FIBROMYALGIA MOLDOFSKY QUESTIONNAIRE (FMQ):
USE OF A TOOL TO AID DIAGNOSIS
Le Lay K1, Boussetta S2, Moldofsky H3, Taieb C4
1Pierre Fabre, Boulogne-billancourt, France, 2Pierre Fabre, Boulogne Billancourt, France, 3Centre for Sleep and Chronobiology, Toronto, ON, Canada, 4Pierre Fabre, Boulogne, FRANCE, France

OBJECTIVES: To establish pertinent levels of FMQ (Fibromyalgia Moldofsky Questionnaire) score to guide a subject’s further treatment, METHODS: The FMQ questionnaire, was administered to a representative community sample of 1500 subjects in UK along with two validated questionnaires (LFESSQ London Fibromyalgia Epidemiology Study Screening Questionnaire and CES-D Center for Epidemiologic Studies Depression Scale) and a questionnaire assessing a decline in the restorative effects of sleep (SQA Sleep Quality Assessment). A descriptive analysis of the score was carried out using socio-demographic data (gender, age, type of town and socio-professional class) and the complaints reported by the subjects interviewed, RESULTS: The FMQ score was higher among women and those over 50 (5.0 ; 5.3). Women aged over 50 had an even higher FMQ score (5.5), which agreed with existing epidemiological data on fibromyalgia. There was no relationship between the FMQ score and geographic location, income, profession and sick leave prescribed by a doctor (regardless of length). The FMQ score was 3.0 in subjects who did not state any pain and 4.1 in those who did not respond positively on the LFESSQ. It increased to 8.7 among those who screened positive on the LFESSQ. The FMQ score varied between 9.7 and 10.4 in subjects who responded positively on the LFESSQ and who also experienced depressive symptoms, fatigue or a decline in the restorative effects of sleep. The FMQ score was 10.7 for subjects who screened positive on the LFESSQ and who also experienced fatigue and depressive symptoms, and increased to 11.3 when the four symptoms were experienced at once, CONCLUSIONS: A FMQ score of less than 3 excludes a presumptive diagnosis of fibromyalgia syndrome and an FMQ score of above 8 should lead to specialist investigations.

RESTORATIVE EFFECT OF SLEEP: VALIDATION OF THE SQA (SLEEP QUALITY ASSESSMENT)
Le Lay K1, Boussetta S2, Moldofsky H3, Taieb C4
1Pierre Fabre, Boulogne, France, 2Centre for Sleep and Chronobiology, Toronto, ON, Canada

OBJECTIVES: To validate the SQA (Sleep Quality Assessment) questionnaire which will help to identify subjects who with an unrestorative sleep, METHODS: The SQA questionnaire, was administered to a representative sample of 1500 subjects from the general UK population along with three questionnaires (FMQ: Fibromyalgia Moldofsky Questionnaire, LFESSQ London Fibromyalgia Epidemiology Study Screening Questionnaire, and CES-D Center for Epidemiologic Studies Depression Scale). The maximum score of 30 showed a large decline in the restorative effect of sleep. Internal consistency, structural and clinical validity were tested, RESULTS: Internal consistency was highly satisfactory (aCronbach > 0.8). The items making up each dimension were highly relevant to the dimension that they covered (R > 0.4) and no item presented a significant correlation (>0.8) with another item. Subjects responding positively on the LFESSQ had an SQA score that was significantly higher than subjects who responded negatively (14.6 vs 8.7). Similar differences were observed between subjects with and without probable depressive symptoms (15.2 vs 8.4) and a strong presumption of fibromyalgia syndrome (16.9 vs 8.0). The SQA score was 7.0 in subjects who did not report any pain and 7.1 in those who did not respond positively on the LFESSQ. It increased to 14.7 among those who screened positive on the LFESSQ. The CES-D score increased significantly with the SQA score. The SQA score was 16.7 [13.9–17.4] among subjects who screened positive on the LFESSQ and who either experienced fatigue or depressive symptoms or both, CONCLUSIONS: The restorative effect of sleep is reduced when the SQA score is greater or equal to 14 and good when the SQA score is less than 7. An SQA score of between 7 and 14 necessitates further examinations, which may include investigating physiological function during sleep.

