Results A total of 6336 tests were performed of which 4454 (70.1%) were negative for paracetamol. The Table 1 shows the number of tests by year and result. Using the Chi Squared test there were no significant differences before and after September 1998 (p = 0.7).

Abstract SAT0243 Table 1

	95/96	96/97	97/98	98/99	99/00
All Tests	1063	1380	1365	1182	1346
All Positive Tests	319	362	403	358	440
Results >1.3 mmol/l	23	27	27	27	28

Conclusion These results do not suggest that the incidence of paracetamol overdose has been affected by the over-the-counter pack size reduction at least in the Tayside region of Scotland. Further measures to reduce the burden of paracetamol overdose to the healthcare system must be considered along with effective ways of obtaining paracetamol for appropriate clinical use.

SAT0244 CONCOMITANT USE OF GASTROPROTECTIVE AGENTS AMONG USERS OF NONSTEROIDAL ANTIINFLAMMATORY DRUGS IN ITALY

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Background Beside life-threatening gastrointestinal (GI) adverse events (e.g. perforation, ulcer or bleeding), non-steroidal anti-inflammatory drug (NSAID) use is associated with less severe GI symptoms, which may result in the concurrent use of GI protective agents (GPAs) and/or antacids and therefore increased medical costs.
Objectives Analyse the patterns of use of GI protective agents among NSAID users.
Methods During ten days of consultation, 913 NSAID users were identified among 20,668 patients seen by 103 general practitioners in the Sicily region of Italy from December 1998 to June 1999. Physicians filled out data collection forms regarding the type and indication of NSAIDs and the use of adjuvant therapy to prevent or treat adverse GI effects of NSAID therapy during the past 6 months.
Results The mean age of the patients was 61 years and 61% were females. Indications for NSAID therapy included osteoarthritis/arthrosis in 61% of the patients, rheumatoid arthritis in 9%, and other reasons, most notably non-articular pain in 28%. Based on the number of prescriptions (Rx) and the number of patients (pts), the most frequently prescribed NSAID was nimesulide (24% Rx, 37% pts), followed by diclofenac (24% Rx, 32% pts), piroxicam (17% Rx, 24% pts), and ketoprofen (9% Rx, 12% pts) accounting for 75% of all NSAID prescriptions. The mean duration of all NSAID therapy varied between 60 to 120 days depending on the specific NSAIDs used by the patients during the 6 months prior to the visit. Of all NSAID users, 50.3% used a GI medication, including GPAs [including proton pump inhibitors (PPI), H2-antagonists, and misoprostol] and antacids (Rx or OTC). Although certain variations existed, the use of GPAs and antacids was consistent across all NSAIDs including those newer products such as ArthrotecÒ and meloxicam. Concomitant use of H2-antagonists occurred in 14% of all NSAID users, PPI in 8%, misoprostol in 15%, and antacids in 22%. The mean duration of GPA use varied between 73 to 96 days during the 6-month period. About 40% of H2 antagonists, 21% PPI, 86% misoprostol, and 62% antacids were prescribed to prevent NSAID adverse events and the remaining were for treatment.
Conclusion Concurrent use of gastroprotective agents and antacids was observed in more than half of the patients taking NSAIDs, and their use was consistent across individual products. The concomitant use of GPAs and/or antacids with NSAIDs does not only incur inconvenience to the patients because of polypharmacy but also increase healthcare costs.

SAT0245 IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE FROM ANAKINRA THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS NOT USING DMARDS

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Background
Objectives To evaluate the effect of anakinra on health related quality of life (HRQOL) as measured by the Nottingham Health Profile (NHP), in subjects with rheumatoid arthritis not using DMARDs.
Methods In a 24-week, multicenter, randomised, double-blind clinical trial conducted in Europe, 473 subjects received either one of three doses of anakinra (30 mg, 75 mg, or 150 mg) or placebo SC QD. Subjects were excluded if they used DMARDs within six weeks of entry, or if they had failed therapy with more than three DMARDs. The NHP was administered in selected countries at baseline and at weeks 12 and 24 (n = 353). The NHP consists of 38 items which assess physical mobility (MOB), pain (PAIN), energy (ENRG), sleep (SLP), emotional reactions (EMO), and social isolation (ISO). The NHP is scored so that lower scores indicate better HRQOL and negative change scores indicate improvements. The mean change in each NHP scale score was compared between subjects receiving anakinra (all doses combined) and those on placebo. All subjects who completed at least one post-baseline assessment were included (n = 328) and the last-observation was carried forward in the case of missing data.
Results Subjects using anakinra experienced statistically significant improvements in all six NHP scales. These improvements exceeded those for subjects on placebo for all six scales, four of which were statistically significant.

Abstract SAT0245 Table 1 Mean change in NHP scales from baseline to week 24

	MOB	PAIN	ENRG	SLP	EMO	ISO
Anakinra (n = 245)	-8.89	-17.27	-18.88	-9.55	-11.51	-4.91
Placebo (n = 83)	0.19	-7.89	-4.82	-3.27	-3.48	-0.49
Difference	-9.08	-9.38	-14.06	-6.28	-8.03	-4.42
P-Value	<0.01	0.02	0.01	0.13	0.01	0.12

Conclusion Subjects receiving anakinra experienced statistically significant improvements in their NHP scores that exceeded those for subjects on placebo. These improvements were seen in

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 it's 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 a 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 it's 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