both physical and psychosocial domains. In subjects who are not receiving DMARD therapy, anakinra leads to improvements in health-related quality of life.

SAT0246 CHARACTERISING THE EFFECTS OF ANAKINRA THERAPY ON FUNCTIONAL STATUS OF PATIENTS WITH RHEUMATOID ARTHRITIS USING METHOTREXATE

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Background

Objectives To characterise the effects of anakinra on the functional status of subjects with rheumatoid arthritis using methotrexate.

Methods In a large multidose placebo controlled study of anakinra in subjects with rheumatoid arthritis (RA), functional status was evaluated at baseline and after 24 weeks of therapy using the Health Assessment Questionnaire (HAQ). The HAQ includes questions designed to assess functional status as related to dressing and grooming (D&G), arising (ARI), eating (EAT), walking (WLK), hygiene (HYG), reach (RCH), grip (GRP), and activities (ACT). Comparisons between Methotrexate (MTX) alone (n = 74), and anakinra + MTX (n = 131), based on the combined data for the two highest doses (1 mg/kg and 2 mg/kg), were analysed using change in scores from baseline through 24 weeks.

Results Change scores for all eight of the HAQ scales (Table 1) were positive, and six were statistically significant. The biggest effects were seen in reach, hygiene, and eating, while walking showed the smallest effect. Furthermore, by the end of the study a greater percentage of subjects on anakinra + MTX reported functionality without any difficulty, as compared to those on MTX alone (data not shown).

Abstract SAT0246 Table 1 Mean change in HAQ scales from baseline to week 24

	D&G	ARI	EAT	WLK	HYG	RCH	GRP	ACT
Anakinra + MTX	-0.38	-0.37	-0.40	-0.19	-0.23	-0.29	-0.45	-0.42
Placebo + MTX	-0.09	-0.16	-0.07	-0.12	0.14	0.07	-0.19	-0.19
Difference	-0.29	-0.21	-0.34	-0.07	-0.36	-0.36	-0.26	-0.23
P-Value	.011	.043	.004	.515	.019	.005	.025	.052

Conclusion Subjects receiving at least 1 mg/kg of anakinra showed statistically significant improvements in functional status as measured by the HAQ. Improvements were evident in almost all of the HAQ scales. Anakinra improves functional status across a wide range of domains in subjects with rheumatoid arthritis.

SAT0247 A CHINESE VERSION OF THE RHEUMATOLOGY ATTITUDES INDEX IS A VALID AND RELIABLE MEASURE OF LEARNED HELPLESSNESS IN SLE PATIENTS

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Background The Rheumatology Attitudes Index is a widely used measure of learned helplessness (LH), an acquired pattern of behaviour in which, as a result of adverse past experiences, individuals believe their efforts will be ineffective. LH is associated with poorer quality of life in a variety of rheumatic diseases, and with increased morbidity and mortality in patients with rheumatoid arthritis. Despite the importance of learned helplessness in rheumatic conditions, there are no validated measures of this construct in Chinese or other Asian languages.

Objectives To assess the internal consistency, reliability and construct validity of a Chinese translation of the Rheumatology Attitudes Index (CRAI) and its Helplessness (CHS) and Internality (CIS) subscales.

Methods The source English RAI was translated into Chinese using standard techniques for cross-cultural adaptation. Chinese-speaking SLE patients completed identical, self-administered Chinese questionnaires containing the CRAI and assessing demographic and socio-economic variables twice within a 2 week period. SLE related activity, damage and quality of life were assessed using the BILAG, SLICC/ACR Damage Index and SF-36 Health Survey respectively. Scale psychometric properties were assessed through factor analysis, Cronbach's alpha, intra-class correlations and quantifying test-retest differences. Relationships between the CRAI, its subscales and external variables (known-groups construct validity) were studied using Spearman's rank correlation.

Results Active disease and disease related damage were present in 52.2% and 49.3% of 69 Chinese speaking SLE patients with a median disease duration of 4.7 years. Internal consistency and reliability were acceptable, with Cronbach's alpha for the CHS, CIS and CRAI being 0.70, 0.69 and 0.74 respectively, mean differences in test-retest scores being 0.47, 0.55 and 0.93 points respectively (representing 1.6 to 2.4% of possible scale ranges) and intra class correlations ranging from 0.72 to 0.83. Factor analysis identified 2 major factors corresponding to the HS and IS subscales of the CRAI. Eight of 10 hypotheses relating the CRAI and CHS to demographic, disease and quality of life variables were confirmed, supporting the construct validity of these scales. **Conclusion** The CRAI and its helplessness subscale are valid and reliable measures of learned helplessness in Chinese speaking SLE patients.

SAT0248 PHARMACOEPIDEMIOLOGICAL PROFILE OF PATIENTS TREATED FOR OSTEOARTHRITIS

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Background Public health decision makers and healthcare payers have become increasingly interested in collecting epidemiological and economic information to improve the allocation of limited health care resources.

Objectives The purpose of this preliminary study was to describe a pharmacoepidemiological profile of patients treated for osteoarthritis (OA) by 21 general practitioners in the Local Health Unit (LHU) of Ravenna.

