sleep. Pain was measured using the scale of facial expressions corresponding to the Visual Analog Scale. For each intervention and specialty, linear regression for repeated measure, corrected by length of stay and use of analgesics, were performed to explain level of pain during hospitalization and at home, respectively. Pain intensity during hospitalization was significantly (p<0.05) lower in general and gynecological robotic surgery versus the open technique, but not versus laparoscopic, while robotic thoracic surgery presented significant changes in pain intensity during hospitalization and at home related to pain with open surgery (p<0.05). Level of pain at home is significantly different for robotic surgery versus laparoscopic, while not versus traditional technique. The study findings suggest that robotic surgery is a valid alternative to traditional technique in the management of pain in patients with thoracic surgery, with surgical interventions to robotic technique vs traditional surgery. Further analysis are in progress to compare results on QoL, not only referred to level of pain, with clinical severity and other indicators of clinical efficacy as length of stay, operating time, and therefore not evident at monthly intervals.

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time, medical/surgical complications to refine a robust measure of effectiveness useful to perform cost effectiveness analysis.

PSY97
CHARACTERISTICS OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) TREATED IN EU WRT SYMPTOMS, FUNCTION, RAMPAGE, EXperiENCING FLARE, AND THOSE EXPERIENCING FLARES IN CLINICAL PRACTICES IN EUROPE
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OBJECTIVES: To assess the characteristics of SLE patients currently on Remission (Group-1), currently with active disease but not experiencing a flare (Group-2) and those who are experiencing flares (Group-3) in Europe (EU).
METHODS: A multi-center medical chart review of adult (16-89 yrs) SLE patients was conducted in 102014 among rheumatologists/ internal medicine physicians in UK/France/ Germany/Italy. SLE patients were recruited from a geographically representative sample in each country. Approx. 5 consecutive eligible persistent active or relapse remitting SLE patients currently managed as part of usual care were identified. Physican abstracted de-identified patient on disease characteristics, lab values and treatment patterns. Patient disease status and humanistic burden was assessed by physician per clinical judgment & patient interaction.
RESULTS: 747 SLE patient charts were abstracted in EU (UK: 156/France: 149/Germany: 148/Italy: 146/Spain: 148; Group-1: 25.7% (range: 19.9% (Italy) - 29.7% (Germany)); Group-2: 56.2% (range: 42.3% (UK) – 66.4% (Italy)), Group-3: 18.1% (range: 13.5 (Germany) – 28.8 (UK)).
Patient characteristics included (Group-1/Group-2/Group-3): age (yrs): 41.4/43.4/40.6; % female: 81.8/80.2/77.8; % on sick leave: 3.6/7.6/17.0; % currently receiving treatment in in-patient setting: 3.17/6.28/1; % hospitalized >=1 in past-year: 23.4/3.2/55.6.
Top-5 organ manifestations were (% Group-1/Group-2/Group-3): musculoskeletal: 90.8/89.9/81.1, mucocutaneous: 86.5/84.0/86.2, haematologic: 45.8/53.5/65.6, renal: 23.4/24.6/73.3, pulmonary: 15.1/13.6/65.7.
In Group-1/Group-2/Group-3, % patients with low C3 and C4 were 33.3/53.9/73.4 and 31.6/53.2/77.5 and % anti-ds-DNA positive were 54.7/71.0/78.5. Humanistic burden (reported via physician ratings, on a scale of 0 (most impact) to 7 (least impact)) was (Group-1/Group-2/Group-3, mean scores): patient ability to perform every-day tasks: 6.11/5.17/4.37, patient ability to work: 5.76/4.93/3.87. CONCLUSIONS: Over half of the SLE patients had an active disease while one-in-five were experiencing a flare in this study cohort, with significant variations observed within SLE. Clinical and humanistic burden varied based on current disease status, with highest burden observed among those experiencing flares.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies
PSY98
ORPHAN DRUG POLICY: APPROACHES TO MARKET ACCESS IN MULTIPLE COUNTRIES
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OBJECTIVES: Despite increasing policy guidance to encourage the development of and access to orphan drugs, the policy landscape indicates a lack of transparency and consistency across countries. The objective of this study is to compare the orphan drug policies in Japan, South Korea and Taiwan. The HFA will be assessed in European Union (EU).
METHODS: A targeted literature review was conducted to identify papers pertaining to orphan drugs in Japan, South Korea and Taiwan, with a focus on quantitative analysis for policy-making related to pricing and reimbursement from the payer perspective. No papers were placed on language. Country specific policy websites were hand-searched.
RESULTS: A total of 3465 abstracts were identified for screening. Of those, 104 were eligible for full-text screening. The definition of prevalence with regard to rare diseases in Japan, South Korea and Taiwan was stricter than in the EU. All of them had introduced regulations, guidelines and incentives to the development of orphan-designated drugs. Strict HTA requirements were waived for rare diseases, although cost-effectiveness data are referenced in South Korea. In Japan and Taiwan, prices were reduced for existing drugs with new orphan-designated indications. Within the existing benefits of national health insurance schemes or under the coverage of rare disease regulations, full reimbursement was given, which is different from the partial reimbursements observed in certain European countries. In some cases, the application of drug treatment can be approved prior to or without market authorisation. The availability of orphan drugs to patients was not inferior to that of the EU. CONCLUSIONS: While access in Japan, South Korea and Taiwan is seemingly not different to the EU, there are no consistent or transparent policies in place in these countries. Policy makers should prepare innovative schemes that offer warranties to both payers and patients and establish a systematic evaluation procedure for manufacturers.