QUALITATIVE STEPS FOR THE DEVELOPMENT OF A QUESTIONNAIRE ASSESSING THE BURDEN OF FIBROMYALGIA ON PATIENTS’ DAILY LIVES
Arnould B1, Bennedjahed K2, Barnes N1, Carbonell JA3, Serra E4, Speede M5, Boussetta S6, Le Lay K7, Taieb C8
1Mapi Values, Lyon, France, 2Mapi Values France, Lyon, France, 3Hospital de la Esperanza, Barcelona, Spain, 4Amiens University Hospital, Amiens, France, 5–, Munich, Germany, 6Pierre Fabre, Boulogne-billancourt, –, France, 7Pierre Fabre, Boulogne-billancourt, France, 8Pierre Fabre, Boulogne, France

OBJECTIVES: To explore functional impact, limitation of daily activities, burden and handicap related to FM in order to define the burden on patients’ daily lives. To gather and organise this material to develop a new Patient-Reported Outcomes (PRO) questionnaire simultaneously in four European languages assessing FM burden on patients’ daily lives. METHODS: PRO questionnaire development follows a rigorous protocol and methodology to ensure its reliability. An international committee of three fibromyalgia experts was set up and included in the whole process. A literature review was conducted using burden- and FM-related keywords. Concepts identified were organised into a model. Exploratory interviews were performed with a total of 15 patients in France, Germany and Spain. They were recorded, transcribed word-for-word and systematically analysed using a specifically developed coding grid. Concepts were organised into a separate model. Confirmatory interviews were
conducted with 9 FM-association counsellors in 3 countries, analysed using the same method and used to enrich the model. Further information was captured with the analysis of 90 letters written by patients to FM-associations. RESULTS: A total of 303 abstracts were retrieved and reviewed. Sixty-seven publications were included and the concepts identified were grouped into the following domains: Burden, Symptoms and Influencing Factors. The exploratory interviews suggested that burden can be divided into: Autonomy, Coping, Pain, Tiredness, Activities of Daily Living, Physical Impact, Social Impact, Psychological Impact, Cognitive Impact, Work, Sleep, Relationship to Medicine and Disease. The letters and counsellor interviews confirmed the conceptual content. CONCLUSIONS: The resulting model illustrates how “burden” is understood by FM patients, and that all areas of daily life are impacted by the disease. The conceptual content will be used for the generation of items for the questionnaire. The development of a questionnaire assessing functional impact and burden will allow the consequences of FM on patients to be more widely recognised.

**PMS61 SHORT-TERM OUTCOMES AND HRQOL AFTER PEDIATRIC EMERGENCY DEPARTMENT (PED) TREATMENT OF MINOR INJURY: A PILOT STUDY**

Stevens HW1, Drendel AL2, Hainsworth KR3

1Medical College of Wisconsin; Children’s Hospital of Wisconsin, Milwaukee, WI, USA, 2Medical College of Wisconsin, Milwaukee, WI, USA

OBJECTIVES: Background: Minor injury is a leading cause of PED visits and a major health care burden. However, little is known about outcomes after treatment and release; care often lacks an evidence base. OBJECTIVES: 1) Gather initial data on the clinical/functional outcomes after PED care, and 2) Test both patient and proxy forms of an acute HRQOL tool in the PED and in telephone follow-up. METHODS: Prospective convenience sample of pediatric patients treated for injury and discharged to home. Demographic and injury data collected at the visit; outcomes by telephone at 7–10 days. The acute Pediatric Quality of Life Inventory 4.0 (PedsQL) was administered at both visit and follow-up. RESULTS: Thirty-five families completed follow-up. Mean patient age = 8 years, 69% male, 49% soft tissue injury, 31% fracture, 17% sprains, 3% CHI. Types/locations of study injuries were in frequencies similar to those in our ED overall. Children had a median of 3 days of pain; 24% reported 17 after the visit. Days for the child’s return to normal activity: median 3, 37% 17. Disruption of normal family activities in 51%, for a median of 5 days, 39% 17. Children with school, work, or other regularly scheduled activities: 55% missed 13 days, 20% missed 17. Parents missed work or school: mean 1 day, 22% 13. The PedsQL was found to be easy to use, had minimal missing items, and good indication construct validity (total scores inversely correlating to days of pain, abnormal activities, and family disruption). CONCLUSIONS: We found significant morbidity for patients and their families after PED visits for minor injury. In this setting, the use of the acute PedsQL patient-proxy forms was feasible with initial indications of good construct validity. Further description and the development/testing of a tool to quantify short-term outcomes are prerequisites to testing effectiveness in ED minor injury care.