Methods Retrospective chronological reading of all prescriptions written for OA. All patients receiving a prescription for a NSAID or rofecoxib were included. The computerised data file, housed in the LHU of Ravenna since January 1996, contains all

demographic characteristics of each patient (including diagnosis by ICD9 code) as well as the ATC code, number of packs, number of tablets per package, and cost for each drug dispensed. Rofecoxib in comparison to conventional NSAIDs and the frequency of use of GI protective agents (proton pump inhibitors, sucralfate, H2-antagonists, misoprostol, and antacids) were considered in a period of follow-up lasted from 3 months (rofecoxib) to 18 months (NSAIDs).

Results A total of 2,935 patients received a treatment on a basis of health assisted population of 26,125 subjects: 2,878 had a NSAID and 57 rofecoxib. Among patients treated with NSAIDs 62% were female and 38% male with a mean age of 63 ± 16 and 59 ± 16 years respectively. The mean age of the patients in therapy with rofecoxib was 69 ± 13 years for female ($p = 0.004$ vs. NSAIDs) and 62 ± 15 years for male. Sixty-eight percent of patients treated with rofecoxib were female. The distribution by age showed that 68% of all treated patients was over 55 years old. The mean prevalence of treatment for OA was 11%. Patients belonging to the CP group who received also a GPA were treated with a significantly higher number of different NSAIDs versus those treated without a GPA (2.30 ± 1.09 vs. 2.04 ± 1.01 , $p < 0.001$ in patients previously treated and 1.92 ± 0.87 vs. 1.78 ± 0.69 , $p = 0.018$ in patients without previous treatment).

Abstract SAT0248 Table 1

	NSAIDs	GPA	Rofecoxib	GPA	±%	p	SE	CI (95%)
Patients with previous treatment								
Occasional Prescription	353	(29.7%)	—	—	—	—	—	—
Continuous prescription	1,054	(46.4%)	39	(20.5%)	-	0.002	8.1	10.0–41.8
Patient without previous treatment								
Occasional prescription	761	(30.1%)	—	—	—	—	—	—
Continuous prescription	710	(39.7%)	11	(9.1%)	-	0.041	13.2	4.8–56.4

Frequency of use of GI protective agents (GPAs).

Conclusion These results confirm previous findings that a large part of elderly population ($> = 55$ years) suffers from OA and is treated with NSAIDs. The remarkable usage of GI protective agents in these patients leads to a consequent increasing of medical costs. Our preliminary data show that rofecoxib significantly improved resources utilisation reducing the frequency of use of GI protective agents (by 56% to 77%). This study provided a high number of drug utilisation data and suggested that a complete prescriptive reading in general practice might be the basis for a larger future work on pharmacoepidemiology and managed care in OA.

SAT0249 GASTROINTESTINAL HEALTH CARE RESOURCE USE AND COSTS ASSOCIATED WITH NONSTEROIDAL ANTIINFLAMMATORY DRUGS: ANALYSIS OF A POPULATION COHORT IN ISRAEL

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Background Gastrointestinal (GI) toxicity is one of the major adverse effects of nonsteroidal antiinflammatory drugs (NSAIDs). Studies in several countries have demonstrated that NSAID-related gastropathy is associated with a considerable economic burden, which includes increased hospitalizations, physician visits, diagnostic tests and use of gastroprotective agents (GPAs) for prophylaxis or treatment.

Objectives This study estimated the gastropathy-related health care resource consumption and costs associated with prescriptions of NSAIDs, in a large cohort in Israel.

Methods We analysed the Maccabi clinical database which covers a population of 1.5 million. Patients who received any NSAID prescription between June 1998 and May 1999 were identified and sub-grouped according to patterns of NSAID consumption (incidental: 1–2 vs chronic: 3 or more prescriptions) and age (< 65 vs 65 years or older). As a population baseline measure of gastropathy rate, age- and sex-matched controls, defined as patients who did not have any NSAID prescriptions during the study period, were randomly selected. Outcome measures included the use of GPAs, gastroenterologist consultations, gastroendoscopy and upper GI imaging tests. Hospitalizations for GI complications were not included in this study.

Results During the one-year study period, 194,814 patients were identified with a total of 365,624 NSAID prescriptions filled. About 82% were incidental users and 18% were chronic NSAID users. Overall, 22% of the NSAID users had GPA prescriptions, compared to 8% of matched controls (a 14% increase in GPA use for patients on NSAIDs). The increases in GPA use were higher among chronic NSAID users and those aged 65 years or older than incidental users and patients below 65 years (20–38% vs 9–10%). H2-blockers comprised 75–80% of the GPA prescriptions, whereas PPI comprised 20–25%. Thus, for each 1 NIS spent on NSAIDs, an additional 0.52 NIS were spent on the treatment or prevention of GI NSAID toxicity (ie, iatrogenic cost factor defined as NSAID drug plus GI costs divided by NSAID drug cost is 1.52); 70% of these costs were spent on GPAs.

Conclusion Our study showed that the healthcare expenditures for management of NSAID-related gastropathy in Israel were substantial and comparable to published data in other countries. This study may have underestimated the total economic impact of NSAID gastropathy in Israel since hospitalizations for GI complications were not included. Efficacy and safety should be the primary parameters for selecting an antiinflammatory agent. When cost is considered, policy and clinical decision-makers need to take into account the total economic impact, which, in addition to the acquisition costs of these agents, should include health care expenditures for diagnosing, treating and preventing GI side effects.