PSY99
MCDA APPROACH TO RANKING RARE DISEASES IN RUSSIA: PRELIMINARY RESULTS
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OBJECTIVES: The ranking and prioritization of rare diseases are crucial in order to determine which of the support measures available are most relevant for management. The methodology we have developed is a set of 16 criteria to assess rare diseases (8 related to the characteristics of disease, and 8 to the characteristics of treatment) was proposed by experts, so multi-criteria decision (MCDA) analysis approach could be useful. The aim of the study was to assess the reliability of the criteria set and to determine the relative importance of 16 criteria.
METHODS: 85 experts were interviewed to estimate the importance of effect of treatment in the decision-making on financing MT for rare diseases. We used 10-point scale, where 10 points mean major importance to the priority indicator, and 1 point mean minor importance. Mean estimates were calculated using descriptive statistics, then means were normalized.
RESULTS: Respondents were 11-14 years old, 70% were doctors, 16% health administrators, 32 practitioners, and 14 researchers. 44 respondents had a scientific degree. The most important criteria were characteristics of treatment - ‘Effect of treatment on quality of life’ and ‘effect of treatment in life expectancy’ with 1 point each. The least important criteria were both characteristics of the disease - ‘Cognitive disorders as manifestations of the disease’ and ‘Additional burden on the daily lives of caregivers’ with 0.2 and 0.1 respectively.
CONCLUSIONS: Characteristics of treatment are more important than characteristics of disease, therefore characteristics of treatment should be given consideration when evaluating rare diseases to determine priority financing.

PSY100
PATTERNS AND TRENDS IN OPIOID USE IN IRAN FROM 2007 TO 2011
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OBJECTIVES: Opioid analgesics are proven to be safe and effective in malignant or nonmalignant pains. The consumption trend of six opioids (Morphine, Codeine, Oxycodeone, Fentanyl, Pethidine, and Methadone) in Islamic Republic of Iran assumed as an indicator for prescription pattern and is evaluated during five year period (2007-2011) as the aim of this study. METHODS: The data of opioid analgesic consumption were collected from FDO (Food and Drug Organization) of Iran. The collected data were converted to DDD (Define Daily Dose) for each of six selected opioids in order to be compared accurately. RESULTS: Overall consumption of opioids was grown during the period of investigation. Putting six selected opioids into two classes of synthetic – the group with the consumption were obviously higher than those of non-synthetic. Opioid analgesics consumption in 2011 was shown to be 4 times more than the opioid consumption in 2007. The CAGR Consumption growth 2007-2011 was estimated 11.11%, 16.46%, 3.91%, 7.36%, and 41.63% for Oxycodone, Methadone, Fentanyl, Morphine, Pethidine and Codeine respectively. The growth rate of mentioned above opioids for the last year of investigation was reported 41.12%, 16.54%, 29.99%, -0.38%, 7.66%, 6.12% respectively. CONCLUSIONS: Like other low consuming countries, consumptions of opioid analgesics in Iran is limited by means of different kinds of barriers. There are also parameters which set a specific orientation in opioid consumption. Analyzing this trend, results in defining the barriers and other parameters clearly.

PSY101
ORPHAN DRUG APPROVALS IN EUROPE: HISTORICAL REVIEW AND TRENDS
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OBJECTIVES: In Europe, orphan designation has been granted by European Medicines Agency since 2000. Molecules with orphan designation can benefit from a number of incentives to guarantee return on investment for manufacturers. Since introduction of orphan legislation, the number of Orphan Drugs (OD) has significantly increased. In 2012, total OD sales reached 13% of the whole pharmaceutical market. This study aims to analyse current situation and trends in OD approvals. METHODS: All ODs approved gaining marketing authorization was identified through secondary data. Approval indication for the same condition were not considered. CONCLUSIONS: Over half of the ODs patients had an active disease while one-in-five were experiencing a flare in this study cohort, with significant variations observed within SLE. Clinical and humanistic burden varied based on current disease status, with highest burden observed among those experiencing flares.

PSY102
COHORT A nalysis of HTA DECISIONS, PRICE, AND REIMBURSEMENT LEVEL OF ORPHAN Drugs in FRANCE AND ITALy
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OBJECTIVES: While there exist a number of incentives to stimulate research and development of orphan drugs (OD), the Health Technology Assessment (HTA) agencies do not share a specific path to be followed in this context. This study aimed at summarizing HTA decisions, price and reimbursement level of OD in France and Italy. Methods: All OD assessed since 2000 with available reimbursement rates and decision details were extracted for each drug using Farmaldata Italian database for Italy and Transparency committee reports, AMELI’s national health insurance and Thiarese databases for France. RESULTS: Among 74 OD approved in France and Italy between 2000 and 2013, 23 ODs in France and 51 ODs in Italy are available in France. All ODs available in France are officially available in Italy. The average delay between the market authorization and the price and reimbursement decision was about 16 and 17 months in France and Italy respectively. In France all available drugs are 7% reimbursed through hospital, 56 molecules are available in retail pharmacy with reimbursement from...