**PMS62 DISCONTINUATION RATE OF THE 1ST AND 2ND ANTI-TUMOR NECROSIS FACTOR THERAPIES IN PATIENTS WITH RHEUMATOID ARTHRITIS IN ITALY**


1Azienda Ospedaliera di Padova, Padova, Italy, 2Ospedale Misericordia e Dolce, Prato, Pisto, Italy, 3University of Florence, Florence, Italy, 4Università di Modena, Modena, Italy, 5University of Padova, Padova, Italy, 6Bristol-Myers Squibb, Rome, Italy, 7Università di Pisa, Pisa, Italy

BACKGROUND: Anti-TNF therapies are efficacious in clinical trials for the treatment of RA. However, their long-term efficacy in daily practice in relation to the specific diagnosis or the use of concomitant DMARD therapy remains to be confirmed. OBJECTIVES: To estimate the proportion of patients with RA, treated with at least one anti-TNF therapy (infliximab [IFX], etanercept [ETN], or adalimumab [ADA]), who were still on the same biologic agent after 3 yrs (36 mths) of follow-up. To estimate the discontinuation rate of patients with RA, treated with the second anti-TNF therapy, after discontinuing the first one. METHODS: Patients attending participating centers who received their first anti-TNF treatment between July 1, 2002 and March 31, 2004, and who gave their consent, were invited to participate to the study. Pts were required to be ≥18 yrs old, with a diagnosis of RA (as defined by the ACR criteria). A total of 711 patients were enrolled in this retrospective cohort study involving a national representative sample of 23 rheumatology centers in Italy, selected according to both geography and treatment setting characteristics. A patient chart review was conducted to collect data on treatment duration, and a diary of therapies was completed. A Kaplan–Meier curve was calculated for each biologic anti-TNF therapy; the event was discontinuation of the drug due to inefficacy or toxicity. RESULTS: Pts’ baseline characteristics were: female 80.8%, mean age 53.3 yrs (range 18–84 yrs), mean duration of disease 9.4 yrs. Of 703 pts who met the inclusion criteria, 248 (35.3%) were treated with IFX, 259 (36.8%) with ETN and 196 (27.9%) with ADA. After a follow-up of 36 months, the discontinuation rate was 43.2% with IFX, 25.8% with ETN and 28.0% with ADA. The discontinuation rate of IFX compared with ETN and ADA was statistically higher (p = 0.0001 and p = 0.0002, respectively). The difference between ADA and ETN was not statistically significant (p = 0.826). Patients who discontinued the first agent and started the second one were 149: ETN 112, INF 12, ADA 25. After 24 months of follow up 78% patients on ETN, 46% on ADA and 25% on INF were still on the same agent. The RR of stopping the second agent increased by 31% (IC 95% 0.96–1.83). CONCLUSIONS: Our results show a higher discontinuation rate of anti-TNF therapies in daily practice in Italy compared with clinical trials. IFX was associated with a significantly higher rate of drug discontinuation than other anti-TNFs. Patients who stopped the first agent and switched to the second one had a discontinuation risk increase of 31%. This results should be taken into account when first agent fails.

**PMS63 PATIENT REPORTED OUTCOMES OF DIFFERENT SURGICAL PROCEDURES IN PATIENTS WITH CARTILAGE DEFECTS OF THE KNEE AFTER 1 TO 5 YEARS**

Brüggenjürgen B, Berger H, Willich SN

1Charité, University Medical Centre, Berlin, Germany; 2Fachhochschule Osnabrück, Osnabrück, Germany

OBJECTIVES: To determine surgical treatment outcomes in patients with cartilage defects according to operative procedures performed. METHODS: In this 5-year retrospective cross-sectional study patients were contacted who had been diagnosed...